HemoSphere Alta Advanced Monitoring Platform

Operator's manual

Edwards

Edwards HemoSphere Alta Advanced Monitoring Platform Operator's Manual

Because of continuing product improvement, prices and specifications are subject to change without notice. Changes to this manual, either in response to user input or to continuing product improvements, are accomplished through reissue. If, in the normal use of this manual, errors, omissions, or incorrect data are noted, please contact Edwards Technical Support or your local Edwards representative.

Edwards Technical Support
United States and Canada (24 hours) .....800.822.9837 or tech_support@edwards.com
Outside the U.S. and Canada (24 hours).....949.250.2222
Europe .....+8001.8001.801 or techserv_europe@edwards.com
In the UK .....0870 606 2040 – Option 4
In Ireland .....01 8211012 – Option 4

CAUTION Federal (USA) law restricts this device to sale by or on the order of a physician.

Manufactured by
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614

Manual version: 2.1; Manual release date: JANUARY 2025; Software version: 2.0.XX

Original release date: 11/15/2023

Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Using This Manual

The Edwards HemoSphere Alta advanced monitoring platform operator's manual is comprised of 14 chapters and 7 appendices. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

Carefully read these instructions for use, which address the warnings, precautions, and residual risks for this medical device.

WARNING Read this operator's manual carefully before attempting to use the Edwards HemoSphere Alta advanced monitoring platform.

Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Alta advanced monitoring platform.

CAUTION Inspect the HemoSphere Alta advanced monitoring platform and all accessories and equipment used with the monitor for damage prior to use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised.

WARNING To prevent injury to patient or user, damage to platform, or inaccurate measurements, do not use any damaged or non-compatible platform accessories, components or cables.

Chapter	Description
1	***Introduction***: Provides an overview of the HemoSphere Alta advanced monitoring platform
2	***Safety and Symbols***: Includes WARNINGS, CAUTIONS, and NOTES that are found in the manual, as well as illustrations of labels found on the HemoSphere Alta advanced monitoring platform and accessories
3	***Installation and Setup***: Provides information about setting up the HemoSphere Alta advanced monitoring platform and connections for the first time
4	***Navigating the HemoSphere Alta Advanced Monitoring Platform***: Provides information on monitoring screen views
5	***User Interface Settings***: Provides information about the various display settings including patient information, language and international units, alarm volume, system time, and system date. It also provides instructions for selecting the screen appearance
6	***Advanced Settings***: Provides information on advanced settings including alarm targets, graphical scales, serial port setup, and Demo Mode
7	***Data Export and Connectivity***: Provides information on monitor connectivity for transferring patient and clinical data
8	***Swan-Ganz Technology Monitoring***: Describes procedures for setup and operation of continuous cardiac output, intermittent cardiac output, and right ventricular end diastolic volume monitoring using Swan-Ganz technology
9	***Pressure Cable Monitoring***: Describes procedures for setup and operation of vascular pressure monitoring

Chapter	Description
10	***ClearSight Technology Monitoring***: Describes the methodology behind ClearSight technology and gives instructions for setup and application of patient monitoring equipment as well as how to measure noninvasive blood pressure, cardiac output, stroke volume, stroke volume variation, and systemic vascular resistance
11	***Venous Oximetry Monitoring***: Describes procedures for calibration and operation of oximetry (oxygen saturation) measurement
12	***Tissue Oximetry Monitoring***: Describes procedures for setup and operation of ForeSight tissue oximetry monitoring
13	***Clinical Tools***: Describes the HemoSphere Alta advanced monitoring platform clinical tools and algorithms.
14	***Help and Troubleshooting***: Describes the Help menu and provides a list of faults, alerts, and messages, with causes and suggested actions

Appendix	Description
A	***Specifications and Device Characteristics***
B	***Accessories***
C	***Equations for Calculated Patient Parameters***
D	***Monitor Settings and Defaults***
E	***Computation Constants***
F	***System Care, Service and Support***
G	***Guidance and Manufacturer's Declaration***

Contents

Edwards

List of Figures

Edwards

List of Tables

Edwards

Introduction 1

Contents

1.1 Intended Purpose of this Manual

This manual describes the features and monitoring options of the Edwards HemoSphere Alta advanced monitoring platform. The HemoSphere Alta advanced monitoring platform displays monitored data obtained through Edwards hemodynamic technologies.

This manual has been prepared for use with the Edwards HemoSphere Alta advanced monitoring platform by trained critical care clinicians, nurses, and physicians in any hospital environment where critical care is administered.

This manual provides the operator of the HemoSphere Alta advanced monitoring platform with setup and operating instructions, device interfacing procedures, and limitations.

1.2 Indications For Use

1.2.1 HemoSphere Alta Advanced Monitoring Platform with Swan-Ganz Technology

The HemoSphere Alta advanced monitor when used with the HemoSphere Alta Swan-Ganz patient cable and Edwards Swan-Ganz catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of cardiac output (continuous [CO] and intermittent [iCO]) and derived hemodynamic parameters in a hospital environment. Pulmonary artery blood temperature monitoring is used to compute continuous and intermittent CO with thermodilution technologies. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards Swan-Ganz catheter and Swan-Ganz Jr catheter indications for use statement for information on target patient population specific to the catheter being used.

The Global Hypoperfusion Index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter. The GHI algorithm is considered to provide additional information regarding the patient's

predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions.

When used in combination with a Swan-Ganz catheter connected to a pressure cable and pressure transducer, the Edwards Lifesciences Smart Wedge algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge algorithm is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Smart Wedge algorithm parameters.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

1.2.2 HemoSphere Alta Advanced Monitoring Platform with HemoSphere Oximetry Cable

The HemoSphere Alta advanced monitor when used with the HemoSphere oximetry cable and Edwards oximetry catheters is indicated for use in adult and pediatric critical care patients requiring monitoring of venous oxygen saturation (SvO_2 and $ScvO_2$) and derived hemodynamic parameters in a hospital environment. Refer to the Edwards oximetry catheter indications for use statement for information on target patient population specific to the catheter being used.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

1.2.3 HemoSphere Alta Advanced Monitoring Platform with HemoSphere Pressure Cable or HemoSphere Alta Monitor – Pressure Cable

The HemoSphere Alta advanced monitor when used with the HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable is indicated for use in adult and pediatric critical care patients in which the balance between cardiac function, fluid status, vascular resistance and pressure needs continuous assessment. It may be used for monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. Refer to the Edwards FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, and TruWave disposable pressure transducer indications for use statements for information on target patient populations specific to the sensor/transducer being used.

The Edwards Acumen Hypotension Prediction Index software feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Acumen Hypotension Prediction Index (HPI) parameter.

When used in combination with the HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable connected to a compatible Swan-Ganz catheter, the Edward Lifesciences Right Ventricular Pressure (RVP) algorithm provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVP algorithm is indicated for critically ill patients over 18 years of age receiving advanced hemodynamic monitoring in the operating room

(OR) and intensive care unit (ICU). The RVP algorithm is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Right Ventricular Pressure (RVP) parameters.

When used in combination with the HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable connected to a compatible Swan-Ganz catheter, the Right Ventricular Cardiac Output (RVCO) feature provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVCO algorithm is intended for use in surgical or non-surgical patients over 18 years of age that require advanced hemodynamic monitoring. The Right Ventricular Cardiac Output provides a continuous cardiac output and derived parameters.

The Cerebral Autoregulation Index (CAI) algorithm is an informational index intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between Mean Arterial Pressure (MAP) and the Absolute Levels of Blood Oxygenation Saturation (StO_2) in patient's cerebral tissue. MAP is acquired by the HemoSphere pressure cable and StO_2 is acquired by the ForeSight oximeter cable. CAI is intended for use in patients over 18 years of age receiving advanced hemodynamic monitoring. CAI is not indicated to be used for treatment of any disease or condition and no therapeutic decisions should be made based solely on the Cerebral Autoregulation Index (CAI) algorithm.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

1.2.4 HemoSphere Alta Advanced Monitoring Platform with ForeSight Oximeter Cable

The non-invasive ForeSight oximeter cable is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no-flow ischemic states. The ForeSight oximeter cable is also intended to monitor relative changes of total hemoglobin of blood under the sensors. The ForeSight oximeter cable is intended to allow for the display of StO_2 and relative change in total hemoglobin on the HemoSphere Alta advanced monitoring platform.

- When used with large sensors, the ForeSight oximeter cable is indicated for use on adults and transitional adolescents ≥40 kg.
- When used with medium sensors, the ForeSight oximeter cable is indicated for use on pediatric subjects ≥3 kg.
- When used with small sensors, the ForeSight oximeter cable is indicated for cerebral use on pediatric subjects <8 kg and non-cerebral use on pediatric subjects <5kg.

The Edwards algorithm for measurement of blood hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight oximeter cable and non-invasive ForeSight IQ sensors in cerebral locations.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

1.2.5 HemoSphere Alta Advanced Monitoring Platform with ClearSight Technology

The HemoSphere Alta monitor when used with the pressure controller and a compatible Edwards finger cuff are indicated for adult and pediatric patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the noninvasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are

difficult. The HemoSphere Alta advanced monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. Refer to the ClearSight finger cuff, ClearSight Jr finger cuff, and Acumen IQ finger cuff indications for use statements for information on target patient population specific to the finger cuff being used.

The Edwards Acumen Hypotension Prediction Index (HPI) software feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Acumen Hypotension Prediction Index (HPI) parameter.

Refer to the Intended Use statement for a complete list of measured and derived parameters available for each patient population.

1.2.6 HemoSphere Alta Advanced Monitoring Platform with Acumen Assisted Fluid Management Feature and Acumen IQ Sensor

The Acumen assisted fluid management (AFM) software feature provides the clinician with physiological insight into a patient's estimated response to fluid therapy and the associated hemodynamics. The Acumen AFM software feature is intended for use in surgical patients ≥18 years of age, that require advanced hemodynamic monitoring. The Acumen AFM software feature offers suggestions regarding the patient's physiological condition and estimated response to fluid therapy. Acumen AFM fluid administration suggestions are offered to the clinician; the decision to administer a fluid bolus is made by the clinician, based upon review of the patient's hemodynamics. No therapeutic decisions should be made based solely on the assisted fluid management suggestions.

The Acumen assisted fluid management software feature may be used with the HemoSphere Alta AFM cable and Acumen IQ fluid meter.

1.3 Contraindications For Use

The HemoSphere Alta advanced monitoring platform while used with the Swan-Ganz technology, oximetry cable or pressure cable has no contraindications for use.

1.3.1 HemoSphere Alta Advanced Monitoring Platform with ForeSight Oximeter Cable

The ForeSight/ForeSight IQ/ForeSight Jr sensor is contraindicated for use on patients:

- with a physical site area too limited for proper sensor placement
- with allergic reactions to sensor adhesive
- undergoing an MRI scan because of associate risk of injury

1.3.2 HemoSphere Alta Advanced Monitoring Platform with ClearSight Technology

The HemoSphere Alta advanced monitor while used with a compatible finger cuff(s) is contraindicated in some patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease. In these patients, blood pressure measurement can become impossible.

No other contraindications were known at the time this operator's manual was published.

1.4 Intended Use Statement

The HemoSphere Alta advanced monitoring platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting.

The HemoSphere Alta advanced monitoring platform is intended for use with compatible Edwards oximetry catheters, Swan-Ganz/Swan-Ganz Jr/Swan-Ganz IQ catheters, FloTrac sensors, FloTrac Jr sensors, Acumen IQ sensors, TruWave disposable pressure transducers, ForeSight /ForeSight Jr/ForeSight IQ sensors, Acumen IQ fluid meter, and ClearSight/ClearSight Jr/Acumen IQ finger cuffs.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta advanced monitoring platform and a connected HemoSphere Alta Swan-Ganz patient cable are listed below in table 1-1. Only iCO, iCI, iSVR, and iSVRI are available to the pediatric patient population.

Table 1-1 HemoSphere Alta Swan-Ganz patient cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
CO	continuous cardiac output	adult only	operating room, intensive care unit, emergency room
sCO	STAT cardiac output		
CI	continuous cardiac index		
sCI	STAT cardiac index		
EDV	right ventricular end diastolic volume		
sEDV	STAT right ventricular end diastolic volume		
EDVI	right ventricular end diastolic volume index		
sEDVI	STAT right ventricular end diastolic volume index		
HR_{avg}	averaged heart rate		
LVSWI	left ventricular stroke work index		
PVR	pulmonary vascular resistance		
PVRI	pulmonary vascular resistance index		
RVEF	right ventricular ejection fraction		
sRVEF	STAT right ventricular ejection fraction		
RVSWI	right ventricular stroke work index		
SV	stroke volume		
SVI	stroke volume index		
SVR	systemic vascular resistance		
SVRI	systemic vascular resistance index		
BT	pulmonary artery blood temperature		
iCO	intermittent cardiac output	adult and pediatric	
iCI	intermittent cardiac index		
iSVR	intermittent systemic vascular resistance		
iSVRI	intermittent systemic vascular resistance index		

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Alta advanced monitoring platform and a connected HemoSphere oximetry cable are listed below in table 1-2.

Table 1-2 HemoSphere oximetry cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
SvO_2	mixed venous oxygen saturation	adult and pediatric	operating room, intensive care unit, emergency room
$ScvO_2$	central venous oxygen saturation		

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Alta advanced monitoring platform and both a connected HemoSphere Alta Swan-Ganz patient cable and oximetry cable are listed below in table 1-3.

Table 1-3 HemoSphere Alta Swan-Ganz patient cable with oximetry cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
DO_2	oxygen delivery	adult and pediatric	operating room, intensive care unit, emergency room
DO_2I	oxygen delivery index		
VO_2	oxygen consumption		
VO_2e	estimated oxygen consumption when $ScvO_2$ is being monitored		
VO_2I	oxygen consumption index		
VO_2Ie	estimated oxygen consumption index when $ScvO_2$ is being monitored		
GHI	global hypoperfusion index	adult only	

A comprehensive list of parameters available while monitoring with the HemoSphere Alta advanced monitoring platform and both a connected HemoSphere Alta Swan-Ganz patient cable and pressure cable are listed below in table 1-4.

Table 1-4 HemoSphere Alta Swan-Ganz patient cable with HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable available parameters list*

Abbreviation	Definition	Patient population	Hospital environment
CO_{20s}	20-second cardiac output[1]	adult only	operating room, intensive care unit, emergency room
CO_{RV}	right ventricular cardiac output[2]		
CI_{20s}	20-second cardiac index[1]		
CI_{RV}	right ventricular cardiac index[2]		
CPO_{RV}	right ventricular cardiac power output[2]		
CPI_{RV}	right ventricular cardiac power index[2]		
DIA_{RVP}	right ventricular diastolic pressure[2]		
MRVP	mean right ventricular pressure[2]		
PAOP	pulmonary artery occlusion pressure[2]		
PR_{RVP}	right ventricular pulse rate[2]		
RV dP/dt	right ventricular systolic slope[2]		
RV EDP	right ventricular end diastolic pressure[2]		
SYS_{RVP}	systolic right ventricular pressure[2]		
SV_{20s}	20-second stroke volume[1]		
SV_{RV}	right ventricular stroke volume[2]		
SVI_{20s}	20-second stroke volume index[1]		
SVI_{RV}	right ventricular stroke volume index[2]		

[1]20-second flow parameters are only available if the 20s flow parameter feature is enabled. Please contact your local Edwards representative for more information on enabling this advanced feature.

[2]RVP and RVCO parameters are available when using a Swan-Ganz IQ catheter.

A comprehensive list of parameters available while monitoring with the HemoSphere Alta advanced monitoring platform and a connected HemoSphere pressure cable or pressure cable – HemoSphere Alta monitor are listed below in table 1-5.

Table 1-5 HemoSphere pressure cable/ HemoSphere Alta monitor – pressure cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
CO	continuous cardiac output[1]	adult and pediatric ≥ 12	operating room, intensive care unit, emergency room
CI	continuous cardiac index[1]		
CPO	cardiac power output		
CPI	cardiac power index		
DIA_{ART}	systemic arterial diastolic blood pressure		
DIA_{RVP}	right ventricular diastolic pressure		
MAP	mean arterial blood pressure		
MRVP	mean right ventricular pressure		
PPV	pulse pressure variation[1]		
PR	pulse rate		
PR_{RVP}	right ventricular pulse rate		
RV dP/dt	right ventricular systolic slope		
RVEDP	right ventricular end diastolic pressure		
SV	stroke volume[1]		
SVI	stroke volume index[1]		
SVR	systemic vascular resistance[1]		
SVRI	systemic vascular resistance index[1]		
SVV	stroke volume variation[1]		
SYS_{ART}	systemic arterial systolic blood pressure		
SYS_{RVP}	right ventricular systolic pressure		
CVP	central venous pressure	adult only	
DIA_{PAP}	pulmonary artery diastolic blood pressure		
dP/dt	systolic slope[2]		
Ea_{dyn}	dynamic arterial elastance[2]		
HPI	Acumen Hypotension Prediction Index[2]		
MPAP	mean pulmonary artery blood pressure		
SYS_{PAP}	pulmonary artery systolic blood pressure		

[1]FloTrac parameters are available when using a FloTrac/FloTrac Jr/Acumen IQ sensor
[2]HPI parameters are available when using an Acumen IQ sensor.

A list of Acumen Assisted Fluid Management (AFM) outputs available for surgical patients ≥18 years of age while monitoring with the HemoSphere Alta advanced monitoring platform and a connected HemoSphere pressure cable or pressure cable -HemoSphere Alta monitor are listed below in table 1-6.

Table 1-6 HemoSphere pressure cable/HemoSphere Alta monitor – pressure cable available AFM output list

AFM output	Patient population	Hospital environment
Fluid Bolus Suggested	≥18 years of age only	operating room, only
Test Bolus Suggested		
Fluid Not Suggested		
Suggestions Suspended		
Bolus In Progress...		
Bolus Complete		
Bolus Complete; Analyzing Hemodynamic Response		
Total tracked volume mL		
Flow Rate mL/hr		
Bolus Volume		
Note: AFM outputs are available when using an Acumen IQ sensor and if the AFM feature is activated. Flow rate mL/hr and Bolus Volume are visible when using automatic fluid tracking mode.		

A comprehensive list of parameters available for adult and pediatric patient populations while monitoring with the HemoSphere Alta advanced monitoring platform and both a connected HemoSphere pressure cable and oximetry cable are listed below in table 1-7.

Table 1-7 HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable with oximetry cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
DO_2	oxygen delivery	adult only	operating room, intensive care unit, emergency room
DO_2I	oxygen delivery index		
VO_2	oxygen consumption		
VO_2e	estimated oxygen consumption when $ScvO_2$ is being monitored		
VO_2I	oxygen consumption index		
VO_2Ie	estimated oxygen consumption index when $ScvO_2$ is being monitored		

Tissue oxygen saturation, StO_2, can be monitored with the HemoSphere Alta advanced monitoring platform and a connected ForeSight oximeter cable as listed below in table 1-8.

Table 1-8 ForeSight oximeter cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
StO_2	tissue oxygen saturation	adult and pediatric	operating room, intensive care unit, emergency room
ΔctHb	relative change in total hemoglobin		
tHb	total hemoglobin	adults and transitional adolescents ≥40 kg	
Total hemoglobin (tHb) is available when monitoring using a HemoSphere ForeSight oximeter cable and two Foresight IQ sensors in cerebral locations			

A comprehensive list of parameters available for adult patient populations while monitoring with the HemoSphere Alta advanced monitoring platform and both a connected HemoSphere pressure cable or pressure cable - HemoSphere Alta monitor and ForeSight oximeter cable are listed below in table 1-9.

Table 1-9 HemoSphere pressure cable or HemoSphere Alta monitor – pressure cable with ForeSight oximeter cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
CAI	cerebral autoregulation index[1]	adult only	operating room, intensive care unit, emergency room
[1]CAI parameter is available when using a ForeSight IQ sensor and if the CAI feature is enabled.			

A comprehensive list of parameters available while monitoring with the HemoSphere Alta advanced monitoring platform and a connected pressure controller are listed below in table 1-10.

Table 1-10 HemoSphere ClearSight technology available parameters list

Abbreviation	Definition	Patient population	Hospital environment
CO	continuous cardiac output	adult and pedatric ≥ 12	operating room, intensive care unit, emergency room
CI	continuous cardiac index		
CPO	cardiac power output		
CPI	cardiac power index		
DIA_{ART}	arterial diastolic blood pressure		
MAP	mean arterial blood pressure		
PPV	pulse pressure variation		
PR	pulse rate		
SV	stroke volume		
SVI	stroke volume index		
SVR	systemic vascular resistance		
SVRI	systemic vascular resistance index		
SVV	stroke volume variation		
SYS_{ART}	arterial systolic blood pressure		
dP/dt	systolic slope[1]	adult only	
Ea_{dyn}	dynamic arterial elastance[1]		
HPI	Acumen Hypotension Prediction Index[1]		

[1]HPI parameters are available when using an Acumen IQ finger cuff and heart reference sensor (HRS) Note: CO/CI and SV/SVI are measured using a reconstructed brachial arterial waveform. All other monitored parameters use a reconstructed radial arterial waveform. SVR/SVRI are derived from CO/CI and MAP along with an entered or monitored CVP value. For more information, see Waveform Reconstruction and Hemodynamic Analysis (ClearSight Technology) on page 173.

A comprehensive list of parameters available for adult patient populations while monitoring with the HemoSphere Alta advanced monitoring platform and both a connected pressure controller and oximetry cable are listed below in table 1-11.

Table 1-11 HemoSphere ClearSight technology with oximetry cable available parameters list

Abbreviation	Definition	Patient population	Hospital environment
DO_2	oxygen delivery	adult only	operating room and intensive care unit
DO_2I	oxygen delivery index		
VO_2	oxygen consumption		
VO_2e	estimated oxygen consumption when $ScvO_2$ is being monitored		
VO_2I	oxygen consumption index		
VO_2Ie	estimated oxygen consumption index when $ScvO_2$ is being monitored		

WARNING Improper use of the HemoSphere Alta advanced monitoring platform could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in chapter 2, before using the platform.

The HemoSphere Alta advanced monitoring platform is intended for use only in patient assessment. This instrument must be used in conjunction with a bedside physiological monitor and/or patient clinical signs and symptoms. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting before initiating treatment options.

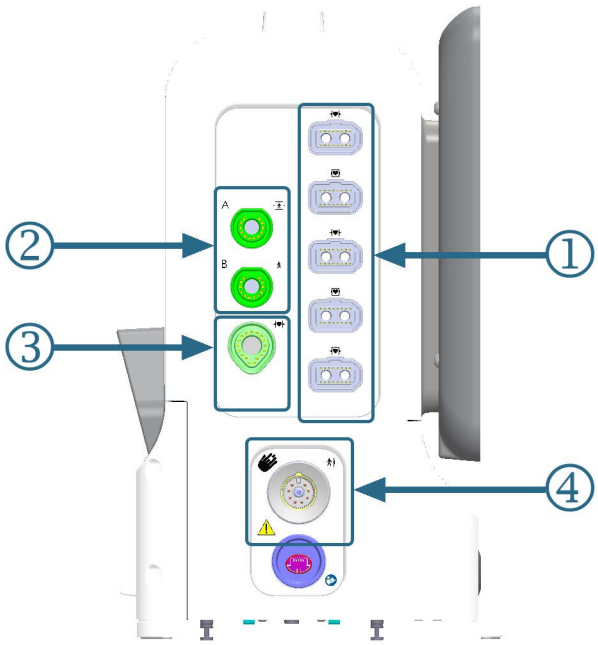
ECG signal input and all parameters derived from heart rate measurements have not been evaluated for pediatric patients and are therefore not available for that patient population.

1.5 Expected Clinical Benefit

The HemoSphere Alta advanced monitoring platform allows you to see and interact with patient hemodynamic parameters. In conjunction with the compatible sensors and predictive decision support software, the HemoSphere Alta advanced monitoring platform facilitates proactive clinical decision-making and insight for individualized patient care.

1.6 HemoSphere Alta Advanced Monitoring Platform Hemodynamic Technology Connections

The HemoSphere Alta advanced monitoring platform is equipped with five common cable ports and two tissue oximetry monitoring ports. Some models may also have a patient cable port for Swan-Ganz monitoring technology or a pressure controller port for ClearSight monitoring technology. The integrated All-on-One hemodynamic monitoring technologies of the HemoSphere Alta advanced monitoring platform provide a quick setup and stability. All technology cable connection points are located on the right side panel. See figure 1-1.



① common cable ports (5)

② tissue oximetry ports (2)

③ Swan-Ganz technology port (1)

④ ClearSight technology port (1)

Figure 1-1 HemoSphere Alta advanced monitoring platform hemodynamic technology connections

Table 1-12 Technology connections available on HemoSphere Alta monitoring platform configurations

Monitor port	Cardiac	All-on-One	Smart Recovery
1. common cable ports (5)	•	•	•
2. tissue oximetry ports (2)	•	•	•
3. Swan-Ganz technology port (1)	•	•	
4. ClearSight technology port (1)		•	•

Each cable is associated with a specific Edwards hemodynamic monitoring technology. Currently available cables that plug into common ports include:

- HemoSphere pressure cable: introduced below and described in detail in chapter 9, *HemoSphere Pressure Cable Monitoring.*
- HemoSphere oximetry cable: introduced below and described in detail in chapter 11, *Venous Oximetry Monitoring.*
- HemoSphere Alta AFM cable: introduced below and described in detail in chapter 13, *Fluid Administration Workflow – Acumen IQ Fluid Meter.*

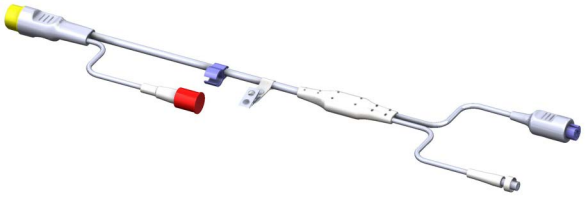
Tissue oximetry monitoring is introduced below and described in detail in chapter 12, *HemoSphere Alta Tissue Oximetry Monitoring.*

HemoSphere Swan-Ganz technology is described below and in detail in chapter 8, *HemoSphere Alta Swan-Ganz Monitoring.*

ClearSight monitoring technology is introduced below and in detail in chapter 10, *HemoSphere Alta ClearSight Technology.*

The HemoSphere Alta advanced monitoring platform is also equipped with a depth camera for gesture commands and a microphone for voice commands. For more on gesture *HemoSphere Alta Advanced Monitoring Platform Gesture Commands* on page 93. For more on voice commands see *HemoSphere Alta Advanced Monitoring Platform Voice Commands* on page 94.

1.6.1 HemoSphere Alta Swan-Ganz Technology



The HemoSphere Alta Swan-Ganz patient cable enables continuous cardiac output (CCO) and intermittent cardiac output (iCO) monitoring with a compatible Edwards Swan-Ganz/Swan-Ganz Jr/Swan-Ganz IQ catheter. Right ventricular end diastolic volume (EDV) monitoring is available with analog input heart rate (HR_{avg}) data from a bedside patient monitor. The HemoSphere Alta Swan-Ganz patient cable plugs into the Swan-Ganz technology port. For more information, see chapter 8, *HemoSphere Alta Swan-Ganz Monitoring*.. Table 1-13 lists the parameters available while using the HemoSphere Alta Swan-Ganz patient cable.

Table 1-13 HemoSphere Alta Swan-Ganz patient cable parameters description

Parameter	Description	Technology
continuous cardiac output (CO)	continuous assessment through advanced thermodilution technology of the volume of blood pumped by the heart measured in liters per minute	Swan-Ganz CCO and CCOmbo catheters
continuous cardiac index (CI)	continuous cardiac output relative to body surface area (BSA)	Swan-Ganz CCO and CCOmbo catheters
global hypoperfusion index (GHI)	index representing the likelihood that the patient may experience a future global hypoperfusion event (SvO_2 60% for at least one minute in duration)	Swan-Ganz CCOmbo catheter or Swan-Ganz IQ catheter with oximetry cable input
intermittent cardiac output (iCO)	intermittent assessment through the bolus thermodilution method of the volume of blood pumped by the heart measured in liters per minute	Swan-Ganz and Swan-Ganz Jr thermodilution catheters
intermittent cardiac index (iCI)	intermittent cardiac output relative to body surface area (BSA)	Swan-Ganz and Swan-Ganz Jr thermodilution catheters
right ventricular ejection fraction (RVEF)	continuous assessment through advanced thermodilution technology and algorithm analysis of the percentage of blood volume ejected from the right ventricle during systole	Swan-Ganz CCOmbo V catheters with ECG signal input
right ventricular end diastolic volume (EDV)	continuous assessment of the volume of blood in the right ventricle at the end of diastole calculated by dividing stroke volume (mL/beat) by RVEF(%)	Swan-Ganz CCOmbo V catheters with ECG signal input

Table 1-13 HemoSphere Alta Swan-Ganz patient cable parameters description (continued)

Parameter	Description	Technology
stroke volume (SV)	amount of blood ejected from the ventricles with each contraction derived from CO assessment and heart rate (SV = CO/HR x 1000)	Swan-Ganz CCO,CCOmbo, and CCOmbo V catheters with ECG signal input
stroke volume index (SVI)	stroke volume relative to body surface area (BSA)	Swan-Ganz CCO,CCOmbo, and CCOmbo V catheters with ECG signal input
systemic vascular resistance (SVR)	a derived measure of impedance to blood flow from left ventricle (afterload)	Swan-Ganz CCO and CCOmbo catheters with MAP and CVP analog pressure signal input
systemic vascular resistance index (SVRI)	systemic vascular resistance relative to body surface area (BSA)	Swan-Ganz CCO and CCOmbo catheters with MAP and CVP analog pressure signal input

1.6.2 HemoSphere Pressure Cable

The HemoSphere Alta pressure cable (HEMAPSC200) and HemoSphere pressure cable (HEMPSC100) enable vascular pressure monitoring with a compatible Edwards pressure transducer/sensor and catheter. A connected FloTrac, FloTrac Jr, or Acumen IQ sensor provides continuous cardiac output (CO) and associated hemodynamic parameters. A connected TruWave transducer provides location based intravascular pressure. The HemoSphere pressure cable plugs into a monitoring cable port. For more information, see chapter 9, *HemoSphere Pressure Cable Monitoring*.. Table 1-14 lists the parameters available while using the HemoSphere pressure cable.

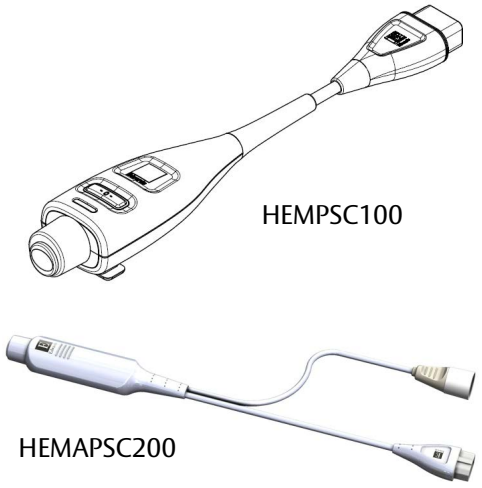


Table 1-14 HemoSphere pressure cable key parameters description

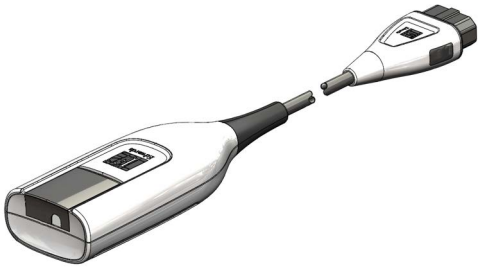
Parameter	Description	Technology
continuous cardiac output (CO)	continuous assessment of the volume of blood pumped by the heart measured in liters per minute using the existing arterial pressure waveform and FloTrac system algorithm	FloTrac, FloTrac Jr, or Acumen IQ sensor
continuous cardiac index (CI)	continuous cardiac output relative to body surface area (BSA)	FloTrac, FloTrac Jr, or Acumen IQ sensor
central venous pressure (CVP)	central venous blood pressure	TruWave pressure transducer at central venous catheter line
diastolic blood pressure (DIA_{ART}/DIA_{PAP}/DIA_{RVP})	diastolic blood pressure measured at the pulmonary artery (PAP), right ventricle (RVP) or a systemic artery (ART)	FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave pressure transducer
systolic slope (dP/dt)*	maximum upslope of the arterial pressure waveform measured from a peripheral artery *	Acumen IQ sensor
dynamic arterial elastance (Ea_{dyn})*	measure of afterload to the left ventricle by the arterial system (arterial elastance) relative to the left ventricular elastance*	Acumen IQ sensor

Table 1-14 HemoSphere pressure cable key parameters description (continued)

Parameter	Description	Technology
Acumen Hypotension Prediction Index (HPI)*	index representing the likelihood that the patient may be trending toward a hypotensive event (MAP<65 mmHg for at least one minute in duration)*	Acumen IQ sensor
mean arterial pressure (MAP)	averaged systemic blood pressure over one cardiac cycle	FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave pressure transducer
mean pulmonary artery pressure (MPAP)	averaged pulmonary artery blood pressure over one cardiac cycle	TruWave pressure transducer at pulmonary artery catheter line
mean right ventricular pressure (MRVP)	averaged right ventricular blood pressure over one cardiac cycle	TruWave pressure transducer at the right ventricle
pulse pressure variation (PPV)	the percent difference between PPmin and PPmax relative to PPmean where PP = SYS-DIA	FloTrac, FloTrac Jr, or Acumen IQ sensor
pulse rate (PR)	number of arterial blood pressure pulses per minute	FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave pressure transducer
right ventricular pulse rate (PR_{RVP})	number of ventricular contractions per minute	TruWave pressure transducer at the right ventricle
right ventricular systolic slope (RV dP/dt)	maximum upslope of the pressure waveform measured at the right ventricle	TruWave pressure transducer at the right ventricle
right ventricular end diastolic pressure (RVEDP)	pressure in the right ventricle at the end of diastole after the pulmonic valve is closed	TruWave pressure transducer at the right ventricle
stroke volume (SV)	volume of blood pumped with each heart beat	FloTrac, FloTrac Jr, or Acumen IQ sensor
stroke volume index (SVI)	stroke volume relative to body surface area (BSA)	FloTrac, FloTrac Jr, or Acumen IQ sensor
systemic vascular resistance (SVR)	a derived measure of impedance to blood flow from left ventricle (afterload)	FloTrac, FloTrac Jr, or Acumen IQ sensor
systemic vascular resistance index (SVRI)	systemic vascular resistance relative to body surface area (BSA)	FloTrac, FloTrac Jr, or Acumen IQ sensor
stroke volume variation (SVV)	the percent difference between SVmin and SVmax relative to SVmean	FloTrac, FloTrac Jr, or Acumen IQ sensor
systolic pressure (SYS_{ART}/SYS_{PAP}/ SYS_{RVP})	systolic blood pressure measured at the pulmonary artery (PAP), right ventricle (RVP) or a systemic artery (ART)	FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave pressure transducer
**HPI parameters are available when using a Acumen IQ sensor.*		

NOTE Cardiac output calculated with the HemoSphere pressure cable may differ from that calculated with the HemoSphere Alta Swan-Ganz patient cable due to methodological and algorithmic differences.

1.6.3 HemoSphere Oximetry Cable



The HemoSphere oximetry cable enables mixed venous oxygen saturation (SvO_2) or central venous oxygen saturation ($ScvO_2$) monitoring with a compatible Edwards oximetry catheter. The HemoSphere oximetry cable plugs into a monitoring cable port and can be used in combination with other hemodynamic monitoring technologies. For more information on oximetry monitoring, see chapter 11, *Venous Oximetry Monitoring*. Table 1-15 lists the parameters available while using the HemoSphere oximetry cable.

Table 1-15 HemoSphere oximetry cable parameters description

Parameter	Description
central venous oximetry ($ScvO_2$)	venous oxygen saturation as measured in the superior vena cava
mixed venous oximetry (SvO_2)	venous oxygen saturation as measured in the pulmonary artery
oxygen consumption (VO_2)	the amount of oxygen used by the body per minute
estimated oxygen consumption (VO_2e)	an estimate of the amount of oxygen used by the body per minute ($ScvO_2$ monitoring only)
oxygen consumption index (VO_2I)	the amount of oxygen used by the body per minute indexed against body surface area (BSA)
estimated oxygen consumption index (VO_2Ie)	an estimate of the amount of oxygen used by the body per minute indexed against body surface area (BSA)

1.6.4 ForeSight Oximeter Cable

The HemoSphere Alta advanced monitoring platform enables tissue oximetry (StO_2) monitoring with a ForeSight oximeter cable and compatible tissue oximetry sensors. For more information on tissue oximetry monitoring, see chapter 12, *HemoSphere Alta Tissue Oximetry Monitoring*. Table 1-16 lists the parameters available while using the ForeSight oximeter cable.

NOTE The following components may have alternative labeling conventions:
ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).
ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

Table 1-16 ForeSight oximeter cable parameters description

Parameter	Description	Technology
tissue oximetry (StO_2)	absolute tissue oxygen saturation as measured at anatomical surface below sensor location	ForeSight/ForeSight Jr sensor detection of near-infrared light reflection
relative change in total hemoglobin (ΔctHb)	trending value calculated from the sum of relative changes in oxygenated hemoglobin and deoxygenated hemoglobin (ΔO2Hb and ΔHHb)	ForeSight/ForeSight Jr sensor detection of near-infrared light reflection

1.6.5 HemoSphere ClearSight Technology

The HemoSphere Alta advanced monitoring platform with a connected compatible pressure controller and finger cuff(s) enables non-invasive measurement of a patient's arterial pressure waveform and calculation of continuous cardiac output (CO) and associated hemodynamic parameters. The pressure controller plugs into the ClearSight technology port. For more information, see chapter 10, *HemoSphere Alta ClearSight Technology.*

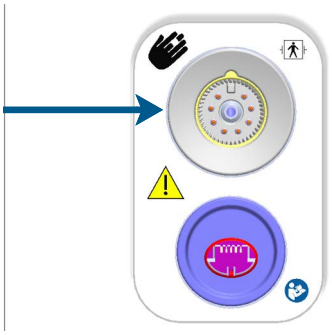


Table 1-17 HemoSphere ClearSight technology key parameters description

Parameter	Description	Technology
continuous cardiac output (CO)	continuous assessment of the volume of blood pumped by the heart measured in liters per minute using the monitored arterial pressure waveform and ClearSight algorithm	ClearSight, ClearSight Jr, or Acumen IQ cuff
continuous cardiac index (CI)	continuous cardiac output relative to body surface area (BSA)	ClearSight, ClearSight Jr, or Acumen IQ cuff
diastolic blood pressure (DIA_{ART})	diastolic blood pressure	ClearSight, ClearSight Jr, or Acumen IQ cuff
systolic slope (dP/dt)*	maximum upslope of the arterial pressure waveform measured from a peripheral artery*	Acumen IQ cuff
dynamic elastance (Ea_{dyn})*	measure of afterload to the left ventricle by the arterial system (arterial elastance) relative to the left ventricular elastance*	Acumen IQ cuff
Acumen Hypotension Prediction Index (HPI)*	index representing the likelihood that the patient may be trending toward a hypotensive event (MAP<65 mmHg for at least one minute in duration)*	Acumen IQ cuff
mean arterial pressure (MAP)	averaged systemic blood pressure over one cardiac cycle	ClearSight, ClearSight Jr, or Acumen IQ cuff
pulse pressure variation (PPV)	the percent difference between PPmin and PPmax relative to PPmean where PP = SYS-DIA	ClearSight, ClearSight Jr, or Acumen IQ cuff
pulse rate (PR)	number of arterial blood pressure pulses per minute	ClearSight, ClearSight Jr, or Acumen IQ cuff

Table 1-17 HemoSphere ClearSight technology key parameters description (continued)

Parameter	Description	Technology
stroke volume (SV)	volume of blood pumped with each heart beat	ClearSight, ClearSight Jr, or Acumen IQ cuff
stroke volume index (SVI)	stroke volume relative to body surface area (BSA)	ClearSight, ClearSight Jr, or Acumen IQ cuff
systemic vascular resistance (SVR)	a derived measure of impedance to blood flow from left ventricle (afterload)	ClearSight, ClearSight Jr, or Acumen IQ cuff
systemic vascular resistance index (SVRI)	systemic vascular resistance relative to body surface area (BSA)	ClearSight, ClearSight Jr, or Acumen IQ cuff
stroke volume variation (SVV)	the percent difference between SVmin and SVmax relative to SVmean	ClearSight, ClearSight Jr, or Acumen IQ cuff
systolic pressure (SYS_{ART})	systolic blood pressure	ClearSight, ClearSight Jr, or Acumen IQ cuff
**HPI parameters are available when using an Acumen IQ finger cuff and heart reference sensor.*		

1.6.6 HemoSphere Alta AFM Cable

The HemoSphere Alta AFM cable enables bolus delivery flow rate tracking in the AFM software feature with a compatible fluid meter. For more information on the AFM software feature, which is an advanced feature, see *Assisted Fluid Management* on page 278.

1.6.7 Documentation and Training

Instructions for Use are included with HemoSphere Alta advanced monitoring platform components. See table B-1, "HemoSphere Alta advanced monitoring platform components," on page 363. For more information on how you can receive training or available documentation for the HemoSphere Alta advanced monitoring platform, contact your local Edwards representative or Edwards Technical Support. See appendix F, *System Care, Service and Support.*

1.7 Manual style conventions

Table 1-18 lists the style conventions used in this manual.

Table 1-18 Operator's manual style conventions

Convention	Description
Bold	Bold text indicates a software term. This word or phrase will appear on the screen as shown.
Bold button	A button is a touch screen access point for the option appearing in bold. For example, the **Back** button appears on-screen as: 
→	An arrow is shown between two on-screen menu options that are selected consecutively by the operator.
	An icon is a touch screen access point for the menu or navigation graphic shown. See table 2-1 on page 61 for full list of menu icons shown on the HemoSphere Alta advanced monitoring platform.

Table 1-18 Operator's manual style conventions (continued)

Convention	Description
Venous Oximetry icon 	Bold text with a menu icon indicates an icon that is paired with a software term or phrase appearing on the screen. For example, the **Venous Oximetry** icon appears on-screen as: 

Abbreviations Found in This Manual

Table 1-19 Acronyms, Abbreviations

Abbreviation	Definition
A/D	analog/digital
AFM	Assisted Fluid Management
ART	systemic arterial blood pressure
BMI	body mass index
BSA	body surface area
BT	blood temperature
CAI	cerebral autoregulation index
CaO_2	arterial oxygen content
CFI	cardiac function index
CI	cardiac index
CI_{20s}	20-second cardiac index
CI_{RV}	right ventricular cardiac index
CO	cardiac output
CO_{20s}	20-second cardiac output
CO_{RV}	right ventricular cardiac output
CCO	continuous cardiac output (used when describing certain Swan-Ganz catheters and HemoSphere Alta patient cable)
CPI	cardiac power index
CPI_{RV}	right ventricular cardiac power index
CPO	cardiac power output
CPO_{RV}	right ventricular cardiac power output
CVP	central venous pressure
ΔctHb	relative change in total hemoglobin
DIA	diastolic blood pressure
DIA_{ART}	systemic arterial diastolic blood pressure
DIA_{PAP}	pulmonary artery diastolic blood pressure
DIA_{RVP}	right ventricular diastolic blood pressure

Table 1-19 Acronyms, Abbreviations (continued)

Abbreviation	Definition
DO_2	oxygen delivery
DO_2I	oxygen delivery index
dP/dt	systolic slope (maximum upslope of the arterial pressure waveform)
DPT	disposable pressure transducer
Ea_{dyn}	dynamic arterial elastance
EDV	end diastolic volume
EDVI	end diastolic volume index
ESV	end systolic volume
ESVI	end systolic volume index
EVLW	extravascular lung water
ELWI	extravascular lung water index
efu	ejection fraction unit
FRT	Fluid Responsiveness Test
FT-CO	FloTrac arterial pressure auto calibrated cardiac output
GDT	goal directed therapy
GEDV	global-end diastolic volume
GEDI	global end-diastolic volume index
GEF	global ejection fraction
GHI	global hypoperfusion index
Hct	hematocrit
HEMPC	pressure controller
HIS	hospital information systems
HGB	hemoglobin
HPI	Acumen Hypotension Prediction Index
HR	heart rate
HR_{avg}	average heart rate
HRS	heart reference sensor

Table 1-19 Acronyms, Abbreviations (continued)

Abbreviation	Definition
IA	Intervention Analysis
iCI	intermittent cardiac index
iCO	intermittent cardiac output
IEC	International Electrotechnical Commission
iSV	intermittent stroke volume
iSVI	intermittent stroke volume index
iSVR	intermittent systemic vascular resistance
iSVRI	intermittent systemic vascular resistance index
IT	injectate temperature
ITBV	intrathoracic blood volume
ITBI	intrathroacic blood volume index
LAEDV	left atrial end diastolic volume
LED	light emitting diode
LVEDV	left ventricular end diastolic volume
LVSWI	left ventricular stroke work index
MAP	mean arterial pressure
MPAP	mean pulmonary artery pressure
MRVP	mean right ventricular pressure
NIBP	noninvasive blood pressure
OR	operating room
PA	pulmonary artery
PAP	pulmonary artery blood pressure
PaO_2	partial pressure of arterial oxygen
PAOP	pulmonary artery occlusion pressure
PAWP	pulmonary artery wedge pressure
PBV	pulmonary blood volume
PBW	predicted blood volume
PPV	pulse pressure variation
POST	power-on self test
PR	pulse rate
PR_{RVP}	right ventricular pulse rate
PvO_2	partial pressure of venous oxygen
PVPI	pulmonary vascular permeability index
PVR	pulmonary vascular resistance
PVRI	pulmonary vascular resistance index
RAEDV	right atrial end diastolic volume
RV	right ventricular
RVEDV	right ventricular end diastolic volume
RVCO	right ventricular cardiac output (algorithm)
RV dP/dt	right ventricular systolic slope (maximum upslope of the right ventricular pressure waveform)
RV EDP	right ventricular end diastolic pressure
RVP	right ventricular blood pressure

Table 1-19 Acronyms, Abbreviations (continued)

Abbreviation	Definition
RVEF	right ventricular ejection fraction
RVSWI	right ventricular stroke work index
SaO_2	oxygen saturation
sCI	STAT cardiac index
sCO	STAT cardiac output
$ScvO_2$	central venous oximetry
sEDV	STAT end diastolic volume
sEDVI	STAT end diastolic volume index
SQI	signal quality indicator
sRVEF	STAT right ventricular ejection fraction
ST	surface temperature
STAT	fast estimate of parameter value
StO_2	tissue oxygen saturation
SV	stroke volume
SV_{20s}	20-second stroke volume
SV_{RV}	right ventricular stroke volume
SVI	stroke volume index
SVI_{20s}	20-second stroke volume index
SVI_{RV}	right ventricular stroke volume index
SvO_2	mixed venous oxygen saturation
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
SVV	stroke volume variation
SYS	systolic blood pressure
SYS_{ART}	systemic arterial systolic blood pressure
SYS_{PAP}	pulmonary artery systolic blood pressure
SYS_{RVP}	right ventricular systolic blood pressure
Tb	blood temperature
tHb	total hemoglobin
Touch	Interact with the HemoSphere Alta advanced monitor by touching the screen.
TD	thermodilution
Ti	injectate temperature
USB	Universal Serial Bus
VO_2	oxygen consumption
VO_2I	oxygen consumption index
VO_2e	estimation of oxygen consumption
VO_2Ie	estimated oxygen consumption index

Safety and Symbols 2

Contents

2.1 Safety Signal Words Definitions

2.1.1 Warning

A warning advises against certain actions or situations that could result in personal injury or death.

WARNING This is how warnings appear throughout the text of this manual.

2.1.2 Caution

A caution advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

CAUTION This is how cautions appear throughout the text of this manual.

2.1.3 Note

A note draws attention to useful information regarding a function or procedure.

NOTE This is how notes appear throughout the text of this manual.

2.2 Warnings

The following are warnings that are used in the HemoSphere Alta advanced monitoring platform operator's manual. They are introduced in the manual where relevant to the function or procedure being described.

- Read this operator's manual carefully before attempting to use the Edwards HemoSphere Alta advanced monitoring platform.
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Alta advanced monitoring platform.
- To prevent injury to patient or user, damage to platform, or inaccurate measurements, do not use any damaged or non-compatible platform accessories, components or cables.
- Improper use of the HemoSphere Alta advanced monitoring platform could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in chapter 2, before using the platform. (chapter 1)
- The HemoSphere Alta advanced monitoring platform is intended for use only in patient assessment. This instrument must be used in conjunction with a bedside physiological monitor and/or patient clinical signs and symptoms. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting before initiating treatment options. (chapter 1)
- ECG signal input and all parameters derived from heart rate measurements have not been evaluated for pediatric patients and are therefore not available for that patient population. (chapter 1)
- Shock hazard! Do not attempt to connect/disconnect system cables while hands are wet. Ensure that hands are dry prior to disconnecting system cables. (chapter 3)
- Explosion Hazard! Do not use the HemoSphere Alta advanced monitoring platform in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. (chapter 3)
- This product contains metallic components. Do NOT use in a Magnetic Resonance (MR) environment. (chapter 3)
- Make sure the HemoSphere Alta advanced monitoring platform is securely positioned or mounted and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment. (chapter 3)
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. (chapter 3)
- The HemoSphere Alta advanced monitoring platform must be positioned in an upright position to ensure IPX1 ingress protection. (chapter 3)
- Do not allow any liquids to splash onto the monitoring screen. Liquid buildup may disable the touchscreen functionality. (chapter 3)
- Do not position the monitor so that it is difficult to access rear panel ports or power cord. (chapter 3)
- Equipment is rated for use with high-frequency surgical equipment. Inaccurate parameter measurements can be caused by interference from high-frequency surgical equipment. To reduce hazards that can arise from the use of high-frequency surgical equipment, only use undamaged patient cables and accessories connected as specified in this operator's manual. (chapter 3)
- This system is rated for use with defibrillators. To ensure proper defibrillator-proof operation, only use undamaged patient cables and accessories connected as specified in this operators manual. (chapter 3)
- All IEC/EN 60950 equipment, including printers, to be positioned no closer than 1.5 meters to the patient's bed. (chapter 3)

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the HemoSphere Alta advanced monitoring platform, including cables specified by the manufacturer. Otherwise, degradation of the performance this equipment could result. (chapter 3)
- Only use Edwards approved batteries with the HemoSphere Alta advanced monitoring platform. Do not charge the battery pack outside of the monitor. Doing so can damage the battery or injure the user. (chapter 3)
- To prevent any interruptions to monitoring during power loss, it is recommended to use the HemoSphere Alta advanced monitoring platform with the battery inserted. (chapter 3)
- In cases of power failure and battery depletion, the monitor will go through a controlled shut off procedure. (chapter 3)
- Do not use the HemoSphere Alta advanced monitoring platform without an installed power cord entry cover. Failure to do so may result in fluid ingress. (chapter 3)
- Do not use extension cords or multiple socket devices to connect the power cord. Do not use detachable power cords other than the power cord provided. (chapter 3)
- To avoid the risk of electric shock, the HemoSphere Alta advanced monitoring platform can only be connected to a supply mains with grounding (protective earth). Do not use three prong to two prong power adaptors. (chapter 3)
- Grounding reliability can only be achieved when the instrument is connected to a receptacle marked “hospital only”, “hospital grade”, or its equivalent. (chapter 3)
- Disconnect the monitor from the AC source by unplugging mains power cable from the AC Mains. The On/Off button on the monitor does not disconnect the system from the AC mains supply. (chapter 3)
- Only use HemoSphere Alta advanced monitoring platform accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy. (chapter 3)
- Upon initiation of a new patient session, the default high/low physiological alarm ranges should be checked to ensure that they are appropriate for the given patient. (chapter 5)
- Perform New Patient or clear the patient data profile whenever a new patient is connected to the HemoSphere Alta advanced monitoring platform. Failure to do so may result in previous patient data in the historical displays. (chapter 5)
- Do not use alarm settings/presets that differ from the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theater. Conflicting alarms can affect patient safety. (chapter 6)
- Ensure that alarm settings/presets are configured appropriately for the patient prior to starting a new monitoring session. (chapter 6)
- Do not turn off the audible alarms in situations in which patient safety could be compromised. (chapter 6)
- Do not lower the alarm volume to a level that prohibits alarms from being adequately monitored. Failure to do so could result in a situation where patient safety is compromised. (chapter 6)
- Visual and audible physiological alarms are activated only if the parameter is configured on the screens as a key parameter (1-8 parameters displayed in parameter tiles). If a parameter is not selected and displayed as a key parameter, the audible and visual physiological alarms are not triggered for that parameter. (chapter 6)

- Do not use the HemoSphere Alta advanced monitoring platform as part of a Distributed Alarm System. The HemoSphere Alta advanced monitoring platform does not support remote alarm monitoring/management systems. Data is logged and transmitted for charting purposes only. (chapter 7)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere Alta Swan-Ganz patient cable (applied part connection, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 8)
- Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance. (chapter 8)
- CO monitoring should always be discontinued when blood flow around the thermal filament is stopped. Clinical situations where CO monitoring should be discontinued include, but are not limited to: • Time periods when a patient is on cardiopulmonary bypass • Partial withdrawal of the catheter so that the thermistor is not in the pulmonary artery • Removal of the catheter from the patient (chapter 8)
- PACEMAKER PATIENTS – Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon displayed heart rate. Keep pacemaker patients under close surveillance. See table A-5 on page 353 for disclosure of the pacemaker pulse rejection capability of this instrument. (chapter 8)
- For patients requiring internal or external pacing support, the HemoSphere Alta advanced monitoring platform should not be used to obtain heart rate and heart rate derived parameters under the following conditions: • pacer pulse synch output from bedside monitor includes the pacer pulse, however, the characteristics are outside of the pacemaker pulse rejection capabilities specifications as listed in Table A-5 • pacer pulse synch output characteristics from bedside monitor cannot be determined (chapter 8)
- Note any discrepancies in heart rate (HRavg) with the patient monitor HR and ECG waveform display when interpreting derived parameters such as SV, EDV, RVEF, and associated index parameters. (chapter 8)
- Do not resterilize or reuse any FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, TruWave transducer, or catheter; refer to the catheter's "directions for use". (chapter 9)
- Do not use a FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, TruWave transducer, or catheter that is wet, damaged, or that has exposed electrical contacts. (chapter 9)
- Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (chapter 9)
- When the pressure cable is not in use, protect the exposed cable connector from fluid. Moisture within the connector may result in the cable malfunctioning or in inaccurate pressure readings. (chapter 9)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere pressure cable (applied part accessory, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 9)
- If the pulmonary artery catheter drifts into the wedge position without inflation of the balloon, spontaneous tip wedging may occur, and the pulmonary artery pressure waveform assumes a wedged appearance, which can impact algorithm accuracy. Take appropriate action, in accordance with standard institutional clinical procedures. (chapter 9)

- Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive maneuver may result in pulmonary infarction. (chapter 9)
- Do not use the HemoSphere Alta advanced monitoring platform as a pulse rate or blood pressure monitor. (chapter 9)
- Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component. (chapter 10)
- Compliance to IEC 60601-1 is only maintained when the pressure controller (applied part connection) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 10)
- Do not sterilize any components of the HemoSphere Alta non-invasive system. The HemoSphere Alta non-invasive system is provided non sterile. (chapter 10)
- Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (chapter 10)
- Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (chapter 10)
- Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks. (chapter 10)
- The HemoSphere Alta non-invasive system monitoring components are not defibrillation proof. Disconnect the system before defibrillating. (chapter 10)
- Only use compatible Edwards finger cuffs, heart reference sensor and other HemoSphere Alta non-invasive system accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy. (chapter 10)
- Always remove HemoSphere Alta non-invasive system sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient. (chapter 10)
- Do not overtighten the pressure controller band or finger cuff(s). (chapter 10)
- Do not apply pressure controller band on injured skin as this can cause further injury. (chapter 10)
- Improper finger cuff placement or sizing can lead to inaccurate monitoring. (chapter 10)
- Do not use the HemoSphere Alta non-invasive system as a heart rate monitor. (chapter 10)
- If using the instrument during full body irradiation, keep all HemoSphere Alta non-invasive system monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected. (chapter 10)
- Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements. (chapter 10)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere oximetry cable (applied part accessory, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 11)

- Do not wrap the main body of the oximetry cable in fabric or place directly on the patient's skin. The surface does get warm (up to 45 °C) and needs to dissipate heat to maintain its internal temperature level. A software fault will trigger if the internal temperature exceeds its limits. (chapter 11)
- Before touching the Recall button to recall oximetry data, confirm that the displayed data matches the current patient. Recalling incorrect oximetry calibration data and patient demographics will result in inaccurate measurements. (chapter 11)
- Compliance to IEC 60601-1 is only maintained when the ForeSight oximeter cable (applied part, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 12)
- Inspect all of the ForeSight oximeter cable connections for damage prior to installation. If any damage is noted, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical support. There is a risk that damaged parts could reduce the performance of the cable or present a safety hazard. (chapter 12)
- To remove any chance of contamination between patients, the ForeSight oximeter cable and cable connections should be cleaned after each case. (chapter 12)
- To reduce the risk of contamination and cross infection, if the ForeSight oximeter cable or cable connections are grossly contaminated, with blood or other bodily fluids, it should be disinfected. If the ForeSight oximeter cable or cable connections cannot be disinfected, it should be serviced, replaced or discarded. Contact Edwards Technical support. (chapter 12)
- To reduce the risk of damaging internal elements of the cable assemblies – within the ForeSight oximeter cable housing – avoid excessive pulling, bending or other types of stress on the cable connections. (chapter 12)
- Sensors are not sterile and therefore should not be applied on abraded, cracked, or lacerated skin. Exercise caution when applying sensors to a site with delicate skin. Applying sensors, tape or pressure to such a site may reduce circulation and/or cause skin deterioration. (chapter 12)
- Do not place sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis, pneumoencephalus, or edema. (chapter 12)
- If electrocautery procedures will be performed, sensors and electrocautery electrodes should be placed as far apart as possible to prevent unwanted skin burns; a distance of at least 15 cm (6 in) is recommended. (chapter 12)
- Use only Edwards supplied accessories with the ForeSight oximeter cable. Edwards accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the ForeSight oximeter cable. Connecting a non-Edwards sensor will cause an appropriate alert on that channel and no StO2 values will be recorded. (chapter 12)
- Sensors are designed for single-patient use, and are not to be reprocessed – re-used sensors present a risk of cross-contamination or infection. (chapter 12)
- Use a new sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies. (chapter 12)
- If a sensor seems damaged in any way, it must not be used. (chapter 12)
- Always read the sensor packaging. (chapter 12)
- Exercise extreme care when applying sensors. Sensor circuits are conductive and must not come into contact with other grounded, conductive parts other than EEG or entropy monitors. Such contact would bridge the patient's isolation and cancel the protection provided by the sensor. (chapter 12)

- Failure to apply sensors properly may cause incorrect measurements. Misapplied sensors or sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation. (chapter 12)
- Do not position a sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the sensor or the patient lying on a sensor) transfers weight from the sensor to the skin, which can injure skin and reduce sensor performance. (chapter 12)
- The sensor site must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site. (chapter 12)
- Do not connect more than one patient to the ForeSight oximeter cable. This may compromise the patient's isolation and cancel the protection provided by the sensor. (chapter 12)
- The ForeSight oximeter cable has been designed to promote patient safety. All cable parts are "Type BF Defibrillation Proof" and are protected against the effects of the defibrillator discharge and may remain attached to the patient. Cable readings may be inaccurate during defibrillator use and up to twenty (20) seconds thereafter. (chapter 12)
- No separate actions are required when using this equipment with a defibrillator, but only Edwards-supplied sensors must be used for proper protection against the effects of a cardiac defibrillator. (chapter 12)
- Do not come into contact with patients during defibrillation, or serious injury or death could result. (chapter 12)
- If the accuracy of any value displayed on the monitor is questionable, determine the patient's vital signs by alternative means. The functions of the alarm system for patient monitoring must be verified at regular intervals and whenever the integrity of the product is in doubt. (chapter 12)
- tHb measurements should not be used exclusively to treat patients. A review of all of the patient's laboratory blood testing is recommended prior to making clinical decisions. Inconsistent measurements should be supplemented with additional testing to obtain a valid result. (chapter 12)
- The accuracy of total hemoglobin measurement may be compromised by conditions impacting local blood flow hemodynamics intermittently such as asymmetric carotid stenosis and occurrence of undiagnosed focal stroke during the course of monitoring. (chapter 12)
- Clinical procedures that inject compounds that have optical absorption characteristics between 660-900 nm, such as indocyanine green (contrast agent) or methylene blue (for treatment of high methemoglobin) may lead to inaccurate or erroneous measurements. A calibration or recalibration of the tHb parameter is recommended after these procedures. (chapter 12)
- Clinical procedures mitigating elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) or dyshemoglobin through blood transfusion or other means may lead to inaccurate or erroneous measurements. Other factors that may affect measurement accuracy include conditions such as myoglobin, hemoglobinopathies, anemia, sickle cell anemia, pooled blood under the skin, interference from foreign objects in sensor path, bilirubinemia, externally applied coloring, high levels of HGB or Hct and birthmarks. A calibration or recalibration of the tHb parameter is recommended after these procedures. (chapter 12)
- The Acumen Hypotension Prediction Index, HPI, should not be used exclusively to treat patients. A review of the patient's hemodynamics is recommended prior to initiating treatment. (chapter 13)
- The global hypoperfusion index, GHI, should not be used exclusively to treat patients. A review of all of the patient's hemodynamics is recommended prior to initiating treatment. (appendix 13)
- The Cerebral Autoregulation Index (CAI), should not be used exclusively to treat patients. A review of all of the patient's hemodynamics is recommended prior to initiating treatment. (appendix 13)

- The Assisted Fluid Management feature should not be used exclusively to treat the patient. A review of the patient's hemodynamics is recommended throughout the monitoring session to assess fluid responsiveness. (appendix 13)
- Only use approved HemoSphere Alta advanced monitoring platform accessories, cables and or components that have been supplied and labeled by Edwards. Using unapproved accessories, cables and or components may affect patient safety and measurement accuracy. (appendix B)
- The HemoSphere Alta advanced monitoring platform contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages. (appendix F)
- Shock or fire hazard! Do not immerse the HemoSphere Alta advanced monitoring platform or monitor cables in any liquid solution. Do not allow any fluids to enter the instrument. (appendix F)
- Do not, under any circumstances, perform any cleaning or maintenance of the ForeSight oximeter cable while the module is being used to monitor a patient. The monitor must be turned off and the HemoSphere Alta advanced monitoring platform power cord disconnected, or the cable must be disconnected from the monitor and the sensors removed from the patient. (appendix F)
- Before starting cleaning or maintenance of any sort, check the ForeSight oximeter cable, cable connections, sensors, and other accessories for damage. Check the cables for bent or broken prongs, cracks, or fraying. If any damage is noted, the cable must not be used until it has been inspected and serviced or replaced. Contact Edwards Technical Support. (appendix F)
- There is a risk of serious injury or death if this procedure is not followed. (appendix F)
- Explosion Hazard! Do not open battery, dispose of in fire, store at high temperature or short circuit. It may ignite, explode, leak or get hot, causing serious personal injury or death. (appendix F)
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. (appendix G)
- No modification of the HemoSphere Alta advanced monitoring platform is allowed. (appendix G)
- Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic ant-theft systems and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Alta advanced monitoring platform. Guidance on maintaining appropriate separation between communications equipment and the HemoSphere Alta advanced monitoring platform is provided in table G-3. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere monitoring platform. (appendix G)

2.3 Cautions

The following are cautions that are used in the HemoSphere Alta advanced monitoring platform operator's manual. They are introduced in the manual where relevant to the function or procedure being described.

- Federal (USA) law restricts this device to sale by or on the order of a physician.
- Inspect the HemoSphere Alta advanced monitoring platform and all accessories and equipment used with the monitor for damage prior to use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised.
- Users should carefully consider whether to use pulse rate or heart rate, particularly in clinical conditions such as arrhythmia. This decision should be guided by the specific clinical context and medical judgment to ensure accuracy and optimal patient care. (chapter 3)

- Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use. (chapter 3)
- To avoid corruption of data on the HemoSphere Alta advanced monitoring platform, always disconnect the HemoSphere Alta Swan-Ganz patient cable and oximetry cable from the monitor before using a defibrillator. (chapter 3)
- ClearSight technology pressure output signal to a patient monitor only intended to be connected to a pressure signal input port of Type BF or CF on the patient monitor that is protected against the effects of a discharge of a cardiac defibrillator. (chapter 3)
- Do not expose the HemoSphere Alta advanced monitoring platform to extreme temperatures. Refer to environmental specifications in appendix A. (chapter 3)
- Do not expose the HemoSphere Alta advanced monitoring platform to dirty or dusty environments. (chapter 3)
- Do not obstruct the HemoSphere Alta advanced monitor ventilation openings. (chapter 3)
- Do not use the HemoSphere Alta advanced monitoring platform in environments where strong lighting makes the LCD screen difficult to view. (chapter 3)
- Do not use the monitor as a handheld device. (chapter 3)
- When moving the instrument, be sure to turn off the power and remove the connected power cord. (chapter 3)
- Do not use the voice command function in the vicinity of other HemoSphere Alta advanced monitoring platforms. Doing so may unintentionally initiate voice commands with those other monitors. (chapter 4)
- Use a virus scan on any USB stick before inserting to prevent a virus or malware infection. (chapter 7)
- Inaccurate cardiac output measurements may be caused by: • Incorrect placement or position of the catheter • Excessive variations in pulmonary artery blood temperature. Some examples that cause BT variations include, but are not limited to: * status post cardiopulmonary bypass surgery * centrally administered cooled or warmed solutions of blood products * use of sequential compression devices • Clot formation on the thermistor • Anatomical abnormalities (for example, cardiac shunts) • Excessive patient movement • Electrocautery or electrosurgical unit interference • Rapid changes in cardiac output (chapter 8)
- Inaccurate 20-second flow parameter measurements may be caused by: • Incorrect placement or position of the catheter • Improperly zeroed and/or leveled transducer • Over- or under-damped pressure line • Adjustments to the PAP line made after start of monitoring (chapter 8)
- Refer to Appendix E to ensure computation constant is the same as specified in the catheter package insert. If the computation constant differs, enter the desired computation constant manually. (chapter 8)
- Sudden changes in PA blood temperature, such as those caused by patient movement or bolus drug administration, may cause an iCO or iCI value to be computed. To avoid falsely triggered curves, inject as soon as possible after the Inject message appears. (chapter 8)
- Do not use any FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave transducer past its labeled “Use By Date.” Products used beyond this date may have compromised transducer or tubing performance, or compromised sterility. (chapter 9)
- Excessive dropping of the HemoSphere pressure cable may result in cable damage and/or malfunction. (chapter 9)
- The effectiveness of FT-CO measurements in pediatric patients under 12 years of age has not been evaluated. (chapter 9)

- Inaccurate FT-CO measurements can be caused by factors such as: • Improperly zeroed and/or leveled sensor/transducer • Over- or under-damped pressure lines • Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to: * Intra-aortic balloon pumps • Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure, including but not limited to: * Extreme peripheral vasoconstriction which results in a compromised radial arterial pressure waveform * Hyperdynamic conditions as seen in post liver transplant • Excessive patient movement • Electrocautery or electrosurgical unit interference Aortic valve regurgitation may cause an over estimation of Stroke Volume / Cardiac Output calculated depending on the amount of valvular disease and the volume lost back into the left ventricle. (chapter 9)
- Always grasp the connector, not the cable, when connecting or disconnecting the cable. (chapter 9)
- Do not twist or bend the connectors. (chapter 9)
- To prevent cable damage, do not apply excessive force to the pressure cable zero button. (chapter 9)
- Inaccurate PAOP measurements may be caused by: • Incorrect placement or position of the catheter • Catheter balloon is either not fully inflated or is overinflated • Improperly zeroed and/or leveled transducer • Over- or under-damped pressure line • Adjustments to the PAP line made after start of monitoring (chapter 9)
- The effectiveness of HemoSphere Alta non-invasive system has not been evaluated in patients under 12 years of age. (chapter 10)
- Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use. (chapter 10)
- Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis. (chapter 10)
- The HemoSphere Alta non-invasive system is not intended for use as an apnea monitor. (chapter 10)
- In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible. (chapter 10)
- Inaccurate non-invasive measurements can be caused by factors such as: • Improperly calibrated and/or leveled HRS • Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to: * Intra-aortic balloon pumps • Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure. • Poor blood circulation to the fingers. • A bent or flattened finger cuff. • Excessive patient movement of fingers or hands. • Artifacts and poor signal quality. • Incorrect placement of finger cuff, position of finger cuff, or finger cuff too loose. • Electrocautery or electrosurgical unit interference. (chapter 10)
- Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation. (chapter 10)
- The effectiveness of Edwards compatible finger cuffs has not been established in pre-eclamptic patients. (chapter 10)
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against the ECG heart rate. (chapter 10)
- The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias.The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis. (chapter 10)
- Monitoring without an HRS may lead to measurement inaccuracies. Ensure patient remains still with accurately measured finger to heart height difference. (chapter 10)

- Do not place the patient in a non-supine position while monitoring without an HRS. This may lead to an inaccurate vertical offset entry for the HRS and measurement inaccuracies. (chapter 10)
- Do not perform a BP calibration during monitoring periods when blood pressure appears unstable. This may result in inaccurate blood pressure measurements. (chapter 10)
- ClearSight system pressure output signal to a patient monitor only intended to be connected to a pressure signal input port of Type BF or CF on the patient monitor that is protected against the effects of a discharge of a cardiac defibrillator. See table 10-5 for symbols that appear next to accepted connection ports. (chapter 10)
- Make sure that the oximetry cable is securely stabilized to prevent unnecessary movement of the attached catheter. (chapter 11)
- The catheter tip or calibration cup must not get wet before an in vitro calibration is performed.The catheter and the calibration cup must be dry for an accurate oximetry in vitro calibration. Flush the catheter lumen only after the in vitro calibration has been completed. (chapter 11)
- Performing an in vitro calibration after the oximetry catheter has been inserted into the patient will yield an inaccurate calibration. (chapter 11)
- The SQI signal is sometimes affected by the use of electrosurgical units. Attempt to distance electrocautery equipment and cables from the HemoSphere Alta advanced monitoring platform and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call your local Edwards representative for assistance. (chapter 11)
- Do not disconnect the oximetry cable while calibration or data recall are in process. (chapter 11)
- If the oximetry cable is being transferred from a HemoSphere Alta advanced monitoring platform to another HemoSphere Alta advanced monitoring platform, check that the patient height, weight, and BSA are correct prior to beginning monitoring. Re-enter patient data, if necessary. (chapter 11)
- Avoid placing the ForeSight oximeter cable where the status LED cannot be easily seen. (chapter 12)
- Applying too much pressure may break the retaining tab, which may present a risk of the cable falling on the patient, bystander, or operator. (chapter 12)
- Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the cable in any position that might present a risk that the cable may fall on the patient, bystander or operator. (chapter 12)
- Avoid placing the ForeSight oximeter cable under sheets, or blanket that could restrict air flow around the cable that may increase the cable's case temperature and present an injury. (chapter 12)
- Sensors should not be placed on high density hair areas. (chapter 12)
- The sensor must be able to rest flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the sensor and the skin will affect the validity of the data collected and may result in an alarm message. (chapter 12)
- When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection. (chapter 12)
- Once patient monitoring has started, do not replace the sensor or disconnect the sensor for more than 10 minutes to avoid restarting the initial StO2 calculation. (chapter 12)
- Measurements may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment, and measurements may be inaccurate during use of such equipment. (chapter 12)

- Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate or erroneous measurements, as may intravascular dyes or any substance containing dyes that change usual blood pigmentation. Other factors that may affect measurement accuracy include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in the Sensor path, Bilirubinemia, externally applied coloring (tattoos), high levels of HGB or Hct and birthmarks. (chapter 12)
- When compared to earlier software versions, a ForeSight oximeter cable with a software version of V3.0.7 or later and used with pediatric sensors (small and medium) is more responsive in the display StO2 values. Specifically, in the range below 60%, StO2 measurements could be reported lower than in earlier software versions. Clinicians should consider the faster response and potentially modified StO2 values when using V3.0.7 software, especially if they are experienced with earlier software versions of the ForeSight oximeter cable. (chapter 12)
- Inaccurate tHb values may be caused by • Inaccurate relative change in tissue hemoglobin (ΔctHb) measurements • Inaccurate laboratory blood gas analyzer measurements (chapter 12)
- The effectiveness of the HPI parameter during minimally-invasive monitoring has been established using radial arterial pressure waveform data. The effectiveness of the HPI parameter using arterial pressure from other sites (e.g., femoral) has not been evaluated. (chapter 13)
- The HPI parameter may not provide advanced notice of a trend towards a hypotensive event in situations where a clinical intervention results in a sudden non-physiological hypotensive event. If this occurs, the HPI feature will provide the following without delay: a high alert popup, a high priority alarm, and an HPI value of 100 will be displayed indicating that the patient is undergoing a hypotensive event. (chapter 13)
- Exercise caution when using the absolute values of dP/dt. Pressure will change distally due to narrowing of vessels and frictional forces within the vessels. While absolute dP/dt may not be an accurate measure of cardiac contractility, trends may be helpful. (chapter 13)
- Exercise caution when using dP/dt in patients with severe aortic stenosis, since the stenosis may reduce the coupling between the left ventricle and the afterload. (chapter 13)
- The dP/dt parameter, although predominantly determined by changes in LV contractility, may be impacted by afterload during periods of vasoplegic states (venoarterial decoupling). During these periods, dP/dt may not reflect changes in LV contractility. (chapter 13)
- The HPI parameter information provided in table 13-16 and table 13-17 is presented as general guidance and may not be representative of individual experience. A review of the patient's hemodynamics is recommended prior to initiating treatment. (chapter 13)
- The HPI parameter information provided in table 13-26 and table 13-27 is presented as general guidance and may not be representative of individual experience. A review of the patient's hemodynamics is recommended prior to initiating treatment. (chapter 13)
- Inaccurate GHI values may be caused by: • Inaccurate cardiac output measurements • Inaccurate SvO2 measurements • Incorrect placement or position of the catheter • Excessive variations in pulmonary artery blood temperature. Some examples that cause BT variations include, but are not limited to: * status post cardiopulmonary bypass surgery * centrally administered cooled or warmed solutions of blood products * use of sequential compression devices • Clot formation on the thermistor • Anatomical abnormalities (for example, cardiac shunts) • Excessive patient movement • Electrocautery or electrosurgical unit interference • Rapid changes in cardiac output (chapter 13)
- The GHI parameter may not provide advanced notice of a trend towards a global hypoperfusive event in situations where a clinical intervention results in a sudden non-physiological hypoperfusive event. If this occurs, the GHI feature will provide the following without delay: a medium priority alarm, and an GHI value of 100 will be displayed indicating that the patient is undergoing a hypoperfusive event. (chapter 13)

- Inaccurate CAI values may be caused by: • Inaccurate Mean Arterial Pressure (MAP) measurements • Inaccurate cerebral StO2 measurements (chapter 13)
- The Assisted Fluid Management software feature relies on information provided by the clinician to accurately assess fluid responsiveness. (chapter 13)
- Fluid management suggestions provided by the AFM feature can be compromised by factors such as: • Inaccurate FT-CO measurements • Acute changes in FT-CO measurements secondary to vasoactive medication administration, patient repositioning or surgical interventions • Bleeding at rates similar to, or greater than, the rate of fluid delivery • Arterial line interference Always review patient hemodynamic status before complying with AFM suggestions. (chapter 13)
- Accurate stroke volume variation (SVV) measurement is necessary for the AFM software feature to make fluid management suggestions. Patients must be: • mechanically ventilated • have a tidal volume of ≥8 mL/kg (chapter 13)
- Use of any fluids not listed in the specified Fluid Type list or choosing the incorrect fluid type may result in measurement inaccuracies. (chapter 13)
- The presence of confounding factors during bolus delivery may lead to an incorrect fluid recommendation by the AFM software. Therefore, boluses delivered in the presence of confounding factors should be discarded. Potential confounding factors include but are not limited to: • Vasoactive agent was administered during bolus administration • Additional fluid given after primary bolus administered • Subject repositioning • Ventilatory changes • Surgical manipulation • Arterial line interference * External compression (i.e., leaning on A-line) * ABG draw, fast flush * Overdamping of Line • Vascular clamping • Additional line of fluid simultaneously opened during bolus administration • Known acute hemorrhage during fluid administration • Inaccurate FT-CO measurements (chapter 13)
- Inaccurate RVCO values may be caused by: • Inaccurate or noisy right ventricular pressure • Incorrect placement of position of the catheter • Excessive patient movement • Inaccurate Intermittent Cardiac Output (iCO) values (chapter 13)
- If any of the ForeSight oximeter cable LEDs fail to turn on, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical Support. There is a risk that damaged parts could reduce the performance of the cable. (chapter 14)
- Do not pinch any heart reference sensor tubes or wires under the pressure controller cover during application. Be careful the only wire between the back mounting notch is the pressure controller cable. (appendix B)
- Do not lift PCCVR from any other point than the front tab. (appendix B)
- Clean and store the instrument and accessories after each use. (appendix F)
- Follow all cleaning instructions carefully to ensure that the monitor and platform cables are thoroughly cleaned. After cleaning, inspect the HemoSphere Alta advanced monitor and all accessories for any residue or foreign material. If residue is still visible after cleaning, please repeat the cleaning instructions. Follow any additional cleaning instructions provided by the manufacture of listed approved cleaning agents. (appendix F)
- The HemoSphere Alta advanced monitoring platform and monitor cables are electrostatic discharge (ESD) sensitive. Do not attempt to open cable housing or use if the housing has been damaged. (appendix F)
- Do not pour or spray liquid on any portion of the HemoSphere Alta advanced monitoring platform, accessories or cables. (appendix F)
- Do not use any disinfecting solution other than the types specified. (appendix F)
- DO NOT: Allow any liquid to come in contact with the power connector Allow any liquid to penetrate connectors or openings in the monitor case If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the monitor. Disconnect power immediately and call your Biomedical Department or local Edwards representative. (appendix F)

- Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing. (appendix F)
- Do not use any other cleaning agents, spray, or pour cleaning solution directly on platform cables. Do not steam, radiate, or EO sterilize platform cables. Do not immerse platform cables. (appendix F)
- Do not steam, radiate, or EO sterilize the HemoSphere oximetry cable. Do not immerse the HemoSphere oximetry cable. (appendix F)
- If any electrolytic solution, for example Ringer's lactate solution, is introduced into the cable connectors while they are connected to the monitor, and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts. (appendix F)
- Do not immerse any cable connectors in detergent, isopropyl alcohol or glutaraldehyde. (appendix F)
- Do not use a hot air gun to dry cable connectors. (appendix F)
- Device contains electronics. Handle with care. (appendix F)
- Do not disinfect the heart reference sensor or pressure controller by autoclave or gas sterilization. (appendix F)
- Do not immerse the pressure controller, heart reference sensor, or any cable connectors in fluid. (appendix F)
- Clean and store the heart reference sensor after each use. (appendix F)
- Recycle or dispose of the lithium-ion battery in accordance to all federal, state, and local laws. (appendix F)
- The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: · Reorient or relocate the receiving device. · Increase the separation between the equipment. · Consult the manufacturer for help. (appendix G)
- The wireless Quality of Service (QoS) may be influenced by the presence of other devices that create radio frequency interference (RFI). Such RFI devices may include electrocautery equipment, cellular telephones, wireless PC and tablets, pagers, RFID, MRI, or other electrically powered devices. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength. (appendix G)
- Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. (appendix G)
- Industry Canada requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems. (appendix G)

2.4 User Interface Symbols

The following are icons that appear on the HemoSphere Alta advanced monitoring platform screen. For more information about screen appearance and navigation, see chapter 4, *Navigating the HemoSphere Alta Advanced Monitoring Platform*. Certain icons will only appear while monitoring with a specific hemodynamic technology, as specified.

Table 2-1 Monitor display symbols

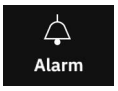
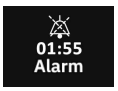
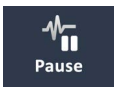
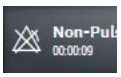
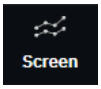
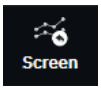
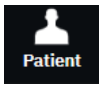
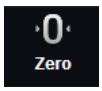
Symbol	Description
Navigation Bar Icons	
	no alarms
	audible alarms
	alarms paused (silenced with one touch) with countdown timer (see *Silence Audible Alarms* on page 81)
	reset alarms (alarm sub-menu)
	silence alarms indefinitely (alarm sub-menu, pass code protected)
	alarms silenced
	monitoring pause (enter non-pulsatile mode, alarm sub-menu)
	non-pulsatile mode with elapsed time from monitoring pause
	select monitoring screen
	return to monitoring screen
	patient data menu (end session)
	patient data menu (demographics skipped)
	zero pressure (HemoSphere pressure cable and ClearSight technology)

Table 2-1 Monitor display symbols (continued)

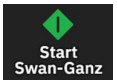
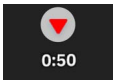
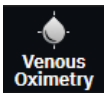
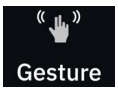
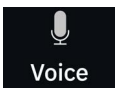
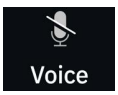
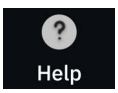
Symbol	Description
	select monitoring mode (multi-sensor mode disabled)
	begin CO monitoring (HemoSphere Alta Swan-Ganz patient cable)
	stop CO monitoring with CO countdown timer (see *CO Countdown Timer* on page 141) (HemoSphere Alta Swan-Ganz patient cable)
	start noninvasive monitoring (HemoSphere Alta ClearSight technology)
	stop noninvasive monitoring (HemoSphere Alta ClearSight technology)
	resume noninvasive monitoring after cuff pressure release (HemoSphere Alta ClearSight technology)
	venous oximetry settings and calibration
	clinical tools side panel
	gesture interaction enabled
	gesture interaction disabled
	voice interaction enabled (English only)
	voice interaction disabled
	help menu

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	settings menu
Clinical Tools Side Panel Menu Icons	
	Assisted Fluid Management
	Derived Value Calculator
	iCO Thermodilution (intermittent cardiac output) (HemoSphere Alta Swan-Ganz patient cable)
	Events and Intervention
	HRS Calibration (HemoSphere Alta ClearSight technology)
	Hypotension Prediction Index
	Fluid Responsiveness Test (advanced feature)
	Blood Pressure Calibration (HemoSphere Alta ClearSight technology)
	Goal Directed Therapy
	TPTD (transpulmonary thermodilution)
Menu Navigation Icons	
	exit or return to main monitoring screen
	return to previous menu
	cancel
	enter
	keypad backspace key

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	move cursor left
	move cursor right
	item enabled/selected
	item not enabled/ selected
	menu option selected (radio button)
	menu option not selected (radio button)
	item enabled (toggle button)
	item disabled (toggle button)
Parameter Tile Icons	
	parameter audible alarm indicator: paused
	parameter audible alarm indicator: indefinitely silenced
	signal quality indicator bar See *Signal Quality Indicator* on page 194 (HemoSphere oximetry cable) See *SQI* on page 183 (HemoSphere Alta ClearSight technology)
	SVV filtering exceeded indicator: High degree of pulse rate variability may be impacting SVV values
	venous oximetry calibration (HemoSphere oximetry cable)
	CVP value manually entered (SVR/SVRI only)
	Default CVP value used (SVR/SVRI only)
	ΔctHb value (StO_2 only)
Information Bar Icons	
	battery life indicator icons on information bar See table 4-6 on page 111

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	Wi-Fi signal See table 7-1 on page 133
	screen brightness
	alarm volume
	lock screen
	screen capture
	beat-to-beat heart rate (HemoSphere Alta Swan-Ganz patient cable with ECG input)
	time until cuff pressure release mode (HemoSphere Alta ClearSight technology, see *Cuff Pressure Release Mode* on page 185)
	time until conclusion of cuff pressure release mode (HemoSphere Alta ClearSight technology, see *Cuff Pressure Release Mode* on page 185)
	HemoSphere remote connectivity status icon See table 7-2 on page 135
Intervention Analysis Icons	
	intervention analysis type indicator for custom event (gray)
	intervention analysis type indicator for positional challenge (purple)
	intervention analysis type indicator for a fluid challenge (blue)
	intervention analysis type indicator for intervention (green)
	intervention analysis type indicator for system generated intervention (oximetry, BP calibration, white)
	intervention analysis type indicator for event (yellow)
	edit comments icon

Table 2-1 Monitor display symbols (continued)

Symbol	Description
AFM Icons	
	Assisted Fluid Management (AFM) icon on the side panel
	AFM fluid status icons on AFM dashboard. For more information, see table 13-60 on page 284
	start or re-start Assisted Fluid Management (AFM) session
	pause Assisted Fluid Management (AFM) session
	edit end time or bolus volume
	Time-in-Target displayed on SVV parameter tile (automatic GDT session)
	AFM settings
	AFM context help
	end Assisted Fluid Management (AFM) session
GDT Tracking Icons	
	parameter enabled on GDT side panel
	edit GDT parameter targets
	start GDT tracking session
	pause GDT tracking session
	stop GDT tracking session
	accept target range for SV optimization
	Time-In-Target symbol on GDT tracked parameters
HPI Icons	
	HPI side panel icon

2.5 Symbols on Product Labels

This section provides the symbols that are on the HemoSphere Alta advanced monitoring platform and other available HemoSphere Alta advanced monitoring platform accessories, including platform cables.

Table 2-2 Symbols on product labels

Symbol	Description
	Manufacturer
	Date of manufacture
Rx only	Caution: Federal (USA) law restricts this device to sale by, or on the order of a physician.
IPX1	Provides protection against vertically falling water to IPX1 standard
IPX4	Extent of protection against ingress of objects
	Separate collection for electrical and electronic equipment in accordance with EC directive 2012/19/EU.
	Federal Communications Commission (FCC) compliance - USA only
	This device contains a non-ionizing radiation transmitter, which can cause RF interference with other devices near this device.
	Follow instructions for use
	Follow instructions for use on the website
	Instructions for use in electronic form is available by phone or website address.
	Intertek ETL
#	Model number
SN	Serial number
UDI	Unique device identifier

Table 2-2 Symbols on product labels (continued)

Symbol	Description
	MR unsafe
LOT	Batch code
QTY	Quantity
	Lead-free
	Underwriters Laboratories product certification mark
	Recyclable Lithium-Ion
	Technical conformity mark (Japan)
	Do not disassemble
	Do not incinerate
MD	Medical device
	Importer
	EMVCo Contactless Indicator
Connector Identification Labels	
	Equipotential terminal stud
	USB 2.0
	Ethernet connection

Table 2-2 Symbols on product labels (continued)

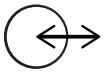
Symbol	Description
	Pressure (DPT) output
	Caution: Consult Instructions for use for important cautionary information
	Defibrillation proof type CF applied part or connection
	Defibrillation proof type BF applied part or connection
	Type BF applied part or connection
	Continuous noninvasive arterial blood pressure
	Remove the pressure controller cover from this end
	Do not remove pressure controller cover from this end
	ECG input from external monitor
	High-Definition Multimedia Interface output
	Connector: serial COM output (RS232)
Additional Packaging Labels	
	Fragile, handle with care
	This end up

Table 2-2 Symbols on product labels (continued)

Symbol	Description
	Lithium ion batteries packed with or contained in equipment
	Store in a cool, dry place
	Do not use if package is damaged and consult instructions for use
	Box made from recyclable cardboard
	Use-by date
	Environment-friendly use period (EFUP) - China only

NOTE For all accessory product labels, refer to symbol table contained in accessory instructions for use.

2.6 Applicable Standards

Table 2-3 Applicable standards

Standard	Title
IEC 60601-1:2005/AMD1:2012/ AMD2:2020	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance; amendment 1 (2012); amendment 2 (2020)
IEC 60601-1-2: 2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-34: 2011	Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 80601-2-49:2018	Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment/monitors
ISO80601-2-56:2017/ AMD1:2018	Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement; amendment 1 (2018)

2.7 HemoSphere Alta Advanced Monitoring Platform Essential Performance

The monitor shall provide display of continuous CO and intermittent CO with a compatible Swan-Ganz catheter according to the specifications provided in appendix A, *Specifications and Device Characteristics* on page 349. The platform shall provide display of intravascular blood pressure with a compatible FloTrac, FloTrac Jr, or Acumen IQ sensor or compatible TruWave DPT according to the specifications provided in appendix A. The platform shall provide display of SvO_2/$ScvO_2$ with a compatible oximetry catheter according to the specifications provided in appendix A. The platform shall provide noninvasive measurement of arterial blood pressure with a compatible Edwards finger cuff according to the specifications provided in appendix A. The platform shall provide display of StO_2 with a compatible oximeter cable and sensor according to the specifications provided in appendix A. The platform shall provide alarm, alert, indicator, and/or system status when unable to provide accurate measurement of the applicable hemodynamic parameter. For more information, see *Essential Performance Characteristics* on page 349.

Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.

3

Installation and Setup

Contents

3.1 Unpacking

Examine the shipping container for any signs of damage that may have occurred during transit. If any damage is detected, photograph the package and contact Edwards technical support for assistance. Do not use if the package or contents are damaged. Perform a visual inspection of the packaging contents for damage. Damage may include cracks, scratches, dents or any signs that the monitor or cable housing may be compromised. Report any evidence of external damage.

3.1.1 Packaging Contents

The HemoSphere Alta advanced monitoring platform packaging configurations will vary depending upon the kit ordered. All platforms are shipped with a mains power cord and certain regions contain a USB stick containing this operator's manual. Additional items may be included and shipped based on the bundle configuration. See Table 3-1. Disposable and accessory items may be delivered separately. It is recommended that the user confirm the receipt of all ordered equipment. Refer to appendix B: *Accessories*, for a full list of available accessories.

Table 3-1 HemoSphere Alta advanced monitoring platform configurations

HemoSphere Alta advanced monitoring platform cardiac kit	HemoSphere Alta advanced monitoring platform smart recovery kit	HemoSphere Alta advanced monitoring platform all-on-one kit
• HemoSphere Alta cardiac monitor • mains power cord • operator's manual (by region) • HemoSphere Alta Swan-Ganz patient cable • HemoSphere oximetry cable* • HemoSphere pressure cable / HemoSphere Alta monitor – pressure cable • ForeSight oximeter cable	• HemoSphere Alta smart recovery monitor • mains power cord • operator's manual (by region) • HemoSphere pressure cable / HemoSphere Alta monitor – pressure cable • ClearSight technology cables (pressure controller and HRS)	• HemoSphere Alta all-on-one monitor • mains power cord • operator's manual (by region) • HemoSphere Alta Swan-Ganz patient cable • HemoSphere pressure cable / HemoSphere Alta monitor – pressure cable • ClearSight technology cables (pressure controller and HRS) • HemoSphere oximetry cable • ForeSight oximeter cable • HemoSphere Alta AFM cable
**Optional*		

3.1.2 Required Accessories for Platform Cables

The following tables identify accessories required to display specific monitored and calculated parameters for the specified hemodynamic technology cable:

Table 3-2 Cables and catheters required for monitoring parameters with HemoSphere Alta Swan-Ganz patient cable

	Monitored and calculated parameters									
Required cable/catheter	CO	CO_{20s}*	EDV	RVEF	SVR	iCO	SV	SV_{20s}*	CO_{RV}/ SV_{RV}‡	GHI†
ECG cable or PR from ART waveform**			•	•			•	•		
analog pressure input cable(s)					•					
injectate temperature probe						•				
Swan-Ganz thermodilution catheter or Swan-Ganz Jr thermodilution catheter						•				
Swan-Ganz CCO catheter or Swan-Ganz CCOmbo catheter	•				•	•	•			
Swan-Ganz CCOmbo V catheter	•	•	•	•	•	•	•	•		•
Swan-Ganz IQ catheter						•			•	•
TruWave transducer*		•						•	•	
HemoSphere oximetry cable										•

** 20 second flow parameters are only available while monitoring with a CCOmbo V catheter (models 777F8 and 774F75) and require a pulmonary artery pressure signal through a HemoSphere pressure cable connection. See "20-Second Flow Parameters" on page 142.*

***Pulse rate (PR) from pressure cable or ClearSight cuff monitored arterial waveform can be used when heart rate (HR) from ECG cable is connected/available.*

†Global hypoperfusion index (GHI) algorithm is only available while monitoring with a CCOmbo V catheter (model 777F8) or an IQ catheter (model AIQSGF8) and HemoSphere oximetry cable connection.

‡RVCO algorithm parameters are only available while monitoring with an IQ catheter (model AIQSGF8) and require a right ventricular pressure signal through a HemoSphere pressure cable connection. See "Right Ventricular Cardiac Output Algorithm" on page 304.

CAUTION Users should carefully consider whether to use pulse rate or heart rate, particularly in clinical conditions such as arrhythmia. This decision should be guided by the specific clinical context and medical judgment to ensure accuracy and optimal patient care.

NOTE Not all parameters can be monitored or calculated in pediatric patients. See table 1-1 on page 30 for available parameters.

Table 3-3 Sensor options for monitoring parameters with HemoSphere pressure cable/HemoSphere Alta monitor – pressure cable

	Monitored and calculated parameters									
Pressure sensor/ transducer options	CO	SV	SVV/ PPV	SVR*	PR	SYS/ DIA/ MAP	MPAP	CVP	RVP	HPI/ dP/dt / Ea_{dyn}
FloTrac sensor or FloTrac Jr sensor	•	•	•	*	•	•				
TruWave transducer					•	•	•	•	•	
Acumen IQ sensor**	•	•	•	*	•	•				•

**CVP monitoring, CVP manual entry, or default CVP value is used to calculate SVR.*

***The Acumen IQ sensor is required to access the AFM software feature. For more information see "Assisted Fluid Management" on page 278.*

Table 3-4 Finger cuff options for monitoring parameters with non-invasive ClearSight technology

	Monitored and calculated parameters						
Finger cuff options (one required)	CO	SV	SVV/ PPV	SVR*	PR	SYS/ DIA/ MAP	HPI/ dP/dt / Ea_{dyn}
ClearSight finger cuff or ClearSight Jr finger cuff	•	•	•	*	•	•	
Acumen IQ finger cuff	•	•	•	*	•	•	•

**CVP monitoring, CVP manual entry, or default CVP value is needed to calculate SVR*

Table 3-5 Catheters required for monitoring parameters with HemoSphere oximetry cable

	Monitored and calculated parameters	
Required catheter	$ScvO_2$	SvO_2
PediaSat oximetry catheter or compatible central venous oximetry catheter	•	
Swan-Ganz oximetry catheter		•

Table 3-6 Accessories required for monitoring parameters with ForeSight oximeter cable

	Monitored and calculated parameters		
Required accessory	**Tissue oximetry (StO_2)**	**Relative change in hemoglobin (ΔctHb)**	**Total hemoglobin (tHb)**
ForeSight/ForeSight Jr sensor	•	•	
ForeSight IQ sensor	•	•	•

WARNING **Shock hazard!** Do not attempt to connect/disconnect system cables while hands are wet. Ensure that hands are dry prior to disconnecting system cables.

CAUTION Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use.

To avoid corruption of data on the HemoSphere Alta advanced monitoring platform, always disconnect the HemoSphere Alta Swan-Ganz patient cable and oximetry cable from the monitor before using a defibrillator.

3.2 HemoSphere Alta Advanced Monitoring Platform Connection Ports

The following monitor views illustrate the connection ports and other key features of the front, rear, and side panels of the HemoSphere Alta advanced monitor.

3.2.1 Monitor Front

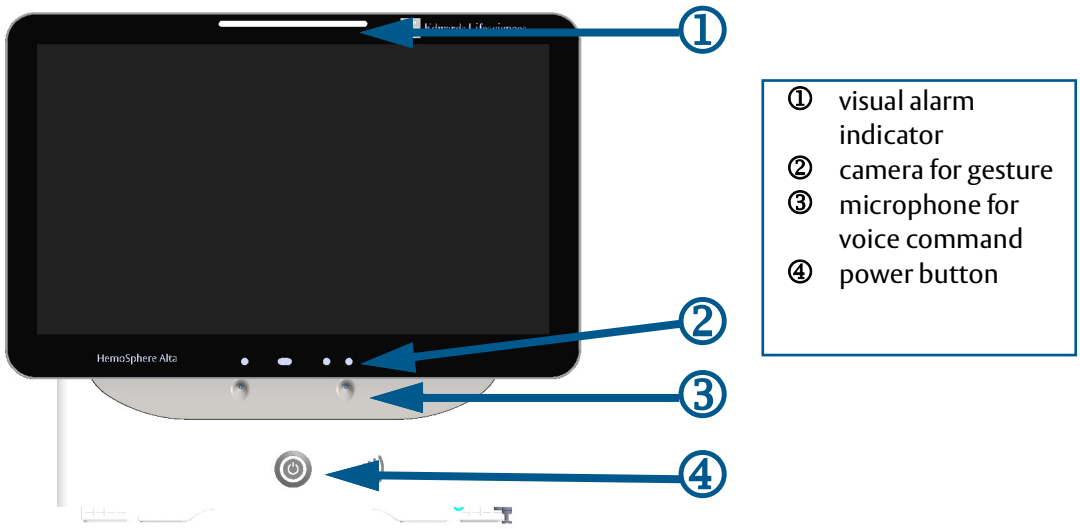


Figure 3-1 HemoSphere Alta advanced monitor front view

3.2.2 Monitor Rear

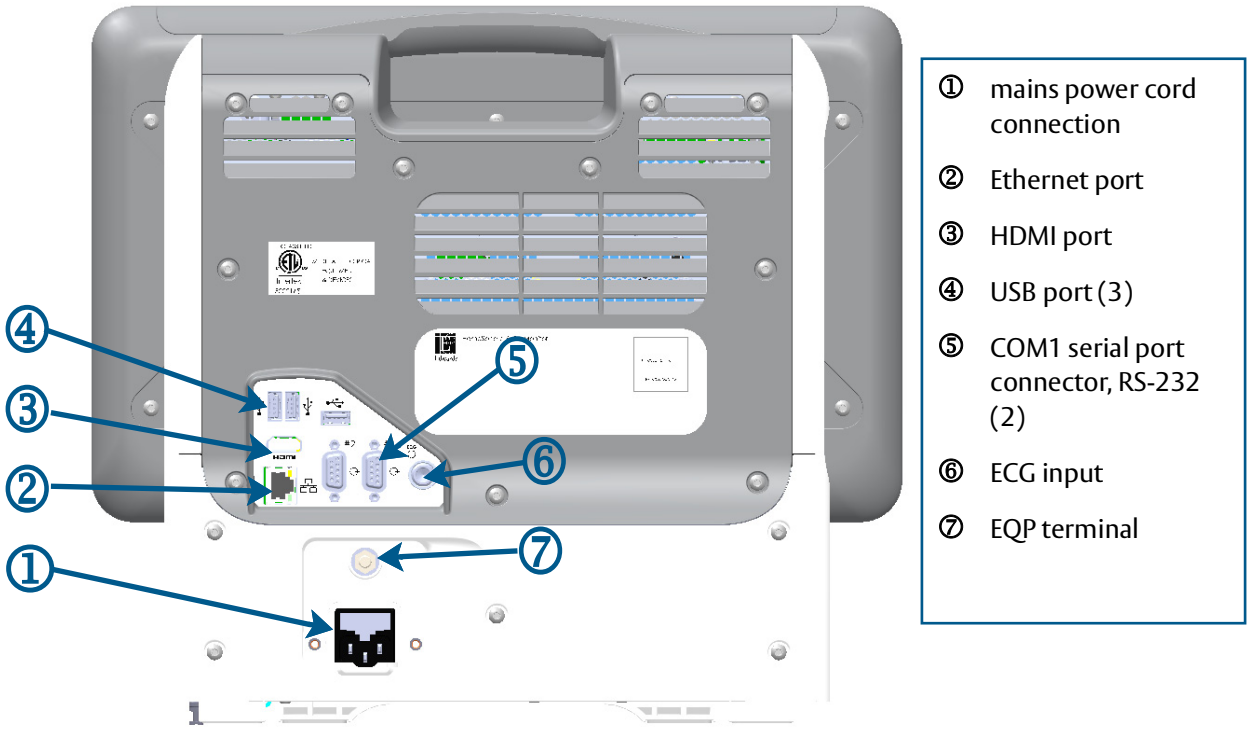


Figure 3-2 HemoSphere Alta advanced monitor rear view

3.2.3 Monitor Bottom Panel

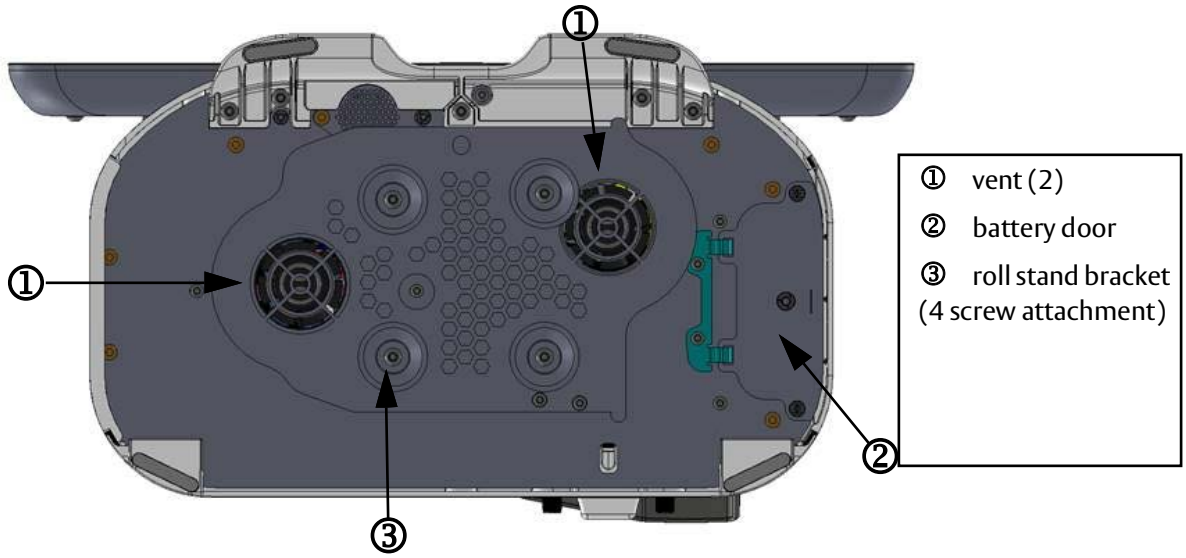
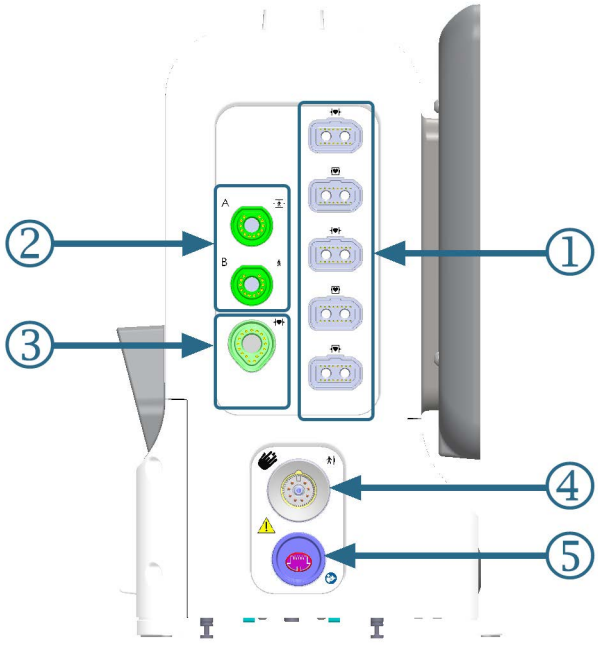


Figure 3-3 HemoSphere Alta advanced monitor bottom panel

3.2.4 Monitor Left Panel



① common cable ports (5)

② tissue oximetry ports (2)

③ Swan-Ganz technology port (1)

④ ClearSight technology port (1)

⑤ non-invasive pressure-out port (1)*

Figure 3-4 HemoSphere Alta advanced monitor left panel

***CAUTION** ClearSight technology pressure output signal to a patient monitor only intended to be connected to a pressure signal input port of Type BF or CF on the patient monitor that is protected against the effects of a discharge of a cardiac defibrillator.

3.3 HemoSphere Alta Advanced Monitoring Platform Installation

3.3.1 Mounting Options and Recommendations

The HemoSphere Alta advanced monitoring platform should be placed on a stable flat surface or securely mounted on a compatible stand, according to your institution's practices. The operator should be positioned in front of the monitor and at close proximity during use. The device is intended to be used by only one user at a time. A roll stand for the HemoSphere Alta advanced monitoring platform is available as an optional accessory. See "Additional Accessories Description" on page 364 more information. Contact your local Edwards representative for recommendations on additional mounting options.

WARNING **Explosion Hazard!** Do not use the HemoSphere Alta advanced monitoring platform in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

This product contains metallic components. Do NOT use in a Magnetic Resonance (MR) environment.

Make sure the HemoSphere Alta advanced monitoring platform is securely positioned or mounted and that all cords and accessory cables are appropriately arranged to minimize the risk of injury to patients, users or the equipment.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

The HemoSphere Alta advanced monitoring platform must be positioned in an upright position to ensure IPX1 ingress protection.

Do not allow any liquids to splash onto the monitoring screen. Liquid buildup may disable the touchscreen functionality.

Do not position the monitor so that it is difficult to access rear panel ports or power cord.

Equipment is rated for use with high-frequency surgical equipment. Inaccurate parameter measurements can be caused by interference from high-frequency surgical equipment. To reduce hazards that can arise from the use of high-frequency surgical equipment, only use undamaged patient cables and accessories connected as specified in this operator's manual.

This system is rated for use with defibrillators. To ensure proper defibrillator-proof operation, only use undamaged patient cables and accessories connected as specified in this operators manual.

All IEC/EN 60950 equipment, including printers, to be positioned no closer than 1.5 meters to the patient's bed.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the HemoSphere Alta advanced monitoring platform, including cables specified by the manufacturer. Otherwise, degradation of the performance this equipment could result.

CAUTION Do not expose the HemoSphere Alta advanced monitoring platform to extreme temperatures. Refer to environmental specifications in appendix A.

Do not expose the HemoSphere Alta advanced monitoring platform to dirty or dusty environments.

Do not obstruct the HemoSphere Alta advanced monitor ventilation openings.

CAUTION Do not use the HemoSphere Alta advanced monitoring platform in environments where strong lighting makes the LCD screen difficult to view.

Do not use the monitor as a handheld device.

3.3.2 Battery

The HemoSphere Alta advanced monitoring platform has an internal battery to support uninterrupted operation during power loss. To access the battery remove the 2 captive screws (see figure 3-3 on page 71). To facilitate removal of the screws, hold the battery door closed while unscrewing. Similarly, hold the door closed while re-installing the battery door and tightening the screws.

NOTE To ensure that the battery charge level displayed on the monitor is accurate, please condition the battery before first use. For information on battery maintenance and conditioning, see "Battery Maintenance" on page 386.

The HemoSphere Alta monitor battery is intended as a backup power source during power-loss and can only support monitoring for a limited time period.

WARNING Only use Edwards approved batteries with the HemoSphere Alta advanced monitoring platform. Do not charge the battery pack outside of the monitor. Doing so can damage the battery or injure the user.

To prevent any interruptions to monitoring during power loss, it is recommended to use the HemoSphere Alta advanced monitoring platform with the battery inserted.

In cases of power failure and battery depletion, the monitor will go through a controlled shut off procedure.

3.3.3 Connecting Power Cord

Before connecting the power cord to the rear panel of the monitor, ensure that the power entry cover is installed:

1. If the power entry cover is already installed, remove the two screws (image 3, figure 3-5) that attach the power entry cover to the rear panel of the monitor.
2. Connect the detachable power supply cord. Ensure that the plug is seated securely. (image 1, figure 3-5)
3. Attach the power cord entry cover over the plug by routing the power cord through the cover opening and then pressing the cover and gasket up against the rear panel of the monitor, aligning the two screw holes. (image 1, figure 3-5)
4. Reinsert the screws to fasten the cover onto the monitor. (image 3, figure 3-5)
5. Plug power cord into a hospital grade outlet.

WARNING Do not use the HemoSphere Alta advanced monitoring platform without an installed power cord entry cover. Failure to do so may result in fluid ingress.

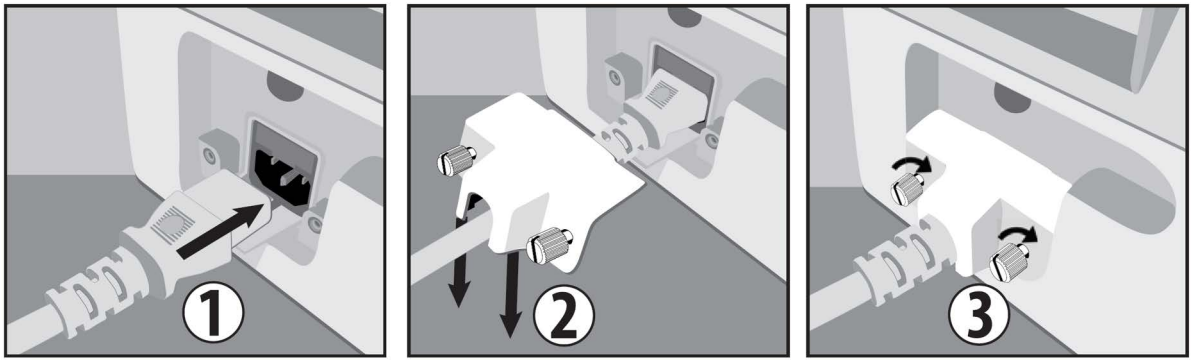


Figure 3-5 HemoSphere Alta advanced monitor power entry cover - installation steps

3.3.3.1 Equipotential Connection

This monitor MUST be grounded during operation (Class I equipment according to IEC 60601-1). If a hospital grade or three-prong receptacle is not available, a hospital electrician must be consulted to ensure proper grounding. An equipotential terminal is provided on the rear panel of the monitor (figure 3-2) to be connected to an equipotential grounding system (equipotential cable).

WARNING Do not use extension cords or multiple socket devices to connect the power cord. Do not use detachable power cords other than the power cord provided.

To avoid the risk of electric shock, the HemoSphere Alta advanced monitoring platform can only be connected to a supply mains with grounding (protective earth). Do not use three prong to two prong power adaptors.

Grounding reliability can only be achieved when the instrument is connected to a receptacle marked "hospital only", "hospital grade", or its equivalent.

Disconnect the monitor from the AC source by unplugging mains power cable from the AC Mains. The On/Off button on the monitor does not disconnect the system from the AC mains supply.

CAUTION When moving the instrument, be sure to turn off the power and remove the connected power cord.

3.3.4 Connecting and Disconnecting a Hemodynamic Monitoring Cable

Most monitoring cable ports are equipped with a magnetic latch mechanism. Inspect the cable for damage before connecting. A monitoring cable will snap into place when it is properly seated in the port. The pressure controller cable connection does not have a magnetic latch. To disconnect a cable, hold at the plug to pull it away from the monitor.

3.3.5 Connecting Cables from External Devices

The HemoSphere Alta advanced monitoring platform utilizes analog input monitored data to calculate certain hemodynamic parameters. This includes data from the ECG monitor input port. All analog input cable connections are located on the rear panel of the monitor (figure 3-2). See *Required Accessories for Platform Cables* on page 68 for a list of calculated parameters available with certain cable connections.

IMPORTANT NOTE The HemoSphere Alta advanced monitoring platform is compatible with ECG analog inputs from any external patient monitor that has analog output ports which meet the signal input specifications identified in appendix A, Table A-5 of this operator's manual. These provide a convenient means to utilize information from a patient monitor to calculate additional hemodynamic parameters for display. This is an optional feature that does not impact the HemoSphere Alta advanced monitoring platform's primary function of monitoring cardiac output (with the HemoSphere Alta Swan-Ganz patient cable) or venous oxygen saturation (with the HemoSphere oximetry cable).

WARNING Only use HemoSphere Alta advanced monitoring platform accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

3.4 Initial Start Up

3.4.1 Start Up Procedure

To turn on and off the monitor, press the power button located on the front panel. After turning on the monitor, the Edwards screen is displayed followed by the Power-On Self Test (POST) screen. The POST verifies the monitor meets basic operating requirements by exercising critical hardware components and is performed each time the system is turned on. POST status message is displayed on the startup screen along with system information such as serial numbers and software version numbers.

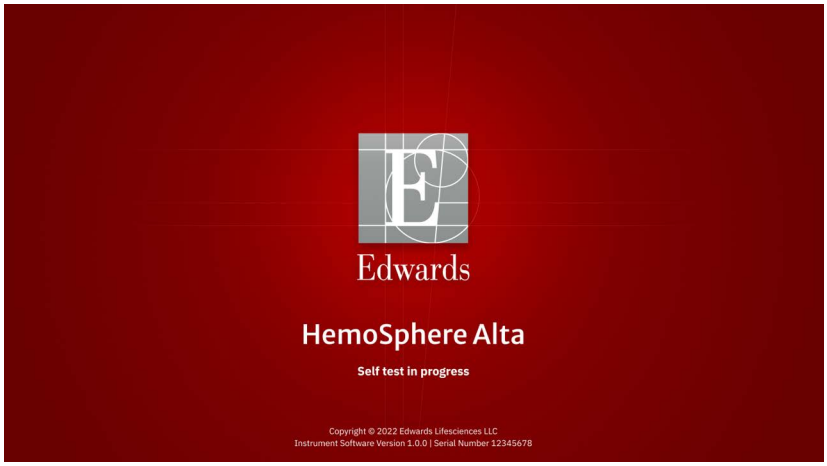


Figure 3-6 Startup screen

NOTE If the diagnostic tests detect an error condition, a system error screen will replace the startup screen. See Chapter 14: *Troubleshooting* or appendix F: *System Care, Service and Support*. Otherwise, call your Edwards Lifesciences representative for assistance.

3.4.2 Select Device ID

Upon initial HemoSphere Alta advanced monitoring platform startup, the user can select a Device ID or name for the monitor on the **Welcome** screen. The Device ID defaults to the monitor serial number but can be changed to any 20 character name. The Device ID is displayed at the center of the status bar. See "Status Bar" on page 109.

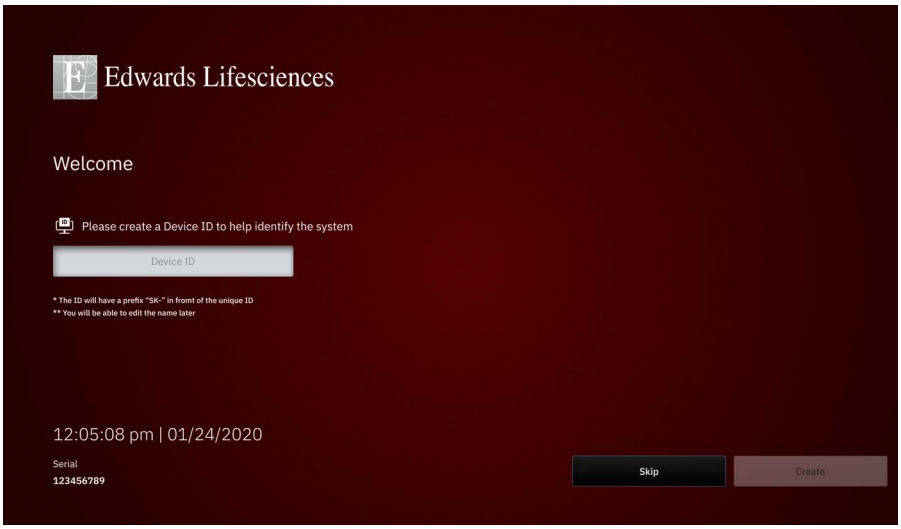


Figure 3-7 Device ID screen

The **Device ID** can be changed at any time from the **Device ID** screen through **Settings** → **Advanced Settings** → **Device ID** using a secure user password. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.

3.5 Power Off and Power Save Mode

To power the monitor off, touch the power button. See ② in Figure 3-1 on page 70. The following options will be displayed:

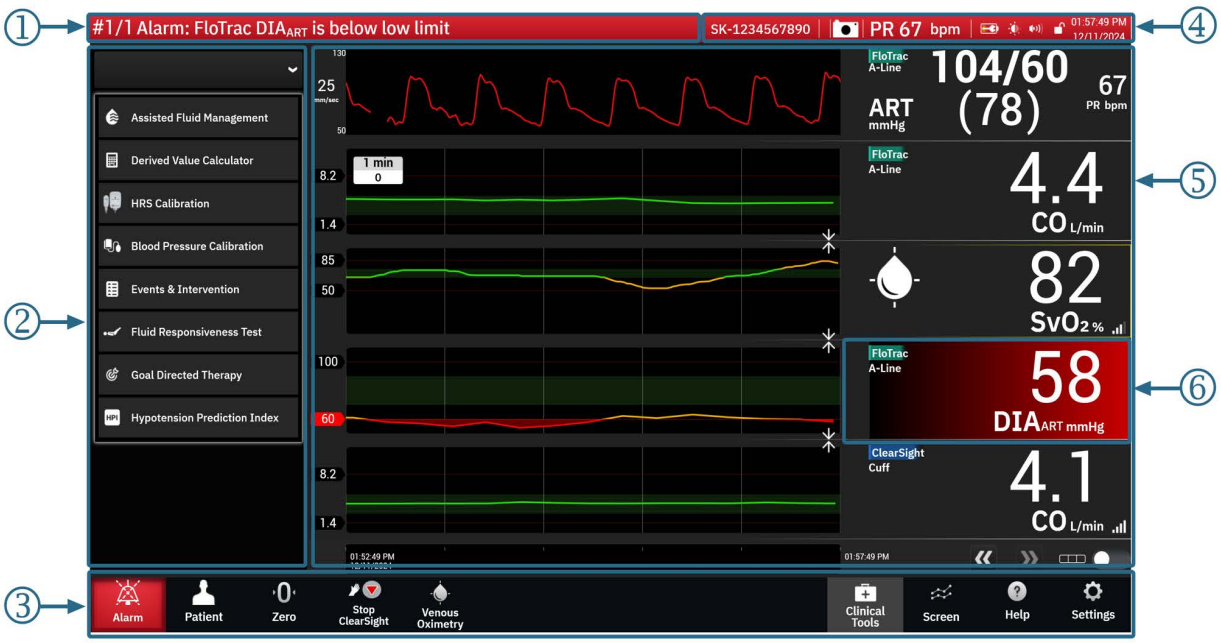
- **End Session**: Touch **Yes** to stop the current monitoring session and put the monitor in **Power Save Mode**. This prevents a full power cycle and the monitor can restart with screen touch activation.
- **Shutdown**: This will power off the monitor.
- **Cancel:** Returns you to the screen displayed prior to touching the power button.

Navigating the HemoSphere Alta Advanced Monitoring Platform 4

Contents

4.1 HemoSphere Alta Advanced Monitor Screen Appearance

All monitoring functions are initiated by touching the appropriate area on the touch screen. The layout of the HemoSphere advanced monitoring platform screen gives the clinician quick access to critical monitoring screens and menus to provide an ease of use. The navigation bar, located on bottom of the screen, includes various controls for stopping and starting monitoring, selecting monitoring screens, accessing the side panel for clinical tools, adjusting system settings, accessing voice and gesture, and silencing alarms. The main components of the HemoSphere Alta advanced monitor screen are shown below in figure 4-1. The main window displays the current monitoring view or menu screen. For details on monitoring view types, see *Monitor Views* on page 82. For details on other screen features, see the referenced sections in figure 4-1.



① status bar – notifications (section 4.9)
② clinical tools side panel(section 4.6)
③ navigation bar (section 4.2)
④ status bar – icons (section 4.8)
⑤ main window (monitoring view, section 4.3)
⑥ parameter tile (section 4.3.2)

Figure 4-1 HemoSphere Alta advanced monitor screen features

4.2 Navigation Bar

The navigation bar is present on most screens. Exceptions are the startup screen and screens indicating the HemoSphere Alta advanced monitoring platform has stopped monitoring. The example shown below for figure 4-1 is with non-invasive and invasive monitoring technologies connected with multi-sensor mode enabled. All available icons are described in detail below.

① silence audible alarm
② patient entry
③ zero pressure
④ start Swan-Ganz monitoring
⑤ start ClearSight technology monitoring
⑥ venous oximetry
⑦ clinical tools
⑧ monitoring screen
⑨ gesture
⑩ help
⑪ settings

Additional Icons

stop ClearSight technology monitoring

stop Swan-Ganz technology monitoring

voice off

gesture off

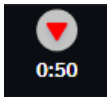
alarms silenced

alarms paused

Non-Pulsatile Mode active

Figure 4-2 Navigation bar and icons

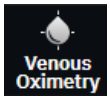
Start Swan-Ganz CO Monitoring. While monitoring with the HemoSphere Alta Swan-Ganz patient cable, the start CO monitoring icon allows the user to initiate CO monitoring directly from the navigation bar. See *Continuous Cardiac Output* on page 139.



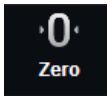
Stop Swan-Ganz CO Monitoring. The stop monitoring icon indicates that CO monitoring using the HemoSphere Alta Swan-Ganz patient cable is underway. The user can immediately stop monitoring by touching this icon and then **OK** on the confirmation popup.

Start Non-invasive Monitoring. While monitoring with the ClearSight non-invasive technology, the start monitoring icon allows the user to initiate non-invasive blood pressure and CO monitoring directly from the navigation bar. See *General Troubleshooting of HemoSphere Non-Invasive System Monitoring* on page 180.

Stop Non-Invasive Monitoring. The stop noninvasive monitoring icon indicates that noninvasive blood pressure and hemodynamic parameter monitoring using ClearSight technology is underway.

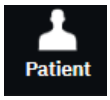


Venous Oximetry Monitoring. Touch here to access the venous oximetry settings and calibration screen. This icon will glow if a venous oximetry calibration is required. See *Venous Oximetry Setup* on page 190.



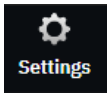
Zero & Waveform. This icon allows the user to access the **Zero & Waveform** screen directly from the navigation bar. See *Zero & Waveform Screen* on page 170.

Select Monitoring Mode. Touch here to switch between monitoring modes when multi-sensor mode is disabled. See *Multi-Sensor Advanced Monitoring Mode* on page 108. The current monitoring mode will be displayed under this icon on the navigation bar.

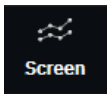


Patient. Touch this icon to view and edit current patient demographics and information. Touch the **End Session** button on the **Patient** screen at the end of each patient monitoring session to properly end monitoring. The new patient data screen will appear and the previous monitoring session will end and cannot be resumed.

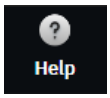
Patient (Demographics Skipped). This icon appears on the navigation bar when patient demographics have been skipped. Touch this icon at any point to enter patient demographics. If the default patient mode is pediatric, the patient mode will remain pediatric. Parameters available for monitoring are limited when patient demographics are skipped. See *Patient Data* on page 118.



Settings. The **Settings** icon provides access to general settings, patient alarm/target settings, advanced settings, **Demo Mode**, and data export. For more information on the settings menu, see *Settings Menu Navigation and Password Protection* on page 115.



Screen. This icon provides access to following three configuration screens: **Trend**, **Cockpit** and **Split**. When a monitoring view screen is selected, that monitoring mode is immediately displayed.



Help. See chapter 14: *On Screen Help*

Silence Audible Alarms. Touch and hold the Alarm icon on the navigation bar to access the alarm sub-menu. The following option are available:

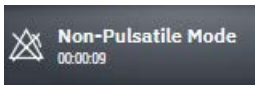
1 **Pause**: Touch this icon to pause CO monitoring and enter Non-Pulsatile mode. A confirmation banner will appear to confirm suspension of CO monitoring operations. Exception: Blood pressure monitoring, tissue oximetry monitoring, and associated alarms will remain active during Non-Pulsatile Mode. See table D-3 on page 374 for active parameters. During Non-Pulsatile Mode, all blood pressure averaging time defaults to 5 seconds with a 2 second update rate. See table 5-4 on page 122.

2 **Reset:** This will reset any latching fault that is no longer active. Active latching faults will continue to alarm.

3 **Silence:** This will silence all audio and visual indicator alarms for up to five minutes. The alarm pause interval options are 1, 2, 3, 4 and 5 minutes. New physiological alarms are silenced during the pause period. An exception to this is the Global Hypoperfusion Index (GHI) parameter, which will be silenced for 15 minutes (see *GHI Alarm* on page 269). Alarms will resume sounding after the pause period has elapsed. Faults are silenced until the fault is cleared and re-occurs. If a new fault occurs, the alarm sound will resume.

Audible Alarms Silenced. Indicates that alarms are temporarily silenced and a countdown timer appears. An alarm paused indicator will appear on any parameter tile that is currently alarming.

Silence All Alarms Permanently. Touch this icon on the alarm expansion menu to silence all alarms indefinitely. Selecting this alarm silence option requires a **Super User** password. See *Settings Menu Navigation and Password Protection* on page 115.



Resume Monitoring. After Non-Pulsatile mode confirmation, an elapsed time will appear on the navigation bar. A "**Non-Pulsatile Mode**" message will be displayed. To return to monitoring, touch the non-pulsatile mode icon.

4.3 Monitor Views

There are three primary monitoring views: **Trend** (graphical or tabular trend), **Cockpit**, and **Split**. Depending on the monitoring view selected, up to ten monitored parameters can be displayed.

To switch between monitoring views:

- Touch the **Screen** icon on the navigation bar.

  OR

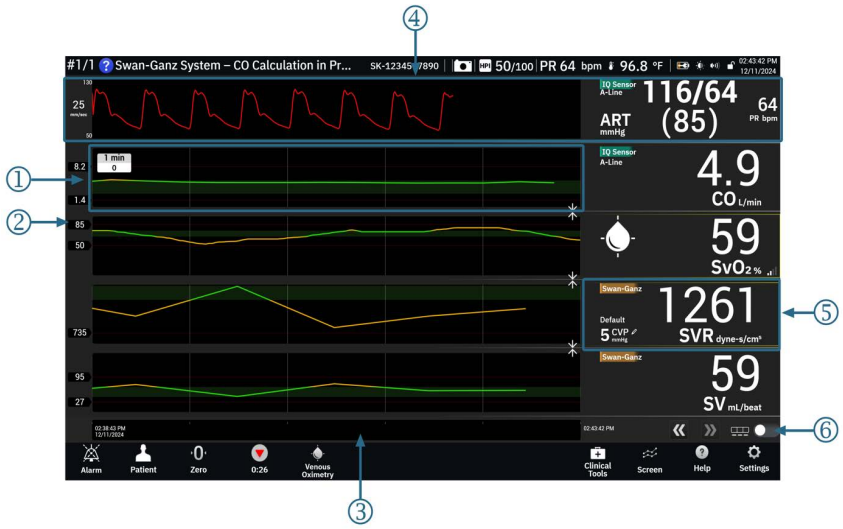
- Use the gesture command (see *HemoSphere Alta Advanced Monitoring Platform Gesture Commands* on page 93).

4.3.1 Trend Monitoring View

The **Trend** screen displays the current status and history of monitored parameters. The trend of parameter values can be viewed in graphical or tabular format. Displayed parameters are considered "key parameters" and are selected by accessing the parameter configuration menu. See *Change Parameters* on page 86.

4.3.1.1 Graphical Trend Screen

The main features of the graphical trend screen are outlined in figure 4-3 and below.



① graphical trend plot

② y-axis with threshold data labels

③ time range

④ blood pressure waveform display

⑤ graphical trend tile (touch here to access parameter configuration menu)

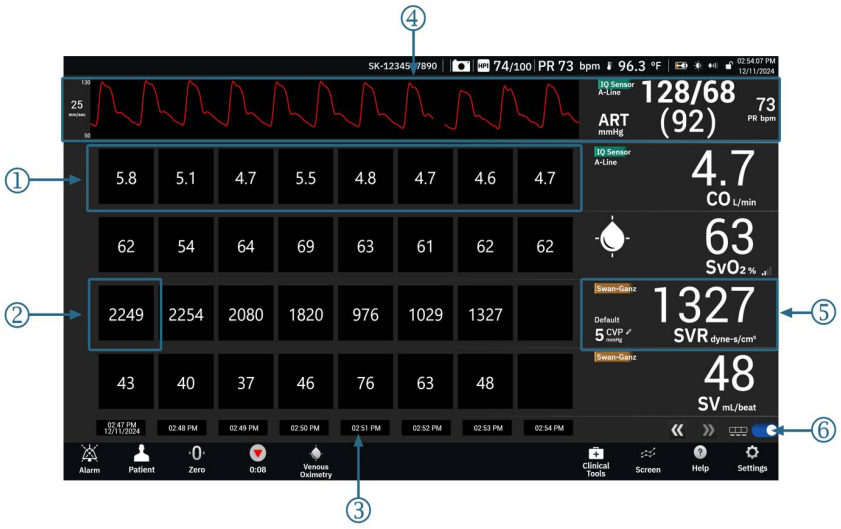
⑥ graphical/tabular toggle switch

Figure 4-3 Graphical trend screen

1. The graphical trend plot displays data over a predetermined time period (see 3). The plot line is colored based on user defined thresholds/targets for that parameter.
2. The y-axis displays data tags of the user defined thresholds. To change thresholds, touch anywhere on the graphical trend tile (see 5) for that parameter to access the parameter menu.
3. The time range (x-axis) for the trend plot can be modified by touching anywhere along the x-axis. Options range from 1 minute to 72 hours.
4. If a blood pressure waveform parameter is selected as a key parameter, it appears at the top of the screen.
5. The graphical trend tile displays the parameter name and value along with other key elements. For more information on this and accessing the parameter menu, see *Parameter Tiles - Parameter Configuration Menu* on page 86.
6. To toggle to tabular trend, touch the tabular trend toggle switch  .

4.3.1.2 Tabular Trend Screen

The tabular trend screen displays selected key parameters and their history in a tabular format. The main features of the tabular trend screen are outlined in figure 4-4 and below.



① tabular trend cells

② oldest tabular trend cell

③ time point

④ blood pressure waveform display

⑤ tabular trend tile (touch here to access parameter configuration menu)

⑥ graphical/tabular toggle switch

Figure 4-4 Tabular trend screen

1. The tabular trend cells display data over a predetermined time period (see 3).
2. The oldest time point displayed is determined by the **Tabular Increment** (see 3).
3. The tabular increment (x-axis) for the tabular trend display can be modified by touching anywhere along the x-axis. Options range from 1 minute to 60 minutes.
4. If a blood pressure waveform parameter is selected as a key parameter, it appears at the top of the screen.
5. The tabular trend tile displays the parameter name and value along with other key elements. For more information on this and accessing the parameter menu, see *Parameter Tiles - Parameter Configuration Menu* on page 86.
6. To toggle to tabular trend, touch the tabular trend toggle switch  .

The amount of history shown for monitored parameters can be configured by adjusting the time scale. Touch anywhere on the y-axis time scale to access the **Time Range** (graphical trend) or **Tabular Increment** (tabular trend).

4.3.1.3 Graphical Trend Features

When the target range for the parameter is enabled, the graph color codes the plot line, green indicating within the target range, yellow indicating the value is outside the target range but within the physiological alarm range, and red indicating the value is outside the alarm range. When the target range is disabled for the parameter the plot line is white. Color plotting can be disabled through general settings.

Touch settings icon  → **Trend Target Colors** toggle switch.

The colors match those of the clinical target indicator (parameter tile outline) on the key parameter tiles in the graphical trend graph when targets are enabled for the parameter. The alarm limits for each parameter are displayed as numerical values on the graph y-axis. See ② in figure 4-3 on page 83.

The plot turns a red shade for alarming parameters.

NOTE The graphical trend for the Acumen Hypotension Prediction Index parameter, HPI, displays as a white trend line when not in alarm range and a red trend line when in alarm range.

To combine plots, drop the parameter plot onto another graphical trend plot, or touch the combine icon located between plots. The y-axis values for the second parameter will appear on the right side of the plot. To return to separate graphical trend plots, touch the expand icon.

Scaling of the y-axis of the graphical trend plot is accessed from the parameter configuration menu by selecting the Y scale tab. When the parameter is out of range of the scale, a blue pulsing arrow appears in the direction of the parameter's value.

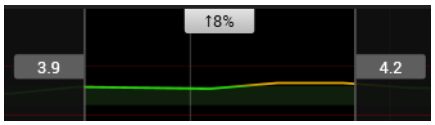
4.3.1.4 Graphical/Tabular Trend Scroll Mode

Up to 72 hours of monitored parameter data can be viewed by scrolling back. To start scrolling, swipe to the right/left on the graphical trend plot. The screen will return to live mode two minutes after the scroll button has been touched, or touch the current time arrow displayed at the right side of the time axis. While in scroll mode the user can scroll to data older than the current time scale displays.

NOTE It is not possible to scroll forward from the most recent data or before the oldest data. The graph will scroll only as far as data is available.

4.3.1.5 Trend Selection

Touch the trend plot with two fingers to view the change in value of a parameter over a specific monitoring time frame.



A time frame is demarcated by two vertical gray lines and parameter values at those time points for lower and upper end of the time frame. The percentage change of the parameter value over that time frame is displayed in the center. Drag the gray value boxes on any parameter trend plot to move the time frame. Scroll back or forward to move the time frame over the monitoring time period. To lock the selection, touch the unlock icon at the bottom of the screen. To unlock and move the trend time frame, touch the lock icon.

4.3.1.6 Live Blood Pressure Waveform Display

To display the real-time blood pressure waveform, select a **Pressure Waveform** parameter as a key parameter. A live pressure waveform graph panel will be displayed above the first monitored parameter graph. A numeric reading of the beat to beat systolic, diastolic and mean arterial pressure will be displayed above the first monitored parameter tile. To change the sweep speed (x-axis scale) of the graph, touch the pressure waveform parameter tile to access the parameter configuration menu.

4.3.2 Parameter Tiles - Parameter Configuration Menu

Parameter tiles are located on the right side of the graphical/tabular trend screens. The cockpit monitoring view is composed of larger format parameter globes which function identically as described below. Touching anywhere inside of a parameter tile will open the settings menu for that parameter. From here, you can change the parameter, add new parameters, and configure other display features for that parameter including alarms and targets.

4.3.2.1 Change Parameters

1. Touch the displayed parameter label located inside the parameter tile to change it to a different parameter.
2. Touch the **Select Parameter** button from the parameter configuration menu.
3. The parameter selection menu shows all selected key parameters highlighted in blue color. The currently selected parameter is highlighted in yellow. Available parameters appear on the screen without highlights. Figure 4-5 shows the parameter selection menu while monitoring with all available technologies in Multi-Sensor mode. The appearance of this window while monitoring with other HemoSphere Alta advanced monitoring platform configurations can vary from what is shown in figure 4-5.
   Parameters are further organized into categories within the selected technology. Categories, listed below, are grouped together on the parameter selection configuration menu. See figure 4-5.

Pressure Waveform. Select a blood pressure waveform parameter to view the blood pressure waveform display at the top of the screen. Pressure waveform parameters include:

- **ART**. Blood pressure parameters monitored from an arterial line (minimally-invasive or reconstructed non-invasive): Wave (pressure waveform), MAP, SYS_{ART}, DIA_{ART}, PR, and PPV.
- **PAP**. Blood pressure parameters monitored from a pulmonary arterial line: Wave (pressure waveform), MPAP, SYS_{PAP}, and DIA_{PAP}.
- **CVP**. Blood pressure parameters monitored from a central venous line: Wave (pressure waveform) and CVP.
- **RVP**. Blood pressure parameters monitored from a right ventricular placed line: Wave (pressure waveform), MRVP, SYS_{RVP}, DIA_{RVP}, and PR_{RVP}.

Flow. Flow parameters measure blood flow from the left or right heart (depending on connected technology) and include CO (CO, sCO, CO_{20s}, or CO_{RV}), CI (CI, sCI, CI_{20s}, or CI_{RV}), CPO (CPO or CPO_{RV}), CPI (CPI or CPI_{RV}), SV (SV, SV_{20s}, or SV_{RV}), SVI (SVI, SVI_{20s}, or SVI_{RV}), and SVV.

Resistance. Resistance parameters SVR and SVRI are related to systemic resistance to blood flow.

RV Function. These parameters which include EDV, EDVI, and RVEF are volumetric indicators of the right ventricle (RV).

Acumen. Parameters listed here are only available with a connected Acumen IQ sensor or cuff. This includes HPI, Ea_{dyn}, and dP/dt.

Venous Oximetery. Venous oximetry parameters include venous oximetry (SvO_2/$ScvO_2$) and GHI (global hypoperfusion index).

Tissue Oximetry. Tissue oximetry parameter is $StO_2$and is labeled by which channel the sensor is connected to. Other tissue oximetry parameters include tHb and CAI.

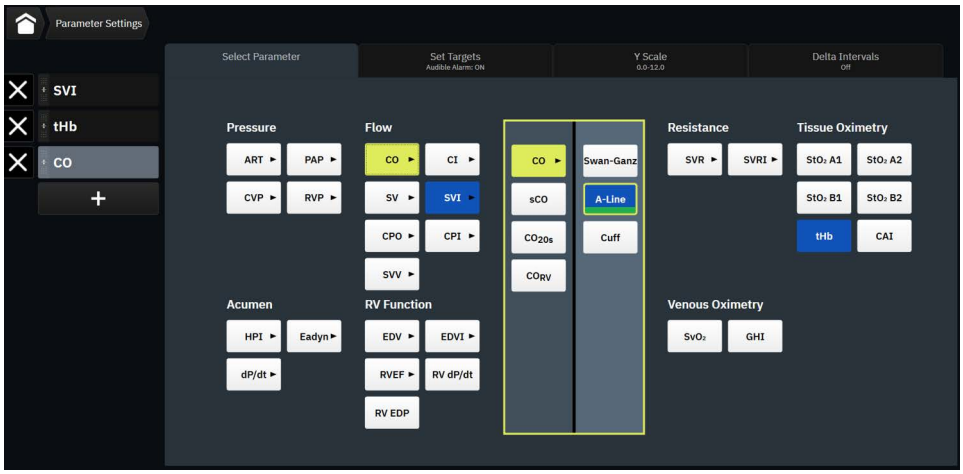


Figure 4-5 Example of key parameter selection tile configuration menu

4 Touch an available parameter to select the replacement parameter.

5 To change the order of any key parameter, touch and hold the parameter tile until the tile and trend plot appears with a blue outline. Drag and drop the parameter tile and trend plot to the new desired location to update the order of key parameters.

4.3.2.2 Change Alarm/Target

The **Set Targets** screen lets the user view and set up alarm and target values for the selected parameter or enable/disable the audible alarm and target settings. The target settings can be adjusted with a numbered key pad or with the scroll buttons when a minor adjustment is needed.

1 Touch the displayed parameter label located inside the parameter tile to change it to a different parameter.

2 Touch the **Set Targets** tab from the parameter configuration menu.

For more information, see *Alarms/Targets* on page 123.

NOTE The alarms limits and target ranges for the Acumen Hypotension Prediction Index parameter, HPI, are not adjustable.

4.3.2.3 Status Indicators

A parameter tile is outlined in color to indicate the patient's current status. The color changes as the patient's status changes. Items on the tile that appear underlined can be touched to access a configuration menu. The tiles may display additional information:

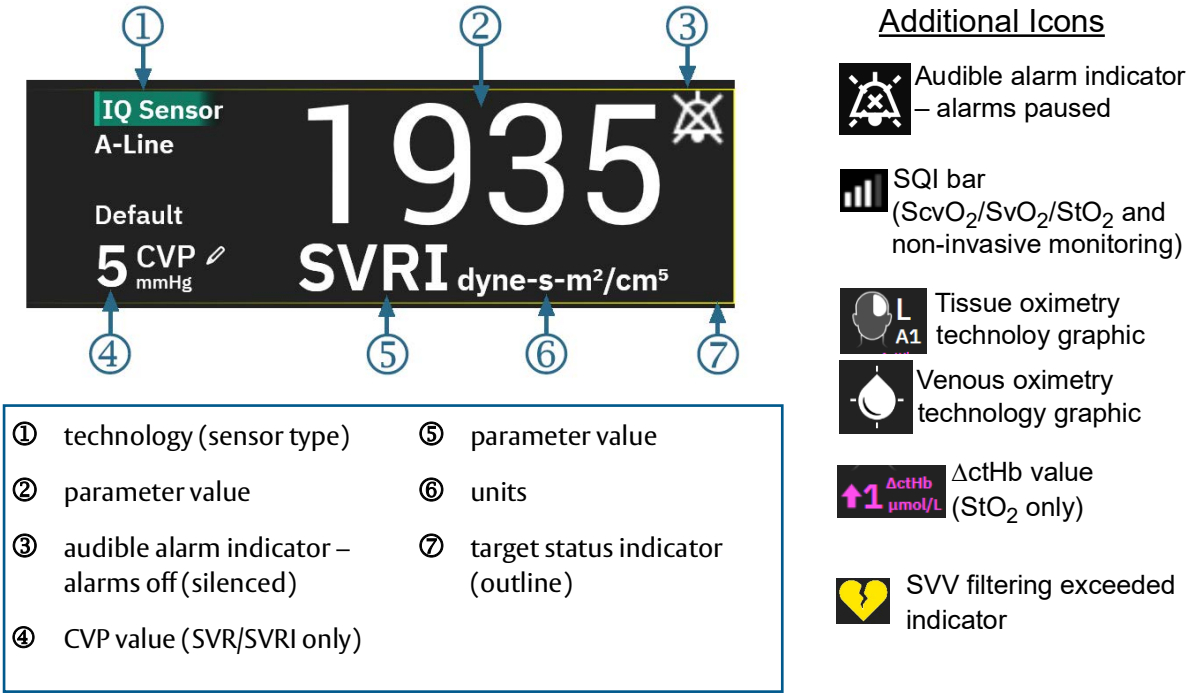
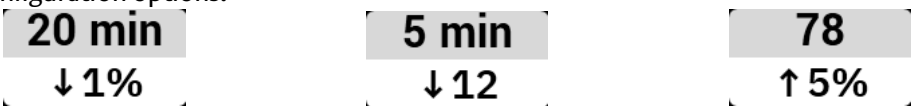


Figure 4-6 Parameter tile

Status Bar Messages. When a fault, alert, or alarm condition occurs, the message(s) will be displayed on the status bar until the condition is cleared. When there is more than one fault, alert or alarm, the message is cycled every two seconds.

When a fault condition occurs, parameter calculations are stopped, and each affected parameter tile displays the last value, time, and date at which the parameter was measured.

Continuous Change Interval. This indicator displays the percentage of change or absolute value of change, along with the time period over which it changed, or reference value. See *Delta Intervals / Averaging* on page 121 for configuration options.



SVV Filtering Exceeded Indicator. The SVV filtering exceeded indicator symbol appears on the SVV parameter tile if a high degree of pulse rate variability is detected that could affect the SVV value.

SQI Bar. The SQI bar is a reflection of the signal quality during oximetry or noninvasive monitoring. Signal quality is based on the catheter condition and positioning within the vessel for intra-vascular oximetry or the near-infrared light tissue perfusion index for tissue oximetry. For oximetry indicator levels, see table 11-3,

"Signal quality indicator levels," on page 194. For noninvasive finger cuff monitoring, SQI is based on the quality of the pressure waveform signal from the plethysmograph sensor of the finger cuff. For noninvasive SQI levels, see table 10-2, "Arterial waveform SQI levels," on page 183.

Target Status Indicators. The colored indicator outlining each monitoring tile indicates the patient's clinical status. For indicator colors and their clinical indications, see table 6-2, "Target status indicator colors," on page 125.

NOTE When using the Acumen Hypotension Prediction Index parameter, HPI, the patient status indicators differ from those described. Refer to *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225 for the patient status indicators available when using the Acumen Hypotension Prediction Index feature.

4.3.2.4 CVP Entry (SVR/SVRI only)

The CVP Entry screen allows the user to input a patient's CVP value to derive continuous SVR/SVRI calculation when MAP data is also available.

1. Touch anywhere in the **SVR/SVRI** parameter tile → **CVP Entry** tab.
2. Enter the CVP value.
3. Touch the home icon  to return to the main monitoring screen.

NOTE CVP entry is not available when the HemoSphere pressure cable and a TruWave transducer are monitoring CVP (see table 4-1 on page 89 and *Pressure Cable Monitoring with a TruWave pressure transducer (DPT)* on page 158).

The default value for CVP when no source is detected is 5 mmHg. If using the default CVP value (5 mmHg), periodically review and update CVP using CVP manual entry as changes are necessary when the actual CVP value differs significantly. This default value can be changed. See *CVP Settings* on page 129.

CVP values can be sourced in the following ways:

- Monitored directly with a TruWave pressure transducer and HemoSphere pressure cable (see *Pressure Cable Monitoring with a TruWave pressure transducer (DPT)* on page 158).
- As a static value entered manually by the user (**CVP Entry**).

When multiple sources for CVP are available, the monitor will prioritize the values according to table 4-1 on page 89.

Table 4-1 CVP value prioritization

Priority	CVP value used
1	HemoSphere pressure cable and TruWave pressure transducer
2	Manual **CVP Entry** / default CVP value

4.3.3 Split Screen

The **Split** screen monitoring view displays a graphical trend monitoring view on the left side of the screen and the choice of following three screens shown on the right:

1 physiology 

2 goal positioning 

3 graphical trend with up to 5 additional graphical trend parameter plots  .

4.3.3.1 Physiology Screen

Touch the physiology icon  on the right side of the **Split** screen to view the physiology screen. A large scale (full body) graphic of the patient is the default view. Monitored parameters are shown in mini parameter tiles. Parameters shown are fixed based on the currently connected technologies and are not selectable. In the physiology screen the image of the beating heart is a visual representation of the heart rate and is not an exact representation of beats per minute.

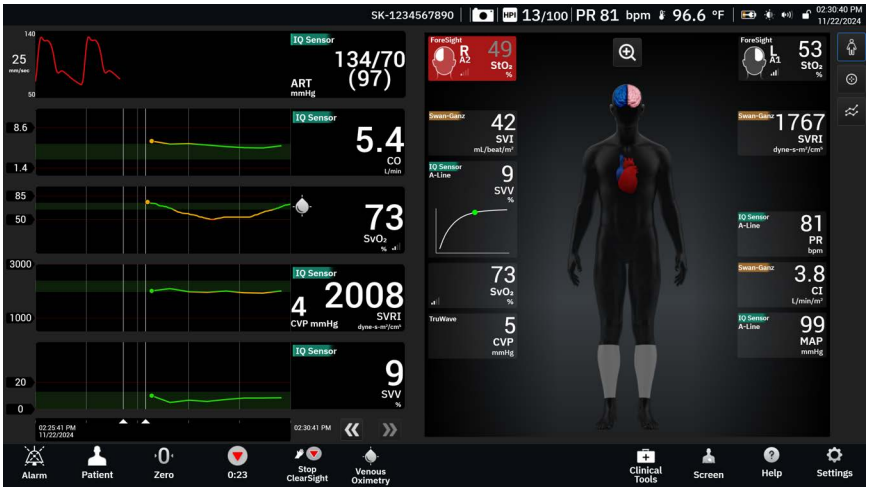


Figure 4-7 Split screen with large scale physiology selection

Touch the magnification icon to view an animation depicting the interaction between the heart, blood, and vascular system. Continuous parameter values are displayed in association with the animation.

Figure 4-8 Split screen with magnified physiology selection

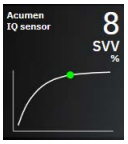
Key features of this screen are listed below.

1. $ScvO_2$/SvO_2 parameter data and signal quality indicator (SQI) are displayed here while the HemoSphere oximetry cable is connected and actively monitoring venous oxygen saturation.
2. Cardiac output (CO/CI), pulse rate (PR), and mean arterial pressure (MAP) is indicated on the arterial side of the vascular system animation. The blood flow animation rate will adjust based on the CO/CI value and the low/high target ranges selected for that parameter.
3. Systemic Vascular Resistance, indicated in the center of the vascular system animation, is available while monitoring CO/CI and utilizing MAP and CVP analog pressure signal inputs from a connected patient monitor or two HemoSphere pressure cables, as SVR =[(MAP-CVP)/CO]*80. While in minimally-invasive or noninvasive monitoring mode, only CVP is required using the CVP entry screen, CVP monitoring through a HemoSphere pressure cable. The level of constriction shown in the vessel will adjust based on the derived SVR value, and the low/high target ranges selected for that parameter.
4. For connected tissue oximetry sensors, color of the connected sensor locations on the patient body graphic correspond to the current monitored value. For values that are within the upper and lower target range, somatic sensor types appear gray and cerebral sensor types appear pink. For values that are below the lower target range (low physiologic alarm), the sensor location on the body appears blue. For values that are above the upper target range (high physiologic alarm), the sensor location on the body appears red.

NOTE The alarms/targets settings can be adjusted through the Alarms / Targets setting screen (see *Patient and Custom Alarm/Targets Settings Screen* on page 126) or by selecting the desired parameter as a key parameter, and accessing the tile configuration menu by touching inside of the parameter tile.

The example shown in figure 4-7 is while monitoring with a HemoSphere Alta Swan-Ganz patient cable. Differences in appearance and parameters will occur with other monitoring modes. For example, while monitoring within FloTrac sensor, FloTrac Jr sensor, or Acumen IQ sensor monitoring mode, HR_{avg} is replaced by PR, PPV and SVV appear (if configured), and EDV and RVEF are not shown.

SVV Slope Indicator. The SVV slope indicator is a visual representation of the Frank-Starling curve used when assessing the stroke volume variation (SVV) value. This appears on the physiology screen while using minimally-invasive and non-invasive monitoring technologies. The color of the lantern changes based upon set target ranges. An SVV value of l3% is displayed approximately at the inflection point of the curve.



The user has the ability to enable or disable the display of the SVV lantern, parameter value, and the SVV filtering exceeded indicator from the monitor settings – monitoring screens settings menu. The default setting is enabled. The system will not show the SVV lantern on the SVV indicator curve when the SVV filtering exceeded indicator is on.

4.3.3.2 Goal Positioning Screen

The Goal Positioning screen allows the user to monitor and track the relationship of two key parameters by plotting them against each other on an XY plane. Touch the goal positioning icon on the right side of the Physio monitoring screen to display this plot.

A single green circle dot represents the intersection of the two parameters and moves in real time as parameter values change. The additional circles represent the historical parameter trend with the smaller circles indicating older data.

The green target box represents the intersection of the green parameter target zone. The red dashed lines represent the parameter alarm limits.

The default y-axis parameter is CO and default x-axis parameter is SV. When multiple technologies are connected, the source will default to Swan-Ganz catheter technology and then FloTrac sensor technology.

Figure 4-9 Goal positioning screen

The following adjustments can be made on this screen:

- To change either axis parameter, touch on the axis to view the **GPS** (goal positioning screen) menu for that axis.
- To adjust the time interval between the historical trend circles, touch the trend interval icon  displayed on the screen.
- Continue touching the trend interval icon until **Off** appears to turn off historical trend circles.
- To adjust the scale of the X or Y axis, touch along the corresponding axis to view the **GPS** (goal positioning screen) menu for that axis.
- If the current intersection of parameters moves outside the scale of the X/Y plane, a message will appear indicating this to the user.

4.3.4 Cockpit Screen

This monitoring screen, shown in figure 4-10, displays large parameter globes with the values of the parameter being monitored. Cockpit parameter globes graphically indicate alarm/target ranges and values, and utilize needle indicators to show where the current parameter value falls. Similar to standard parameter tiles, the value within the globe will flash when the parameter is alarming.

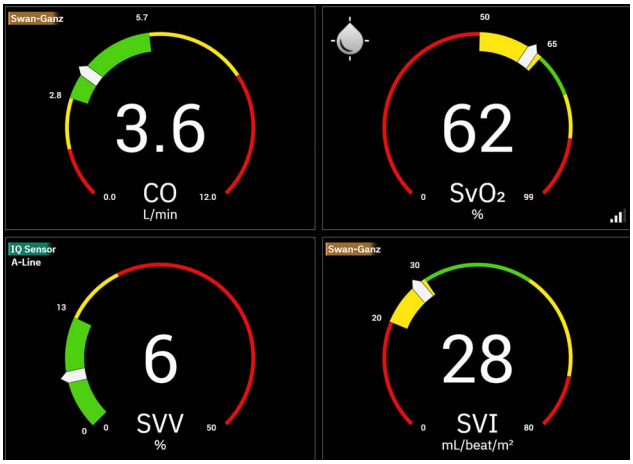


Figure 4-10 Cockpit monitoring screen

The key parameter globes shown on the cockpit screen display a more complex target and alarm indicator than the standard parameter tile. The full display range of the parameter is used to create a gauge from the graphical trends minimum to maximum settings. A needle is used to indicate the current value on the circular gauge scale. When target ranges are enabled, red (alarm zone), yellow (warning target zone), and green (acceptable target zone) are used to indicate the target and alarm regions within the circular gauge. When target ranges are not enabled, the circular gauge area is all gray in color and target or alarm indicators are removed. The value indicator arrow changes to indicate when the values are out of the gauge scale limits. Touch the plus icon ( ) to add more key parameters to the screen.

4.4 HemoSphere Alta Advanced Monitoring Platform Gesture Commands

The HemoSphere Alta advanced monitoring platform has gesture command capability and will deliver audio responses to simple gesture commands. There are two main gesture commands:

1. Silence audio alarms
2. Switch monitoring view screens

To use gesture commands:

1. Enable the **Gesture interaction** setting through the **Interactivity** setting screen. Touch settings icon → **Advanced Settings** button → **Interactivity** button. This menu requires a Secure user password. Contact your hospital administrator or IT department for passwords.
2. Touch on the **Gesture** icon Gesture on the navigation bar to enable the camera.

3 Use the wake gesture by raising your hand to the level of the camera and create an open palm facing the monitor. The monitor enters into an awake state indicated by a blue border around the screen and a blue **Gesture** icon on the navigation bar. This functionality is similar to the voice awake state. See figure 4-11 on page 95 for an image of how the blue border will appear in the awake state.

4 Use hand gestures to communicate the desired command. Available hand gestures are listed in table 4-2.

Table 4-2 HemoSphere Alta advanced monitoring platform hand gesture commands

Command	Hand gesture	Expected result
Wake	Open palm, facing monitor	Monitor enters an awakened state and awaits next command
Silence alarms	Transition from an open palm to a closed fist, facing monitor	Audible chime and alarm pause entered 
Switch monitoring view	"swipe motion" (right to left)	Switch to next available monitoring screen. Options rotate between **Trend**, **Cockpit** and **Split**. See *Monitor Views* on page 82.

5 After completing the hand gesture command, listen and watch monitor for expected result.

4.5 HemoSphere Alta Advanced Monitoring Platform Voice Commands

The HemoSphere Alta advanced monitoring platform has voice command capability and will deliver audio responses to simple voice commands.

NOTE Voice commands are only available when the system language is set to **English**.

For example, to silence the alarms, say "Hey Alta, silence the alarms." There are three main voice commands:

1 Silence audio alarms
2 Give an alarm readout
3 Give a parameter readout

To use voice commands:

1 Enable the **Voice interaction** setting through the **Interactivity** setting screen. Touch settings icon  → **Advanced Settings** button → **Interactivity** button. This menu requires a Secure user password. Contact your hospital administrator or IT department for passwords.

2 Touch on the **Voice** icon  on the navigation bar to enable the microphone.

3 Use the wake phrase which is "Hey, Alta." The monitor enters into a listening state indicated by a blue border around the screen and a blue **Voice** icon on the navigation bar.

Figure 4-11 Voice listening state (English only)

4 Speak the desired command. Voice command options and aliases are listed in table 4-3. If no voice command is desired, say "Cancel." The monitor will exit listening mode.

5 Listen for the response. This will be an audible chime if the command was an action, such as "Alta, silence the alarms" or an audible response if the command was a request for information.

6 If the voice command is not recognized, the monitor will respond with "Sorry, what was that?" If this occurs, repeat the wake command and request, or try one of the alternate command options listed in the table. Additional troubleshooting tips to improve speech comprehension include:

- Volume: speak louder and direct volume towards microphone
- Articulation: speak clearly and enunciate each word
- Cadence: speak at a conversational pace

If problems persist, use the touch screen to interact with the monitor.

CAUTION Do not use the voice command function in the vicinity of other HemoSphere Alta advanced monitoring platforms. Doing so may unintentionally initiate voice commands with those other monitors.

Table 4-3 HemoSphere Alta advanced monitoring platform voice commands (English only)

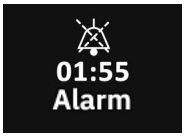
Command	Command options	Expected result
Silence alarms	• acknowledge alarm • acknowledge alarms • acknowledge the alarm • acknowledge the alarms • alarm acknowledge • alarm pause • alarm silence • hush • mute alarm • mute alarms • mute the alarm • mute the alarms • quiet • quiet alarm • quiet alarms • quiet the alarm • quiet the alarms • silence • silence alarm • silence alarms • silence the alarm • silence the alarms • pause alarm • pause alarms • pause the alarm • pause the alarms	Audible chime and alarm pause entered 
Give an alarm readout	• alarm readout • alert readout • give me the alarm • give me the alarms • give me the alert • give the alarm • give the alarms • give the alert • read the alarm • read the alarms • read the alert • readout alarm • readout alarms • readout alert • readout the alarm • readout the alarms • readout the alert • show me the alarm • show me the alarms • show me the alert • show the alarm • show the alarms • show the alert • tell me the alarm • tell me the alarms • tell me the alert • what is alarming • what is causing alarm • what is causing alarms • what is causing alert • what is causing the alarm • what is causing the alarms • what is causing the alert • what is going on • what is happening • what is the alarm • what is the alarms • what is the alert • what is the problem • what is wrong • what is your alarm • what is your alarms • what is your alert • what's alarming • what's causing alarm • what's causing alarms • what's causing alert • what's causing the alarm • what's causing the alarms • what's causing the alert • what's going on • what's happening • what's the alarm • what's the alarms • what's the alert • what's the problem • what's wrong • what's your alarm • what's your alarms • what's your alert • why are you alarming • why is the alarm going off	Audible response with current alarm conditions If there are no active alarms, response is “There are no active alarms.”

Table 4-3 HemoSphere Alta advanced monitoring platform voice commands (English only) (continued)

Command	Command options	Expected result
Give a parameter readout	• [parameter[1]] number • [parameter] readout • [parameter] report • [parameter] value • [technology[1]] [parameter] number • [technology] [parameter] readout • [technology] [parameter] report • [technology] [parameter] value • readout [parameter]* • readout [technology] [parameter]* • readout current [parameter] • readout current [technology] [parameter] • readout [her/his/their/my/the] [parameter]* • readout her/his/their/my/the [technology] [parameter]* • readout her/his/their/my/the current [parameter] • readout her/his/their/my/the current [technology] [parameter] • show me [parameter]* • show me [technology] [parameter]* • show me current [parameter] • show me current [technology] [parameter] • show me [her/his/their/my/the] [parameter]* • show me [her/his/their/my/the] [technology] [parameter]* • show me [her/his/their/my/the] current [parameter] • show me [her/his/their/my/the] current [technology] [parameter] • what is [parameter] • what is [technology] [parameter] • what is current [parameter] • what is current [technology] [parameter] • what is [her/his/their/my/the] [parameter] • what is [her/his/their/my/the] [technology] [parameter] • what is [her/his/their/my/the] current [parameter] • what is [her/his/their/my/the] current [technology] [parameter] • what's [parameter] • what's [technology] [parameter] • what's current [parameter] • what's current [technology] [parameter] • what's [her/his/their/my/the] [parameter] • what's [her/his/their/my/the] [technology] [parameter] • what's [her/his/their/my/the] current [parameter] • what's [her/his/their/my/the] current [technology] [parameter]	Audible response with current parameter values
Give a parameter readout at a certain time ago	With the addition of the options listed below, all command options listed for "Give a parameter readout" indicated with an asterisk (*) can be requested for a certain length of time in past. For example, "Hey Alta, readout [parameter] [time] ago. • readout my/the patient's [parameter[1]] [time] ago • readout my/the patient's [technology] [parameter] [time] ago • show me my/the patient's [parameter] [time] ago • show me my/the patient's [technology[1]] [parameter] [time] ago • what was [parameter] [time] ago • what was [technology] [parameter] [time] ago • what was her/his/my/the/their [parameter] [time] ago • what was her/his/my/the/their [technology] [parameter] [time] ago • what was my/the patient's [parameter] [time] ago • what was my/the patient's [technology] [parameter] [time] ago	Audible response with parameter values at a certain length of time in past

Table 4-3 HemoSphere Alta advanced monitoring platform voice commands (English only) (continued)

Command	Command options	Expected result
Give a parameter readout at a specific time point	With the addition of the options listed below, all command options listed for "Give a parameter readout" indicated with an asterisk (*) can be requested for a specific time point. For example, "Hey Alta, readout [parameter] at [time]".	Audible response with parameter values at a specific time point
	• readout my/the patient's [parameter[1]] at [time] • readout my/the patient's [technology] [parameter] at [time] • show me my/the patient's [parameter] at [time] • show me my/the patient's [technology[1]] [parameter] at [time] • what was [parameter] [time] ago • what was [technology] [parameter] at [time] • what was her/his/my/the/their [parameter] at [time] • what was her/his/my/the/their [technology] [parameter] at [time] • what was my/the patient's [parameter] at [time] • what was my/the patient's [technology] [parameter] at [time]	

4.6 Clinical Tools

The clinical tools side panel gives tools related to the current connected monitoring technology. Clinical Tools can be accessed by touching the **Clinical Tools** icon on the navigation bar. Some clinical tools options are available across all monitoring technologies and certain side panel menu options are related to the current monitoring mode (e.g., while monitoring with the HemoSphere Alta Swan-Ganz patient cable). Clinical tools related to a specific monitoring technology include:

- **Blood Pressure Calibration** (HemoSphere ClearSight technology)
- **iCO** (HemoSphere Alta Swan-Ganz patient cable)

The following clinical tools are available across most monitoring technologies.

4.6.1 HPI Secondary Screen

The Acumen Hypotension Prediction Index (HPI) software can be activated with an Acumen IQ sensor connected or with an Acumen IQ cuff and heart reference sensor (HRS) connected. For more information, see *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225.

4.6.2 Assisted Fluid Management

The Acumen assisted fluid management (AFM) software feature provides clinical decision support for the management of patient fluids. For more information on this advanced feature, see *Assisted Fluid Management* on page 278 for more information.

4.6.3 Goal Directed Therapy

Enhanced parameter tracking allows a user to manage key parameters in the optimal range. For more information, see *Enhanced Parameter Tracking* on page 308.

4.6.4 Fluid Responsiveness Test

With the **Fluid Responsiveness Test** (**FRT**), clinicians have the ability to assess preload responsiveness. Preload responsiveness is assessed by tracking the changes in **SV, SVI, CO** or **CI** in response to a fluid challenge (**Passive Leg Raise** or **Fluid Bolus**). For more information, see *Fluid Responsiveness Test* on page 311.

4.6.5 Derived Value Calculator

The Derived Value Calculator allows the user to compute certain hemodynamic parameters and provides a convenient way to display these parameters for one-time calculation.

Calculated parameters are based on monitoring mode and may include: DO_2/DO_2I, ESV/ESVI, SV/SVI, VO_2/VO_2I, VO_2e/VO_2Ie, SVR/SVRI, LVSWI (indexed only), RVSWI (indexed only), and PVR/PVRI.

1. Touch the **Clinical Tools** icon → **Derived Value Calculator** button.
2. Enter the required values and the derived calculations will automatically display.
3. Touch the **Log Values** button to enter values in system for future review of them through the **Events & Intervention** side panel. See *Events & Intervention* on page 99.

4.6.6 Events & Intervention

The **Events & Intervention** side panel provides a list of parameter-related and system events that occurred during monitoring and a menu of intervention types, details and notes section.

Touch the **Clinical Tools** icon → **Events & Intervention** button.

4.6.6.1 Event Scrolling

The Events & Intervention side panel displays a list of parameter-related and system events that occurred during monitoring. This includes the start time and duration of any faults, alerts, physiological alarms, or system messages. Up to 72 hours of events and alarm messages are recorded in order with the most recent event at the top

The following events are included in the event review log.

Table 4-4 Reviewed events

Identifying Icon and Category	Event message	When time logged
AFM	Discarded analysis	An AFM session is active and a bolus analysis has been declined
	Fluid bolus {0} analysis started	An AFM session is active and a bolus analysis has begun {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses
	Fluid bolus {0} analysis completed	An AFM session is active and a bolus analysis has been completed {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 **AFM**	Hemodynamic values compromised	An AFM session is active and the measurements are compromised
	Fluid bolus {0} started (user-specified)	An AFM session is active and a user-specified bolus has ended {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses
	Fluid bolus {0} ended (user-specified)	An AFM session is active and a user-specified bolus is started {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses
	Fluid bolus {0} started	An AFM session is active and a bolus is started per recommendation of the AFM algorithm {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses
	Fluid bolus {0} ended	An AFM session is active and a bolus recommended by the AFM algorithm is ended {0} is the number identifying the bolus within the current AFM session Note: {0}(number) is inclusive of boluses started per recommendation of the AFM algorithm and user-specified boluses
	Fluid Bolus Suggested	The AFM algorithm is suggesting a bolus
	No fluid bolus suggested	The AFM algorithm is not suggesting a bolus
	Fluid suggestion declined	An AFM session is active and the user declines a bolus that was suggested by the AFM algorithm
	Test Bolus Suggested	The AFM algorithm is suggesting a test bolus
	Nearing maximum case volume	An AFM session is active and the AFM bolus is paused by the system as tracked case volume is approaching max case volume
	Exceeded maximum case volume	An AFM session is active and the AFM bolus is paused by the system as tracked case volume exceeds max case volume
	Settings changed: Fluid Strategy - {0}	An AFM session is active and the user changes the **Fluid Strategy** where {0} is **10%**, **15%** or **20%**
	Settings changed: Surgery Mode - {0}	An AFM session is active and the user changes the **Surgery Mode** where {0} is **Open** or **Laparoscopic/Prone**
	Settings changed: Max Case Volume - {0}	An AFM session is active and the user changes the **Max Case Volume** where {0} is t the new maximum case volume in mL
	Settings changed: Fluid Type – {0}	An AFM session is active and the user changes the **Fluid Type** where {0} is the new fluid type selected
	Settings changed: Fluid Tracking Mode – {0}	An AFM session is active and the user changes the **Fluid Tracking** mode where {0} is **Fluid Meter** or **Manual**

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 **AFM**	Started - fluid tracking: {0}, surgery mode: {1}, fluid strategy: {2}	The user starts an AFM session {0} is the type of fluid tracking (Manual) {1} is the current surgery mode {2} is the current fluid strategy
	Ended Bolus Volume	An AFM session is stopped where the total tracked volume at the end of AFM session is listed below "**Bolus Volume**."
 **Alarm**	Alarm: {0} {1} exceeded high limit Alarm: {0} {1} is below low limit	An alarm occurs where {0} indicates technology type (such as Acumen IQ sensor) and {1} indicates the parameter alarming. For more on alarms, see *Alarms/Targets* on page 123.
 **Alert**	Alert: {0}	An alert occurs where {0} is the alert message. For a list of system alerts, see chapter 14, *Troubleshooting*.
 **Zero**	Acumen IQ Zeroed – ART	A connected Acumen IQ sensor monitoring arterial pressure is zeroed
	ClearSight System Calibrated – HRS	A connected heart reference sensor (HRS) is calibrated
	FloTrac Sensor Zeroed – ART	A connected FloTrac sensor or FloTrac Jr sensor monitoring arterial pressure is zeroed
	TruWave Zeroed – ART TruWave Zeroed – CVP TruWave Zeroed – PAP TruWave Zeroed – RVP	A connected TruWave pressure transducer is zeroed where the pressure waveform is: ART, CVP, PAP, or RVP
 **Blood Pressure Calibration**	BP calibration cleared (automatically)	The existing BP calibration is cleared automatically
	BP calibration cleared (manually)	The existing BP calibration is cleared by the user
	BP calibration failed	The initial calibration failed or the system is requesting a recalibration
	BP calibration successful – Reference: SYS {0}, DIA: {1}	Blood pressure calibration is successfully completed where {0} is the user-entered reference value for SYS and {1} is the user-entered value for DIA
 **ClearSight Technology**	Cuff 1 monitoring Cuff 2 monitoring	Non-invasive monitoring is active on the cuff indicated
	CO monitoring started	The user begins non-invasive system monitoring
	CO monitoring started – No HRS – {0}	The user begins non-invasive system monitoring without an HRS where {0} is the verified height offset between the monitored finger and heart.
	CO monitoring stopped	The user or system stops non-invasive system monitoring
	Proceeding without HRS	The user has switched from non-invasive monitoring with an HRS to non-invasive monitoring without an HRS
	Proceeding with HRS	The user has switched from non-invasive monitoring without an HRS to non-invasive monitoring with an HRS
	72 hour limit reached	Non-invasive system monitoring has stopped due to 72 hour limit

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 **ClearSight Technology**	Cuff 8 hour limit reached	Monitoring for 8 continuous hours on a single cuff has occurred
	Cuff Pressure Released	A cuff pressure release has occurred
	Cuff Pressure Release Acknowledged	The **Acknowledge** button is touched on "**Pressure Release Upcoming**" notification popup
	Cuff pressure release postponed	Monitoring is extended to delay a finger cuff pressure release
	Switched Cuff - Restarting	Monitoring has stopped on one finger cuff and is switching to other connected finger cuff
 **Derived Value Calculation**	Values logged	Parameter values are entered and logged into the derived value calculator
 **Fault**	Fault: {0}	A fault occurs where {0} is the fault message. For a list of system faults, see chapter 14, *Troubleshooting*.
 **FRT**	Bolus baseline started	An FRT baseline measurement is started (Fluid challenge type: **Fluid Bolus**)
	Bolus baseline complete	An FRT baseline measurement is completed with a valid measurement (Fluid challenge type: **Fluid Bolus**)
	Unstable baseline value	An FRT baseline measurement is stopped with a valid measurement however the measurement is unstable (Fluid challenge type: **Fluid Bolus**)
	Insufficient baseline data	An FRT baseline measurement is stopped and invalid (Fluid challenge type: **Fluid Bolus**)
	Bolus baseline canceled	An FRT baseline measurement is canceled (Fluid challenge type: **Fluid Bolus**)
	Bolus started	An FRT challenge measurement is started (Fluid challenge type: **Fluid Bolus**)
	Bolus canceled	An FRT challenge measurement is canceled (Fluid challenge type: **Fluid Bolus**)
	Insufficient bolus data	An FRT challenge measurement is stopped and invalid (Fluid challenge type: **Fluid Bolus**)
	Bolus Complete	An FRT challenge measurement is completed with a valid measurement. This occurs at the end of the challenge duration or when the user touches **End Now**. The results of the FRT are displayed, including the parameter analyzed, baseline value, resulting (challenge) value, and the percentage change in value. (Fluid challenge type: **Fluid Bolus**)
	Passive leg raise baseline started	An FRT baseline measurement is started (Fluid challenge type: **Passive Leg Raise**)
	Passive leg raise baseline complete	An FRT baseline measurement is completed with a valid measurement (Fluid challenge type: **Passive Leg Raise**)

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 FRT	Unstable baseline value	An FRT baseline measurement is stopped with a valid measurement however the measurement is unstable (Fluid challenge type: **Passive Leg Raise**)
	Insufficient baseline data	An FRT baseline measurement is stopped and invalid (Fluid challenge type: **Passive Leg Raise**)
	Passive leg raise baseline canceled	An FRT baseline measurement is canceled (Fluid challenge type: **Passive Leg Raise**)
	Passive leg raise started	An FRT challenge measurement is started (Fluid challenge type: **Passive Leg Raise**)
	Passive leg raise canceled	An FRT challenge measurement is canceled (Fluid challenge type: **Passive Leg Raise**)
	Insufficient passive leg raise data	An FRT challenge measurement is stopped and invalid (Fluid challenge type: **Passive Leg Raise**)
	Passive leg raise complete	An FRT challenge measurement is completed with a valid measurement. This occurs at the end of the challenge duration or when the user touches **End Now**. The results of the FRT are displayed, including the parameter analyzed, baseline value, resulting (challenge) value, and the percentage change in value. (Fluid challenge type: **Passive Leg Raise**)
 GDT	Started	A GDT tracking session is started
	Paused	A GDT tracking session is paused
	Resumed	A GDT tracking session is resumed
	Settings changed	GDT tracking session targets are updated
	Ended	A GDT tracking session is stopped. Tracked parameters and corresponding time-in-target results are displayed.
 HPI	Alert popup displayed	Acumen Hypotension Prediction Index, HPI, alert becomes active. [HPI only]
	Alert: {0} - {1}, {2} - {3}	Acumen Hypotension Prediction Index, HPI, smart trend alert becomes active where {0} and {2} are the categories; {1} and {3} are the alarming parameters associated with those categories
	Smart trend initiated: change threshold: {0}, change interval: {1}, preload: {2}, afterload:{3}, contractility:{4}	Acumen Hypotension Prediction Index, HPI, smart trend initiated, where {0} is the Δ **Threshold %** menu setting (10%, 15%, or 20%) {1) is the Δ **Time Interval** menu setting (5 min, 10 min, 15 min, or 20 min) {2} is the preload parameter (SVV, SVI, or PPV) {3} is the afterload parameter (SVR) {4} is the contractility parameter (CI or dP/dt)
	Smart trend configuration updated: change threshold: {0}, change interval: {1}, preload: {2}, afterload:{3}, contractility:{4}	Acumen Hypotension Prediction Index, HPI, smart trend updated, with new settings: {0} is the Δ **Threshold %** menu setting (10%, 15%, or 20%) {1) is the Δ **Time Interval** menu setting (5 min, 10 min, 15 min, or 20 min) {2} is the preload parameter (SVV, SVI, or PPV) {3} is the afterload parameter (SVR) {4} is the contractility parameter (CI or dP/dt)

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
HPI **HPI**	Popup enabled	"**Always Show HPI and Alert**" setting is toggled on in HPI setting menu
	Popup disabled	"**Always Show HPI and Alert**" setting is toggled off in HPI setting menu
	Smart alerts enabled	"**Smart Trend Alerts**" setting is toggled on in HPI setting menu
	Smart alerts disabled	"**Smart Trend Alerts**" setting is toggled off in HPI setting menu
	Smart alerts threshold changed: {0} {1} changed to {2}	The alarm threshold for smart trend configured parameter is changed where {0} is the category (preload, afterload or contractility), {1} is the associated parameter, and {2} is the new threshold value
	Alert acknowledged*	Acumen Hypotension Prediction Index, HPI, alert is acknowledged*. [HPI only]
	Alert cleared (acknowledged)*	Acumen Hypotension Prediction Index, HPI, alert is cleared as the HPI value was lower than 75 for the last two consecutive 20-second updates. The HPI high alert popup was acknowledged* prior to the alert clearing. [HPI only]
	Alert cleared (not acknowledged)*	Acumen Hypotension Prediction Index, HPI, alert is cleared as the HPI value was lower than 75 for the last two consecutive 20-second updates. The HPI high alert popup was not acknowledged* prior to the alert clearing. [HPI only]
 **Intervention Type**	Intervention subtype action	When user logs data for the intervention For more information on intervention types, see *Intervention* on page 107.
 **Intervention Updated**	intervention type {0} to {1}	An intervention has been updated to the marker shown, where {0} is the previous intervention data field and value (type, time, detail or comment), and {1} is the new value for that data field
 **Monitoring**	CVP manually entered	A CVP value has been manually entered
	Non-pulsatile Mode started	Active CO monitoring paused to prevent audible alarms and parameter monitoring. Blood pressure and tissue oximetry monitoring and alarms continued.
	Non-pulsatile Mode ended	Normal CO monitoring resumed. Audible alarms and parameter monitoring were activated.
 **Patient**	Session started	A patient monitoring session is started
	Information updated	The user has saved updated patient demographic information
	Auto restart	The previous patient session was automatically restarted
 **Smart Wedge**	Wedge Detected	Smart Wedge algorithm detects wedge pressure in pulmonary artery
	Computed	PAOP pressure measurement is completed by algorithm
	Ended	PAOP pressure and Wedge Quality are displayed
 **Swan-Ganz**	CO monitoring started	When invasive (Alta Swan-Ganz patient cable) CO monitoring is started
	CO monitoring stopped	When the user or system stops invasive (Alta Swan-Ganz patient cable) CO monitoring

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 **System**	System Restart Recovery	When the system has resumed monitoring without being prompted following a power cycle
	Time updated	The system clock is updated
	Data Export Failed	An error occurred during the data export process
	Data download unsuccessful	An error occurred during the export data process
	Clinical data deletion unsuccessful	An error occurred during the clinical data deletion process
	CVP source changed	The CVP parameter value source is switched from manual entry to pressure cable or from pressure cable to manual entry
	CO averaging updated – {0}	The CO/pressure averaging time has changed to the indicated value ({0})
 **tHb**	tHb Monitoring started	When tHb monitoring is started
	tHb Monitoring Stopped	When the user or system stops tHb monitoring
	tHb Calibration Started	**Calibration** button on the tHb settings screen is touched
	tHb Calibration Canceled	tHb calibration is canceled or it times out. Blood draw details are displayed
	tHb Blood drawn	**Draw** button on tHb calibration or recalibration screen is touched. Blood draw details are displayed.
	tHb Calibration finished	tHb calibration is completed and entered hemoglobin value is listed
	tHb Recalibration Started	**Recalibration** button on the tHb settings screen is touched
	tHb Recalibration Canceled	tHb recalibration is canceled or it times out
	tHb Recalibration finished	tHb recalibration is completed and entered hemoglobin value is listed
 **Venous Oximetry**	In Vitro – Calibration started	An In vitro calibration process has started
	In Vitro – Calibration error	An error occurs during the In vitro calibration process
	In Vitro calibration – Wall artifact or wedge detected	The system detects a wall artifact or wedge during the In vitro calibration process
	In Vitro calibration – Unstable signal	An unstable signal is detected during the In vitro calibration process
	In Vitro – Monitoring started	Venous oximetry monitoring has started
	In Vitro – Calibration finished	In vitro calibration is successfully completed
	In Vivo – Calibration started	An In vivo calibration process has started
	In Vivo – Blood drawn	The user has touched the **Draw** button to indicate time when blood is drawn
	In Vivo – Calibration error	An error occurs during the In vivo calibration process
	In Vivo – Monitoring started	The user has touched the **Start Monitoring** button after entering lab results from blood draw
	In Vivo – Calibration finished	In vivo calibration is successfully completed
	Recall data successful	When recalled oximetry calibration data is accepted by the user

Table 4-4 Reviewed events (continued)

Identifying Icon and Category	Event message	When time logged
 **Venous Oximetry**	Calibration is more than 24 hours old	The time at which it has reached 24 hours since the oximetry cable was last calibrated
	No calibration data available	**Recall Oximetry Data** button is touched but the connected oximetry cable does not have any calibration data available.
	HGB value updated	Oximetry cable update completes following the HGB update process
	Oximetry Cable Reset	The Oximetry Cable Reset button is touched
	New Catheter	The New Catheter button is touched
	Oximetry disconnected	An oximetry cable disconnection is detected
 **Tissue Oximetry**	ΔctHb reset successful	The **Reset ΔctHb** button is touched on the **ctHb Tools** screen and ΔctHb baseline is successfully reset
	Sensor location updated: {0}, {1}	The tissue oximetry sensor location has been updated where {0} is the sensor channel and {1} is the sensor location
	Patient mode updated: {0}	The patient monitoring mode is updated where {0} is **Peds** (pediatric) or **Adults**
	Averaging updated: {0}, {1}	The averaging time used to smooth monitored data points has been adjusted where {0} is the tissue oximetry port (**Port A** or **Port B**) and {1} is the averaging speed (**Slow**, **Normal**, or **Fast**)
	Skin Check Reminder	The skin check reminder popup appears on-screen
	Sensor off check acknowledged	The sensor off check warning popup is acknowledged by touching **Acknowledge**
** Acknowledgment is logged when the user touches either button on the HPI High Alert popup.*		

4.6.6.2 Intervention

Touch the **Intervention** button at the bottom of the **Events & Intervention** side panel to view a menu of intervention types, details and a notes section.

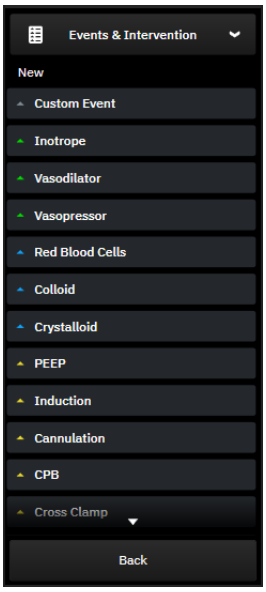


Figure 4-12 Clinical Tools – Intervention menu

To enter a **New Intervention**:

1. Select the **Intervention** type from the **New** intervention menu. Scroll up or down to view all available intervention types. Categories are listed in table 4-5 on page 108
2. Select a detail for the intervention. Options include: **Unspecified**, **Decrease**, **Increase**, **Start**, or **Stop**. Fluid intervention types have options of volume amount or unspecified.
3. Touch within the **Comments** pane access a keyboard and enter any notes about the intervention (optional).
4. Touch the **Log** button to enter the intervention.
5. The intervention will appear at the top of the **Events & Intervention** side panel. Touch the **Back** button to return to the main **Events & Intervention** side panel. The intervention will also be logged with other parameter-related and system events.

To edit a previously used **Intervention**:

1. Select the intervention from the list of other parameter-related and other system events on the main **Events & Intervention** side panel. Interventions are marked by a colored triangle.
2. To change the time of the selected intervention, touch on **Time Adjust.** Use the back button to delete the time entry and enter the updated time on keypad. Touch the check icon → **Save** button. The following message will appear: "**Intervention Updated**".
3. To change the date, touch on **Date Adjust**. Use the back button to delete the time entry and enter the updated time on keypad. Touch the check icon → **Save** button. The following message will appear: "**Intervention Updated**".
4. To add, edit, or remove a note, touch within the **Comment** pane to access the keyboard and update the notes. Touch the check icon → **Save** button. The following message will appear: "**Intervention Updated**".

Table 4-5 Intervention types

Intervention	Indicator	Type
Intervention	(green)	Inotrope Vasodilator Vasopressor
Positional	(purple)	Passive Leg Raise Trendelenburg
Fluids	(blue)	Red Blood Cells Colloid Crystalloid Fluid Bolus*
Event	(yellow)	PEEP Induction Cannulation CPB Cross Clamp Cardioplegia Pump Flow Circulatory Arrest Warming Cooling Selective Cerebral Perfusion
Custom	(gray)	Custom Event
System generated*	(white)	BP Calibration Oximetry Calibration
System generated markers appear on trend plot and events menu but are not editable from the "Recent**" list on intervention pane.*		

NOTE Interventions initiated through the Clinical Tools menu, such as **Venous Oximetry**, **BP Calibration**, or fluid responsiveness tests, are system generated and cannot be entered through the intervention analysis menu.

After selection of the intervention type, markers indicating the intervention are visually displayed on all graphs. Touch these markers to access the intervention side panel for more information and to edit previous interventions.

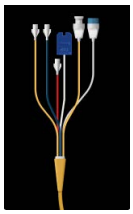
4.7 Multi-Sensor Advanced Monitoring Mode

Enabling multi-sensor advanced monitoring mode allows a user to set parameters to the same type for any connected sensor source. For example, cardiac output (CO) options will have a secondary selection tab popup do display the available sources for CO (A-line [Acumen IQ or FloTrac sensor], Swan-Ganz catheter, or Cuff (ClearSight or Acumen IQ]). See figure 4-5 on page 87. To enable or disable this mode:

1 Touch the settings icon → **Advanced Settings** button and enter the **Secure User** password. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
2 Touch the **Parameter Source Settings** button.
3 Toggle the Multi Sensor/Multi-Technology Advanced Monitoring Mode switch on/off.

When this feature is toggled off, the monitoring mode must be selected with each new patient session. To switch between monitoring modes, touch the icon on the navigation bar and select one of the following:

Minimally-Invasive Monitoring Mode Button. The user can select this button for minimally-invasive hemodynamic monitoring using a pressure cable. Monitoring with a TruWave DPT is also available while in this mode.



Invasive Monitoring Mode Button. The user can select this button for invasive hemodynamic monitoring using the HemoSphere Alta Swan-Ganz patient cable.

Non-Invasive Monitoring Mode Button. The user can select this button for non-invasive hemodynamic monitoring using ClearSight monitoring technology..

Oximetry monitoring is available across all monitoring modes. The letter "S" (S) will appear on the x-axis of the graphical trends monitoring view at the point in time when the monitoring mode switch occurred.

4.8 Status Bar

The status bar appears on all active monitoring screens. It displays the Device ID, current time, date, battery status, screen brightness menu shortcut, alarm volume menu shortcut, help screen shortcut, event review shortcut, and the lock screen symbol. While monitoring with the HemoSphere Alta Swan-Ganz patient cable, the status bar may display blood temperature and heart rate from an analog input. While monitoring with the HemoSphere pressure cable the status bar may display CO/pressure averaging time and HPI parameter values. For more information on the Acumen Hypotension Prediction Index feature (HPI), which is an advanced feature, see *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225. While monitoring ClearSight technology, the status bar may display HPI parameter values and a cuff pressure release countdown

clock. See *Cuff Pressure Release Mode* on page 185. Figure 4-13 shows an example of a status bar while monitoring with the HemoSphere Alta Swan-Ganz patient cable with averaged ECG heart rate data from an analog input.

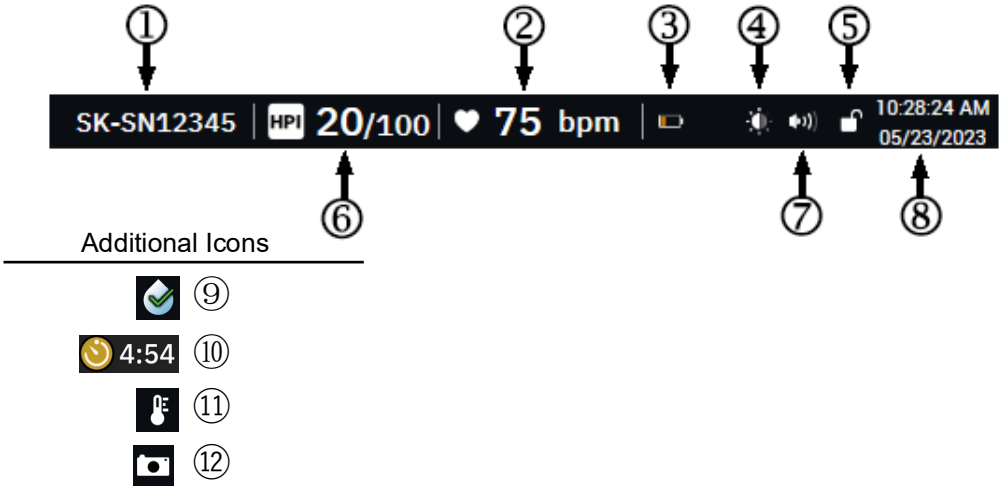


Figure 4-13 Status bar – icons

① Device ID	⑤ lock screen	⑨ AFM algorithm status
② heart rate[1]	⑥ HPI parameter[2]	⑩ cuff release countdown[3]
③ battery status	⑦ alarm volume	⑪ blood temperature[1]
④ screen brightness	⑧ date/time	⑫ snapshot

[1] *invasive HemoSphere Alta Swan-Ganz patient cable monitoring*
[2] *Acumen IQ sensor or Acumen IQ cuff monitoring*
[3] *non-invasive HemoSphere ClearSight technology monitoring*

4.8.1 Device ID

The Device ID serves as a device identifier. For more information see *Select Device ID* on page 77.

4.8.2 Status Bar Quick Settings Menu

Touch on the right side of the status bar to access a menu for the following functions:

- **Brightness**: Touch on either end of the scale to adjust the screen brightness or toggle the **Auto Adjust** switch to automatically adjust screen brightness to the ambient light.
- **Alarm Volume:** Touch on either end of the scale to adjust the alarm volume from **Low** to **High**.

- **Lock**: Select a time frame for the screen to enter locked mode. A lock screen icon will appear on the status bar . To unlock the screen, access the status bar menu and touch the **Unlock Screen** button.

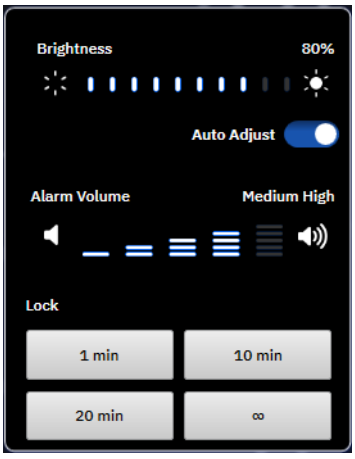


Figure 4-14 Status bar quick settings menu

4.8.3 Battery

The HemoSphere Alta advanced monitoring platform allows for uninterrupted monitoring during power loss. Battery life is indicated on the status bar by the symbols shown in table 4-6. To ensure that the battery charge status displayed on the monitor is correct, it is recommended to perform periodic checks of battery health through battery conditioning. For information on battery maintenance and conditioning, see *Battery Maintenance* on page 386.

Table 4-6 Battery status

Battery symbol	Indication
	The battery has 100% charge
	The battery has 100% charge and is connected to mains power (not charging).
	The battery has greater than 50% charge remaining
	The battery has less than 50% charge remaining.
	The battery has less than 20% charge remaining.
	The battery is charging and connected to mains power.
	The battery is depleted
	The battery is not installed. A battery connection is not detected by the monitor.

WARNING	In cases of power failure and battery depletion, the monitor will go through a controlled shut off procedure.

4.8.4 Screen Capture

The snapshot icon captures an image of the screen at the current time. A USB stick attached to one of the USB ports (rear panel) of the HemoSphere Alta advanced monitor is required to save the image.

Touch the snapshot icon located on the status bar  .

4.9 Status Bar – Notifications

The notification bar appears at the top of all active monitoring screens below the status bar. It displays faults, alarms, alerts, some warnings and notifications. When there is more than one fault, alert or alarm, the message is cycled every two seconds.The message number out of total messages is displayed on the left. Touch this to toggle through the current messages. Touch the question icon to access the help screen for non-physiological alarm messages.

Figure 4-15 Status bar

4.10 Monitor Screen Navigation

There are several standard navigational procedures on the screen.

4.10.1 Vertical Scrolling

Some screens will have more information than fits on the screen at one time. If vertical arrows appear at the top or bottom of a review list, use your finger to scroll up or down on the list.

4.10.2 Navigation Icons

There are some buttons that always perform the same function:

Home. The home icon takes you to the most recently viewed monitoring screen and stores any modification made to data on the screen.

Return. The return icon takes you to the previous menu screen and stores any modification made to data on the screen.

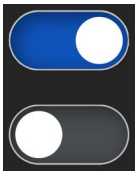
Enter. The enter icon stores any modification made to data on the screen and returns to the monitoring screen or brings up the next menu screen.

Cancel. The cancel icon causes any entries to be discarded.

On some screens, for example Patient Data, there is no cancel button. As soon as a patient's data is entered, it is stored by the system.

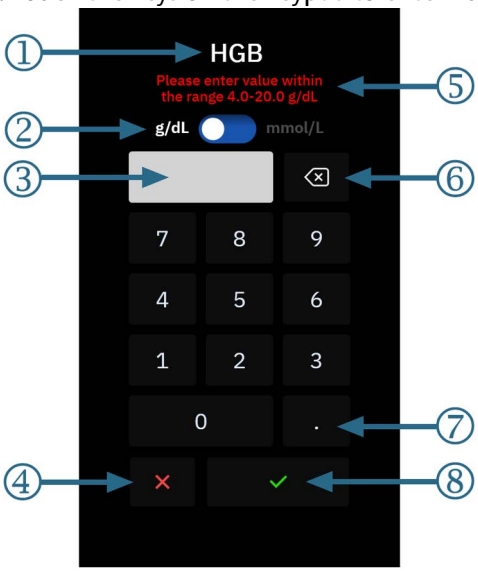
Value button. Some screens have square buttons as shown below. These can have default values or be blank. Touch the button to display a keypad.

Toggle button. When an option exists between two choices, such as on/off, a toggle button appears.



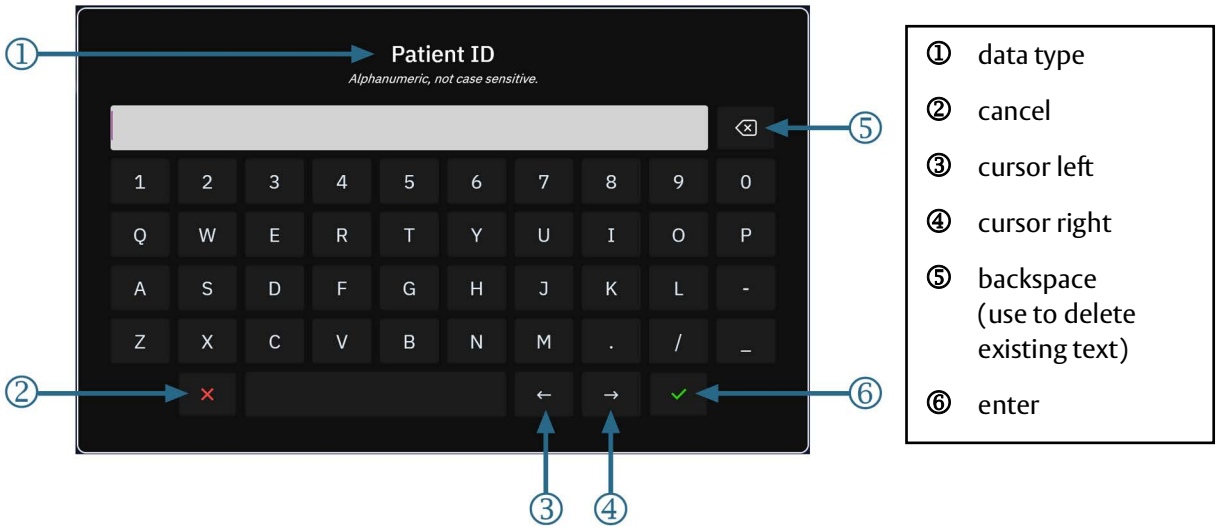
Touch on the opposite side of the button to switch the choice.

Keypad. Touch the keys on the keypad to enter numeric data.



① data type
② units (toggle if applicable)
③ entered value box
④ cancel
⑤ input range (shown when entered value is blank)
⑥ backspace (use to delete existing values)
⑦ decimal (if applicable)
⑧ enter

Keyboard. Touch the keys on the keyboard to enter alphanumeric data.



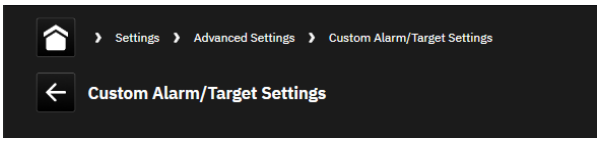
User Interface Settings 5

Contents

5.1 Settings Menu Navigation and Password Protection

HemoSphere Alta monitor settings are accessed through the settings icon on the navigation bar.

The navigation path within the settings menu is displayed at the top of the current settings screen. For example, the path "**Settings → Advanced Settings → Custom Alarm/Targets Settings**" is displayed as shown:



To move back a settings level to **Advanced Settings**, touch the back icon

To return to the main monitoring screen, touch the home icon .

Two settings menu options are password protected: **Advanced Settings** and **Export Data**. These buttons are indicated by a lock symbol as shown in figure 5-1.

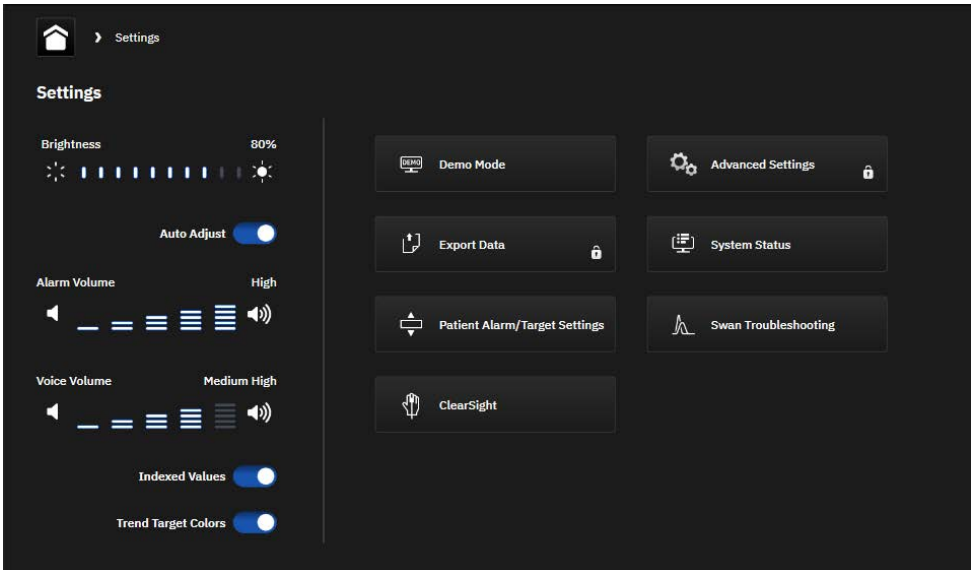


Figure 5-1 Primary settings screen

The HemoSphere Alta advanced monitoring platform has three levels of password protection.

Table 5-1 HemoSphere Alta advanced monitoring platform password levels

Level	Digits required	User description
Super User	four to seven	clinicians
Secure User	eight	hospital authorized personnel
Edwards User	rolling password	internal Edwards use only

Any settings or features described in this manual that require a password are **Super User** features. The **Super User** and **Secure User** passwords require a reset during system initialization the first time a password screen is accessed. Contact your hospital administrator or IT department for passwords. If a password is entered incorrectly ten times, the password keypad will become locked for a certain time period. Monitoring will remain active. In the event of forgotten passwords, contact your local Edwards representative.

To access the **Advanced Settings** features described in table 5-2,

touch settings icon → **Advanced Settings** button**.** All alarm settings and **Advanced Settings** are described in "Advanced Settings" on page 123.

Table 5-2 Advanced settings menu navigation and password protection

Advanced settings menu selection	Sub-menu selection	Super User	Secure User	Edwards User
Custom Alarm/Target Settings		•	•	•
Parameter Source Settings		•	•	•
CVP		•	•	•

Table 5-2 Advanced settings menu navigation and password protection (continued)

Advanced settings menu selection	Sub-menu selection	Super User	Secure User	Edwards User
General	Date and Time	no access	•	•
	Units of Measurement	no access	•	•
	Language	no access	•	•
	Screen Snapshot	no access	•	•
Device ID		no access	•	•
Password		no access	•	•
Interactivity		no access	•	•
Software Update		no access	•	•
Connectivity	Wi-Fi	no access	•	•
	Serial Port	no access	•	•
	HemoSphere Remote	no access	•	•
Features Management		no access	•	•
Tissue Oximetry		no access	•	•
AFM		no access	•	•
Settings Profile		no access	•	•
Alarm Settings		no access	•	•
Engineering[1]		no access	•	•
Data Wipe[1]		no access	•	•
Reset to Factory Defaults[1]		no access	•	•

[1] *These settings require a cessation of monitoring.* ***Engineering***, ***Data Wipe*** *and* ***Reset to Factory Defaults*** *require a power cycling of the monitor.*

To access the **Export Data** features described in table 5-3, touch settings icon → **Export Data** button**.** All **Export Data** settings are described in "Data Export and Connectivity Settings" on page 131.

Table 5-3 Export data menu navigation and password protection

Export data menu selection	Super User	Secure User	Edwards User
Case Report	•	•	•
Monitoring Data	•	•	•
GDT Report	•	•	•
Diagnostics Logs	•	•	•
Clinical Data	no access	•	•

5.1.1 Changing Passwords

Changing passwords requires **Secure User** access. Contact your hospital administrator or IT department for password. To change passwords:

1. Touch settings icon → **Advanced Settings** button.
2. Enter the **Secure User** password.

3 Touch **Password** button.

4 Enter the new **Super User** and/or **Secure User** password digits in both value boxes until the **Confirm** button is active.

5 Touch the **Confirm** button.

5.2 Patient Data

After the system is turned on, the user has the option to either continue monitoring the last patient or to start monitoring a new patient. See figure 5-2.

NOTE If data for the last patient monitored is 12 hours or older, the only option is to start a new patient.

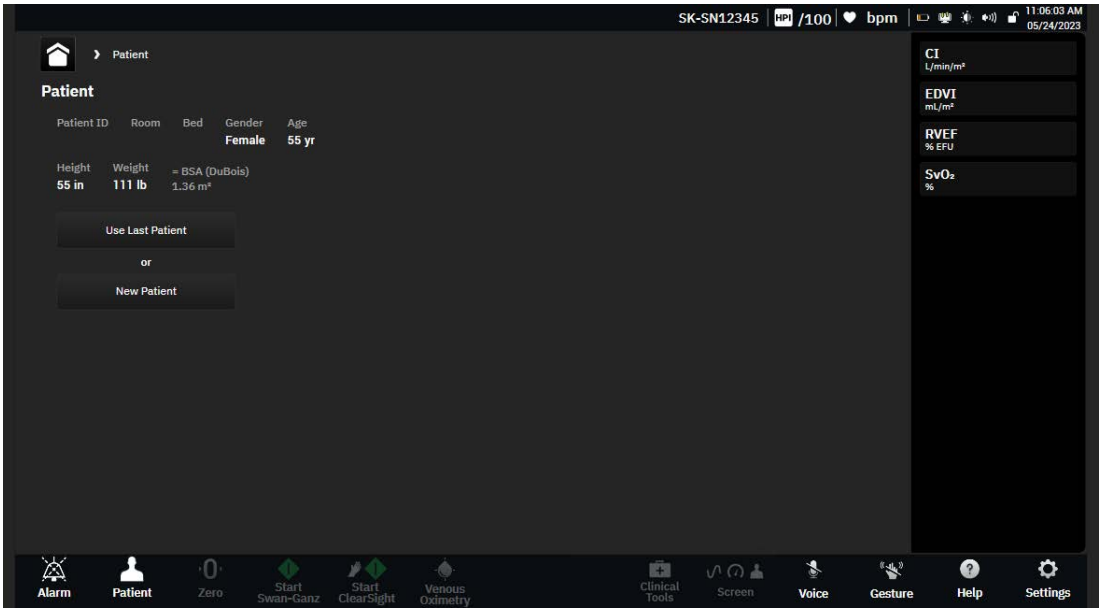


Figure 5-2 New or continuing patient screen

5.2.1 New Patient

Starting a new patient clears all previous patient data. The alarm limits and continuous parameters are set to their default values.

WARNING Upon initiation of a new patient session, the default high/low physiological alarm ranges should be checked to ensure that they are appropriate for the given patient.

The user has the option of entering a new patient upon initial startup of the system or while the system is running.

WARNING Perform **New Patient** or clear the patient data profile whenever a new patient is connected to the HemoSphere Alta advanced monitoring platform. Failure to do so may result in previous patient data in the historical displays.

1 After turning on the monitor, the new or continuing patient screen appears (figure 5-2). Touch **New Patient** and continue to step 2.

OR

Touch **Skip** to start monitoring without inputting the patient's demographics and continue to step 12.

OR

If the monitor is already on, touch the **Patient** icon 

on the Navigation bar and continue to step 2.

NOTE If the user skips entering patient demographics, only the following limited parameters can be monitored: StO_2, ΔctHb, SYS_{ART}, SYS_{PAP}, DIA_{ART}, DIA_{PAP}, MAP, PR, MPAP, and CVP..CCO monitoring with a Swan-Ganz catheter is disabled. Venous oximetry calibration is also unavailable.

2 The new patient data screen appears. See figure 5-3.

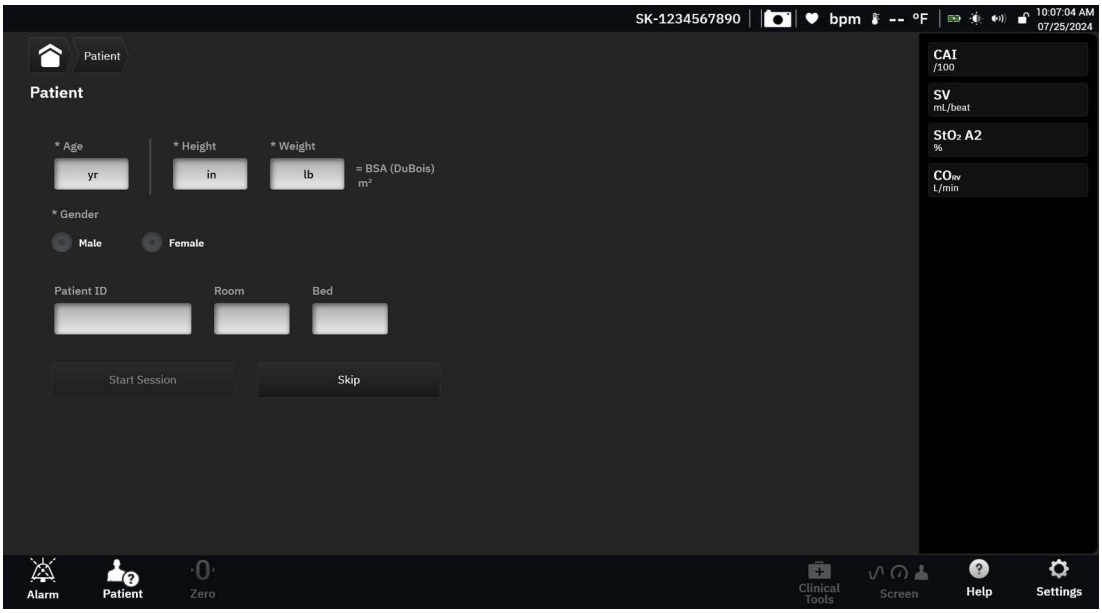


Figure 5-3 New Patient Data screen

3 Touch the check icon  on the keypad/keyboard to save each patient demographic selection value and return to the patient data screen.

4 Touch **Patient ID** button and use the keyboard to enter the patient's hospital ID.

5 Touch **Height** button and use the keypad to enter the patient's height. The unit default for your language is at the upper right of the keypad. Touch it to change the unit of measurement.

6 Touch **Age** and use the keypad to enter the patient's age.

7 Touch **Weight** and use the keypad to enter the patient's weight. The unit default for your language is at the upper right of the keypad. Touch it to change the unit of measurement.

8 Use the radio buttons for **Gender** and select **Male** or **Female**.

9 The **BSA** is calculated from the height and weight using the DuBois formula.

10 If desired, enter the Room and Bed for the patient. Entering this information is optional.

11 Touch the **Start Session** button.

NOTE	The **Start Session** button is disabled until all patient data is entered.

12 Select the appropriate monitoring mode on the **Monitoring Mode Selection** window. See *Multi-Sensor Advanced Monitoring Mode* on page 108. Refer to instructions for starting monitoring with the desired hemodynamic monitoring technology.

OR

If Multi-Technology Advanced Monitoring mode is enabled, proceed to monitoring setup with connected monitoring technology.

5.2.2 Continue Monitoring Patient

If the last patient's data is less than 12 hours old, the patient's demographics and patient ID will be displayed when the system is turned on. When monitoring of the last patient is continued, the patient's data is loaded and the trend data is retrieved. The most recently viewed monitoring screen is displayed. Touch **Use Last Patient**.

5.2.3 View Patient Data

1 Touch the **Patient** icon 

on the Navigation bar.

2 Current patient data screen will appear. If necessary, patient demographic information can be edited. Use the back button  on keypad/keyboard to delete current Patient data and enter new information. Touch the **Save** button to confirm changes.

3 Touch the home icon  to return to the monitoring screen.

5.3 General Monitor Settings

The general monitor settings are those that affect every screen. These settings are shown on the left side of the settings screen (see figure 5-1 on page 116) and include screen brightness, alarm volume, voice volume, parameter index value display choice, and trend targets.

NOTE	If power is lost and restored to the HemoSphere Alta advanced monitoring platform, the system settings prior to the power loss, including alarm settings, alarm volume, target settings, monitoring screen, parameter configuration, language and unit selection, are automatically restored to last configured settings.

5.4 Demo Mode

Demonstration mode is used to display simulated patient data to assist in training and demonstration. Demonstration mode displays data from a stored set and continually loops through a predefined data set. During **Demo Mode**, the HemoSphere Alta advanced monitoring platform user interface retains the same functionality as a fully operational platform. Simulated patient demographics must be entered to demonstrate the selected monitoring mode functions. The user can touch the controls as if a patient was being monitored.

When **Demo Mode** is entered, trended data and events are cleared from being displayed and saved for return to patient monitoring.

1 Touch settings icon  → **Demo Mode** button.

NOTE When the HemoSphere Alta advanced monitoring platform runs in **Demo Mode**, all audible alarms are disabled. A "Demo Mode" banner is displayed across the information bar to alert the user to the use of simulated patient data.

2 Touch **Yes** on the **Demo Mode** confirmation screen.

3 The HemoSphere Alta advanced monitoring platform must be restarted prior to monitoring a patient.

Make sure that **Demo Mode** is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data.

5.4.1 End Demo Mode

To end the **Demo Mode**, power cycle the monitor.

If any cables are connected during a **Demo Mode** session, an **End Demo Mode** popup will appear. The monitor must be shut down to end Demo Mode and reestablish monitoring capabilities.

5.5 Delta Intervals / Averaging

The **Delta Intervals** screen lets the user select the continuous change % or value interval. While monitoring with a FloTrac sensor or FloTrac Jr sensor, the user can also change the CO/pressure averaging time.

NOTE The screen will return to the monitoring view after two minutes of inactivity.

The **CO/Pressure Averaging Time** radio buttons are only available with FloTrac sensor monitored parameters.

Touch anywhere on the parameter tile → **Delta Intervals** tab.

5.5.0.1 Display Parameter Value Change

The change in value or percent change in value of a key parameter over a selected time interval can be displayed on a parameter's graphical trend plot.

1 Toggle on the **Enabled** switch to display this feature.

2 Under the **Method** heading, select the period of time for which the change interval is displayed: **Time** or **Reference**.

- If Time is selected, select one of the following time interval options:
  - 1 min
  - 3 min
  - 5 min
  - 10 min
  - 15 min
  - 20 min
  - 25 min
  - 30 min

If **Reference** is selected, the change interval will be calculated from the start of monitoring. This start value can be adjusted under **Reference Value**.

3 Under the **Measured Delta** heading, select the format for which the change interval is displayed:

- **Value Δ** 5 min ↓12 . The change in parameter value is displayed as an absolute value.
- **Percentage Δ** 20 min ↓1% . The change in parameter value is displayed as a percentage change.

5.5.0.2 CO/Pressure Averaging Time - Menu for FloTrac Sensor and ClearSight Cuff Only

Selection of this menu option is only available for FloTrac sensor and ClearSight cuff monitored parameters. The following interval options are available:

- 5 sec
- 20 sec (default and recommended time interval)
- 5 min

The **CO/Pressure Averaging Time** selection affects the averaging time and display update rate of CO and other additional parameters while in minimally-invasive and non-invasive monitoring mode. See table 5-4 below for details of which parameter averaging and update rates are affected based on menu selection.

Table 5-4 CO/pressure averaging time and display update rates

	Parameter update rate		
CO/Pressure Averaging Time menu selection	**5 sec***	**20 sec**	**5 min***
Cardiac Output (CO)	2 sec	20 sec	20 sec
Stroke Volume (SV)	2 sec	20 sec	20 sec
Systolic Pressure (SYS)	2 sec	20 sec^	20 sec^
Diastolic Pressure (DIA)	2 sec	20 sec^	20 sec^
Mean Arterial Pressure (MAP)	2 sec	20 sec^	20 sec^
Pulse Rate (PR)	2 sec	20 sec^	20 sec^
Central Venous Pressure (CVP)	2 sec†	n/a†	n/a†
Mean Pulmonary Artery Pressure (MPAP)	2 sec†	n/a†	n/a†
Stroke Volume Variation (SVV)	20 sec**	20 sec	20 sec
Pulse Pressure Variation (PPV)	20 sec**	20 sec	20 sec

*When an Acumen IQ sensor/cuff is connected, all Acumen IQ sensor/cuff monitored parameters will be available with 20 second averaging interval / 20 second update rate only. This includes Acumen parameters: HPI, Ea_{dyn}, and dP/dt

^When using a TruWave transducer or during Non-Pulsatile mode (except PR), only 5 second averaging with a 2 second update rate is available.

†Parameter averaging time is always 5 seconds with an update rate of 2 seconds for CVP and MPAP.

**When this averaging interval is selected, SVV and PPV are only available with 20 second averaging and a 20 second update rate.

NOTE For real-time blood pressure waveform displayed on the blood pressure waveform display (see *Live Blood Pressure Waveform Display* on page 86) or on the Zero & Waveform screen (see *Zero & Waveform Screen* on page 170), the update rate is always 2 seconds.

Advanced Settings 6

Contents

6.1 Alarms/Targets

There are two types of alarms on the HemoSphere Alta advanced monitoring platform intelligent alarm system:

1. Physiological alarms: These are set by the clinician and signify the upper and/or lower alarm ranges for configured key continuous parameters.
2. Technical alarms: This alarm signifies a device fault or alert.

Physiological alarms occur with either Medium or High priority. Only parameters that are displayed on tiles (key parameters) will have active visual and audible alarms.

Among technical alarms, faults are of medium or high priority, and will halt operation of the related monitoring activity. Alerts are of low priority and will not halt any monitoring activity.

All alarms have an associated text displayed on the status bar. The intelligent alarm system will actively cycle through every active alarm text on the status bar. In addition, alarms will generate the visual alarm indicator shown in table 6-1. For additional information, see table 14-1 on page 316.

Table 6-1 Visual alarm indicator colors

Alarm priority	Color	Light pattern
High	red	Flashing ON/OFF
Medium	yellow	Flashing ON/OFF
Low	yellow	Solid ON

The visual alarm indicator will indicate the highest active alarm priority. Alarm messages displayed on the status bar are outlined in the alarm priority color indicated in table 6-1. The audible tone associated with the highest priority active alarm will be played. Where the priority levels are the same, physiological alarms take priority over faults and alerts. All technical alarms are generated once detected by the system; there is no inherent delay in alarms from the point of detection. For physiological alarms, the delay is the amount of time it takes to calculate the next physiological parameter after the parameter is out of range continuously for five or more seconds:

- HemoSphere Alta Swan-Ganz patient cable continuous CO and associated parameters: varies, but is typically around 57 seconds (see *CO Countdown Timer* on page 141)
- HemoSphere pressure cable continuous CO and associated FloTrac sensor measured parameters: varies based on CO/pressure averaging time menu selection and associated update rate (see table 5-4, “CO/pressure averaging time and display update rates,” on page 122)
- HemoSphere pressure cable arterial blood pressure parameters (SYS/DIA/MAP) while arterial waveform is displayed: 2 seconds
- HemoSphere pressure cable with TruWave DPT measured parameters: 2 seconds

- HemoSphere Alta ClearSight technology continuous CO and associated hemodynamic parameters: 20 seconds
- HemoSphere Alta ClearSight technology arterial blood pressure parameters (SYS/DIA/MAP) while arterial waveform is displayed: 5 heartbeats
- Oximetry: 2 seconds

All alarms are logged and stored for the given patient and can be accessed via the Export Data function (see *Export Data* on page 131). The Export Data log is cleared when initiating a new patient (see *New Patient* on page 118). The current patient can be accessed from up to 12 hours following a system power-off.

WARNING Do not use alarm settings/presets that differ from the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theater. Conflicting alarms can affect patient safety.

Ensure that alarm settings/presets are configured appropriately for the patient prior to starting a new monitoring session.

6.1.1 Silence Alarms

6.1.1.1 Physiological Alarms

Physiological alarms can be silenced directly from the monitoring screen by touching the silence audible alarms icon 

. The physiological alarm audio tone is silenced for a user selected alarm pause time period. No audio tone or LED visual alarm indicator (blinng yellow or red) for any physiological alarm, medium or high priority, will be emitted during this alarm pause period, including new physiological alarms triggered during this time. If a technical alarm is generated during this alarm pause time period, the audio silence will be cleared, allowing alarm audio tones to resume. The user can also manually clear the alarm pause period by pressing the alarm silence button again. Once the alarm pause period has elapsed, active physiological alarms will resume audio sound.

For information on physiological alarm priorities, see *Alarm Priorities* on page 376.

NOTE Physiological parameters can be configured to have no alarms. See sections 6.1.5 and 6.1.6.

WARNING Do not turn off the audible alarms in situations in which patient safety could be compromised.

6.1.1.2 Technical Alarms

During an active technical alarm, the user can silence the audio alarm (low, medium and high priority) by touching the silence audible alarms icon 

. The visual alarm indicator will remain active. The audio tone will remain inactive unless another technical or physiological alarm condition triggers, or the original technical alarm resolves and re-triggers.

6.1.2 Set Alarm Volume

The alarm volume ranges in 20% increments from low (20%) to high (100%) with a default of medium-high (80%). It applies to physiological alarms, technical faults, and alerts. Alarm volume can be changed at any time from the status bar (see *Status Bar Quick Settings Menu* on page 110) or from the main settings page (see *General Monitor Settings* on page 120). Alarm volume settings are retained following a monitor power cycle.

WARNING Do not lower the alarm volume to a level that prohibits alarms from being adequately monitored. Failure to do so could result in a situation where patient safety is compromised.

6.1.3 Set Targets

Targets are visual indicators set by the clinician to indicate if the patient is in the ideal target zone (green), warning target zone (yellow), or alarm zone (red). Target colors are displayed as a shaded outline around parameter tiles (see figure 4-6). The use of target zone ranges can be enabled or disabled by the clinician. Alarms (high/low) differ from target zones in that the alarm parameter value flashes and has an audible alarm.

Parameters that can "Alarm" are listed on the **Custom Alarm/Target Settings** screen. High/low alarms by default also become the ranges for the red caution zone for that parameter.

Some parameters, such as certain HPI algorithm parameters, DO NOT have the ability to set a high/low alarm. Target behavior and range of HPI algorithm parameters are described in *HPI on Information Bar* on page 232.

Table 6-2 Target status indicator colors

Color	Indication
Green	Acceptable – Green target zone is considered an ideal range for parameter as set by the clinician.
Yellow	Yellow target zone is considered a warning range and visually indicates that the patient has exited the ideal range but has not entered the alarm or caution range as set by the clinician.
Red	Red alarm and/or target zones can be considered "Alarm" parameters and are present on the **Custom Alarm/Target Settings** screen. High/low alarms by default also become the range for the red caution zone for that parameter. Parameters which DO NOT have the ability to set a high/low alarm will not be present on the **Custom Alarm/Target Settings** screen for that parameter but can still have target ranges set. Ranges for the alarm and/or target zone are to be set by the clinician.
Gray	If a target is not set, the status indicator appears as gray.

6.1.4 Patient and Custom Alarm/Targets Settings Screen

The **Patient Alarm/Target Settings** screen allows the clinician to view and set up alarms and targets for each parameter. These settings are only valid for the current patient monitoring session. From the **Patient Alarm/Target Settings** screen, located from the main **Settings** menu, the user can adjust targets, enable/disable audible alarms and targets, and configure certain settings across all parameters.

The **Custom Alarm/Targets Settings** screen behaves similar to the **Patient Alarm/Target Settings** screen but these settings apply across multiple monitoring sessions and create a set of custom alarm/target settings for the monitor. See table 6-3 for feature highlights of these two settings menus.

Table 6-3 Patient versus Custom Alarm/Targets Settings screen

Behavior	Patient Alarm/Target Settings	Custom Alarm/Target Settings
Alarm/target configuration values	Alarm/target values configured on this menu are for the current patient monitoring session only as a **Changed** setting	Configure parameter alarm/target values across all monitoring sessions on monitor as a **Custom Default** setting
Indexed/non-indexed parameters	Indexed or non-indexed setting not configurable	"**Set Parameters according to Indexed Value**" toggle setting is available
Navigation path	settings icon → **Patient Alarm/Target Settings**	settings icon → **Advanced Settings** button → **Custom Alarm/Target Settings** button
Password	Not pass code protected	Pass code protected
Two minute time-out	Yes	Yes
Configure all	Configure all targets on/off, audio alarms on/off, Edwards defaults or custom defaults	Restore any custom defaults to Edwards defaults only
Parameter order	Key parameters first, then predefined order	Predefined order
When changes applied	For the current monitoring session	For subsequent monitoring session(s)

6.1.4.1 Modify Alarms/Targets for Current Monitoring Session

To view and modify parameter alarms/targets for the current monitoring session only:

1. Touch the settings icon → **Patient Alarm/Target Settings** button.
2. Touch anywhere in a parameter's target/alarm value box to display the keypad for that value and adjust accordingly. The parameter will be labeled as "**Changed**". See table 6-4 for default labels.
3. Toggle the **Target** switch or **Silence Audible Alarm** switch for any individual parameter to turn the alarm/target values or audible alarms off for that parameter.

Table 6-4 Target defaults

Default name	Description
Custom Default	A custom default target range was set for the parameter and the parameter target range has not been modified from that default.
Edwards Default	The parameter target range has not been changed from the original settings.
Changed	Parameter target range was changed for this patient. This is a patient level only setting.

NOTE Visual and audible alarm settings are only applicable to parameters being displayed.

Alarm/Target settings screens have a two minute inactivity timer and will return to the main monitoring screen.

The red, yellow and green range rectangles are fixed shapes, and don't change size/shape.

6.1.4.2 Modify Alarms/Targets Across All Monitoring Sessions

To view and modify parameter alarms/targets for the custom defaults to be used across all monitoring sessions:

1. Touch the settings icon → **Advanced Settings** button and enter the required password.
2. Touch **Custom Alarm/Target Settings** button.
3. Use the toggle button to switch on "**Set Parameters according to Indexed Value**". This will display all parameters and alarm/target values to their indexed values, if applicable. See figure 6-1.

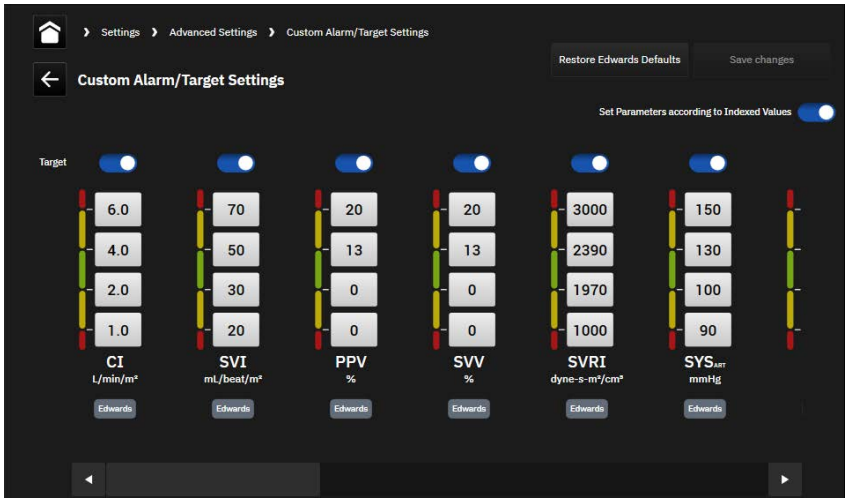


Figure 6-1 Custom Alarm/Target Settings screen

4. Touch anywhere in a parameter's alarm/target value box to display the keypad for that value and adjust accordingly. The parameter will be labeled as "**Custom**". See table 6-4 for default labels. Touch **Save Changes** button to save parameter changes to custom default data set.
5. Toggle the **Target** switch for any individual parameter to turn the alarm/target values off for that parameter.
6. Touch Restore Edwards Defaults button to restore all configured custom defaults to Edwards defaults. Touch **Restore** on confirmation popup to confirm. All targets will be enabled.

NOTE Custom Alarm/Target settings retain their configuration and persist from previous sessions after power cycling the monitor.

Custom defaults configured during an active patient monitoring session will not be applied to the current monitoring session but will be applied to subsequent patient monitoring sessions.

NOTE Custom Alarm/Target settings for CPO/CPI are only configurable for CPO, and not CPI.

6.1.5 Configure All Targets

Alarms/Targets can easily be configured or changed all at the same time for a current monitoring session. From the **Configure All** screen, the user can:

- Restore all parameter alarm and target settings to Custom Defaults.
- Restore all parameter alarm and target settings to Edwards Defaults.
- Enable or disable audible physiological alarms for all applicable parameters.
- Enable or disable targets for all applicable parameters.

1. Touch the settings icon → **Patient Alarm/Target Settings** button → **Configure All** button.
2. To enable or disable all audible physiological alarms for all parameters, toggle the **Silence All Audible Alarms** button within the **Audible Alarm** box.
3. To enable or disable all targets for all parameters, toggle the **All Targets** button within the **Audible Alarm** box.
4. To restore all settings to the custom defaults (configured on Custom Alarm/Target Settings screen), select the **Custom Default** radio button and touch **Restore** button. The message, "**Touch "Configure All" to reset all target parameter settings values for patient to Custom Default**" appears on a confirmation popup. Touch **Configure All** to confirm the restore.
5. To restore all settings to the Edwards defaults, select the **Edwards Default** radio button and touch **Restore** button. The message, "**Touch "Configure All" to reset all target parameter settings values for patient to Edwards Default**" appears on a confirmation popup. Touch **Configure All** to confirm the restore.

6.1.6 Configure Targets and Alarms for One Parameter

The **Set Targets** screen lets the user set up alarm and target values for the selected parameter. The user can also enable or disable the audible alarm or the parameter target ranges. Adjust the target settings by using the numbered keypad or by using the scroll buttons when a minor adjustment is needed.

1. Touch inside a tile to open the parameter configuration menu.
2. Touch on the **Set Targets** tab.
3. To disable the audible alarm for the parameter, touch the **Silence Audible Alarm** toggle switch.

NOTE The alarms limits for the Acumen Hypotension Prediction Index, HPI, or the Global Hypoperfusion Index, GHI, are not adjustable. Target behavior and range of HPI are described in *HPI Alarm* on page 231. Target behavior and range of GHI are described in *GHI Alarm* on page 269.

4. To disable visual targets for the parameter, touch the **Target** toggle switch. The target indicator for that parameter will appear gray.

5 Use the arrows to adjust the zone settings or touch the value button to open a numeric keypad.

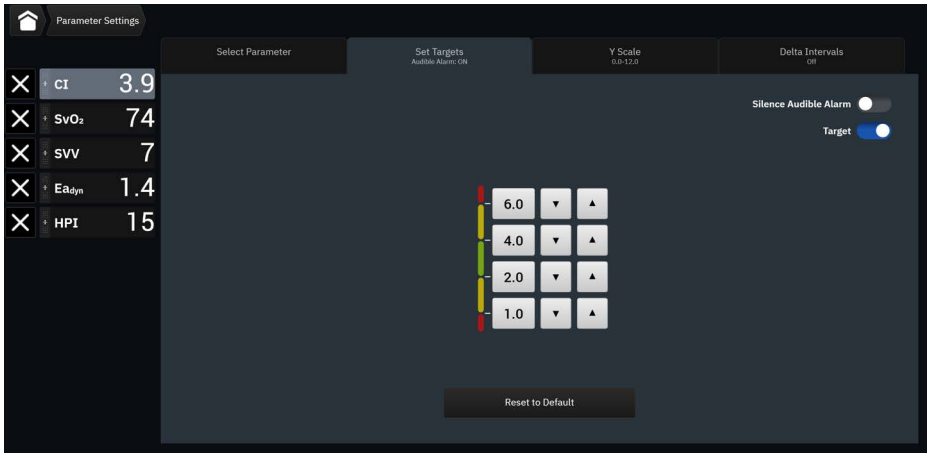


Figure 6-2 Set individual parameter alarms and targets

6 To restore alarm/target values back to the Edwards default touch **Reset to Default** button.

7 To cancel, touch the exit icon .

WARNING Visual and audible physiological alarms are activated only if the parameter is configured on the screens as a key parameter (1-8 parameters displayed in parameter tiles). If a parameter is not selected and displayed as a key parameter, the audible and visual physiological alarms are not triggered for that parameter.

6.2 CVP Settings

CVP values can be sourced in the following ways:

- Monitored directly with a TruWave pressure transducer and HemoSphere pressure cable (see *Pressure Cable Monitoring with a TruWave pressure transducer (DPT)* on page 158).
- As a static value entered manually by the user (see *CVP Entry (SVR/SVRI only)* on page 89).

When none of these sources is detected or entered, the monitor will assign a default value for CVP. The monitor's configured default value is used for all patient monitoring sessions. To change this default CVP value:

1 Touch the settings icon → **Advanced Settings** button and enter the required password.

2 Touch **CVP** button.

3 Touch on the value button for default CVP value to enter a CVP value (mmHg).

6.3 Parameter Source Settings

6.3.1 20-Second Flow Parameter Settings

This parameter setting automatically switches the display of 20-second flow parameters (CO_{20s}, CI_{20s}, SV_{20s}, SVI_{20s}) to the standard averaged equivalent (CO, CI, SV, and SVI) when the PA pressure signal is poor. For more information on the 20-second flow parameters, see *20-Second Flow Parameters* on page 142.

1 Touch the settings icon → **Advanced Settings** button and enter the required password.
2 Touch **Parameter Source Settings** button.
3 Under "**20-Second Flow Parameters**", touch the toggle button to switch the setting to on or off.

NOTE 20-second flow parameters are available when monitoring with the HemoSphere Alta Swan-Ganz patient cable and a PA (pulmonary artery) pressure signal is also monitored through a connected HemoSphere pressure cable, TruWave DPT, and CCOmbo V catheter (models 777F8 and 774F75). In addition, the 20-second flow parameter feature must be activated. Please contact your local Edwards representative for more information on enabling this advanced feature.

6.3.2 Multi-Sensor Advanced Monitoring Mode

Enabling multi-sensor advanced monitoring mode allows user to set parameters to the same type for any connected sensor source. For example, cardiac output (CO) options will have a secondary selection tab popup do display the available sources for CO (A-line [Acumen IQ or FloTrac sensor], Swan-Ganz catheter, or Cuff (ClearSight or Acumen IQ]). See figure 4-5 on page 87. To enable or disable this mode:

1 Touch the settings icon → **Advanced Settings** button and enter the required password.
2 Touch **Parameter Source Settings** button.
3 Toggle the Multi Sensor/Multi-Technology Advanced Monitoring Mode switch on/off.

Data Export and Connectivity Settings 7

Contents

7.1 Export Data

The **Export Data** screen lists a number of data export features of the HemoSphere Alta advanced monitoring platform. This screen is password protected. From this screen clinicians can export diagnostic reports or export monitoring data reports. The **Export Data** screen allows the user to export monitored patient data to a USB device in Windows Excel XML 2007 format.

NOTE The screen will return to the monitoring view after two minutes of inactivity.

1. Touch the settings icon → **Export Data** button.
2. Enter password when prompted. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
3. Ensure a USB device has been inserted.
4. Use the check boxes to select the type of data to download from the available options . Options may include Case Report, GDT Report, Monitoring Data, or Diagnostic Logs. See below for details on these options.
5. Use the drop-down menu next to "**Select the session to be downloaded**" to select the **Live Session** (current session) or any monitoring session from the past 72 hours.
6. Use the **Hide Patient Identity** toggle button to de-identify and exclude patient demographic data from any data export.

NOTE When exceeding 4GB of data the USB storage device should not use FAT32 formatting.

CAUTION Use a virus scan on any USB stick before inserting to prevent a virus or malware infection.

7. Touch the **Download** button. A popup window will show download progress of each item selected for the data export.

7.1.1 Monitoring Data

To generate a spreadsheet of monitored patient data:

1. Select the box next to **Monitoring Data**  .
2. Under the **Interval** heading, select the radio button next to the desired frequency of the data to download. The shorter the frequency, the greater the amount of data. Options are:
   - 20 seconds (default)
   - 1 minute
   - 5 minutes
3. Use the **Hide Patient Identity** toggle button to de-identify and exclude patient demographic data from any data export.
4. Touch the **Download** button to export .

NOTE All alarms are logged and stored for the given patient and can be accessed via the **Monitoring Data** download. Alarm data logging discards older data when the log becomes full. The **Monitoring Dat**a log is cleared when initiating a new patient. The current patient can be accessed from up to 12 hours following a system power-off. This log also contains timestamped alarm conditions and the system power-off time.

7.1.2 Case Report

To generate a PDF report of key parameters:

1. Select the box next to **Case Report**  .
2. Use the edit icon  to view the case report parameter selection menu.
3. Select desired parameters from the list. A maximum of ten parameters can be selected.
4. Use the **Hide Patient Identity** toggle button to de-identify and exclude patient demographic data from any data export.
5. Touch the **Download** button to export a PDF.

7.1.3 GDT Report

To generate a PDF report of GDT tracking sessions:

1. Select the box next to **GDT Report**  .
2. Use the edit icon  to view the GDT tracking session list.
3. Select the desired GDT tracking session(s) from the list. Scroll through the list to select older tracking sessions.
4. Use the **Hide Patient Identity** toggle button to de-identify and exclude patient demographic data from any data export.
5. Touch the **Download** button to export a PDF.

NOTE Do not disconnect the USB device until the "**Download Successful**" message appears.

If a message appears stating that the USB device is out of space, insert a different USB device and restart the download.

7.1.4 Diagnostic Export

The capturing of all events, alerts, alarms and monitoring activity is logged if investigations or detailed troubleshooting is needed. A **Diagnostic Logs** export option within the **Export Data** settings menu is provided where this information can be downloaded for diagnostic purposes. This information may be requested by Edwards service personnel to help troubleshoot issues. In addition, this engineering section provides detailed software revision information of connected platform components.

1. Touch the settings icon → **Export Data** button.
2. Enter the **Super User** password. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
3. Select the box next to **Diagnostics Logs** .
4. Insert an Edwards approved USB flash drive into one of the available monitor USB ports.
5. Touch **Download** and allow the diagnostic export to complete as indicated on the screen.

The diagnostic data will be located in a folder labeled with the monitor serial number on the USB flash drive.

7.2 Wireless Settings

The HemoSphere Alta monitor can connect to available wireless networks. For information on connecting to a wireless network contact your local Edwards representative.

Wi-Fi connection status is indicated on the information bar by the symbols shown in table 7-1.

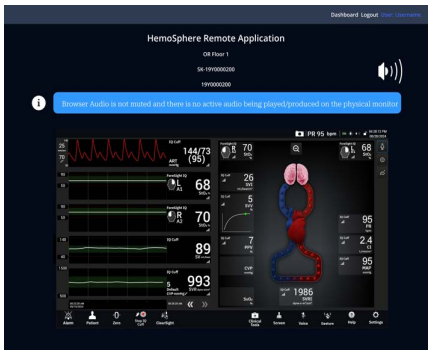
Table 7-1 Wi-Fi connection status

Wi-Fi Symbol	Indication
	very high signal strength
	medium signal strength
	low signal strength
	very low signal strength
	no signal strength
	no connection

7.3 HemoSphere Remote Connectivity

The HemoSphere Alta advanced monitoring platform has the ability to interface with the HemoSphere Remote web application to view a live stream of any connected monitor at an activated site. The HemoSphere remote proxy server needs to be correctly installed and provisioned before it can be paired to the HemoSphere Alta advanced monitoring platform. For questions on installation of the HemoSphere Remote server at your site, contact your Edwards representative. Refer to your local Edwards representative for more information.

7.3.1 HemoSphere Remote Web Application



The HemoSphere Remote web application is intended to provide data display from connected HemoSphere Alta advanced monitor(s) on a compatible web browser. It facilitates remote display of information from connected HemoSphere Alta monitor(s) within a specified physical area (e.g. within hospital network), where the user can access the live display of the connected monitor for independent review. The live stream of patient monitoring sessions shows exactly what is currently being viewed on the monitor including hemodynamic parameter and associated data such as alarm notifications, and parameter waveform data. The HemoSphere Remote web application is designed for user convenience and does not control the connected HemoSphere Alta monitor or alter the data provided by the monitor.

If protected health information or patient demographic information are being viewed on the monitor at anytime, that information is not transmitted to the HemoSphere Remote application. For more information on the HemoSphere Remote web application, refer to your Edwards representative.

7.3.2 HemoSphere Remote Pairing

The HemoSphere Alta advanced monitoring platform needs to be paired with the HemoSphere Remote server to enable HemoSphere Remote connectivity.

1. Touch the settings icon → **Advanced Settings** button and enter the Secure User password.

   All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
2. Touch **Connectivity** button → **HemoSphere Remote** button. The Pairing tab will display the current connection status.
3. Import server and client certificates using the **Server Certificates** and **Client Certificates** tabs.
4. Enter the **Hostname** and **Port** for the HemoSphere Remote application. Touch the **Connect** button.
5. After successful pairing, a green arrow and monitor symbol will be displayed on the HemoSphere Remote connection screen and on the information bar . For troubleshooting on potential pairing issues, see *HemoSphere Remote Application Connectivity Errors* on page 322.

HemoSphere Remote application connectivity status is indicated on the information bar by the symbols shown in table 7-2.

For help with this process, contact your Edwards representative.

Table 7-2 HemoSphere Remote application connectivity status

Info bar symbol	Connection status	Indication
no symbol	Not Paired	The HemoSphere Alta advanced monitoring platform is not paired with HemoSphere Remote application server
	Connected	The HemoSphere Alta advanced monitoring platform is successfully connected with the HemoSphere Remote application server
	Error	A connection failure occurred during or after attempting to pair the HemoSphere Alta advanced monitoring platform with HemoSphere Remote application server.
	Not Connected	A previously connected HemoSphere Remote application server has become disconnected.

7.3.3 Physiological Alarms and Device Faults

The HemoSphere Alta advanced monitoring platform sends currently displayed physiological alarms and device faults to a connected HemoSphere Remote application. All alarm and target settings are configured on the HemoSphere Alta advanced monitoring platform.

WARNING Do not use the HemoSphere Alta advanced monitoring platform as part of a Distributed Alarm System. The HemoSphere Alta advanced monitoring platform does not support remote alarm monitoring/management systems. Data is logged and transmitted for charting purposes only.

7.4 Cyber Security

This chapter outlines ways in which patient data can be transferred to and from the HemoSphere Alta advanced monitoring platform. It is important to note that any facility using the HemoSphere Alta advanced monitoring platform must take measures to protect the privacy of a patients personal information in accordance with country-specific regulations, and consistent with the facility's policies for managing this information. Steps that can be taken to safeguard this information and the general security of the HemoSphere Alta advanced monitoring platform include:

- **Physical Access**: Limit use of the HemoSphere Alta advanced monitoring platform to authorized users. The HemoSphere Alta advanced monitoring platform has password protection for certain configuration screens. Passwords should be protected. See *Settings Menu Navigation and Password Protection* on page 115 for more information.
- **Active Use**: Users of the monitor should take measures to limit patient data storage. Patient data should be removed from the monitor after a patient is discharged and patient monitoring has ended.
- **Network Security**: The facility must take measures to ensure the security of any shared network to which the monitor may be connected to.
- **Device Security**: Users should only use Edwards approved accessories. In addition, ensure that any connected device is free of malware.

The use of any HemoSphere Alta advanced monitoring platform interface outside of its intended purpose could pose cyber security risks. No HemoSphere Alta advanced monitoring platform connections are meant to control the operations of another device. All available interfaces are shown in *HemoSphere Alta Advanced Monitoring Platform Connection Ports* on page 70 and specifications for these interfaces are listed in table A-5, "HemoSphere Alta advanced monitoring platform technical characteristics," on page 353.

7.4.1 Cybersecurity Updates

When a cybersecurity update to the HemoSphere Alta monitor is required, Edwards will issue and provide Emergency patches to customers within 60 days after the identification of a cybersecurity incident and Cybersecurity patches within 120 days after the identification of a cybersecurity incident. All other vulnerabilities will be addressed in routine updates and communicated to customers upon request. To maintain device security, it is recommended that cybersecurity controls are implemented such as, but not limited to, internal hardening methodologies, role-based access control (RBAC), and adding the HemoSphere Alta monitor into a subnet dedicated to medical devices. For additional recommendations on maintaining devices security please contact your local Edwards representative or Edwards Technical Support.

7.4.2 Vulnerability Management

Vulnerability scans are performed on the monitor by Edwards on a routine basis to ensure HemoSphere Alta monitor software remains in a secure state. If a critical and/or highly-exploitable vulnerability is discovered, customers will be directly notified by Edwards via email within 30 days and a patch will be provided as applicable. Additionally, customers can access Edwards' Product Security website at https://www.edwards.com/healthcare-professionals/products-services/support/product-security to review cybersecurity bulletins. For additional inquiries, please contact your local Edwards representative or Edwards Technical Support.

7.4.3 Cybersecurity Incident Response

If there is or has been a suspected cybersecurity incident(s) that has affected the HemoSphere Alta monitor, please contact your local Edwards representative or Edwards Technical Support. It is recommended that an internal cybersecurity incident response plan be in place which includes – but is not limited to – an incident response policy, incident response procedures, short and long term goals for the organization, and metrics for measuring the success of the plan. Along with mitigation recommendations from Edwards, these actions should return the product to secure operability.

7.4.4 HIPAA

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the U.S. Department of Health and Human Services, outlines important standards to protect individually identifiable health information. If applicable, these standards should be followed during monitor use.

HemoSphere Alta Swan-Ganz Monitoring 8

Contents

8.1 Connecting the HemoSphere Alta Swan-Ganz Patient Cable

The HemoSphere Alta Swan-Ganz patient cable is compatible with all approved Edwards Swan-Ganz pulmonary artery catheters. The HemoSphere Alta Swan-Ganz patient cable acquires signals to and from a compatible Edwards Swan-Ganz catheter for CO, iCO and EDV/RVEF monitoring. This section provides an overview of the HemoSphere Alta Swan-Ganz patient cable connections. See figure 8-1.

WARNING Compliance to IEC 60601-1 is only maintained when the HemoSphere Alta Swan-Ganz patient cable (applied part connection, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator.

Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance.

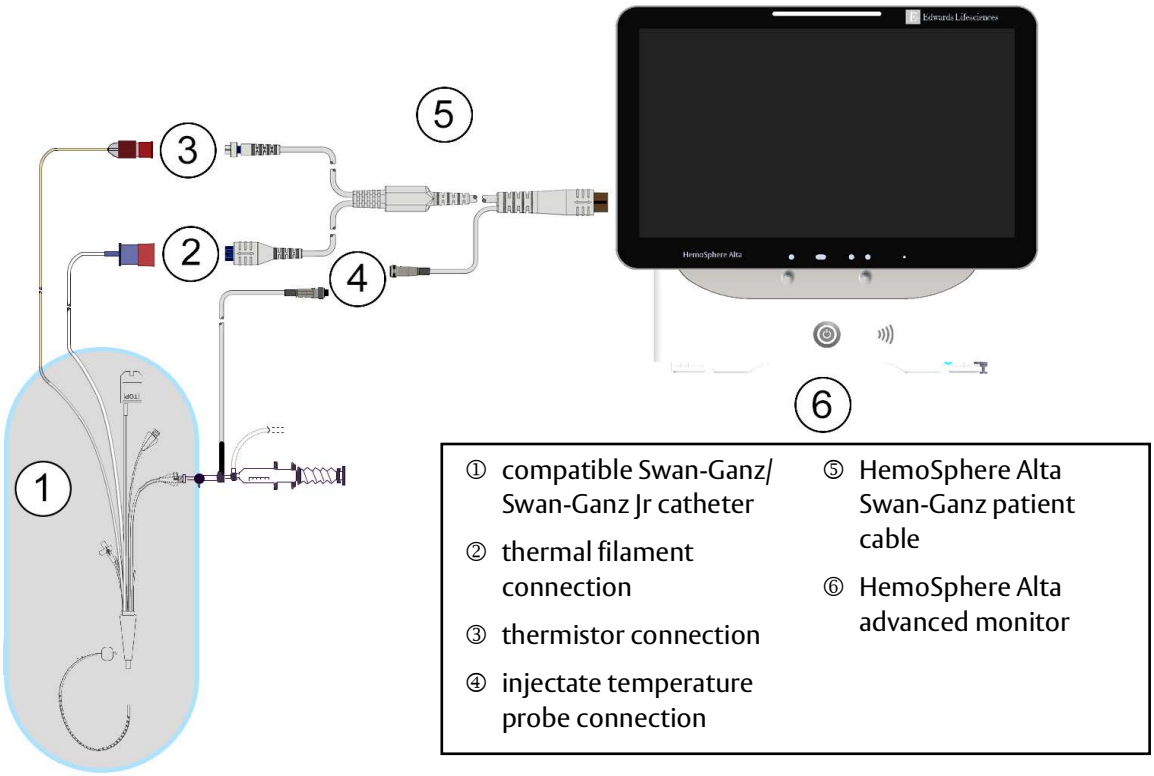


Figure 8-1 HemoSphere Alta Swan-Ganz patient cable connection overview

NOTE Appearance of catheters and injectate systems shown in this chapter are for example only. Actual appearance may vary depending on catheter and injectate system models.

Pulmonary artery catheters are TYPE CF defibrillation proof APPLIED PARTS. Patient cables that attach to the catheter, such as the patient CCO cable, are not intended to be applied parts but may come into contact with the patient and meet the relevant applied part requirements per IEC 60601-1.

1. Plug the HemoSphere Alta Swan-Ganz patient cable into the HemoSphere Alta advanced monitor.
2. Press the power button to turn on the HemoSphere Alta advanced monitoring platform and follow steps for entering patient data. See *Patient Data* on page 118.
3. Connect the compatible Swan-Ganz catheter to the HemoSphere Alta Swan-Ganz patient cable. See Table 8-1 for available parameters and required connections.

Table 8-1 Available HemoSphere Alta Swan-Ganz patient cable parameters and required connections

Parameter	Required connection	See
CO	thermistor and thermal filament connection	*Continuous Cardiac Output* on page 139
CO_{20s}, CI_{20s}, SV_{20s}, SVI_{20s}	thermistor and thermal filament connection *PAP signal from pressure cable	*20-Second Flow Parameters* on page 142

Table 8-1 Available HemoSphere Alta Swan-Ganz patient cable parameters and required connections (continued)

Parameter	Required connection	See
iCO	thermistor and injectate (bath or in-line) probe	*Intermittent Cardiac Output* on page 143
EDV/RVEF (SV)	thermistor and thermal filament connection *HR analog input to HemoSphere Alta advanced monitoring platform or PR from ART waveform (pressure cable or ClearSight cuff)	*EDV/RVEF Monitoring* on page 148
SVR	thermistor and thermal filament connection *MAP and CVP input to HemoSphere Alta advanced monitoring platform	*SVR* on page 151

NOTE Pulmonary artery pressure data is available with a HemoSphere pressure cable connection. See Chapter 9: Pressure Cable Monitoring with an Alta Swan-Ganz patient cable on page 9-160 for more information.

4 Follow the necessary directions for monitoring. See *Continuous Cardiac Output* on page 139, *Intermittent Cardiac Output* on page 143 or *EDV/RVEF Monitoring* on page 148.

NOTE Previous compatible monitoring platforms required a Patient CCO Cable Test before monitoring. This step is not required with the HemoSphere Alta Swan-Ganz patient cable.

8.2 Continuous Cardiac Output

The HemoSphere Alta advanced monitoring platform measures cardiac output continuously by introducing small pulses of energy into the blood stream and measuring blood temperature via a pulmonary artery catheter. The maximum surface temperature of the thermal filament used to release these pulses of energy within the blood is 48 °C. Cardiac output is computed using proven algorithms derived from the conservation of heat principles, and indicator dilution curves that are obtained by cross-correlation of energy input and blood temperature waveforms. After initialization, the HemoSphere Alta advanced monitoring platform continuously measures and displays the cardiac output in liters per minute without operator calibration or intervention.

8.2.1 Connecting the Patient Cables

1 Connect the HemoSphere Alta Swan-Ganz patient cable to the monitor as previously described in section 8.1.

2 Attach the catheter end of the patient cable to the thermistor and thermal filament connectors on the Swan-Ganz CCO catheter. These connections are emphasized as numbers ② and ③ in Figure 8-2 on page 140.

3 Verify that the CCO catheter is properly inserted into the patient.

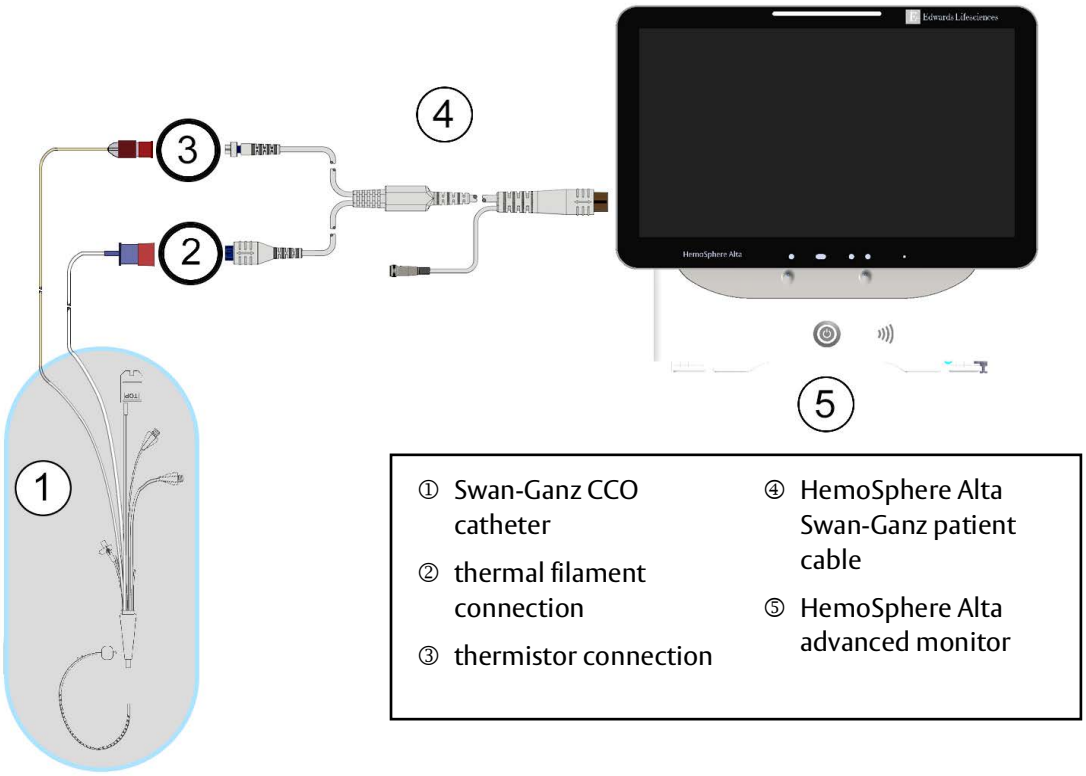
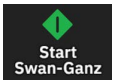


Figure 8-2 CO connection overview

8.2.2 Initiating Monitoring

WARNING CO monitoring should always be discontinued when blood flow around the thermal filament is stopped. Clinical situations where CO monitoring should be discontinued include, but are not limited to:

- Time periods when a patient is on cardiopulmonary bypass
- Partial withdrawal of the catheter so that the thermistor is not in the pulmonary artery
- Removal of the catheter from the patient

When the system is properly connected, touch the start monitoring icon 

on the navigation bar to begin CO monitoring. The CO countdown timer will appear on the stop monitoring icon. After approximately 5 to 12 minutes, when sufficient data has been obtained, a CO value will appear in the parameter tile. The CO value displayed on the screen will be updated approximately every 60 seconds.

NOTE No CO value will be displayed until sufficient time-averaged data is available.

8.2.3 Thermal Signal Conditions

In some situations where patient conditions create large changes in pulmonary artery blood temperature over several minutes, the monitor may take longer than 6 minutes to obtain an initial CO measurement. When CO monitoring is in progress, updating of the CO measurement may also be delayed by unstable pulmonary artery blood temperature. The last CO value and measurement time will be displayed in place of an updated CO value. Table 8-2 shows the alert/fault messages that appear on the screen at different time points while the signal stabilizes. Refer to table 14-9, "HemoSphere Alta Swan-Ganz patient cable CO faults/alerts," on page 323 for more information on CO faults and alerts.

Table 8-2 Unstable thermal signal time lapse for CO alert and fault messages

Condition	Notification	Alert	Fault
	Swan-Ganz System – CO Calculation in Process	**Swan-Ganz System – Retrieving Measurement**	**Swan-Ganz System - CO – Thermal Signal Loss***
Monitoring Commencing: time from commencement without CO measurement	3 ½ minutes	6-15 minutes	30 minutes
Monitoring in Progress: time from last CO update	5 seconds from expiry of CO countdown timer	6 minutes	20 minutes
**Latching fault*			

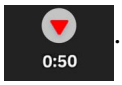
A fault condition terminates monitoring. A fault condition could result from migration of the catheter tip into a small vessel preventing the thermistor from accurately sensing the thermal signal. Check catheter position and reposition the catheter, if necessary. After verifying patient status and catheter position, CO monitoring may be resumed by touching the start monitoring icon 

.

CAUTION Inaccurate cardiac output measurements may be caused by:

- Incorrect placement or position of the catheter
- Excessive variations in pulmonary artery blood temperature. Some examples that cause BT variations include, but are not limited to:
  - status post cardiopulmonary bypass surgery
  - centrally administered cooled or warmed solutions of blood products
  - use of sequential compression devices
- Clot formation on the thermistor
- Anatomical abnormalities (for example, cardiac shunts)
- Excessive patient movement
- Electrocautery or electrosurgical unit interference
- Rapid changes in cardiac output

8.2.4 CO Countdown Timer

The CO countdown timer is located on the stop monitoring icon 

. This timer alerts the user as to when the next CO measurement will take place. The time to the next CO measurement varies from 60 seconds to 3 minutes or longer. A hemodynamically unstable thermal signal may delay CO calculations.

8.2.5 STAT CO

For longer time spans between CO measurements, the STAT CO is available. The STAT CO (sCO) is a fast estimate of the CO value and is updated every 60 seconds. Select sCO as a key parameter to view STAT CO values. Select CO and sCO as key parameters while viewing the graphical/tabular trends split screen and CO monitored data is graphically plotted alongside tabular/numerical data for STAT values of sCO. See *Split Screen* on page 89.

8.2.6 20-Second Flow Parameters

The 20-second flow parameters are available when monitoring with the HemoSphere Alta Swan-Ganz patient cable and a PA (pulmonary artery) pressure signal is also monitored through a connected HemoSphere pressure cable, TruWave DPT, and CCOmbo V catheter (models 777F8 and 774F75). A pulse contour analysis of the pulmonary artery pressure signal is used in combination with the CCO thermodilution algorithm to obtain a faster parameter calculation for CO, CI, SV and SVI. The 20-second flow parameters are labeled with "20s" (CO_{20s}, CI_{20s}, SV_{20s}, SVI_{20s}). These parameters are only available if the 20s flow parameter feature is enabled. Please contact your local Edwards representative for more information on enabling this advanced feature. For more information on PA monitoring, see *Pressure Cable Monitoring with an Alta Swan-Ganz patient cable* on page 160.

CAUTION Inaccurate 20-second flow parameter measurements may be caused by:

- Incorrect placement or position of the catheter
- Improperly zeroed and/or leveled transducer
- Over- or under-damped pressure line
- Adjustments to the PAP line made after start of monitoring

8.2.6.1 PAP Waveform Troubleshooting

The calculation of 20-second flow parameters is highly dependent on a good pulmonary artery pressure waveform. Use the **Zero** 

icon on the navigation to view the pressure waveform screen. Touch the expand icon  to view and evaluate the PAP waveform. The features of a good waveform include:

- Dicrotic notch with minimal dip between systole and diastole
- Clean signal without noise or high-frequency artifacts
- Minimal "whip" artifacts caused by catheter tip movement in the right ventricle
- Sharp waveform morphology and minimal over-damping due to bubbles or kinking in tubing

PAP waveforms that do not display the above listed features have not been validated. These waveforms may result in a loss of 20-second flow parameter calculation.

8.2.7 Right Ventricular Cardiac Output Algorithm

Right ventricular cardiac output (CO_{RV}) and stroke volume (SV_{RV}) are available when monitoring right ventricular pressure (RVP) with a pressure cable and Swan-Ganz IQ catheter. The RVCO algorithm can utilize iCO values from an iCO thermodilution set as an optional input for calculating RVCO parameters. See *Intermittent Cardiac Output* on page 143 for steps. After an iCO measurement is made and accepted, RVCO parameters will display "CAL" on the parameter tile to indicate they have been calibrated. For more information and clinical validation for this algorithm, see *Right Ventricular Cardiac Output Algorithm* on page 304

8.3 Intermittent Cardiac Output

The HemoSphere Alta Swan-Ganz patient cable measures cardiac output intermittently using the bolus thermodilution technique. With this technique, a small amount of sterile physiological solution (e.g., saline or dextrose) at a known volume and temperature — cooler than blood temperature — is injected through the catheter injectate port, and the resultant decrease in blood temperature is measured by the thermistor in the pulmonary artery (PA). Up to six bolus injections can be completed in one series. The average value of the injections in the series is displayed. The results of any series may be reviewed, and the user can remove individual iCO (bolus) measurements that may have been compromised (e.g., patient movement, diathermia, or operator error).

8.3.1 Connecting Patient Cables

1. Connect the HemoSphere Alta Swan-Ganz patient cable to the monitor as previously described in section 8.1.
2. Attach the catheter end of the patient cable to the thermistor connector on the Swan-Ganz, Swan-Ganz IQ, or Swan-Ganz Jr iCO catheter as shown by ② in figure 8-3.
3. Verify that the catheter is properly inserted into the patient.

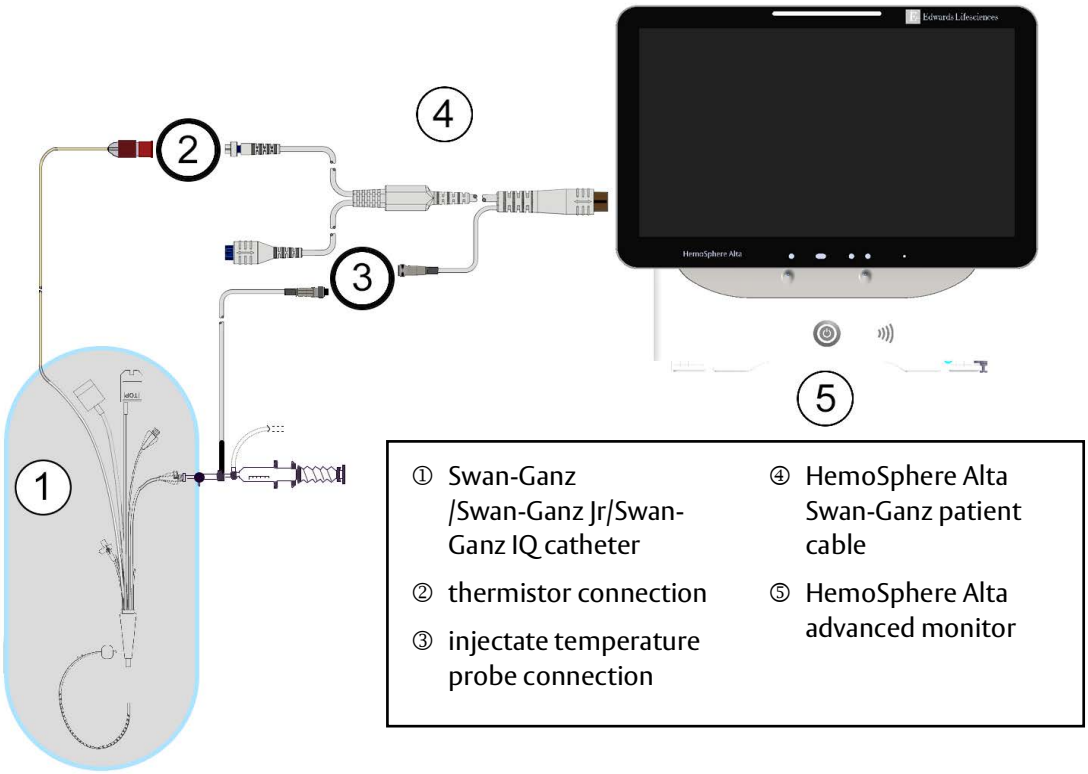


Figure 8-3 iCO connection overview

8.3.1.1 Probe Selection

An injectate temperature probe senses injectate temperature. The selected probe is connected to the patient CCO cable (figure 8-3). Either of two probes may be used:

- An in-line probe is connected to the flow-thru housing on the CO-Set/CO-Set+ injectate delivery system.
- A bath probe measures the temperature of the injectate solution. Bath probes are intended to measure the temperature of a sample solution that is kept at the same temperature as the sterile solution used for injectate when calculating bolus cardiac output.

Connect the injectate temperature probe (in-line or bath) to the injectate temperature probe connector on the patient CCO cable illustrated by ③ in figure 8-3.

8.3.2 Configuration Settings

The HemoSphere Alta advanced monitoring platform provides the operator with the choice of entering a specific computation constant, or configuring the HemoSphere Alta Swan-Ganz patient cable to allow it to automatically determine the computation constant by selecting the injectate volume and catheter size. The operator can also select the parameter display type and bolus mode.

Touch the **Clinical Tools** icon → **iCO Thermodilution** button. If another clinical tool is active, use the drop down menu to select **iCO Thermodilution**. Use the arrows (,) to scroll through and select iCO thermodilution menu options.

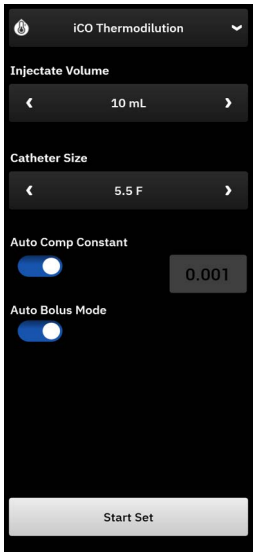


Figure 8-4 iCO side panel – New set configuration menu

CAUTION Refer to Appendix E to ensure computation constant is the same as specified in the catheter package insert. If the computation constant differs, enter the desired computation constant manually.

NOTE The HemoSphere Alta Swan-Ganz patient cable will automatically sense the type of temperature probe in use (ice bath or in-line). The module will use this information to determine the computation constant.

If an injectate temperature (IT) probe is not detected by the monitor, the message "Fault: Swan-Ganz System – Injectate Probe Connection Error" is displayed.

8.3.2.1 Select Injectate Volume

Select a value for the **Injectate Volume**. The available choices are:

- **10 mL**
- **5 mL**
- **3 mL** (bath type probe only)

When a value is chosen, the computation constant is automatically set.

8.3.2.2 Select Catheter Size

Select a catheter size from the **Catheter Size** menu. The available choices are:

- **5.5F**
- **6F**
- **7F**
- **7.5F**
- **8F**

When a value is chosen, the computation constant is automatically set.

8.3.2.3 Select Computation Constant

To manually enter a computation constant, toggle off the **Auto** selection for **Comp Constant**. Touch the **Comp Constant** value button and enter a value on the keypad. If a computation constant is manually entered, injectate volume and catheter size are automatically set, and value entry is set to **Auto**.

8.3.2.4 Select Bolus Mode

Toggle on or off **Auto** for the **Bolus Mode**. The default mode is **Auto** on. In the **Auto** mode, the HemoSphere Alta advanced monitoring platform automatically highlights an **Inject** message upon achieving a baseline blood temperature. To enter manual mode, toggle **Auto** off for **Bolus Mode**. Manual mode operation is similar to the **Auto** mode except that the user must touch the **Inject** button prior to each injection. The following section provides instructions for both of these bolus modes.

8.3.3 Instructions for Bolus Measurement Modes

The HemoSphere Alta Swan-Ganz patient cable factory default setting for bolus measurement is **Auto** mode. In this mode, the HemoSphere Alta advanced monitoring platform highlights an **Inject** message upon achieving a baseline blood temperature. During manual mode, the operator will initiate when to inject by touching the **Inject** button. When an injection is complete, the module computes a value and is ready to process another bolus injection. Up to six bolus injections can be completed in one series.

The following provides step-by-step instructions for performing bolus cardiac measurements starting from the iCO new set configuration side panel.

1 Touch the **Start Set** button at the bottom of the iCO new set configuration side panel after selecting thermodilution configuration settings.

  The button is disabled if:

  - The injectate volume is invalid or not selected
  - Injectate temperature (Ti) is not connected
  - Blood temperature (Tb) is not connected

- An iCO fault is active

If continuous CO measurements are active, a popup window will appear to confirm the suspension of CO monitoring. Touch the **Yes** button to continue to iCO measurements.

NOTE During bolus CO measurements, any parameters calculated using an ECG input signal (HR_{avg}) are unavailable.

2 The iCO new set screen appears with **Wait** above a status bar at the top of the side panel.

NOTE During auto bolus mode, the side panel is locked until the set is completed or canceled. During manual mode, the side panel is locked during bolus delivery and thermodilution measurement.

3 When in auto mode and the thermal baseline is established **Inject** appears at the top of the side panel status bar, signifying when to begin the bolus injection series.

OR

If in manual mode, **Ready** will appear at the top of the side panel when the thermal baseline is established. Touch the **Inject** button when ready to inject and then **Inject** appears on the screen.

4 Use a rapid, smooth, continuous method to inject the bolus with the volume amount previously selected.

CAUTION Sudden changes in PA blood temperature, such as those caused by patient movement or bolus drug administration, may cause an iCO or iCI value to be computed. To avoid falsely triggered curves, inject as soon as possible after the **Inject** message appears.

Once a bolus is injected, the thermodilution washout curve appears on the screen, **Computing** is shown above the status bar and the resultant iCO measurement is displayed.

5 When the thermal washout curve is complete the HemoSphere Alta advanced monitoring platform will highlight **Wait** and then **Inject** – or **Ready** during manual mode – when a stable thermal baseline is reached again. Repeat steps 2 through 4 up to six times as desired. The highlighted messages are repeated as follows:

Auto: **Wait** → **Inject** → Computing

Manual: **Ready** → **Inject** → Computing

NOTE When the bolus mode is set to **Auto**, the maximum time allowed between the appearance of the Inject message and injection of the bolus is four minutes. If no injection is detected within this time interval, the **Inject** message will disappear and the **Wait** message will reappear.

While the bolus mode **Auto** toggle is off (manual mode), the operator has a maximum of 30 seconds in which to make a bolus injection after touching the **Inject** button. If no injection is detected within the time interval, the **Inject** button is enabled again and the **Inject** message disappears.

If a bolus measurement is compromised, as indicated by an alert message, an  will appear in place of the CO/CI value displayed on screen.

To discontinue iCO (bolus) measurements, touch the cancel icon  .

6 After the desired number of bolus injections has been performed, review the set of washout curves by touching the **Review Set** button.

7 Remove any of the six injections in the set by selecting it on the review screen list and touching the trash can icon .

A red "X" appears over the waveform removing it from the averaged CO/CI value.

Waveforms that are irregular or questionable will have an next to the waveform data set.

If desired, touch the cancel icon at the bottom of the side panel to delete the entire bolus set. Touch the **Yes** button to confirm.

8 Touch the **Accept** button after completing the review of bolus injections to use the averaged CO/CI value or touch the add button + to resume the series and add additional bolus injections (up to six) for averaging.

CO Monitoring. If the system is properly connected for continuous CO monitoring, touch the start monitoring icon Start Swan-Ganz to begin CO monitoring at any time.

8.3.4 Thermodilution Summary Screen

After the set has been accepted, the set summary will be displayed as a time stamped event on the Events & Intervention side panel. This summary screen can be accessed anytime by touching the **Clinical Tools** icon → **Events & Intervention**. Scroll through the events list and select the desired Thermodilution set to view the summary.

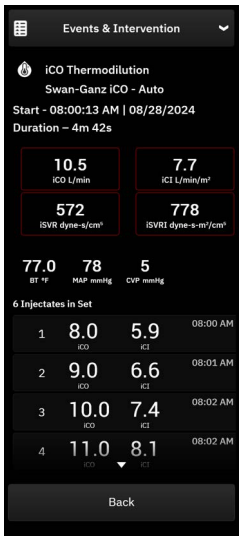


Figure 8-5 Thermodilution summary screen

8.4 EDV/RVEF Monitoring

Right ventricular end diastolic volume (EDV) monitoring is available in conjunction with CO monitoring mode when using a Swan-Ganz CCOmbo V catheter and ECG signal input. Pulse rate (PR) from a pressure cable or ClearSight cuff monitored arterial waveform can be used in place of an ECG heart rate (HR) signal if available. During EDV monitoring, the HemoSphere Alta advanced monitoring platform continuously displays EDV and right ventricular ejection fraction (RVEF) measurements. EDV and RVEF are time-averaged values that can be numerically displayed in parameter tiles, and graphically trended over time in the graphical trend view.

In addition, estimates of EDV and RVEF values at approximately 60 second intervals are calculated and displayed by selecting sEDV and sRVEF as key parameters.

8.4.1 Connecting Patient Cables

1. Connect the HemoSphere Alta Swan-Ganz patient cable as previously described in section 8.1.
2. Attach the catheter end of the patient cable to the thermistor and thermal filament connectors on the Swan-Ganz CCOmbo V catheter. These connections are emphasized by ② and ③ in figure 8-6.
3. Verify that the catheter is properly inserted into the patient.

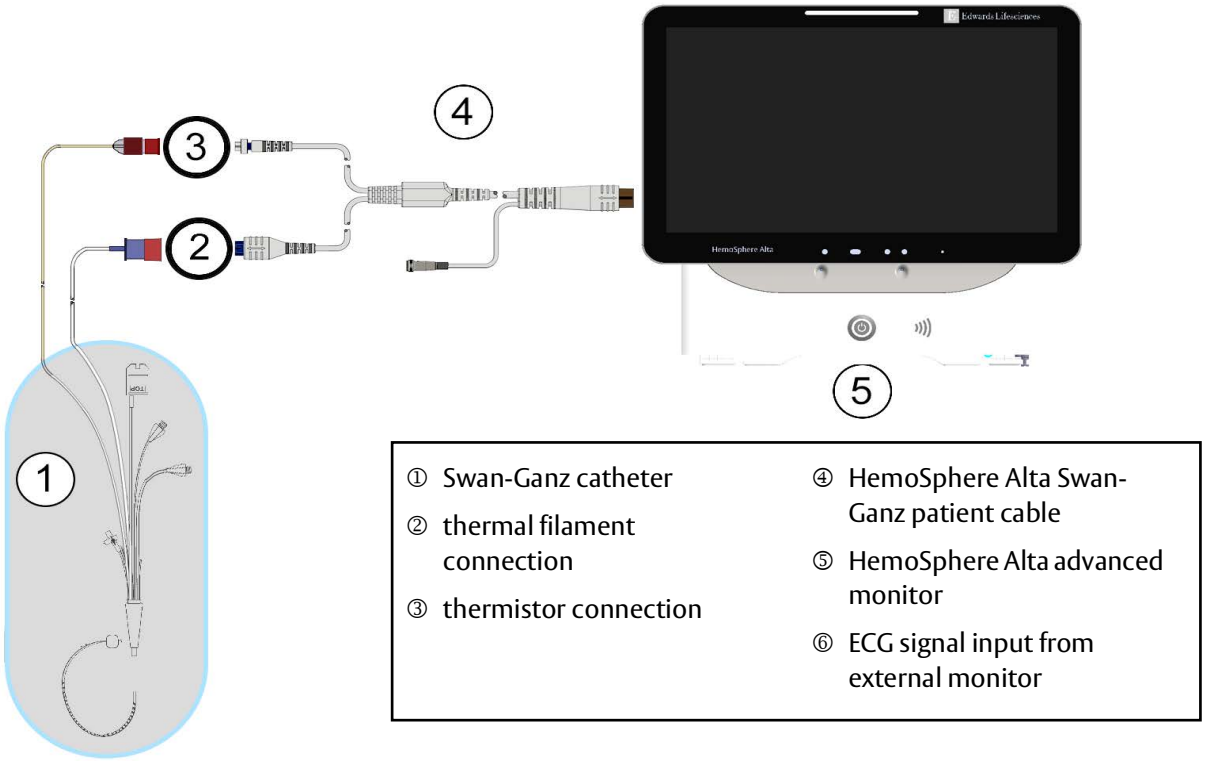


Figure 8-6 EDV/RVEF connection overview

8.4.2 Connecting the ECG Interface Cable

Connect the ECG interface cable's 1/4 inch miniature phone plug to the ECG monitor input on the rear panel of the HemoSphere Alta advanced monitor. ECG

Connect the other end of the interface cable to the bedside monitor's ECG signal output. This will provide an

average heart rate (HR_{avg}) measure to the HemoSphere Alta advanced monitoring platform for EDV and RVEF measurements. Pulse rate (PR) from a pressure cable or ClearSight cuff monitored arterial waveform can be used in place of an ECG heart rate (HR) signal if available. For compatible ECG cables, contact your local Edwards representative.

IMPORTANT NOTE **The HemoSphere Alta advanced monitoring platform is compatible with an ECG analog input from any external patient monitor that has an analog output port which meets the ECG signal input specifications identified in appendix A, Table A-5 of this operator's manual. The ECG signal is used to derive heart rate which is then used to calculate additional hemodynamic parameters for display. This is an optional feature that does not impact the HemoSphere Alta advanced monitoring platform's primary function of monitoring cardiac output (with the HemoSphere Alta Swan-Ganz patient cable) and venous oxygen saturation (with the HemoSphere oximetry cable). Device performance testing was conducted using ECG input signals.**

WARNING **PACEMAKER PATIENTS** – Rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon displayed heart rate. Keep pacemaker patients under close surveillance. See table A-5 on page 353 for disclosure of the pacemaker pulse rejection capability of this instrument.

For patients requiring internal or external pacing support, the HemoSphere Alta advanced monitoring platform should not be used to obtain heart rate and heart rate derived parameters under the following conditions:

- pacer pulse synch output from bedside monitor includes the pacer pulse, however, the characteristics are outside of the pacemaker pulse rejection capabilities specifications as listed in Table A-5
- pacer pulse synch output characteristics from bedside monitor cannot be determined

Note any discrepancies in heart rate (HRavg) with the patient monitor HR and ECG waveform display when interpreting derived parameters such as SV, EDV, RVEF, and associated index parameters.

ECG signal input and all parameters derived from heart rate measurements have not been evaluated for pediatric patients and are therefore not available for that patient population.

NOTE When an ECG input connection or disconnection is first detected, a brief notification message will be displayed on the status bar.

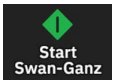
SV is available with any compatible Swan-Ganz catheter and an ECG signal input. For EDV/RVEF monitoring, a Swan-Ganz CCOmbo V catheter is required.

8.4.3 Initiating Measurement

WARNING CO monitoring should always be discontinued when blood flow around the thermal filament is stopped. Clinical situations where CO monitoring should be discontinued include, but are not limited to:

- Time periods when a patient is on cardiopulmonary bypass

- Partial withdrawal of the catheter so that the thermistor is not in the pulmonary artery
- Removal of the catheter from the patient

When the system is properly connected, touch the start monitoring icon 

to begin CO monitoring. The CO countdown timer will appear on the stop monitoring icon. After approximately 5 to 12 minutes, when sufficient data has been obtained, an EDV and/or RVEF value will appear in the configured parameter tiles. The EDV and RVEF values displayed on the screen will be updated approximately every 60 seconds.

NOTE No EDV or RVEF value will be displayed until sufficient time-averaged data is available.

In some situations where patient conditions create large changes in pulmonary artery blood temperature over several minutes, the monitor may take longer than 9 minutes to obtain an initial EDV or RVEF measurement. In these cases, the following alert message will appear 9 minutes after monitoring has commenced:

Alert: Swan-Ganz System – EDV – Retrieving Measurement

The monitor will continue to function and no user action is required. When continuous EDV and RVEF measurements are obtained, the alert message will be removed and the current values will be displayed and plotted.

NOTE CO values may still be available even when EDV and RVEF are not.

8.4.4 Active EDV Monitoring

When EDV monitoring is in progress, updating of the continuous EDV and RVEF measurement may be delayed by unstable pulmonary artery blood temperature. If the values are not updated for 8 minutes, the following message will appear:

Alert: Swan-Ganz System – EDV – Retrieving Measurement

In cases when the average heart rate goes out of range (i.e., less than 30 bpm or greater than 200 bpm) or when no heart rate is detected, the following message will appear:

Alert: Swan-Ganz System – EDV – Heart Rate Signal Out of Range

Continuous EDV and RVEF monitoring values will no longer be displayed. This condition could result from physiologic changes in the patient's status or the loss of the ECG analog signal. Check the ECG interface cable connections and reconnect if necessary. After verifying patient status and cable connections, EDV and RVEF monitoring will automatically be resumed.

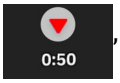
NOTE SV, EDV, and RVEF values are dependent on accurate heart rate calculations. Care should be taken that accurate heart rate values are being displayed, and that double counting should be avoided, especially in case of AV pacing.

If the patient has an atrial or atrial-ventricular (AV) pacer, the user should assess for the presence of double sensing (for accurate HR determinations, only one pacer spike or one contraction per cardiac cycle should be sensed). In the event of double sensing, the user should:

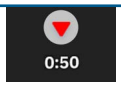
- Reposition the reference lead to minimize atrial spike sensing

- Select appropriate lead configuration to maximize HR triggers and minimize atrial spike sensing, and
- Assess appropriateness of milliamperage (mA) pacing levels.

The accuracy of continuous EDV and RVEF determinations is dependent upon a consistent ECG signal from the bedside monitor. For additional troubleshooting, see table 14-10, "HemoSphere Alta Swan-Ganz patient cable EDV and SV faults/alerts," on page 325 and table 14-13, "HemoSphere Alta Swan-Ganz patient cable general troubleshooting," on page 327.

If EDV monitoring is stopped, by touching the stop monitoring icon 

, the parameter tile target indicator for EDV and/or RVEF will become gray, and a time stamp will be placed below the value indicating the time that the last value was measured.

NOTE Pressing the stop monitoring icon 

will stop EDV, RVEF and CO monitoring.

If EDV monitoring is resumed, a gap will appear in the plotted line of the trend graph indicating the time period when continuous monitoring was interrupted.

8.4.5 STAT EDV and RVEF

A hemodynamically unstable thermal signal may delay the HemoSphere Alta advanced monitoring platform from displaying an EDV, EDVI and/or RVEF value after monitoring has been initiated. The clinician may use the STAT values, which presents estimates of EDV or EDVI, and RVEF values updated approximately 60 seconds. Select sEDV, sEDVI, or sRVEF as a key parameter to view STAT values.

8.5 SVR

While performing CO monitoring, the HemoSphere Alta advanced monitoring platform can also calculate SVR by utilizing MAP and CVP pressure signal inputs from connected pressure cables or CVP entry for CVP values. See *CVP Entry (SVR/SVRI only)* on page 89 for additional CVP sources and system prioritization.

8.6 Global Hypoperfusion Index (GHI) Algorithm Feature

The global hypoperfusion index (GHI) algorithm can be activated in Invasive monitoring mode with a connected Swan-Ganz catheter and oximetry cable. The GHI algorithm uses inputs from the CCO or RVCO and oximetry algorithms to determine the GHI value. The global hypoperfusion index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. Future hemodynamic instability correlates to when mixed venous oxygen saturation (SvO_2) drops to 60% or less for one minute. For more information on the GHI algorithm, see *Global Hypoperfusion Index (GHI) Algorithm Feature* on page 266.

HemoSphere Pressure Cable Monitoring 9

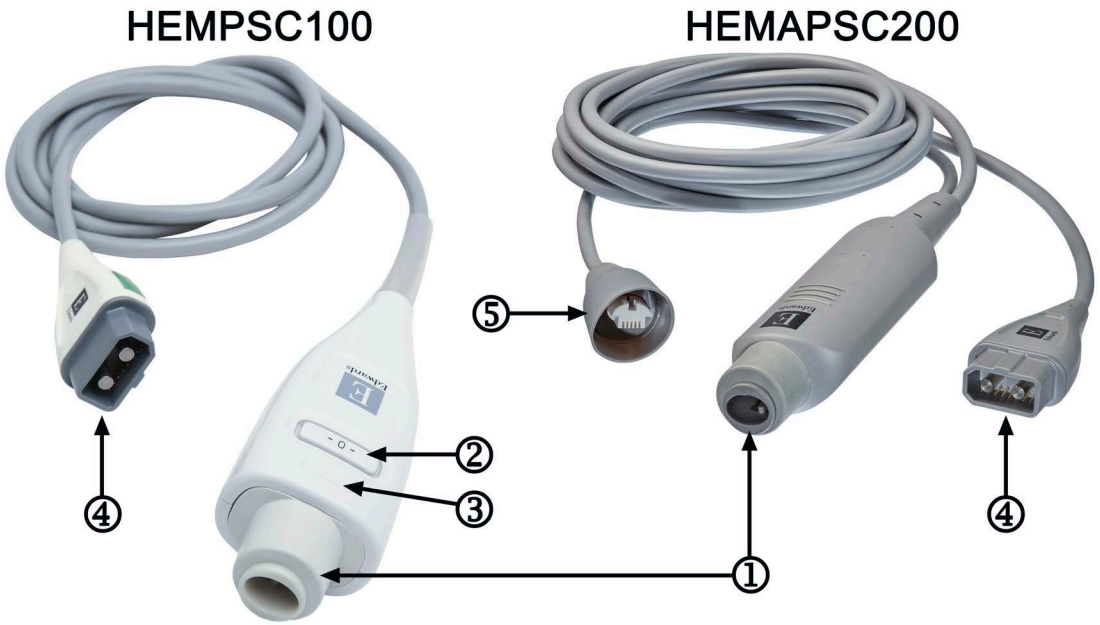
Contents

9.1 Pressure Cable Overview

The HemoSphere pressure cable is a reusable device that connects with the HemoSphere Alta advanced monitor on one end ④ and any approved single Edwards disposable pressure transducer (DPT) or sensor on the other end ①. See Figure 9-1 on page 153. The HemoSphere pressure cable acquires and processes a single pressure signal from a compatible Edwards DPT, such as the TruWave DPT, or a FloTrac sensor. A FloTrac or Acumen IQ sensor connects to an existing arterial catheter to provide minimally invasive hemodynamic parameters. A TruWave transducer can connect to any compatible pressure monitoring catheter to provide location based intravascular pressure. Refer to the directions for use provided with each catheter for specific instructions on catheter placement and use, and for relevant warnings, cautions and notes. The connected technology type appears on the top of the parameter tile (see Figure 4-2 on page 80). The three technology types available are based on the paired sensor/transducer: **FloTrac** sensor**,** FloTrac Jr sensor, Acumen IQ sensor (**IQ Sensor**) or **TruWave** sensor. Parameters in the parameter configuration menu are categorized by technology. The appearance and connection points for the HemoSphere pressure cable are shown in figure 9-1.

Pressure Type Color Insert. If desired, the appropriate color insert can be used on the pressure cable to indicate the monitored pressure type (HemoSphere pressure cable only, HEMPSC100). See ③ in figure 9-1. The colors are as follows:

- Red for arterial pressure (ART)
- Blue for central venous pressure (CVP)
- Yellow for pulmonary artery pressure (PAP)
- Green for other monitored pressure (such as RVP)



① pressure transducer/sensor connection

② zero button /status LED (HEMPSC100 only)

③ color insert for pressure type (HEMPSC100 only)

④ HemoSphere Alta advanced monitor connection

⑤ pressure-out connection (HEMAPSC200 only)

Figure 9-1 HemoSphere pressure cable

Table 9-1 HemoSphere pressure cable configurations and available key parameters

Available key parameters	Pressure cable configuration						
	FloTrac/ FloTrac Jr/ Acumen IQ sensor	FloTrac/ FloTrac Jr/ Acumen IQ sensor with CVP entry or monitored CVP	FloTrac/ Acumen IQ sensor with CVP entry or monitored CVP and oximetry cable	TruWave transducer connected to arterial line	TruWave transducer connected to central line	TruWave transducer connected to pulmonary artery catheter	TruWave transducer connected to catheter at right ventricular level
CO/CI	•	•	•				
CPO/CPI	•	•	•				
SV/SVI	•	•	•				
SVV/PPV	•	•	•				
SVR/SVRI		•	•				
$SvO_2/ScvO_2$			•				
PR	•	•	•	•			
SYS_{ART}	•	•	•	•			
DIA_{ART}	•	•	•	•			

Table 9-1 HemoSphere pressure cable configurations and available key parameters (continued)

Available key parameters	Pressure cable configuration						
	FloTrac/ FloTrac Jr/ Acumen IQ sensor	FloTrac/ FloTrac Jr/ Acumen IQ sensor with CVP entry or monitored CVP	FloTrac/ Acumen IQ sensor with CVP entry or monitored CVP and oximetry cable	TruWave transducer connected to arterial line	TruWave transducer connected to central line	TruWave transducer connected to pulmonary artery catheter	TruWave transducer connected to catheter at right ventricular level
MAP	•	•	•	•			
MPAP						•	
SYS_{PAP}						•	
DIA_{PAP}						•	
CVP		•	•		•		
HPI*	•	•	•				
dP/dt*	•	•	•				
Ea_{dyn}*	•	•	•				
MRVP							•
SYS_{RVP}							•
DIA_{RVP}							•
PR_{RVP}							•
RVEDP							•
RV dP/dt							•

***NOTE** The Acumen Hypotension Prediction Index parameter, HPI, is monitored using a Acumen IQ sensor connected to a radial arterial catheter. See *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225 for more information.

WARNING Do not resterilize or reuse any FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, TruWave transducer, or catheter; refer to the catheter's "directions for use".

Do not use a FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, TruWave transducer, or catheter that is wet, damaged, or that has exposed electrical contacts.

Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance.

Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications.

When the pressure cable is not in use, protect the exposed cable connector from fluid. Moisture within the connector may result in the cable malfunctioning or in inaccurate pressure readings.

WARNING Compliance to IEC 60601-1 is only maintained when the HemoSphere pressure cable (applied part accessory, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator.

CAUTION Do not use any FloTrac sensor, FloTrac Jr sensor, Acumen IQ sensor, or TruWave transducer past its labeled "Use By Date." Products used beyond this date may have compromised transducer or tubing performance, or compromised sterility.

Excessive dropping of the HemoSphere pressure cable may result in cable damage and/or malfunction.

9.2 FloTrac Sensor, FloTrac Jr Sensor, and Acumen IQ Sensor Monitoring

The HemoSphere pressure cable serves as an Edwards FloTrac sensor connecting cable for the HemoSphere Alta advanced monitoring platform. The HemoSphere pressure cable with a connected FloTrac, FloTrac Jr, or Acumen IQ sensor uses the patient's existing arterial pressure waveform to continuously measure cardiac output (FloTrac arterial pressure autocalibrated cardiac output [FT-CO]). With the input of patient height, weight, age, and gender, a specific vascular compliance is determined. The FloTrac algorithm's automatic vascular tone adjustment recognizes and adjusts for changes in vascular resistance and compliance. Cardiac output is displayed on a continuous basis by multiplying the pulse rate and calculated stroke volume as determined from the pressure waveform. The FloTrac, FloTrac Jr, or Acumen IQ sensor measures variations of arterial pressure proportional to stroke volume.

The HemoSphere pressure cable and FloTrac, FloTrac Jr, or Acumen IQ sensor, use the patient's existing arterial pressure waveform to continuously measure stroke volume variation (SVV). SVV is a sensitive indicator of the patient's preload responsiveness when the patient is 100% mechanically ventilated with a fixed rate and tidal volume, and no spontaneous breaths. SVV is always used best in conjunction with stroke volume or cardiac output assessment.

When using the Acumen IQ sensor, the patient's existing arterial pressure waveform is used to continuously measure, the systolic slope (dP/dt), and dynamic arterial elastance (Ea_{dyn}). Ea_{dyn} is a measure of the afterload to the left ventricle by the arterial system (arterial elastance) relative to left ventricular elastance (dynamic arterial elastance). See *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225 for more information on the Acumen IQ sensor and the Acumen Hypotension Prediction Index (HPI) feature. Activation of the Acumen HPI feature is only available in certain areas. Please contact your local Edwards representative for more information on enabling this advanced feature.

Available parameters using FloTrac technology include cardiac output (CO), cardiac index (CI), cardiac power output (CPO), cardiac power index (CPI), stroke volume (SV), stroke volume index (SVI), stroke volume variation (SVV), systolic pressure (SYS), diastolic pressure (DIA), mean arterial pressure (MAP), and pulse rate (PR). When using a Acumen IQ sensor and the Acumen HPI feature is activated, additional available parameters include dynamic arterial elastance (Ea_{dyn}), systolic slope (dP/dt), pulse pressure variation (PPV), and Acumen Hypotension Prediction Index parameter (HPI). When the FloTrac, FloTrac Jr, or Acumen IQ sensor is paired with the patient's central venous pressure (CVP), systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI) are also available.

CAUTION The effectiveness of FT-CO measurements in pediatric patients under 12 years of age has not been evaluated.

Inaccurate FT-CO measurements can be caused by factors such as:
- Improperly zeroed and/or leveled sensor/transducer
- Over- or under-damped pressure lines
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  * Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure, including but not limited to:
  * Extreme peripheral vasoconstriction which results in a compromised radial arterial pressure waveform
  * Hyperdynamic conditions as seen in post liver transplant
- Excessive patient movement
- Electrocautery or electrosurgical unit interference

Aortic valve regurgitation may cause an over estimation of Stroke Volume / Cardiac Output calculated depending on the amount of valvular disease and the volume lost back into the left ventricle.

9.2.1 Connect FloTrac, FloTrac Jr, or Acumen IQ Sensor

1. Connect one end of the pressure cable to the HemoSphere Alta advanced monitoring platform.
2. To de-air and prime I.V. bag and FloTrac, FloTrac Jr, or Acumen IQ sensor: Invert normal saline I.V. bag (anticoagulation per institution policy). Spike I.V. bag with fluid administration set, keeping drip chamber upright. While keeping I.V. bag inverted, gently squeeze air out of bag with one hand while pulling flush tab (Snap-tab) with the other hand until air is emptied from I.V. bag and drip chamber is filled half-way.
3. Insert I.V. bag into the Pressure Bag and hang on I.V. pole (DO NOT INFLATE).
4. With gravity only (no pressure in Pressure Bag), flush FloTrac/FloTrac Jr sensor holding pressure tubing in upright position as the column of fluid raises through the tubing, pushing air out of the pressure tubing until the fluid reaches the end of the tubing.
5. Pressurize the Pressure Bag until it reaches 300 mmHg.
6. Fast-flush the FloTrac/FloTrac Jr sensor and tap on tubing and stopcocks to remove any residual bubbles.
7. Use a straight in or out motion to connect the green connector of the primed FloTrac/FloTrac Jr sensor. The pressure cable LED that surrounds the zero button (see ② in figure 9-1) will flash green indicating that the pressure sensor is detected. A yellow light indicates a fault condition. If this occurs refer to the status bar for specific fault condition details.
8. Connect tubing to arterial catheter, then aspirate and flush system to assure no residual bubbles remain.
9. Use routine transducer calibration procedures (according to institutional policy) to ensure proper pressure signals are being transmitted. Refer to the FloTrac, FloTrac Jr, or Acumen IQ sensor's instructions for use.
10. Follow steps for entering patient data. See *Patient Data* on page 118.
11. Follow the instructions below for zeroing the FloTrac, FloTrac Jr, or Acumen IQ sensor.

CAUTION Always grasp the connector, not the cable, when connecting or disconnecting the cable.

CAUTION Do not twist or bend the connectors.

9.2.2 Set Averaging Time – FloTrac Sensor Only

1. Touch within a FloTrac sensor monitored parameter tile to access the tile configuration menu.
2. Touch the **Delta Intervals** tab.
3. Select a radio button under **CO/Pressure Averaging Time**. The following options are available:
   - 5 sec
   - 20 sec (default and recommended time interval)
   - 5 min

   For more information on **CO/Pressure Averaging Time** menu choices, see *Delta Intervals / Averaging* on page 121. Acumen IQ sensor averaging time defaults to 20 seconds.

9.2.3 Zero Arterial Pressure

The FloTrac, FloTrac Jr, or Acumen IQ sensor must be zeroed to atmospheric pressure to ensure accurate monitoring.

1. Touch the **Zero** icon 

located on the navigation bar

   OR

   Press the physical zero button 

directly on the pressure cable (HEMPSC100 only) and hold for three seconds (see figure 9-1).

CAUTION To prevent cable damage, do not apply excessive force to the pressure cable zero button.

2. The current arterial pressure waveform is displayed and continually updated on the screen. This is to confirm the zero operation is successful.
3. Select **ART** (arterial) next to the listed port for which the active pressure cable is connected. Up to four pressure cables and one oximetry cable can be connected at once.
4. Make sure the sensor is leveled to the patient's phlebostatic axis position according to the instructions for use.

NOTE It is important to keep the FloTrac, FloTrac Jr, or Acumen IQ sensor level to the phlebostatic axis at all times to ensure accuracy of cardiac output.

5. Open the FloTrac/FloTrac Jr sensor stopcock valve to measure atmospheric air. The pressure should display as a flat line.
6. Press the physical zero button 

directly on the pressure cable (HEMPSC100 only) and hold for three seconds, or touch the zero button 

located on the screen. When zeroing is complete, a tone sounds, and "**Zeroed At**" appears along with the current time and date to the right of the waveform plot for the connected pressure cable port.
7. Confirm stable zero pressure value and turn stopcocks such that sensors are reading patient intravascular pressure.

8 Touch the home icon to begin CO monitoring. When the next CO value is calculated, it is displayed and updates will continue as determined by the **CO/Pressure Averaging Time**. Acumen IQ monitored parameters are updated every 20 seconds.

Once CO monitoring is initiated, the blood pressure waveform can also be viewed at any time by touching the **Zero** icon 

on the navigation bar. When unplugging the HemoSphere pressure cable from a compatible monitor or sensors from the pressure cable, always pull at the connection site. Do not pull from cables or use tools to disconnect.

9.2.4 SVR Monitoring

When paired with the FloTrac, FloTrac Jr, or Acumen IQ sensor, the HemoSphere pressure cable can monitor systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI) with a pressure cable monitored CVP, or if the user manually enters the patient's CVP value. For information on monitoring CVP with a connected pressure cable, see *Pressure Cable Monitoring with a TruWave pressure transducer (DPT)* on page 158. For information on CVP source prioritization, see table 4-1 on page 89. To manually input the patient's CVP:

1 Touch anywhere in the **SVR/SVRI** parameter tile → **CVP Entry** tab.
2 Enter the CVP value.
3 Touch the "X" icon to return to the main monitoring screen.

When no source of CVP is detected, the default value assigned is 5 mmHg. To change the default value, see *CVP Settings* on page 129. When using the Acumen Hypotension Prediction Index (HPI) feature, SVR is available on the HPI algorithm side panel.

9.3 Pressure Cable Monitoring with a TruWave pressure transducer (DPT)

The HemoSphere pressure cable connects to a single TruWave pressure transducer to provide location based intravascular pressure. Available pressures measured by a TruWave DPT include:

- CVP: central venous line with central venous pressure (CVP)
- ART: arterial line with diastolic pressure (DIA_{ART}), systolic pressure (SYS_{ART}), mean arterial pressure (MAP), and pulse rate (PR)
- PAP: pulmonary arterial line with diastolic pressure (DIA_{PAP}), systolic pressure (SYS_{PAP}), mean pulmonary arterial pressure (MPAP)
- RVP: right ventricular line with diastolic pressure (DIA_{RVP}), systolic pressure (SYS_{RVP}), mean right ventricular pressure (MRVP), right ventricular pulse rate (PR_{RVP}), right ventricular end diastolic pressure (RVEDP) and right ventricular systolic slope (RV dP/dt).

See table 9-1 for a list of available parameters.

9.3.1 Connect TruWave DPT

1 Connect one end of the pressure cable to the HemoSphere Alta advanced monitor.
2 To de-air and prime I.V. flush bag and TruWave transducer: Invert normal saline bag (anticoagulation per institution policy). Spike I.V. bag with fluid administration set, keeping drip chamber upright. While keeping I.V. bag inverted, gently squeeze air out of bag with one hand while pulling flush tab (Snap-Tab) with the other hand until air is emptied from I.V. bag and drip chamber is filled to desired level (½ or full).

3 Insert flush bag into pressure infuser bag (DO NOT INFLATE) and hang on IV pole at least 2 ft (60cm) above the transducer.

4 With gravity only (no pressure in Pressure Bag), flush TruWave transducer holding pressure tubing in upright position as the column of fluid raises through the tubing, pushing air out of the pressure tubing until the fluid reaches the end of the tubing (flushing under pressure creates turbulence and increased occurrence of bubbles).

5 Pressurize the pressure bag until it reaches 300 mmHg.

6 Fast-flush transducer tubing while tapping on tubing and stopcocks to remove any residual bubbles.

7 Use a straight in or out motion to connect the TruWave DPT to the HemoSphere pressure cable. The pressure cable LED that surrounds the zero button (see ② in figure 9-1) will flash green indicating that the pressure sensor is detected. A yellow light indicates a fault condition. If this occurs refer to the status bar for specific fault condition details.

8 Connect tubing to catheter, and then aspirate and flush system to assure catheter is intra-vascular and remove residual bubbles.

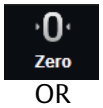
9 Use routine transducer calibration procedures (according to institutional policy) to ensure proper pressure signals are being transmitted. Refer to the TruWave pressure transducer's instructions for use.

10 Follow steps for entering patient data. See *Patient Data* on page 118.

11 Follow the instructions below for zeroing the transducer.

9.3.2 Zero Intravascular Pressure

The TruWave DPT must be zeroed to atmospheric pressure to ensure accurate monitoring.

1 Touch the **Zero** icon 

located on the navigation bar

OR

Press the physical zero button 

directly on the pressure cable and hold for three seconds (HEMPSC100 only, see figure 9-1).

CAUTION To prevent cable damage, do not apply excessive force to the pressure cable zero button.

2 The current intravascular pressure waveform is displayed and continually updated on the screen. This is to confirm the zero operation is successful.

3 Use the pressure type button for the connected pressure cable port (1, 2, 3, 4 or 5) to select the type/location of pressure sensor being used. The waveform color will match the pressure type selected. The choices for **Pressure Transducer** are:

- **ART** (red)
- **CVP** (blue)
- **PAP** (yellow)
- **RVP** (purple)

While using multiple pressure cables, the pressure type configured for the first cable is not an available selection choice for the second pressure cable.

4 Level the stopcock valve (vent port) just above the TruWave transducer to the patient's phlebostatic axis position according to the instructions for use.

5 Open the stopcock valve to measure atmospheric conditions. The pressure should display as a flat line.

6 Press the physical zero button -0- directly on the pressure cable and hold for three seconds (HEMPSC100 only), or touch the zero button 0 located on the screen. When zeroing is complete, a tone sounds, and "**Zeroed At**" appears along with the current time and date to the right of the waveform plot for the connected pressure cable port.

7 Confirm stable zero pressure value and turn stopcocks such that sensors are reading patient intravascular pressure.

8 Touch anywhere outside the Zero panel to return to the monitoring screen. See table 9-1 for which key parameters are available based on the type of configuration.

Once pressure cable monitoring is initiated, the blood pressure waveform can also by viewed at any time by touching the **Zero** icon 0 Zero on the navigation bar.

Parameter values monitored using the TruWave DPT are averaged over a 5 second interval, and displayed every 2 seconds. See table 5-4 on page 122.

9.4 Pressure Cable Monitoring with an Alta Swan-Ganz patient cable

The HemoSphere pressure cable connects to a single Swan-Ganz pulmonary artery pressure port to provide pulmonary artery pressure (PAP) or right ventricular pressure (RVP). Pulmonary wedge pressure is also available with the Smart Wedge algorithm. See *Smart Wedge Algorithm* on page 161.

With a HemoSphere Alta Swan-Ganz patient cable, the pressure cable can be connected to a TruWave DPT on a pulmonary artery line. Monitoring of PAP while monitoring with a HemoSphere Alta Swan- Ganz patient cable also enables monitoring of 20-second parameter values. See *20-Second Flow Parameters* on page 142.

1 Connect one end of the pressure cable to the HemoSphere Alta advanced monitoring platform.

2 Use a straight in or out motion to connect or disconnect the TruWave DPT. Refer to the TruWave pressure transducer's instructions for use and to steps 2-6 in section 9.3.1 above for instructions on flushing air from the system.

3 Use routine transducer calibration procedures (according to institutional policy) to ensure proper pressure signals are being transmitted.

4 Touch the **Zero** icon 0 Zero located on the navigation bar

OR

Press the physical zero button -0- directly on the pressure cable and hold for three seconds (see figure 9-1).

CAUTION To prevent cable damage, do not apply excessive force to the pressure cable zero button.

5 Select **PAP or RVP** on the pressure type button.

6 Level the stopcock valve (vent port) just above the TruWave transducer to the patient's phlebostatic axis position according to the instructions for use.

7 Open the stopcock valve to measure atmospheric conditions. The pressure should display as a flat line.

8 Press the physical zero button -0- directly on the pressure cable and hold for three seconds, or touch the zero button ›0‹ located on the screen. When zeroing is complete, a tone sounds, and "**Zeroed At**" appears along with the current time and date to the right of the waveform plot for the connected pressure cable port.

9 Confirm stable zero pressure value and turn stopcocks such that sensors are reading patient pulmonary artery pressure.

10 To assist with correct placement of the catheter tip in the pulmonary artery, touch the expand icon to view and evaluate the PAP waveform. The current pressure waveform along with a graphic aid of example waveforms for various catheter tip positions is displayed.

11 Touch anywhere outside the Zero panel to return to the monitoring screen. Return to the **Zero** screen at any time to view PAP data.

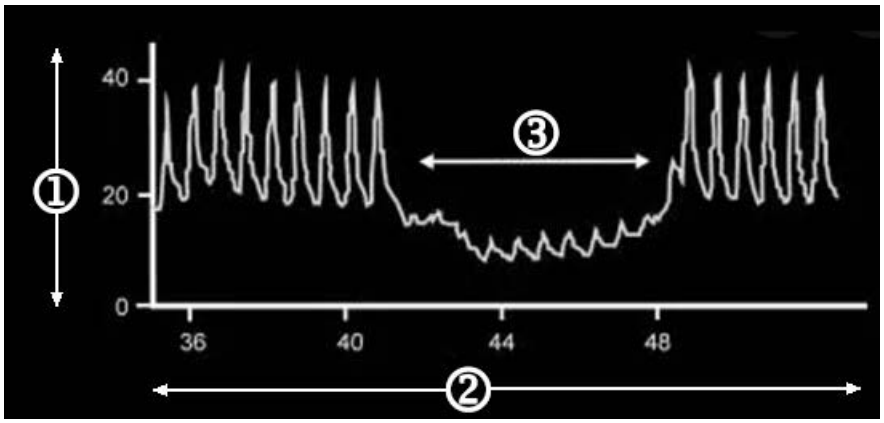
9.4.1 Smart Wedge Algorithm

The Smart Wedge algorithm is designed to provide the value at end-expiration of the pulmonary artery occlusion pressure (PAOP) signal, also called pulmonary wedge pressure, pulmonary capillary wedge pressure (PCWP), or pulmonary artery wedge pressure (PAWP), and to assess the quality of the pulmonary artery occlusion pressure measurement.

Indications for use. When used in combination with a Swan-Ganz catheter connected to a pressure cable and pressure transducer, the Edwards Lifesciences Smart Wedge algorithm measures and provides pulmonary artery occlusion pressure and assesses the quality of the pulmonary artery occlusion pressure measurement. The Smart Wedge algorithm is indicated for use in critical care patients over 18 years of age receiving advanced hemodynamic monitoring. The Smart Wedge algorithm is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Smart Wedge algorithm parameters.

The Smart Wedge algorithm is intended to be used with a Swan-Ganz pulmonary artery catheter connected to the HemoSphere pressure cable and TruWave pressure transducer.

To measure PAOP, a Swan-Ganz catheter is first introduced into the pulmonary artery. When the Swan-Ganz catheter is positioned in one of the smaller pulmonary arteries, the inflated catheter balloon temporarily occludes the artery, allowing the measurement of the PAOP signal, as shown in figure 9-2.



① pulmonary artery pressure (mmHg)

② time (s)

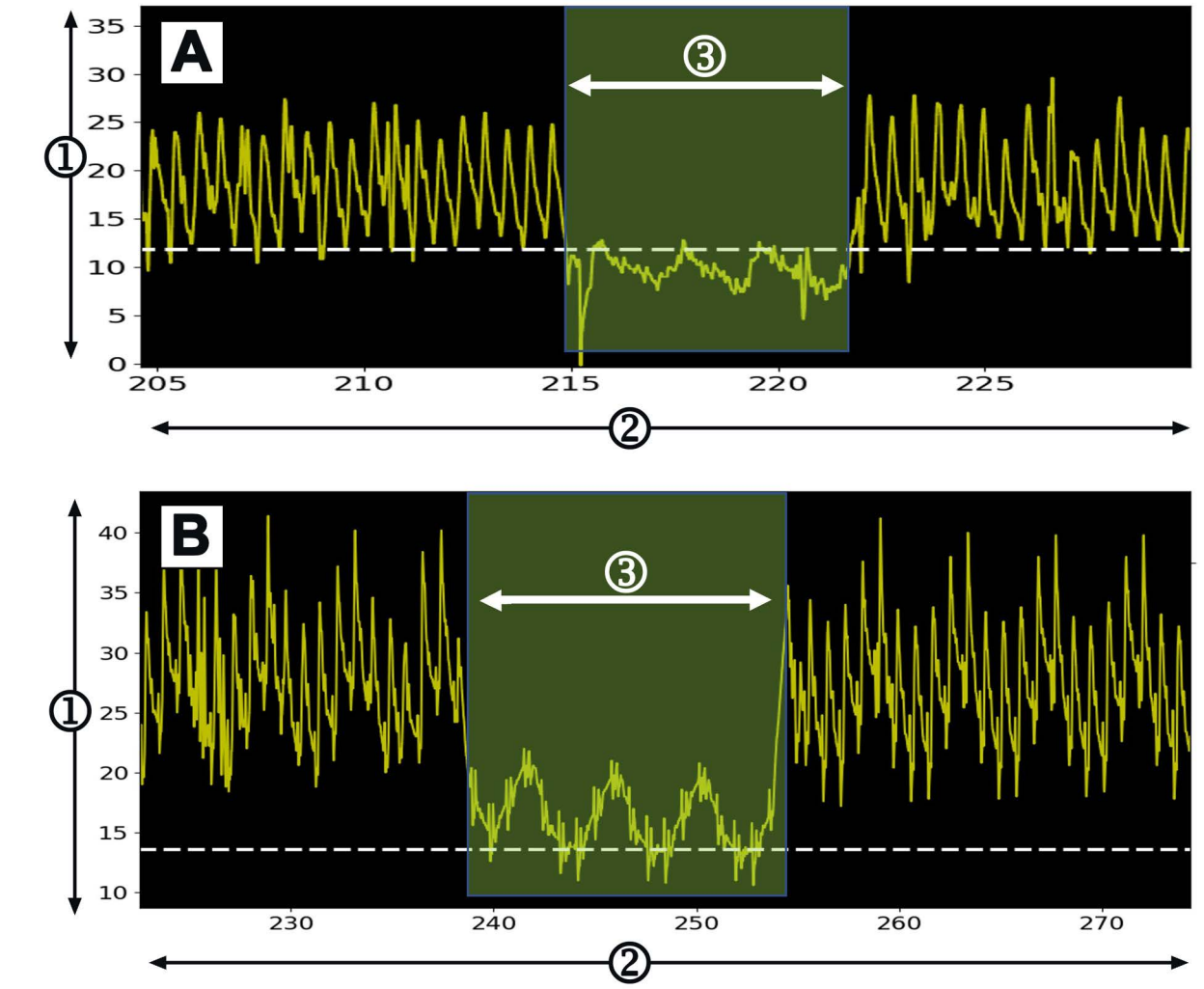
③ PAOP measurement signal

Figure 9-2 Illustration of PAOP measurement

The measured PAOP includes changes in the intrathoracic pressures that occur throughout the respiration

cycle. The respiratory pattern is different for mechanical ventilation (positive pressures) and spontaneous respiration (negative pressures) and therefore needs to be known to the algorithm to compute the correct end-expiration PAOP values, as shown in figure 9-3.

The Smart Wedge algorithm uses the patient's respiration type as well as the pulmonary artery pressure (PAP) signal acquired from a TruWave pressure transducer connected to a Swan-Ganz catheter, which turns into a PAOP signal when the balloon is inflated (wedged). The Smart Wedge algorithm detects potential wedge events, measures PAOP and provides a PAOP quality assessment.



① pulmonary artery pressure (mmHg)	② time (s)	③ PAOP measurement signal

Figure 9-3 Example of Smart Wedge PAOP measurement with spontaneous breathing (A) and mechanical ventilated (B) inputs

Figure 9-3 shows examples of PAOP measurements with different respiration types. The most clinically useful PAOP measurements are taken at the end of expiration [1 2 3] (white dashed lines show Smart Wedge PAOP measurement output at the end of expiration based on respiration type). A) Spontaneous breathing input

defaults the PAOP measurement to the top of the PAOP waveform as indicated by the dashed white line. B) Mechanically ventilated input defaults the PAOP measurement to the bottom of the PAOP waveform as indicated by the dashed white line.

WARNING Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications.

9.4.1.1 PAOP Measurement and Troubleshooting

The following cautions identify catheter and sensor placement and acquisition factors that may impact measurement results.

Precaution. Femoral insertion may lead to a redundancy of the catheter length in the right atrium and difficulties in obtaining a pulmonary artery wedge (occlusion) position.

CAUTION Inaccurate PAOP measurements may be caused by:
- Incorrect placement or position of the catheter
- Catheter balloon is either not fully inflated or is overinflated
- Improperly zeroed and/or leveled transducer
- Over- or under-damped pressure line
- Adjustments to the PAP line made after start of monitoring

Pulmonary artery occlusion pressure (PAOP) values, used to assess cardiac function, are affected by:

- Fluid status[4]
- Myocardial contractility[4]
- Valve and pulmonary circulation integrity[3]

A PAOP measurement is obtained by introducing a Swan-Ganz catheter into the pulmonary artery per hospital policy and the catheter's instructions for use. When the Swan-Ganz catheter is in one of the smaller pulmonary arteries, the inflated catheter balloon occludes the artery allowing the algorithm to record changes in the intrathoracic pressures that occur throughout the respiration cycle and to obtain a PAOP measurement.

The most clinically useful PAOP values are obtained at the end of the respiration cycle when the intrathoracic pressure is fairly constant.[1 2 3]

The Smart Wedge algorithm can be used to obtain a pulmonary artery occlusion pressure (PAOP). This is a suggested measurement that should be used with clinician review.

NOTE The Smart Wedge algorithm requires a decrease in median pressure and pulse pressure between the pulmonary artery (PA) and PAOP waveforms in order to initiate the automated program. If the algorithm fails to distinguish between the two waveforms, you should take the measurement without the Smart Wedge algorithm.

1. Cengiz M, Crapo RO, Gardner RM. The effect of ventilation on the accuracy of pulmonary artery and wedge pressure measurements. Crit Care Med. 1983;11(7):502-507.
2. Bootsma IT, Boerma EC, de Lange F, Scheeren TWL. The contemporary pulmonary artery catheter. Part 1:placement and waveform analysis. J Clin Monit Comput. 2022;36(1):5-15.
3. Ragosta M, Kennedy JLW. Chapter 2 - Normal Waveforms, Artifacts, and Pitfalls. In: Ragosta M, ed. Textbook of Clinical Hemodynamics (Second Edition). Second Edition. Elsevier; 2018:17-55.
4. Mitchell, Joshua D., and David L. Brown. "Invasive hemodynamic monitoring." *Cardiac Intensive Care*. Elsevier, 2018. 465-477.

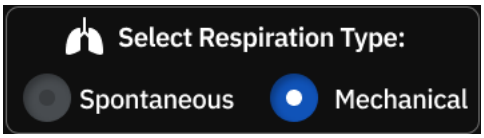
9.4.1.2 PAOP Measurement Procedure

To start the PAOP measurement procedure:

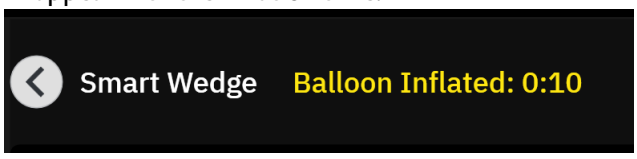
1. Follow steps 1-9 from *Pressure Cable Monitoring with an Alta Swan-Ganz patient cable* on page 160 to connect and zero the Swan-Ganz catheter pulmonary pressure line.
2. To assist with correct placement of the catheter tip in the pulmonary artery, touch the expand icon on the zero screen (Zero located on the navigation bar) to view and evaluate the PAP waveform. The current pressure waveform along with a graphic aid of example waveforms for various catheter tip positions is displayed. Check that the Swan-Ganz catheter balloon is not in a wedged position.

WARNING If the pulmonary artery catheter drifts into the wedge position without inflation of the balloon, spontaneous tip wedging may occur, and the pulmonary artery pressure waveform assumes a wedged appearance, which can impact algorithm accuracy. Take appropriate action, in accordance with standard institutional clinical procedures.

3. Touch the **Smart Wedge** button to initiate the Smart Wedge algorithm.
4. Select the respiration type: Mechanical Ventilation or Spontaneous Respiration.



5. When prompted by the algorithm, touch the **Start Wedge** button and inflate the balloon. Hospital policy and the catheters' Instructions for Use (IFU) should guide balloon inflation technique.
6. A timer will appear with the inflation time.



The waveform changes from the PAP to the PAOP wave. The measurement takes approximately 1-2 respiration cycles (5-15 seconds).

WARNING Do not leave the catheter in a permanent wedge position. Furthermore, avoid lengthy balloon inflation while the catheter is in a wedge position; this occlusive maneuver may result in pulmonary infarction.

NOTE Measure PAOP only when necessary and only when tip is properly positioned. Avoid prolonged maneuvers to obtain PAOP and keep wedge time to a minimum (two respiratory cycles or 10 - 15 seconds), especially in patients with pulmonary hypertension. If difficulties are encountered, discontinue wedge measurements. In some patients, pulmonary arterial end-diastolic pressure can be substituted for PAOP if the pressures are nearly identical, obviating the need for repeated balloon inflation.

In all patients, balloon inflation should be limited to two respiratory cycles, or 10 to 15 seconds.

Avoid prolonged maneuvers to obtain PAOP. If difficulties are encountered, give up the "wedge".

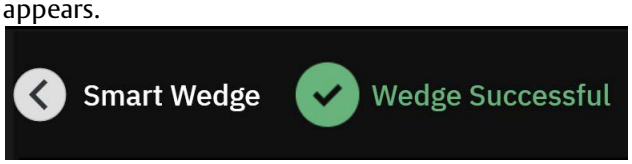
The Smart Wedge algorithm will output a message if either no PAOP measurement is detected after 30 seconds of engaging the Smart Wedge algorithm or if the Smart Wedge algorithm has been engaged for over 60 seconds.

NOTE Detection of a wedged waveform is limited to 60 seconds. Wedges longer than 60 seconds will automatically take user to the "**Edit Wedge**" Screen.

Smart Wedge requires at least 60 seconds of PAP waveform data before Smart Wedge can be engaged.

7 Deflate the balloon once a measurement is obtained/after two attempted respiratory cycles and verify that the waveform returns to pulmonary artery shape.

8 Once deflation is successfully completed, the PAOP value is provided and a "**Wedge Successful**" message appears.



Successful PAOP measurements can be viewed on the **Events & Intervention** side panel at any point.

Touch the **Clinical Tools** icon → **Events & Intervention** button. Scroll through the events to find any completed Smart Wedge events.

NOTE If there was an error while performing the PAOP measurement, the algorithm will output a "Smart Wedge - No Wedge Detected" alert. If no wedge was detected, either pull back the catheter and try again or take the measurement without the Smart Wedge algorithm.

Device user may take a manual PAOP measurement to verify device output. This can be performed on the HemoSphere Alta monitor. See *Manual PAOP Measurement* on page 165.

9.4.1.3 Manual PAOP Measurement

The PAOP measurement can be adjusted or edited at three different points in the Smart Wedge procedure:

After Successful Wedge. After a successful wedge is detected, the balloon is inflated and then deflated, touch the **Edit Wedge** button. Move the X and Y cursors to the desired occlusion pressure point on the waveform and touch the **Save** button. See figure 9-4.

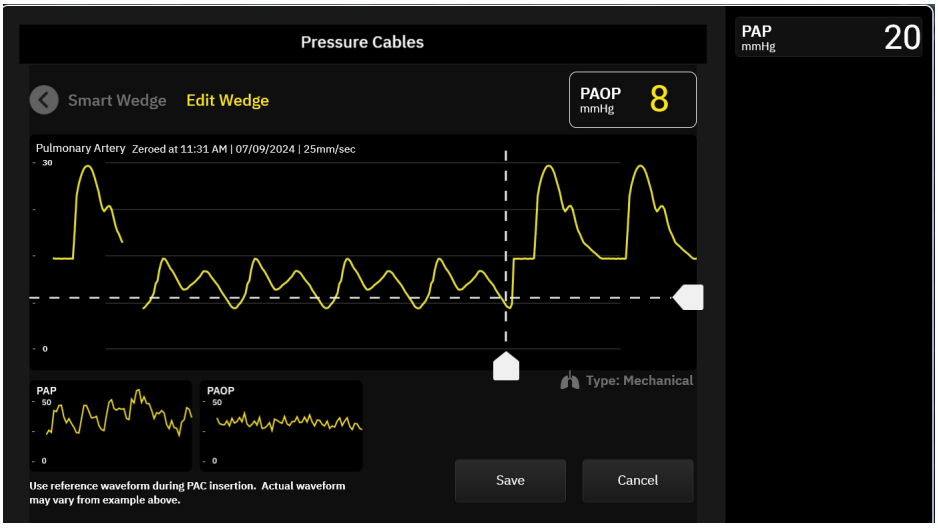


Figure 9-4 Edit Wedge

After Wedge Detected and During Balloon Inflation. After a wedge is detected and while the balloon is inflated, touch the **Freeze** button. Move the X and Y cursors to the desired occlusion pressure point on the waveform and touch the **Save** button. A timer with the inflation time will continue to be displayed next to the text "**Edit Wedge**."

No Wedge Detected. When the system does not detect a wedge, touch the **Freeze** button. Move the X and Y cursors to the desired occlusion pressure point on the waveform and touch the **Save** button

9.4.1.4 Wedge Index

The Wedge Index is a reflection of the quality of the PAOP measurement, where a higher wedge index indicates better quality. A wedge index is present on the PAOP measurement during PAOP monitoring. The wedge index level is calculated with each PAOP measurement update every 1 second. See table 9-2 below for a description of PAOP waveform wedge index levels. Wedge index levels of "**Okay**" and "**Poor**" are typically associated with alert conditions.

Table 9-2 Wedge Index

Wedge Index	Conditions*	Indication of quality
Good (2)	$PAOP_{MeanPressure} < PAP_{Diastolic}$ $0.58 * PAOP_{PulsePressure} + 0.20 * PAOP_{MeanPressure} \leq 7.79$ $PAOP_{MedianPressure} > 2$ mmHg $PAOP_{PulsePressure} > 0.5$ mmHg	Normal

Table 9-2 Wedge Index (continued)

Wedge Index	Conditions*	Indication of quality
Okay (1)	$PAOP_{MeanPressure} < PAP_{Diastolic}$ $0.58 * PAOP_{PulsePressure} + 0.20 * PAOP_{MeanPressure} > 7.79$ $PAOP_{MedianPressure} > 2$ mmHg $PAOP_{PulsePressure} > 0.5$ mmHg	Intermediate (High PAOP Pulse Pressure or High PAOP Mean Pressure)
Poor (0)	$PAOP_{MeanPressure} \geq PAP_{Diastolic}$ $PAOP_{MedianPressure} < 2$ mmHg $PAOP_{PulsePressure} < 0.5$ mmHg	Poor (possible alert status causing limited signal)
**Note: All listed conditions must be valid to trigger the associated wedge index*		

9.4.1.5 Clinical Validation Results

The following tables provide retrospective clinical validation results for the Smart Wedge algorithm. Shown in the tables is PAOP identification performance and PAOP measurement accuracy performance of the Smart Wedge algorithm as compared against the reference (i.e., consensus) from three health care providers (HCPs).

Table 9-3 Performance results of PAOP identification*

Smart Wedge algorithm parameter	Method used to obtain reference value (consensus)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
PAOP Identification (225 PAP waveforms from 129 patients)	Mode of three HCP annotations	100 [100,100]	96 [92, 100]	95 [89, 99]	100 [100, 100]
**Note: Data presented as average value with 95% confidence interval (CI). PPV: positive predictive value, NPV: negative predictive value.*					

Table 9-4 Performance results of PAOP measurements*

Smart Wedge algorithm parameter	Method used to obtain reference value (consensus)	MAE (mmHg)	Bias (mmHg)	Std (mmHg)	Correlation r
PAOP Measurement (110 PAOP measurements from 59 patients)	Average PAOP measurement of three HCPs	1.1 [0.8, 1.5]	0.4 [0.1, 0.7]	1.7 [1.4, 2.0]	0.98
**Note: Data presented as average value with 95% confidence interval (CI). MAE: mean absolute error, Std: standard deviation.*					

Table 9-5 Performance results of PAOP identification for patients with valvular disorders, HCP confirmed arrhythmia, catheter flinging, and heart failure*

Smart Wedge algorithm parameter	Source under test	Method used to obtain reference value (consensus)	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
PAOP Identification (**Patients with valvular disorder**)	Smart Wedge algorithm (N= 12 PAP waveforms from 8 patients)	Mode of three HCP annotations	100 [100,100]	100 [100,100]	100 [100,100]	100 [100,100]
PAOP Identification (**Patients with arrhythmia**)	Smart Wedge algorithm (N= 10 PAP waveforms from 6 patients)		100 [100,100]	100 [100,100]	100 [100,100]	100 [100,100]
PAOP Identification (**Patients with catheter flinging**)	Smart Wedge algorithm (N= 18 PAP waveforms from 10 patients)		100 [100,100]	100 [100,100]	100 [100,100]	100 [100,100]
PAOP Identification (**Patients with heart failure**)	Smart Wedge algorithm (N= 55 PAP waveforms from 33 patients)		100 [100,100]	100 [100,100]	100 [100,100]	100 [100,100]

**Note: Data presented as average value with 95% confidence interval (CI). PPV: positive predictive value, NPV: negative predictive value.*

Table 9-6 Performance results of PAOP measurements for patients with valvular disorders, HCP confirmed arrhythmia, catheter flinging, and heart failure*

Smart Wedge algorithm parameter	Source under test	Method used to obtain reference value (consensus)	MAE (mmHg)	Bias (mmHg)	Std (mmHg)	Correlation r
PAOP measurement (**Patients with valvular disorder**)	Smart Wedge algorithm (N=5 PAOP measurements from 4 patients)	Average PAOP measurement of three HCPs	0.6 [0.4, 0.9]	0.0 [-1.0, 0.9]	0.8 [0.2, 1.4]	1.00
PAOP measurement (**Patients with arrhythmia**)	Smart Wedge algorithm (N=6 PAOP measurements from 6 patients)		0.7 [0.4, 1.0]	0.3 [-0.5, 1.1]	0.8 [0.3, 1.2]	0.99
PAOP measurement (**Patients with catheter flinging**)	Smart Wedge algorithm (N=10 PAOP measurements from 10 patients)		0.5 [0.3, 0.6]	-0.1 [-0.5, 0.3]	0.5 [0.3, 0.8]	0.99
PAOP measurement (**Patients with heart failure**)	Smart Wedge algorithm (N=23 PAOP measurements from 13 patients)		1.3 [0.5, 2.5]	0.5 [-0.4, 1.4]	2.4 [1.5, 3.3]	0.98

**Note: Data presented as average value with 95% confidence interval (CI). MAE: mean absolute error, Std: standard deviation.*

9.5 Zero & Waveform Screen

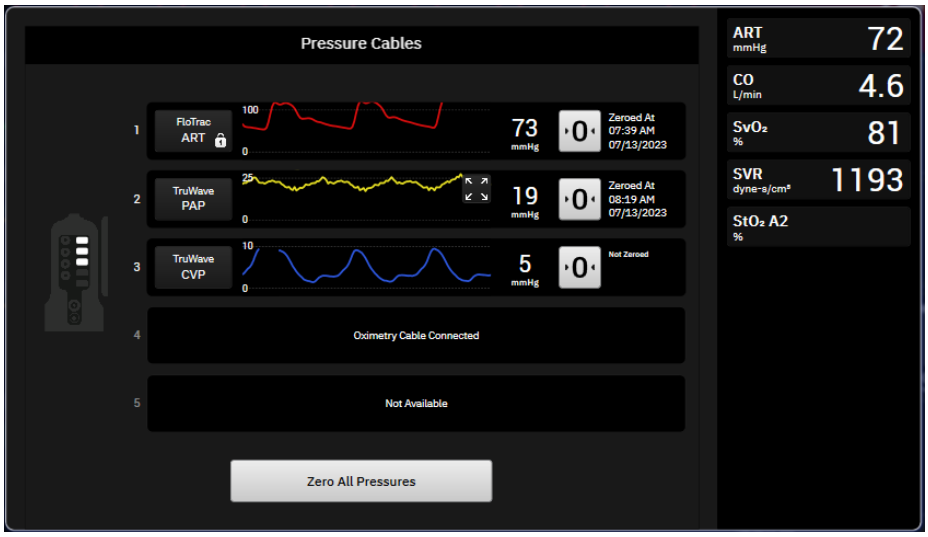


Figure 9-5 Zero screen – Zero pressure cable channels

This screen is accessed through the **Zero** icon 

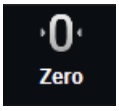
located on the navigation bar and provides two primary functions:

1. Select pressure and zero the sensor
2. Check waveform

9.5.1 Select Pressure and Zero Sensor

As previously described, the primary function of the zero & waveform (**Zero**) screen is to allow the user to zero the attached pressure sensor/transducer. The user is required to zero the sensor before monitoring is initiated with the pressure cable.

9.5.2 Waveform Confirmation



The Zero screen displays the blood pressure waveform. Use this screen or the continuous, real-time blood pressure waveform display (see *Live Blood Pressure Waveform Display* on page 86) to assess the quality of the arterial waveform in response to "Fault: Pressure – Port {0} – Arterial Waveform Compromised". This fault is generated when the arterial pressure signal quality has been poor for too long.

The vertical axis is auto-scaled to the Average BP value ± 50 mmHg.

Monitoring PAP. The Zero screen is also utilized to monitor the pulmonary artery pressure (PAP). While monitoring PAP, touch the expand icon  to view and evaluate the PAP waveform on a screen displaying example waveforms of various catheter tip positions and confirm correct placement in the pulmonary artery.

WARNING Do not use the HemoSphere Alta advanced monitoring platform as a pulse rate or blood pressure monitor.

9.6 Pressure-Out

The HemoSphere Alta pressure cable allows the user to output the pressure waveform to a connected patient monitor. Pressure-out is only available with a connected HemoSphere Alta pressure cable (HEMAPSC200).

1. Connect the pressure-out plug (see ⑤ in Figure 9-1 on page 153) into a compatible patient monitor. Ensure that the selected connector is fully engaged. Refer to the patient monitor instructions for use.
2. Follow steps for zeroing the pressure line to atmospheric pressure. See *Zero Intravascular Pressure* on page 159.
3. While touching the zero button  located on the HemoSphere Alta monitor screen, zero pressure for that signal on the patient monitor at the same time.

HemoSphere Alta ClearSight Technology 10

Contents

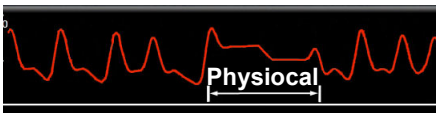
10.1 HemoSphere Alta ClearSight System Methodology

The HemoSphere Alta ClearSight non-invasive monitoring system is composed of the HemoSphere Alta advanced monitoring platform with connected pressure controller, heart reference sensor, and compatible Edwards finger cuff(s). See system connections in Figure 10-1 on page 175. Accurate measurement of the patient's blood pressure and key hemodynamic parameters is based on the Volume Clamp method, Physiocal method and ClearSight algorithm.

10.1.1 Volume Clamp Method

The ClearSight, ClearSight Jr, and Acumen IQ finger cuffs use the Volume Clamp method developed by Czech physiologist J.Peñáz (Penaz J 1973)[1]. The finger cuff is equipped with a plethysmograph sensor, which is a combination of a light source and light receiver, to continuously monitor changes in finger arterial blood volume. An inflatable bladder within the cuff rapidly adjusts to this change in volume to equilibrate the pressure of the cuff with the pressure inside of the artery. The artery is therefore clamped at its "un-stretched" volume and the pressure of the cuff is equal to that of the finger arterial pressure at all times.

10.1.2 Physiocal Method



The Physiocal method, developed by K.H. Wesseling (K.H. Wesseling et al. 1995)[2], is short for physiological calibration. The Physiocal method adjusts for changes in the "un-stretched" volume during a normal measurement period. Cuff pressure is kept constant for one or more heart beats and blood pressure measurement is momentarily interrupted to observe the physiological properties of the finger artery. Early in the measurement period, these interruptions occur regularly. If the properties of the artery are sufficiently constant over time, the interval between Physiocal adjustments will be increased up to 70 heart beats, with higher intervals representing increased measurement stability.

10.1.3 Waveform Reconstruction and Hemodynamic Analysis (ClearSight Technology)

The arterial blood pressure waveform is known to change between the arm and finger arteries due to physiological reasons. ClearSight technology uses advanced processing methods to reconstruct the finger pressure waveform into a radial arterial pressure waveform. Waveform reconstruction yields beat-to-beat values of systolic (SYS), diastolic (DIA) and mean (radial) arterial (MAP) noninvasive pressures. Arterial pulse pressure variation (PPV) is also available. Waveform hemodynamic analysis yields values for pulse rate (PR) using an advanced pulse contour method. Advanced algorithms are used to compute stroke volume variation (SVV) to evaluate dynamic fluid responsiveness.

ClearSight technology uses advanced processing methods to reconstruct the finger pressure waveform into a brachial arterial pressure waveform which yields values for cardiac output (CO), cardiac index (CI), stroke volume (SV), and stroke volume index (SVI) using an advanced pulse contour method.

Cardiac power output (CPO) and cardiac power index (CPI) are derived using MAP and CO. Systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI) are derived using MAP and CO when a central venous pressure (CVP) value is entered or monitored.

All non-invasive parameters selected as a key parameter (see table 1-10, "HemoSphere ClearSight technology available parameters list," on page 36) are averaged and have an update rate of 20 seconds.

If an Acumen IQ finger cuff and HRS are connected and the Acumen Hypotension Prediction Index feature is activated, the Hypotension Prediction Index, HPI, systolic slope (dP/dt), and dynamic elastance (Ea_{dyn}) can be monitored as key parameters. For more information on setup and usage, see *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225.

10.1.4 Heart Reference Sensor

The heart reference sensor (HRS) takes into account differences in pressure between the finger and heart. The hydrostatic pressure changes due to difference in height between the finger and heart are compensated by the HRS. One end of the HRS is placed on the finger at the cuff level, and the other end is placed at heart level.

10.1.5 Discoloration, Numbness, or Tingling of the Fingertip

The Volume Clamp methodology places a continual pressure on the finger which never fully occludes the arteries, but inhibits venous return and causes some venous congestion in the fingertip distal to the cuff. As a result, the patient's fingertip may often experience discoloration (blue or red coloring) after a few minutes of monitoring. After longer periods of monitoring (approximately 30 minutes - 2 hours), some patients may experience some tactile sensations (tingling or numbness) in the fingertip. Immediately after removing the cuff, the middle phalanx often shows a slightly decreased volume and may show some reactive hyperemia or swelling. All of these phenomena generally subside within a few minutes of relieving the cuff pressure. Keeping the fingers and hand warm during the measurement improves the arterialization of the fingertip, which can improve coloration and reduce the rate of occurrence of tactile numbing.

10.1.6 Single Cuff Monitoring

A single compatible Edwards finger cuff can be used for accumulated monitoring of the same patient for up to 8 hours on a single finger. During single cuff monitoring, the HemoSphere noninvasive system will automatically release the pressure in the cuff at regular user selected intervals (30 minutes, 2 hours, and 4 hours). See *Cuff Pressure Release Mode* on page 185.

NOTE After 8 hours of accumulated monitoring on the same finger, the HemoSphere non-invasive system will stop monitoring and display a warning to place the cuff on another finger if continued monitoring is desired.

10.1.7 Double Cuff Monitoring

For monitoring periods lasting longer than 8 hours, the HemoSphere Alta advanced monitoring platform enables two compatible Edwards finger cuffs to be connected simultaneously on separate fingers. In this configuration, the system switches active monitoring between the two cuffs at a user selected interval – 15, 30, or 60 minutes – to allow for minimally interrupted continuous monitoring. See *ClearSight System Settings and Cuff Options* on page 184.

NOTE

The HemoSphere Alta non-invasive system does not continuously monitor a single finger for more than 60 minutes when two cuffs are used. The double cuff monitoring feature allows for minimum interruptions to monitoring for durations of up to 72 hours. Continuous monitoring cannot be extended beyond 60 minutes on a single finger during double cuff monitoring.

When using the double cuff configuration, ensure that each finger is sized separately. It is not uncommon for patients to have two different sized fingers requiring two different sized compatible Edwards finger cuffs. Failure to select the correct finger cuff can result in measurement inaccuracy.

Cuff sizing may not be applicable to all cuffs.

If an Acumen IQ finger cuff and HRS are connected and the Acumen Hypotension Prediction Index feature is activated, the Hypotension Prediction Index feature, HPI parameter, arterial pulse pressure variation (PPV), systolic slope (dP/dt), and dynamic arterial elastance (Ea_{dyn}) can be monitored as key parameters.

For more information on setup and usage, see *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225.

When using the double cuff configuration, both finger cuffs must be an Acumen IQ finger cuff to enable HPI.

Upon starting a measurement, the finger cuff will expire after 72 hours for a single patient.

10.1.8 Methodology References

1 Penaz J (1973), "Photoelectric measurement of blood pressure, volume and flow in the finger" *Digest of the 10th Int Conf Med Biol Engng, Dresden*, p. 104.

2 Wesseling KH, et al. (1995), "Physiocal, calibration finger vascular physiology for Finapres" *Homeostasis* **36** (2-3), pp. 67-82.

10.2 Connecting the HemoSphere Alta Non-Invasive System

HemoSphere Alta ClearSight technology is compatible with all approved Edwards finger cuffs. See figure 10-1 for an overview of the HemoSphere Alta non-invasive system connections.

1 Plug the HemoSphere pressure controller into the ClearSight technology port on the side of the HemoSphere Alta advanced monitor.

2 Press the power button to turn on the HemoSphere Alta advanced monitor and follow steps for entering patient data. See *Patient Data* on page 118.

3 Follow instructions below on how to apply the pressure controller, select finger cuff size and apply the finger cuff(s) to the patient.

NOTE Cuff sizing may not be applicable to all cuffs.

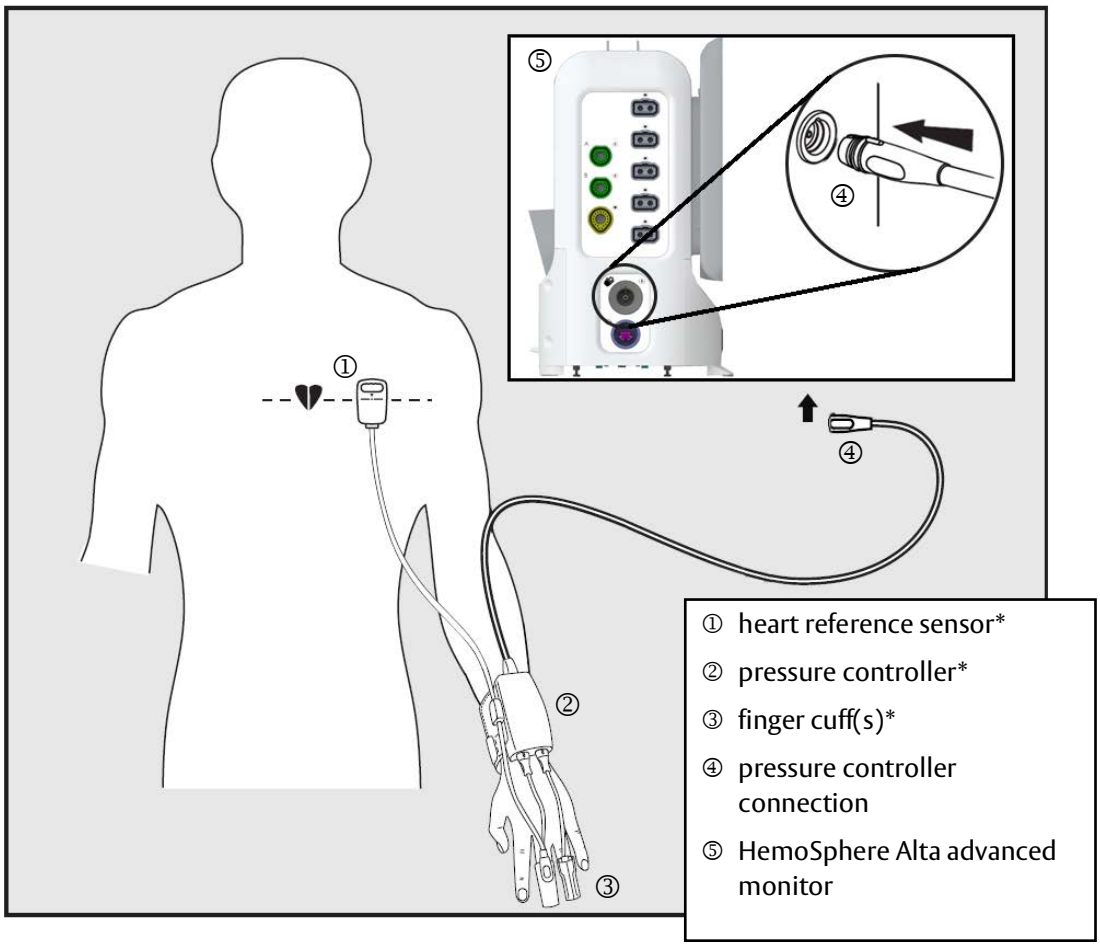


Figure 10-1 HemoSphere non-invasive system connection overview

NOTE Components indicated by a "*" in figure 10-1 legend are APPLIED PARTS as defined in IEC 60601-1 that in normal use necessarily come into physical contact with the patient for the HemoSphere Alta non-invasive system to perform its function.

WARNING Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component.

Compliance to IEC 60601-1 is only maintained when the pressure controller (applied part connection) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator.

WARNING

Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance.

Do not sterilize any components of the HemoSphere Alta non-invasive system. The HemoSphere Alta non-invasive system is provided non sterile.

Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.

Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications.

Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks.

The HemoSphere Alta non-invasive system monitoring components are not defibrillation proof. Disconnect the system before defibrillating.

Only use compatible Edwards finger cuffs, heart reference sensor and other HemoSphere Alta non-invasive system accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

Always remove HemoSphere Alta non-invasive system sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient.

CAUTION

The effectiveness of HemoSphere Alta non-invasive system has not been evaluated in patients under 12 years of age.

Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use.

10.2.1 Apply the Pressure Controller

The pressure controller kit (PC2K or HEMPC2K) consists of a pressure controller (PC2 or HEMPC) and accompanying band (PC2B). A pressure controller cover is available as an accessory. The pressure controller cover secures the heart reference sensor into the pressure controller. See *Pressure Controller Cover* on page 365. Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions for Use. The pressure controller is worn on the patient's wrist and connects to the HemoSphere Alta advanced monitor, HRS and finger cuff(s). See figure 10-2.

.

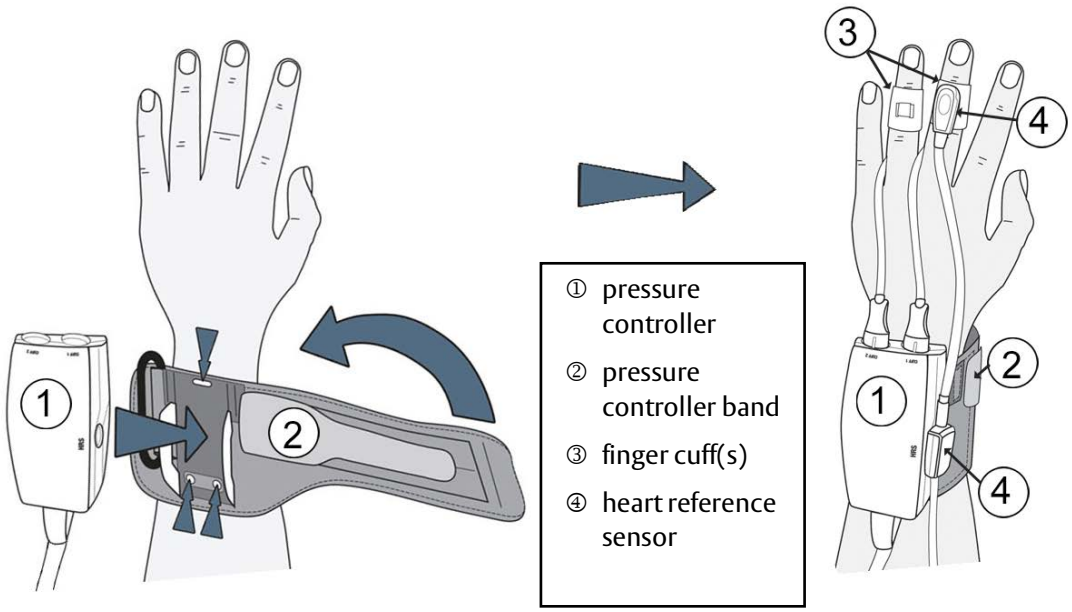


Figure 10-2 Pressure controller application

1. Wrap the pressure controller band around the patient's wrist. The non dominant hand is preferred for monitoring in awake patients. (figure 10-2, left)
2. Snap the pressure controller into the plastic sleeve of the band, making sure that the cuff connectors are facing towards the fingers.
3. Attach the pressure controller cable to the HemoSphere Alta advanced monitor. (figure 10-1)
4. Remove the plastic connector caps in order to connect the finger cuff(s) and heart reference sensor.

NOTE It is recommended that the cuff connector caps be kept and used to protect the pressure controller against the ingress of water and dirt when only a single cuff is used.

WARNING Do not overtighten the pressure controller band or finger cuff(s).

Do not apply pressure controller band on injured skin as this can cause further injury.

10.2.2 Select Finger Cuff Size

Not all cuffs are supplied with a sizing aid. Refer to the product IFU for detailed instructions on proper finger cuff sizing, if applicable.

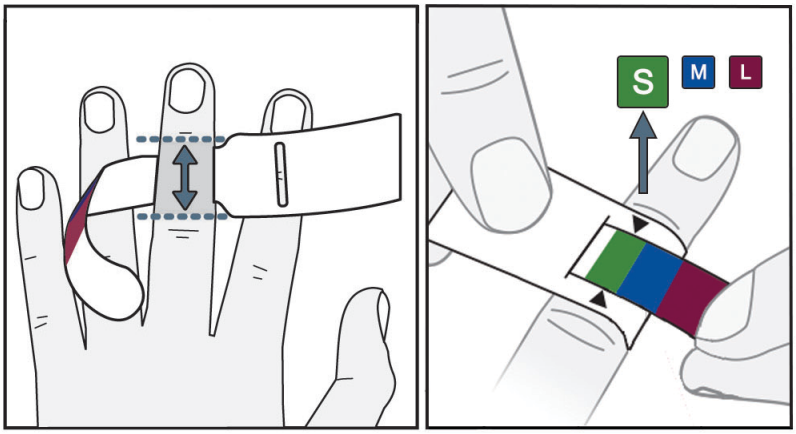


Figure 10-3 Cuff size selection

1. Size the finger(s) that will be used for monitoring by using the finger cuff sizing aid. Best results are obtained from the middle, ring or index finger. The cuff is not intended to be placed on the thumb or previously fractured fingers.
2. Wrap the sizing aid around the middle phalanx of the finger by pulling the color coded smaller end through the slot to create a snug fit.
3. The black arrows indicate suitable cuff size. Match the indicated color with the correct finger cuff size.

WARNING Improper finger cuff placement or sizing can lead to inaccurate monitoring.

10.2.3 Apply Finger Cuff(s)

Refer to the product IFU for detailed instructions on proper compatible Edwards finger cuff placement and actual device illustrations.

Single Patient Use. The ClearSight, ClearSight Jr, and Acumen IQ finger cuffs are designed for single patient use. Upon starting a measurement, the finger cuff will expire after 72 hours for a single patient.

Double Cuff Monitoring. The HemoSphere noninvasive system allows two compatible Edwards finger cuffs to be connected simultaneously to alternate the measurement between two fingers. This feature allows for minimum interruptions to monitoring for durations of up to 72 hours and is required for measurements that take longer than 8 hours. This feature can also be used to increase patient comfort.

10.2.4 Apply the Heart Reference Sensor

The Heart Reference Sensor (HRS) should always be used in conscious patients, freely moving patients or those patients that will be frequently re-positioned during the case. Follow the on-screen prompts or the steps below to connect the HRS.

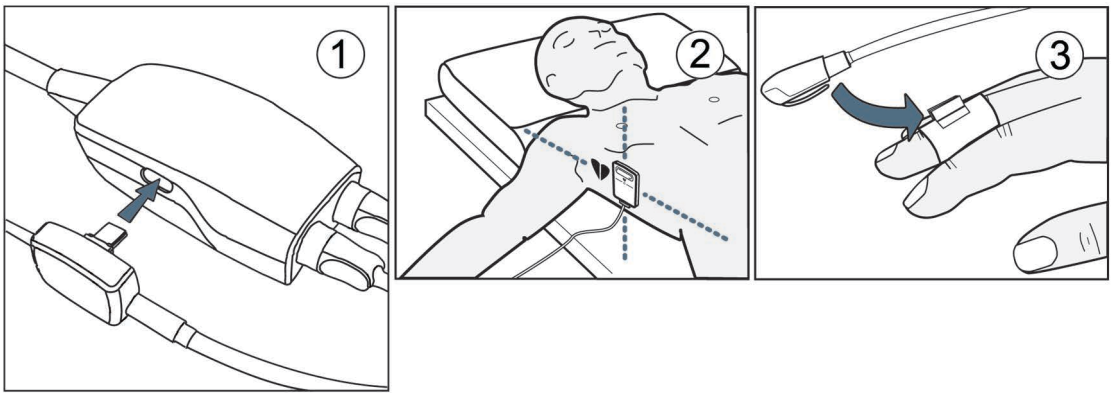


Figure 10-4 Heart reference sensor application

CAUTION Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.

1. Connect the HRS to the pressure controller. See ① in figure 10-4.
2. Place the pressure controller cover on the pressure controller. (optional - see *Pressure Controller Cover* on page 365)
3. Apply the heart end of the HRS to the patient at phlebostatic axis level by using an HRS clip. See ② in figure 10-4.

NOTE If the patient is rotated or moved, the phlebostatic axis will rotate or move with the patient. If necessary, be sure to reapply the heart end of the HRS to ensure that it is still at the same vertical level as the heart in the patient's new position.

4. Attach the other end of the HRS to the finger cuff. See ③ in figure 10-4
5. Touch the **Start ClearSight** icon 

on the navigation bar or on setup help screen to begin monitoring.
6. Touch the **Stop ClearSight** icon 

on the navigation bar to end monitoring at any time.
7. If ClearSight non-invasive blood pressure measurements vary from a reference measurement, assess the integrity of the HRS by performing an HRS calibration. An HRS calibration should be performed as part of the troubleshooting process. See *Calibrate the Heart Reference Sensor* on page 185.

10.2.5 Accuracy of ClearSight Technology Blood Pressure Measurements

Precaution. Correlation of blood pressure measurements to the reference arterial line may be affected during initial system startup and following a system restart.

Table 10-1 provides a summary of repeated measurements from the same patient to provide accuracy of ClearSight non-invasive technology blood pressure outputs.

Table 10-1 95% Confidence interval (CI) results for repeated blood pressure measurements from the same patient (Bootstrap Re-sampling)

Pediatric ≥ 12 years of age	Bias [95% CI]	Precision [95% CI]
SYS (mmHg)	-9.55 [-10.1, -9.02]	13.1 [10.8, 15.4]
MAP (mmHg)	-7.95 [-8.36, -7.55]	9.35 [7.65, 11.1]
DIA (mmHg)	-5.90 [-6.30, -5.50]	9.22 [7.55, 10.9]
Adult	**Bias [95% CI]**	**Precision [95% CI]**
SYS (mmHg)	-2.74 [-4.95, -0.72]	6.15 [4.25, 7.82]
MAP (mmHg)	-1.29 [-2.33, -0.22]	3.14 [2.15, 4.14]
DIA (mmHg)	-1.07 [-2.26, 0.21]	3.71 [2.43, 5.29]

10.2.6 General Troubleshooting of HemoSphere Non-Invasive System Monitoring

Listed below are common issues that may occur during normal monitoring and some troubleshooting steps.

- If waveform does not appear within minutes after monitoring is initiated, check the status bar for any faults or alerts that may indicate there is a problem. Touch **Help** icon on the navigation bar and then the **Guide** button for more information on a displayed message, or see table 14-24, “ClearSight monitoring faults/alerts,” on page 338.
- During measurement, the tip of the finger being monitored by the cuff may show some coloring. This is normal and will disappear within a few minutes of cuff removal.
- During measurement, a conscious patient may notice slight pulsations in the finger to which the cuff is applied. These pulsations will stop momentarily during Physiocals. The patient should be made aware that these irregularities are normal and not caused by the patient’s heart.
- If the patient is responsive, instruct the patient to keep the hand relaxed and not tense the muscles or overstretch the hand.
- Make sure that the blood flow to the hand is not (partially) obstructed, e.g. because the wrist is pressing on a hard surface.
- Some situations, such as cold hands, may make it difficult to start monitoring. If the patient has cold hands, try to warm the hand.

WARNING Do not use the HemoSphere Alta non-invasive system as a heart rate monitor.

If using the instrument during full body irradiation, keep all HemoSphere Alta non-invasive system monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected.

Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements.

CAUTION The HemoSphere Alta non-invasive system is not intended for use as an apnea monitor.

In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud’s disease, blood pressure measurement can become impossible.

CAUTION Inaccurate non-invasive measurements can be caused by factors such as:

- Improperly calibrated and/or leveled HRS
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  - Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure.
- Poor blood circulation to the fingers.
- A bent or flattened finger cuff.
- Excessive patient movement of fingers or hands.
- Artifacts and poor signal quality.
- Incorrect placement of finger cuff, position of finger cuff, or finger cuff too loose.
- Electrocautery or electrosurgical unit interference.

Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation.

The effectiveness of Edwards compatible finger cuffs has not been established in pre-eclamptic patients.

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against the ECG heart rate.

The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias.The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis.

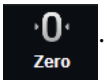
10.3 Optional HRS

With **HRS Usage** set to **Optional**, steps vary from how described previously in *Heart Reference Sensor* on page 173. The ClearSight algorithm must account for differences in pressure due to the change in vertical level of the monitored finger relative to the heart. This can be performed by monitoring with a connected HRS, or by manually entering this height difference in patients that are sedated or stationary.

NOTE The HRS must be used in patients where the vertical level of the finger relative to the heart may change at any time during monitoring

Monitoring without an HRS is only recommended for those patients under general anesthesia with limited or no re-positioning needs anticipated. The HRS can be used during these monitoring conditions, but is not required.

To make HRS use optional, navigate to the ClearSight system settings screen.

1. Touch navigation bar **Settings** icon → **ClearSight** technology button.
2. Under the **HRS Usage** setting, enable the radio button to **Optional**.
3. Disconnect the HRS and touch the navigation bar **Zero** icon 

.
4. Under the **ClearSight** technology tab, a "**Please connect the HRS**" message is displayed with an instructional image on connecting the HRS to the pressure controller. Touch the **Proceed without HRS** button.

CAUTION Monitoring without an HRS may lead to measurement inaccuracies. Ensure patient remains still with accurately measured finger to heart height difference.

Do not place the patient in a non-supine position while monitoring without an HRS. This may lead to an inaccurate vertical offset entry for the HRS and measurement inaccuracies.

NOTE If the Acumen Hypotension Prediction Index feature is enabled, the alert "HRS and Acumen IQ Cuff(s) are required for HPI features" will be displayed. Touch Acknowledge button if the Acumen HPI feature is not desired for the current monitoring session.

To enable HPI software feature, an Acumen IQ finger cuff and HRS are required.

If an HRS is connected a popup screen with the message **HRS Detected** is displayed. To start monitoring with the HRS, touch **Yes** and proceed to step 2 under *Apply the Heart Reference Sensor* on page 178. To monitor without an HRS, disconnect the HRS and proceed with the steps below.

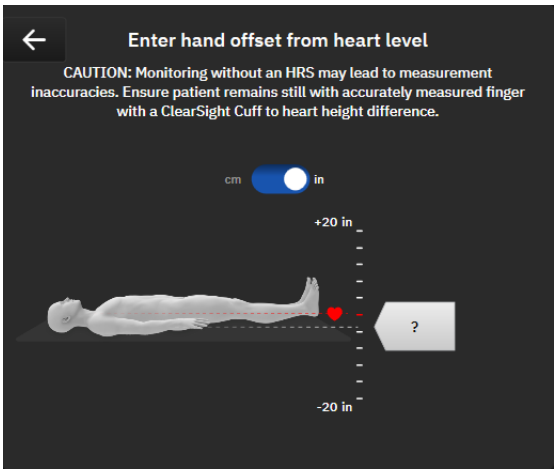


Figure 10-5 Vertical offset entry screen

5 The **Zero** screen in this mode (shown in figure 10-5) will depict a vertical scale bar to represent the offset of the hand relative to the heart; the heart level is set at zero. A positive offset signifies a patient position where the hand is above the heart. Select the units of the scale bar: **cm** (centimeters) or **in** (inches).

6 Use the slider to move the vertical level of the hand and set the offset between the hand and heart.

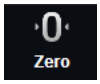
7 Touch the OK icon .

8 Touch the **Start ClearSight** icon Start ClearSight on the navigation bar to start monitoring.

Two alerts will cycle through on the information bar with the texts "**Alert: ClearSight System – No HRS Connected – Verify Patient Positioning**" and "**Alert: ClearSight System – Current Offset {0}**" where {0} is the verified height offset between the monitored finger and heart. The offset value must be updated each time a patient is re-positioned in this mode. In addition, if monitoring is stopped for more than one minute, the vertical offset must be verified again upon restarting monitoring.

10.3.1 Update Offset Value During Monitoring

To update the finger to heart vertical offset value:

1 Touch the navigation bar **Zero** icon 

→ **ClearSight** technology tab.

2 Touch the **Update** button.

3 Use the slider to move the vertical level of the hand to set the offset value to match the new patient position.

4 Touch the OK icon  to confirm the new offset or the cancel icon  to exit the update selection.

10.3.2 Change HRS Usage Setting

To change the monitoring setting to require use of the HRS:

1 Touch navigation bar **Settings** icon  → **ClearSight** technology  button.

2 Under the **HRS Usage** setting, enable the radio button to **Required**.

NOTE ClearSight system settings cannot be configured while monitoring. Stop ClearSight system monitoring, and then proceed to the ClearSight system settings screen to make the desired changes.

10.4 SQI

A signal quality indicator (SQI) is present on all non-invasive parameter tiles during HemoSphere Alta non-invasive system monitoring. SQI level is calculated with each parameter update every 20 seconds. See Table 10-2 for a description of arterial waveform SQI levels. SQI levels of one and two are typically associated with alert conditions. An SQI level of zero is shown when monitoring is initializing (starting or resuming). A zero SQI value can also be associated with a fault condition. See table 14-24 on page 338 for a list of finger cuff faults and alerts.

Table 10-2 Arterial waveform SQI levels

Appearance	Level	Indication
	4	Normal
	3	Intermediate (moderately compromised)
	2	Poor (possible alert status causing limited signal)
	1	Unacceptable (possible alert status causing extremely limited or no signal; see table 14-24 on page 338 for a list of finger cuff alerts)
	0	Pressure waveform unavailable (see table 14-24 on page 338 for a list of finger cuff faults)

10.5 Physiocal Method Display

The Physiocal method is an automatic calibration of the arterial waveform which occurs at regular intervals during non-invasive monitoring. The Physiocal method can be observed on the live pressure waveform display as a stepwise increase in pressure upon startup and as brief interruptions throughout monitoring. The interval between Physiocal method calibrations is displayed on the arterial waveform graph in parenthesis next to the Physiocal method interval icon (see Table 10-3). To accurately account for changes in the finger artery characteristics throughout monitoring, Physiocal method is performed at regular intervals resulting in momentary interruptions to the arterial waveform.

Table 10-3 Physiocal method interval status

Appearance	Physiocal method beats interval	Indication
	≥30	Normal measurement stability
	<30	Frequent Physiocal method interruptions; variable physiological artery properties and decreased measurement stability
	--	Physiocal method being performed or status not available

10.6 ClearSight System Settings and Cuff Options

The ClearSight system settings screen allows the user to select the time interval between cuff pressure release and the switching time interval for double cuff monitoring. This screen also displays sensor status and information for connected finger cuff(s) and HRS.

NOTE Allow for at least 10 minutes of monitoring before reviewing sensor status information.

ClearSight system settings cannot be configured during active non-invasive monitoring or during cuff pressure release mode. Stop ClearSight technology monitoring, and then proceed to the ClearSight system settings screen to make the desired changes.

1 Touch settings icon → **ClearSight** technology button.

2 The left side of the screen displays the following setting options:

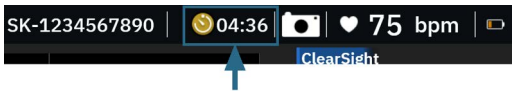
Single cuff pressure release time interval. For single cuff monitoring, select a cuff pressure release time interval from the available options. At the end of the cuff pressure time release interval, the pressure will be released from the cuff for a duration indicated by the countdown timer on the information bar. See *Cuff Pressure Release Mode* on page 185.

Dual cuff switching time interval. For double cuff monitoring, select a switching time interval from the available options.

HRS Usage. The optional heart reference sensor (HRS) feature can be enabled or disabled from this menu screen. If the **Optional** is enabled, the user has the option of manually entering a vertical offset value between the hand and heart instead of using an HRS. See *Optional HRS* on page 181.

3 The right side of the screen displays connected finger cuff(s) and HRS status and information.

10.6.1 Cuff Pressure Release Mode



During single cuff monitoring, the HemoSphere Alta non-invasive system will automatically release pressure from the finger cuff at regular intervals.

When ≤ 5 minutes remain until **Cuff Pressure Release Mode**, a white countdown timer icon will appear on the information bar along with the time remaining until pressure release. A notification pop up will indicate that the countdown clock has been initiated. The user has the option to extend the countdown time until cuff pressure release by touching **Postpone** on the notification popup. Continuous monitoring will not be extended beyond the 8 hour cumulative monitoring limit on a single finger. Refer to *Single Cuff Monitoring* on page 173 and *Double Cuff Monitoring* on page 174.

At the end of the cuff pressure time release interval, pressure will be released from the cuff and monitoring will be temporarily suspended. A notification will appear on the screen to indicate that finger cuff pressure has been released. The cuff pressure release icon will appear orange and the timer will indicate time until monitoring is automatically resumed.

During **Cuff Pressure Release Mode**, a countdown clock appears on the navigation bar. A **Pressure Release Active** popup menu will appear on the screen. This menu can also be accessed by touching the navigation or status bar countdown clocks. Menu options on this popup include: **Postpone** and **Stop Monitoring**.

NOTE	Cuff pressure release intervals can only be changed when monitoring is stopped. Avoid frequent changes to cuff release intervals during a patient monitoring session.

10.7 Calibrate the Heart Reference Sensor

The Heart Reference Sensor (HRS) should be calibrated to ensure optimal performance.

1 Navigate to the HRS Calibration screen by touching the **Clinical Tools** icon 

→ **HRS Calibration** button. If another clinical tool is active, use the drop down menu to select **HRS Calibration.**

2 Connect the HRS to the pressure controller. See ① in figure 10-4.

3 Vertically align both ends of the HRS and touch the Calibrate button.

4 Wait for the indication that the HRS has been calibrated.

10.8 Blood Pressure Calibration

The **BP Calibration** side panel allows the user to calibrate ClearSight finger cuff monitored blood pressure values with reference blood pressure monitored values. Both brachial oscillometric cuff or radial arterial line reference values can be used.

NOTE BP Calibration is not available during double cuff monitoring.

BP Calibration is recommended in pediatric patients.

CAUTION Do not perform a BP calibration during monitoring periods when blood pressure appears unstable. This may result in inaccurate blood pressure measurements.

1. **Clinical Tools** icon → **Blood Pressure Calibration** button. If another clinical tool is active, use the drop down menu to select **Blood Pressure Calibration**.
2. Touch **Add Measurement** to enter the reference BP values.

NOTE Once the **Add Measurement** button is touched, the current ClearSight technology BP values are displayed and the user has five minutes to enter reference BP values. If more than five minutes are needed, the **Add Measurement** button can be touched again to reset the five minute timer.

3. Touch in the value boxes for **SYS** and **DIA** and use the keypad to enter reference blood pressure measurements.
4. Touch **Calibrate** to complete the calibration process. The abbreviation of calibration (**CAL**) will appear above the parameter name on the BP tile to indicate that ClearSight technology BP has been calibrated.
5. To clear the last entered BP reference values, touch **Clear Calibration**.

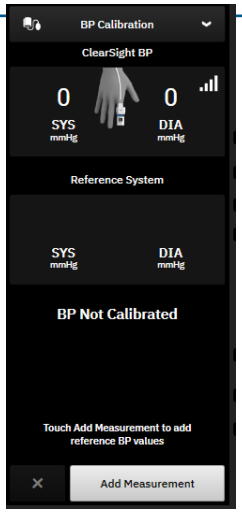


Figure 10-6 BP Calibration side panel

NOTE The current **BP Calibration** will be cleared if monitoring is paused for more than 10 minutes.

If monitoring without an HRS, **BP Calibration** will be disabled for one minute after updating the HRS vertical offset entry.

Table 10-4 provides bias and precision performance data for each parameter of the ClearSight system, comparing BP calibrated with radial line monitored patients and BP Calibration with brachial oscillometric cuff monitored patients.

Table 10-4 BP Calibration performance data

Parameter (units)	Calibration reference	Bias	Precision
Pediatric ≥ 12 years of age			
SYS (mmHg)	Radial	0.18 [0.01, 0.36]	3.98 [3.61, 4.35]
	Brachial	0.86 [0.11, 1.61]	5.86 [4.62, 7.11]
DIA (mmHg)	Radial	-0.29 [-0.43, -0.16]	2.91 [2.64, 3.18]
	Brachial	-1.22 [-2.16, -0.28]	5.20 [4.46, 5.94]

Table 10-4 BP Calibration performance data (continued)

Parameter (units)	Calibration reference	Bias	Precision
MAP (mmHg)	Radial	-0.50 [-0.66, -0.34]	3.54 [3.11, 3.98]
	Brachial	-0.87 [-1.63, -0.12]	5.16 [4.05, 6.26]
Parameter (units)	**Calibration reference**	**Bias**	**Precision**
Adult			
SYS (mmHg)	Radial	2.2 [1.3, 3.1]	2.8 [2.0, 3.5]
	Brachial	3.4 [1.1, 5.5]	5.1 [3.2, 7.0]
DIA (mmHg)	Radial	1.1 [0.4, 1.8]	2.1 [1.6, 2.6]
	Brachial	1.6 [0.3, 2.9]	3.0 [1.6, 4.3]
MAP (mmHg)	Radial	1.3 [0.4, 2.3]	2.8 [2.1, 3.6]
	Brachial	2.0 [0.4, 3.6]	3.7 [2.0, 5.5]
CO (L/min)*	Radial	-0.1 [-0.1, -0.1]	0.6 [0.5, 0.6]
	Brachial	-0.1 [-0.2, -0.0]	0.5 [0.3, 0.6]
SVV (%)	Radial	-0.5 [-0.6, -0.5]	1.3 [1.1, 1.4]
	Brachial	-0.7 [-0.9, -0.4]	1.1 [0.8, 1.4]
PPV (%)	Radial	0.2 [0.1, 0.3]	1.7 [1.6, 1.9]
	Brachial	0.0 [-0.3, 0.3]	1.2 [0.8, 1.5]
Ea_{dyn} (none)	Radial	0.1 [0.1, 0.1]	0.2 [0.1, 0.2]
	Brachial	0.1 [0.0, 0.1]	0.1 [0.1, 0.1]
dP/dt (mmHg/s)	Radial	21.1 [15.0, 27.3]	124.0 [107.0, 141.1]
	Brachial	20.8 [-4.8, 46.3]	105.4 [73.5, 137.3]
HPI (none)	Radial	-0.9 [-1.6, -0.1]	15.8 [14.6, 16.9]
	Brachial	-0.3 [-2.1, 1.4]	5.9 [4.1, 7.7]
PR (bpm) RMSE	Radial	0.59 [0.23,0.91]	N/A
	Brachial	0.27 [0.10,0.44]	N/A

**Note: The bias and precision measurements for the reported parameters are in reference to FloTrac (minimally-invasive) derived measurements and may not represent the performance of the ClearSight (NIBP) system compared to appropriate reference measurements for CO (e.g,. multiple averaged bolus thermodilution measurements).*

10.9 Output Signal to Patient Monitor

The zero pressure settings page provides the user with the option to send the arterial waveform signal to a bedside patient monitor on the **Patient Monitor** tab.

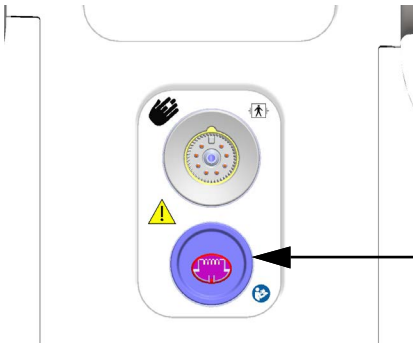
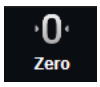


Figure 10-7 Pressure out to external monitor

CAUTION ClearSight system pressure output signal to a patient monitor only intended to be connected to a pressure signal input port of Type BF or CF on the patient monitor that is protected against the effects of a discharge of a cardiac defibrillator. See table 10-5 for symbols that appear next to accepted connection ports.

Table 10-5 Patient monitor connection symbols

Unsafe to connect		Safe to connect	
Appearance	**Description**	**Appearance**	**Description**
	Type B applied part		Defibrillation proof type BF applied part
	Type BF applied part		Defibrillation proof type CF applied part
	Type CF applied part		
 No Symbol	Defibrillation proof type B applied part If no symbol is present next to the patient monitor connection port, do not connect pressure out		

1 Touch the navigation bar **Zero** icon 

→ **ClearSight** technology tab.

2 Plug the compatible pressure-out (DPT) cable into the right panel of the monitor at the pressure out port. The pressure-out (DPT out) port is located below the ClearSight technology connection port. See ⑨ in Figure 10-7 on page 188.

3 Connect the other end of the DPT cable into a compatible patient monitor. Ensure that the selected connector is fully engaged. Refer to the patient monitor instructions for use.

4 Zero patient monitor and confirm 0 mmHg is displayed.
5 Toggle the switch from **Zero** to **Waveform** on the **Patient Monitor** panel of the HemoSphere Alta monitor zero screen.
6 A "**Sending waveform**" message will be displayed when the live waveform is being transmitted to the connected patient monitor.

NOTE Normal interruptions to arterial waveform monitoring, such as during Physiocal, cuff switching, or cuff pressure release mode, can trigger an alert on the patient monitor.

If the ClearSight technology pressure-out sub-system is in a faulted state a notification will appear on the status bar; for example: "ClearSight -Pressure-Out – Hardware Failure." This faulted state status will be communicated to the patient monitor.

Venous Oximetry Monitoring 11

Contents

11.1 Oximetry Cable Overview

The HemoSphere oximetry cable is a reusable device that connects with HemoSphere Alta advanced monitor on one end and any approved Edwards oximetry catheter on the other end. The HemoSphere oximetry cable is a non-contact device and should not touch the patient during normal use. The oximetry cable continuously measures venous oxygen saturation by reflectance spectrophotometry. LEDs within the oximetry cable transmit light fiber optically to the distal end of the catheter. The amount of light absorbed, refracted, and reflected depends on the relative amounts of oxygenated and deoxygenated hemoglobin in the blood. This optical intensity data is gathered by the oximetry catheter, processed by the HemoSphere oximetry cable and displayed on a compatible monitoring platform. Parameter output is mixed venous oxygen saturation (SvO_2) or central venous oxygen saturation ($ScvO_2$).

11.2 Venous Oximetry Setup

Refer to the directions for use provided with each catheter for specific instructions on catheter placement and use, and for relevant warnings, cautions and notes.

Precaution. Unwind the cable carefully while removing it from its packed configuration. Do not pull at the cable to uncoil it. Check that the enclosure door at catheter connection point of the oximetry cable moves freely and latches properly. Do not use the oximetry cable if the door is damaged, open, or missing. If the door becomes damaged, contact Edwards technical support.

The HemoSphere oximetry cable must be calibrated before monitoring. For information on tissue oximetry monitoring, see *HemoSphere Alta Tissue Oximetry Monitoring* on page 198.

1 Connect the HemoSphere oximetry cable to the HemoSphere Alta advanced monitor. The following message will appear:

Venous Oximetry – Cable Initializing, Please Wait

2 If the HemoSphere Alta advanced monitoring platform is not on, turn on the power switch and follow steps for entering patient data. See *Patient Data* on page 118.

3 Remove a section of the catheter tray lid to expose the optical connector.

4 Insert the optical connector of the catheter "TOP" side up into the oximetry cable and snap the enclosure shut.

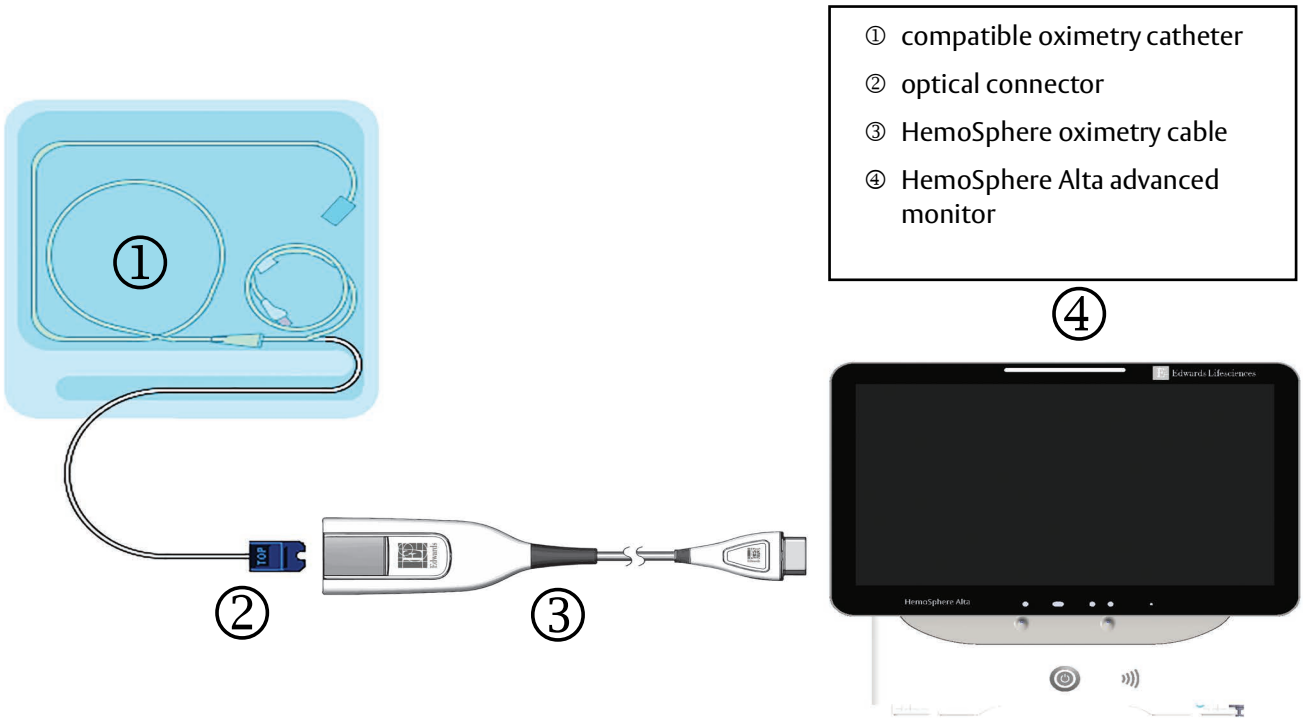


Figure 11-1 Venous oximetry connection overview

NOTE Appearance of catheter shown in figure 11-1 is for example only. Actual appearance may vary depending on catheter model.

When unplugging the HemoSphere oximetry cable from the HemoSphere Alta advanced monitor or catheters from the oximetry cable, always pull at the connection site. Do not pull from cables or use tools to disconnect.

Pulmonary artery and central venous catheters are TYPE CF defibrillation proof APPLIED PARTS. Patient cables that attach to the catheter, such as the HemoSphere oximetry cable, are not intended to be applied parts but may come into contact with the patient and meet the relevant applied part requirements per IEC 60601-1.

CAUTION Make sure that the oximetry cable is securely stabilized to prevent unnecessary movement of the attached catheter.

WARNING Compliance to IEC 60601-1 is only maintained when the HemoSphere oximetry cable (applied part accessory, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator.

Do not wrap the main body of the oximetry cable in fabric or place directly on the patient's skin. The surface does get warm (up to 45 °C) and needs to dissipate heat to maintain its internal temperature level. A software fault will trigger if the internal temperature exceeds its limits.

Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance.

11.3 In Vitro Calibration

In vitro calibration is performed before the catheter is inserted into the patient, using the calibration cup provided in the catheter packaging.

NOTE Once an oximetry cable has been in vitro or in vivo calibrated, faults or alerts can be generated if monitoring venous oximetry without a connected patient catheter.

CAUTION The catheter tip or calibration cup must not get wet before an in vitro calibration is performed.The catheter and the calibration cup must be dry for an accurate oximetry in vitro calibration. Flush the catheter lumen only after the in vitro calibration has been completed.

Performing an in vitro calibration after the oximetry catheter has been inserted into the patient will yield an inaccurate calibration.

1. Touch the oximetry calibration icon  on the **$ScvO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon 

on the navigation bar to show the **Oximetry Setup** screen.
2. Touch **In vitro Calibration** button.
3. On the **In vitro Calibration** screen, enter either the patient's hemoglobin (**HGB**) or hematocrit (**Hct**). Hemoglobin may be entered in either g/dL or mmol/L on the keypad. See Table 11-1 for acceptable ranges.

Table 11-1 In vitro calibration options

Option	Description	Selection range
HGB (g/dL)	Hemoglobin	4.0 to 20.0
HGB (mmol/L)		2.5 to 12.4
Hct (%)	Hematocrit	12 to 60

4. Touch **Calibrate** button to start the calibration process.
5. When the calibration successfully completes, step **3. Catheter Check** will illuminate and the following message appears:
Ensure Catheter is inserted in the patient
6. Insert the catheter as described in the catheter instructions for use.

7 Touch **Start Monitoring** button.

11.3.1 In Vitro Calibration Error

If the HemoSphere Alta advanced monitoring platform is unable to perform an in vitro calibration, an error popup screen appears.

Touch **In vitro Calibration** button to repeat the oximetry calibration process.
OR
Touch **Cancel** button to return to the **Oximetry Setup** menu.

11.4 In Vivo Calibration

Use in vivo calibration to perform a calibration after the catheter has been inserted into the patient.

NOTE This process requires approved personnel to draw waste blood (clearing volume) and a blood sample for laboratory processing. A measured oximetry value must be obtained from a co-oximeter.

For optimal accuracy, in vivo calibration should be performed at least every 24 hours.

Signal quality is displayed during in vivo calibration. It is recommended that calibration be performed only when the SQI level is 1 or 2. See *Signal Quality Indicator* on page 194.

1 Touch the oximetry calibration icon  on the **$ScvO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon 

on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **In vivo Calibration** button.

If setup is unsuccessful, one of the following messages will be displayed:

Wall Artifact or Wedge Detected.
Reposition catheter.
OR
Unstable Signal.
Please Recalibrate.

3 If any of the above error messages are displayed, attempt to troubleshoot the problem as instructed in table 14-28, “Venous oximetry general troubleshooting,” on page 345 and touch **Recalibrate** button to restart the baseline setup.
OR
Touch **Continue** button to proceed to the draw operation.

4 When baseline calibration is successful, touch **Draw** button and then draw the blood sample.

5 Draw the blood sample slowly (2 mL or 2 cc over 30 seconds) and send the blood sample to the lab for measured analysis by co-oximeter.

6 When lab values are received, touch **HGB** button to enter the patient's hemoglobin and touch g/dL or mmol/L or **Hct** button to enter the patient's hematocrit. See Table 11-2 for acceptable ranges.

Table 11-2 In vivo calibration options

Option	Description	Selection range
HGB (g/dL)	Hemoglobin	4.0 to 20.0
HGB (mmol/L)		2.5 to 12.4
Hct (%)	Hematocrit	12 to 60

NOTE When an HGB or Hct value is entered, the system automatically calculates the other value. If both values are selected, the last value entered is accepted.

7 Enter the lab oximetry value (**$ScvO_2$** or **SvO_2**).

8 Touch **Calibrate** button.

11.5 Global Hypoperfusion Index (GHI) Algorithm Feature

The global hypoperfusion index (GHI) algorithm can be activated in Invasive monitoring mode with a connected Swan-Ganz catheter and oximetry cable. The GHI algorithm uses inputs from the CCO or RVCO and oximetry algorithms to determine the GHI value. The global hypoperfusion index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. Future hemodynamic instability correlates to when mixed venous oxygen saturation (SvO_2) drops to 60% or less for one minute. For more information on the GHI algorithm, see *Global Hypoperfusion Index (GHI) Algorithm Feature* on page 194.

11.6 Signal Quality Indicator

Signal quality indicator (SQI) is a reflection of the signal quality based on the catheter condition and position within the vessel. While measuring tissue oximetry, the signal quality is based on the amount of near-infrared light tissue perfusion. The SQI bar boxes fill based on the level of oximetry signal quality. The SQI level is updated every two seconds after oximetry calibration is complete and will display one of four signal levels as described in Table 11-3.

Table 11-3 Signal quality indicator levels

Level	Bars filled	Description
4 - Normal	four	All aspects of the signal are optimal
3 - Intermediate	three	Indicates a moderately compromised signal
2 - Poor	two	Indicates poor signal quality
1 - Unacceptable	one	Indicates a severe problem with one or more aspects of signal quality

Signal quality may be compromised by the following during intravascular oximetry:

- Pulsatility (for example, the catheter tip is wedged)
- Signal Intensity (for example, the catheter is kinked, a blood clot, hemodilution)
- Intermittent vessel wall contact by the catheter

Signal quality is displayed during in vivo calibration and HGB update functions. It is recommended that calibration be performed only when the SQI level is 3 or 4. When SQI is 1 or 2, see *Venous Oximetry Error Messages* on page 342 to determine and resolve the issue.

CAUTION The SQI signal is sometimes affected by the use of electrosurgical units. Attempt to distance electrocautery equipment and cables from the HemoSphere Alta advanced monitoring platform and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call your local Edwards representative for assistance.

11.7 Recall Venous Oximetry Data

Recall Venous Oximetry Data can be used to recall data from the oximetry cable after a patient has been transported away from the HemoSphere Alta advanced monitoring platform. This allows the patients last calibration to be recalled along with the patients demographic data for immediate oximetry monitoring. Calibration data within the oximetry cable must be less than 24 hours old to use this function.

NOTE If patient data has already been entered into the HemoSphere Alta advanced monitoring platform, only system calibration information is recalled. The HemoSphere oximetry cable is updated with current patient data.

1. With the catheter connected to the HemoSphere oximetry cable, unplug the cable from the HemoSphere Alta advanced monitor and transport it with the patient. The catheter should not be disconnected from the oximetry cable.
2. If the oximetry cable is being connected to another HemoSphere Alta advanced monitor, make sure that previous patient data is cleared.
3. Once the patient has been transferred, reconnect the oximetry cable to the HemoSphere Alta advanced monitoring platform and turn it on.
4. Touch the oximetry calibration icon  on the **$ScvO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon 

on the navigation bar to show the **Oximetry Setup** screen.
5. Touch **Recall Oximetry Data** button.
6. If the oximetry cable data is less than 24 hours old, touch **Recall** button to start oximetry monitoring using the recalled calibration information.
   OR
   Touch **Cancel** button and perform an in vivo calibration.

WARNING Before touching the **Recall** button to recall oximetry data, confirm that the displayed data matches the current patient. Recalling incorrect oximetry calibration data and patient demographics will result in inaccurate measurements.

CAUTION Do not disconnect the oximetry cable while calibration or data recall are in process.

7 From the oximetry calibration menu, touch **In vivo Calibration** button to recalibrate the cable. To review patient data that was transported with the oximetry cable, touch the **Patient** button 

on the navigation bar.

CAUTION If the oximetry cable is being transferred from a HemoSphere Alta advanced monitoring platform to another HemoSphere Alta advanced monitoring platform, check that the patient height, weight, and BSA are correct prior to beginning monitoring. Re-enter patient data, if necessary.

NOTE Keep the time and date of all HemoSphere Alta advanced monitoring platforms current. If the date and/or time of the HemoSphere Alta advanced monitoring platform being transported "from" differs from the HemoSphere Alta advanced monitoring platform being transported "to" the following message may appear:
"**Patient data in oximetry cable more than 24 hours old - Recalibrate.**"

If the system needs to be recalibrated, a 10 minute warm up period for the oximetry cable may be required.

11.8 HGB Update

Use the **HGB Update** option to adjust the HGB or Hct value of a previous calibration. The update function can be used only if a previous calibration has been performed, or if the calibration data has been recalled from the oximetry cable.

1 Touch the oximetry calibration icon  on the **$ScvO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon 

on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **HGB Update** button.

3 You can use the displayed HGB and Hct values or touch **HGB** or **Hct** buttons to enter a new value.

4 Touch **Calibrate** button.

5 To stop the calibration process, touch the **Cancel** button.

NOTE To achieve optimal accuracy, we recommended you update the HGB and Hct values when there is a change of 6% or greater in Hct or of 1.8 g/dL (1.1 mmol/L) or greater in HGB. A change in hemoglobin may also affect SQI. Use **HGB Update** to resolve signal quality problems.

11.9 HemoSphere Oximetry Cable Reset

Use HemoSphere oximetry cable reset when the SQI level is continuously low. An oximetry cable reset may stabilize the signal quality. It should be performed only after attempting other actions to resolve the low SQI as defined in Troubleshooting.

NOTE The HemoSphere Alta advanced monitoring platform will not permit an oximetry cable reset before performing a calibration or recalling calibration from the oximetry cable.

1 Touch the oximetry calibration icon  on the **$ScvO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon  on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **Oximetry Cable Reset** button.

3 A progress bar will appear. Do not disconnect the oximetry cable.

11.10New Catheter

Use the **New Catheter** option any time a new catheter is used for a patient. After **New Catheter** is confirmed, oximetry must be re-calibrated. Refer to the directions for use provided with each catheter for specific instructions on catheter placement, calibration type, and use, and for relevant warnings, cautions and notes.

1 Touch the oximetry calibration icon  on the **$ScVO_2$/SvO_2** parameter tile or touch the **Venous Oximetry** icon  on the navigation bar to show the **Oximetry Setup** screen.

2 Touch **New Catheter** button.

3 Touch **Yes** button.

HemoSphere Alta Tissue Oximetry Monitoring 12

Contents

12.1 HemoSphere Alta Tissue Oximetry Monitoring

The ForeSight oximeter cable can be connected to the HemoSphere Alta advanced monitoring platform to enable continuous monitoring of blood oxygen saturation in the tissue (StO_2). The ForeSight oximeter cable is a non-invasive device that measures absolute tissue oxygen saturation. It operates on the principle that blood contains hemoglobin in two primary forms – oxygenated hemoglobin (HbO_2) and de-oxygenated hemoglobin (Hb) – which absorb near-infrared light in different, measurable ways.

Tissue oxygen saturation (StO_2) levels are determined by the ratio of oxygenated hemoglobin to total hemoglobin at the microvascular level (arterioles, venules, and capillaries) in the region to which the sensor is applied:

$$\%StO_2 = \frac{\text{Oxygenated Hemoglobin}}{\text{Total Hemoglobin}} = \frac{HbO_2}{HbO_2 + Hb} \times 100$$

The ForeSight oximeter cable incorporates Edwards technology to project harmless near-infrared light (in five precise wavelengths) through the overlying tissue (e.g. scalp and skull) and into the underlying tissue (e.g. brain) via a disposable sensor on the patient's skin. Reflected light is captured by detectors positioned on the sensor for optimal signal collection. After analyzing the reflected light, the cable provides the tissue oxygen saturation level to the HemoSphere Alta advanced monitoring platform as an absolute number and provides a graphical representation of historical values.

A pulse oximeter only reflects arterial blood oxygen saturation (SpO_2) and requires pulsations to operate; whereas the ForeSight oximeter cable measures even in pulseless conditions and displays the balance of oxygen supply and demand in a target tissue (StO_2), e.g., brain, abdomen, limb muscle. Thus, HemoSphere Alta advanced monitoring platform StO_2 values indicate overall tissue oxygenation state, which provides direct feedback for guiding care interventions.

NOTE The following components may have alternative labeling conventions:
ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).
ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

12.2 ForeSight Oximeter Cable Overview

The following diagrams provide an overview of the ForeSight oximeter cable's physical features.

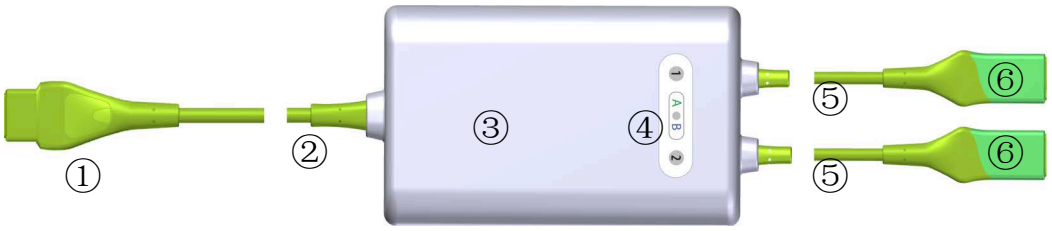


Figure 12-1 ForeSight oximeter cable front view

① monitor connector	③ cable housing	⑤ sensor cables
② monitor cable	④ LED display	⑥ sensor connectors

NOTE The monitor and sensor cables are shown cut; see table A-15 on page 358. For a description of LED status indicators, see *ForeSight Oximeter Cable Sensor Communication* on page 318.

CAUTION Avoid placing the ForeSight oximeter cable where the status LED cannot be easily seen.

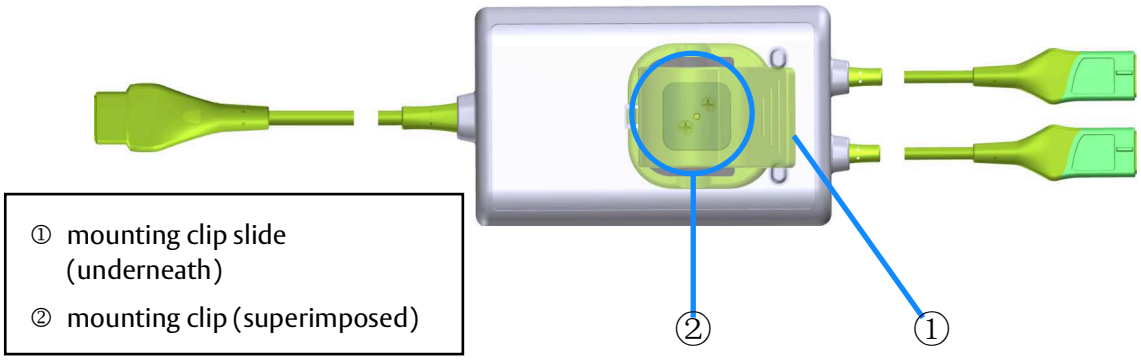


Figure 12-2 ForeSight oximeter cable rear view

NOTE Images of cable housing rear view in this manual are shown without labeling for clarity.

12.2.1 ForeSight Oximeter Cable Mounting Solutions

The ForeSight oximeter cable is packaged with a mounting clip.

Figure 12-3 and figure 12-4 identify attachment points on the mounting clip and cable housing.

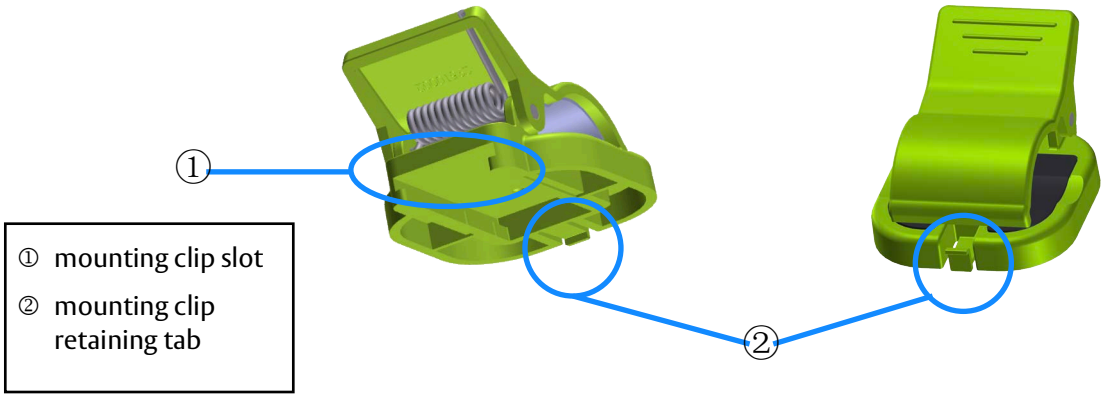


Figure 12-3 Mounting clip attachment points

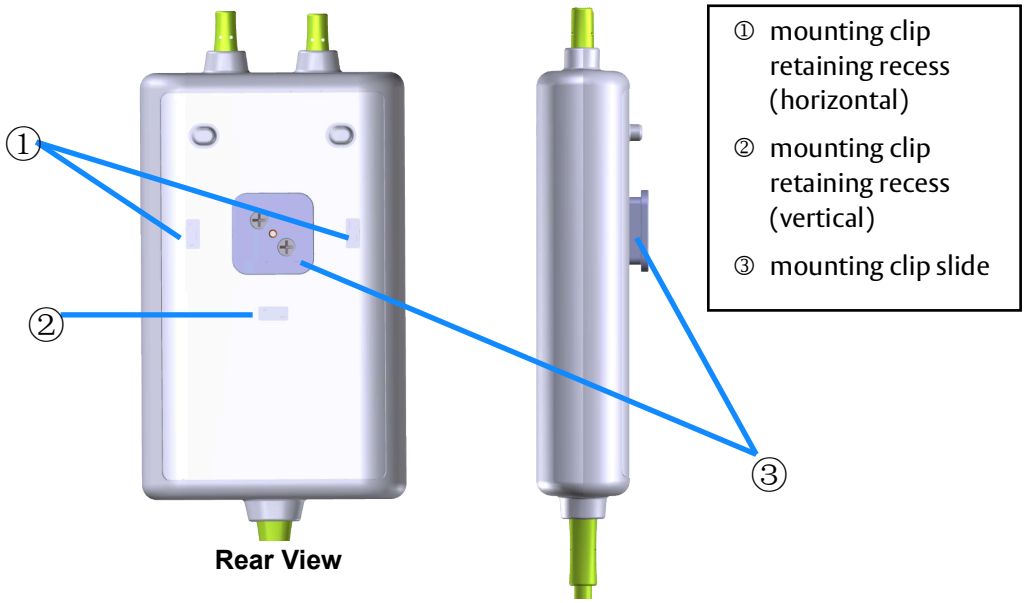


Figure 12-4 Cable housing – mounting clip attachment points

12.2.2 Installing the Mounting Clip

The mounting clip can be attached to the ForeSight oximeter cable either vertically (typical for a bed rail – see figure 12-5) or horizontally (typical for a pole mount – see figure 12-6).

12.2.2.1 Attaching the Mounting Clip Vertically

To attach the mounting clip vertically:

1. On the rear of the cable housing, position the mounting clip with the slot facing the mounting clip slide.
2. Slide the mounting clip towards the top of the cable housing, until the mounting clip retaining tab locks in to the vertical mounting clip retaining recess.

NOTE	The mounting clip is not designed to be attached with the opening facing up.

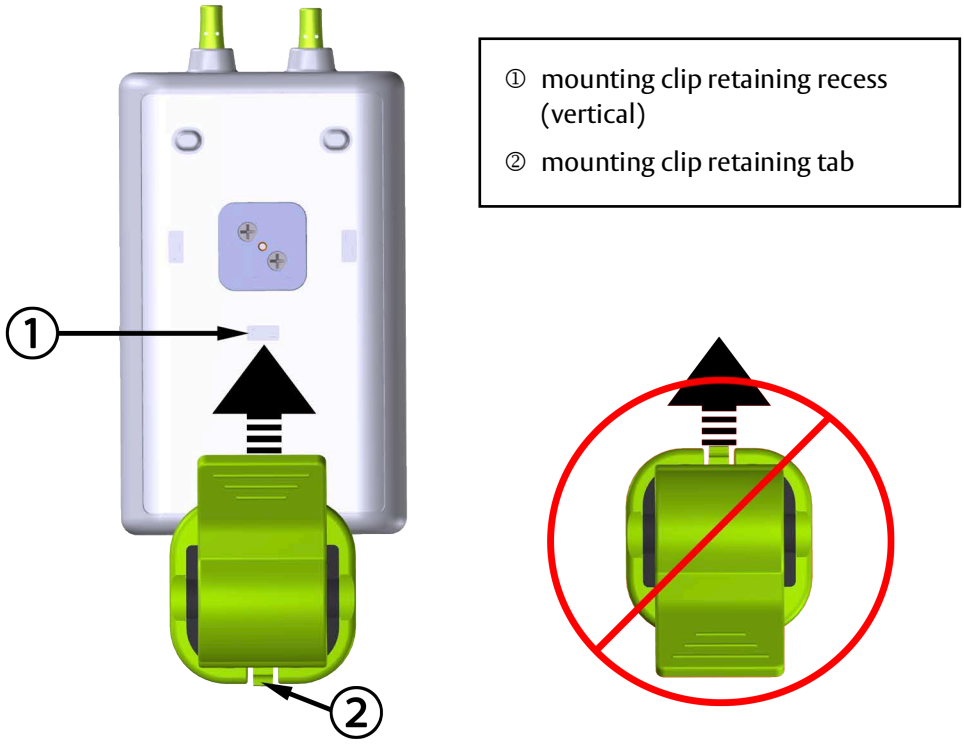


Figure 12-5 Attaching the mounting clip vertically

12.2.2.2 Attaching the Mounting Clip Horizontally

To attach the mounting clip horizontally:

1. Position the mounting clip with the mounting clip retaining tab facing away from the cable housing, from either the left or right.
2. Slide the mounting clip across the rear of the cable housing, until the mounting clip retaining tab locks in to the one of horizontal mounting clip retaining recesses.

NOTE You may attach the mounting clip with the opening facing the left or right side.

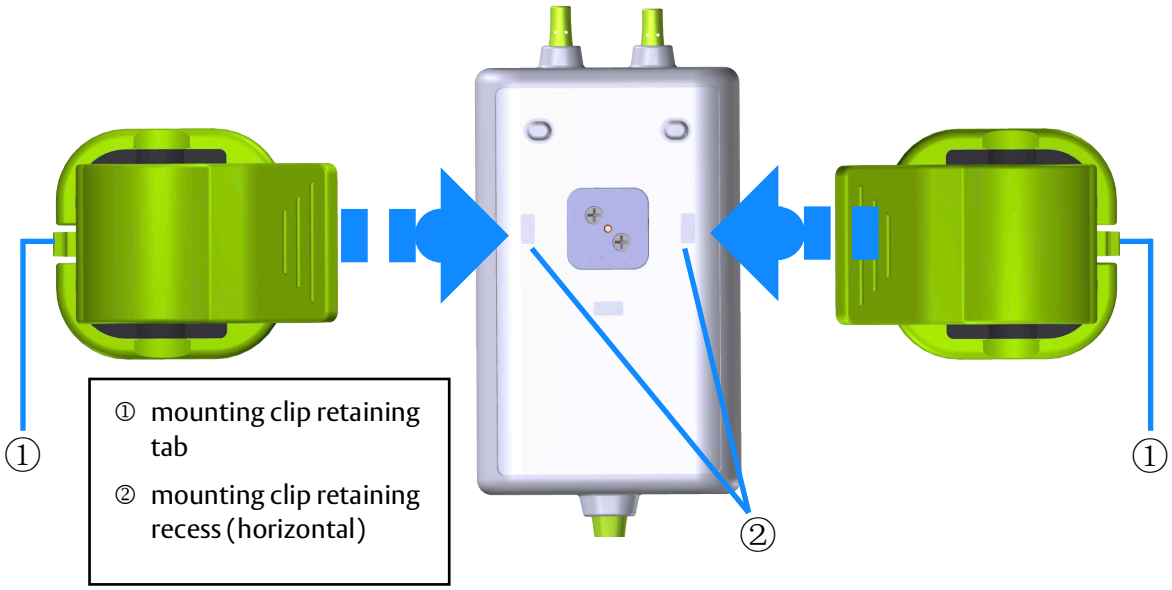


Figure 12-6 Attaching the mounting clip horizontally

12.2.3 Removing the Mounting Clip

To remove the mounting clip from the rear of the cable housing (see figure 12-7 on page 203):

1 Gently lift the mounting clip retaining tab until it disengages from its recess.

CAUTION Applying too much pressure may break the retaining tab, which may present a risk of the cable falling on the patient, bystander, or operator.

NOTE For information on replacement parts, technical support numbers are located on inside cover. See table B-1 on page 363 for approved parts and accessories.

2 Slide the mounting clip in the direction of the mounting clip retaining tab until the mounting clip is free from the mounting clip slide.

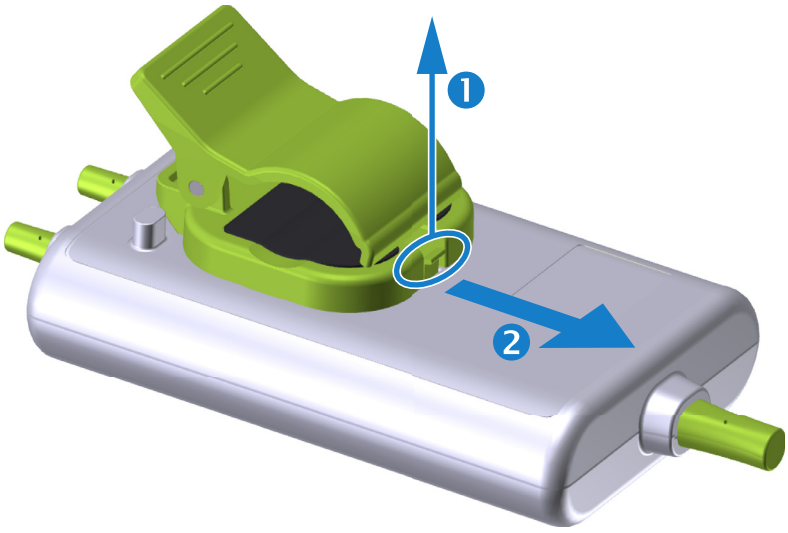


Figure 12-7 Removing the mounting clip

3 Remove the mounting clip from the rear of the cable housing.

CAUTION Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the cable in any position that might present a risk that the cable may fall on the patient, bystander or operator.

Avoid placing the ForeSight oximeter cable under sheets, or blanket that could restrict air flow around the cable that may increase the cable's case temperature and present an injury.

12.3 Connecting the ForeSight Oximeter Cable

The HemoSphere Alta advanced monitoring platform is compatible with a ForeSight oximeter cable and ForeSight/ForeSight Jr sensors.

NOTE The following components may have alternative labeling conventions:

- ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).
- ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

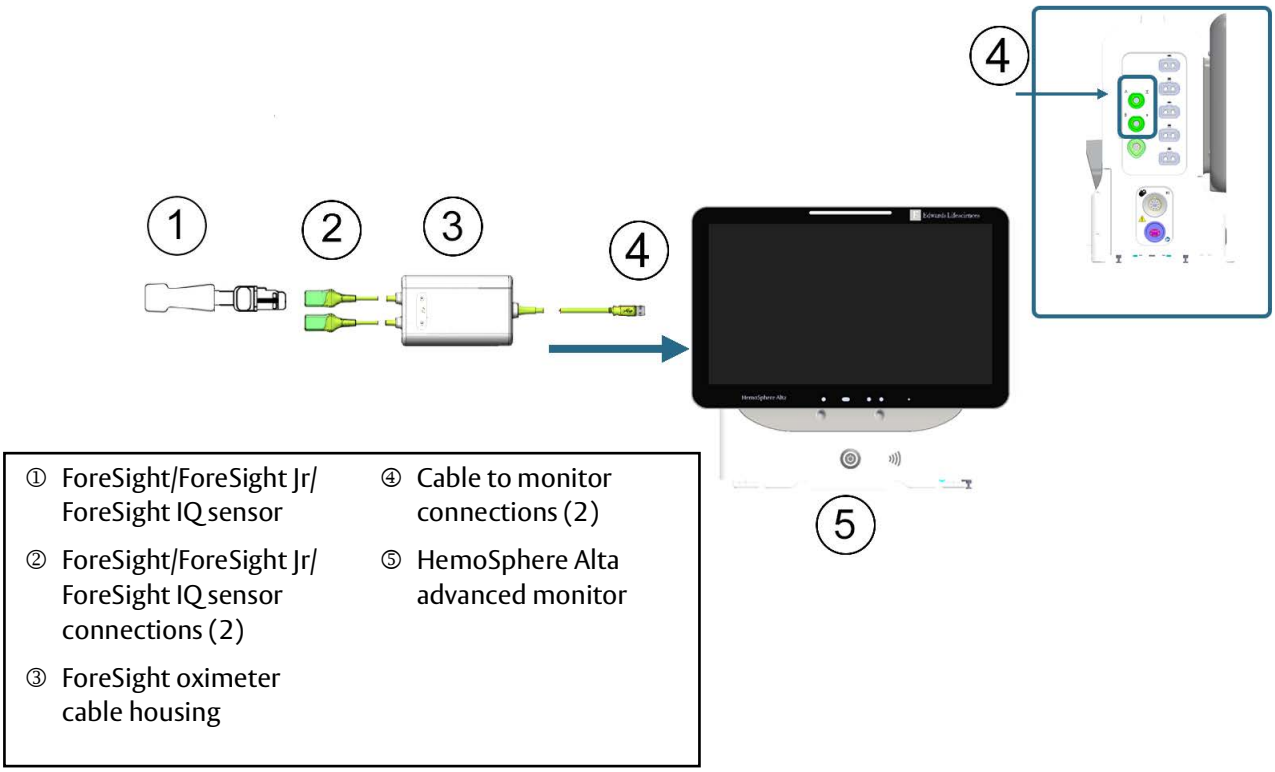


Figure 12-8 Tissue oximetry monitoring connection overview

NOTE

ForeSight/ForeSight Jr/ForeSight IQ sensors are TYPE BF defibrillation proof APPLIED PARTS. Patient cables that attach to the sensors, such as the ForeSight oximeter cable, are not intended to be applied parts but may come into contact with the patient and meet the relevant applied part requirements per IEC 60601-1.

The ForeSight oximeter cable can remain connected to the patient during cardiac defibrillation.

The HemoSphere Alta advanced monitoring platform is shipped with ESD covers for the ForeSight oximeter cable connection ports. After removing them when using the system for the first time, it is recommended that they be kept and used to protect the electrical connection points when the ports are not in use.

WARNING

Compliance to IEC 60601-1 is only maintained when the ForeSight oximeter cable (applied part, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator.

Inspect all of the ForeSight oximeter cable connections for damage prior to installation. If any damage is noted, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical support. There is a risk that damaged parts could reduce the performance of the cable or present a safety hazard.

To remove any chance of contamination between patients, the ForeSight oximeter cable and cable connections should be cleaned after each case.

WARNING To reduce the risk of contamination and cross infection, if the ForeSight oximeter cable or cable connections are grossly contaminated, with blood or other bodily fluids, it should be disinfected. If the ForeSight oximeter cable or cable connections cannot be disinfected, it should be serviced, replaced or discarded. Contact Edwards Technical support.

To reduce the risk of damaging internal elements of the cable assemblies – within the ForeSight oximeter cable housing – avoid excessive pulling, bending or other types of stress on the cable connections.

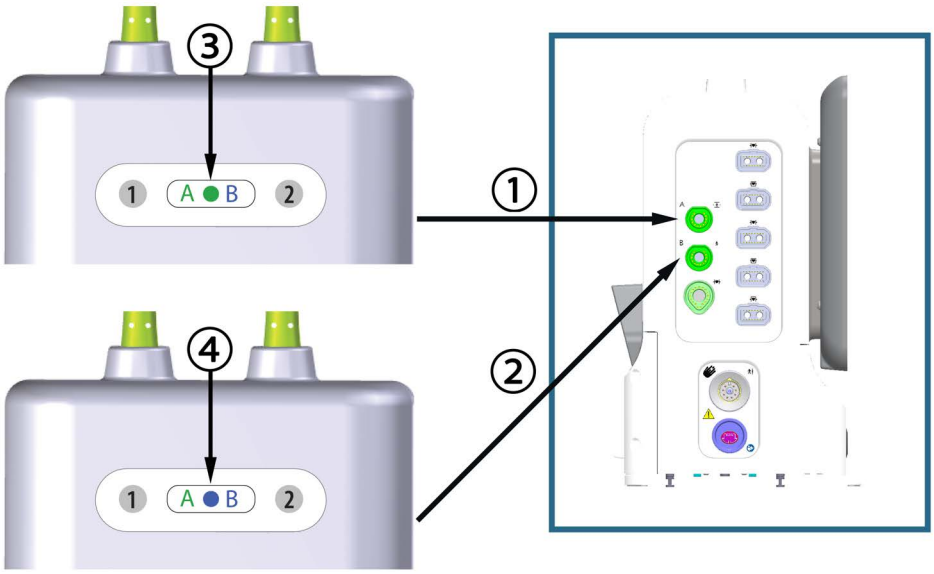
Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance

1. Press the power button to turn on the HemoSphere Alta advanced monitoring platform. All functions are accessed through the touch screen.
2. Ensure proper orientation, then plug the ForeSight oximeter cable into the tissue oximetry port on the left panel of the monitor. See ④ in figure 12-8 on page 204. Up to two ForeSight oximeter cables can be connected to each port.

NOTE The ForeSight oximeter cable only connects one way. If at first the connection does not go in, rotate the connector and try inserting it again.

Do not pull on the ForeSight oximeter cable connections when unplugging it from the HemoSphere Alta advanced monitor.

Once the ForeSight oximeter cable connection has been made to the HemoSphere Alta advanced monitoring platform, the channel 1 and channel 2 status LEDs should turn on. The group status LED will also turn on, indicating the module channels are group A (connected to port A on the left panel of the HemoSphere Alta advanced monitor) or group B (connected to port B on the left panel of the HemoSphere Alta advanced monitor).



① monitor tissue oximetry connection port A

② monitor tissue oximetry connection port B

③ green module group status LED: Channels associated with port A on monitor

④ blue module group status LED: Channels

Figure 12-9 ForeSight oximeter cable status LED

3 Connect the compatible ForeSight sensor(s) to the ForeSight oximeter cable. Up to two ForeSight sensors can be connected to each ForeSight oximeter cable. Available sensor locations are listed in table 12-1. See *Attaching Sensors to the Patient* on page 208 and refer to the ForeSight sensor instructions for use for proper sensor application directions.

4 Add patient data as needed. See *Patient Data* on page 118. Select StO_2 as a key parameter to view monitored tissue oximetry data. See *Parameter Tiles - Parameter Configuration Menu* on page 86.

Table 12-1 Tissue oximetry sensor locations

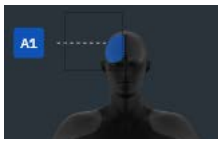
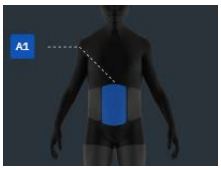
Graphic representation (right)*	Graphic representation (left)*	Adult (≥40 kg) anatomical location* (sensor size)	Pediatric (<40 kg) anatomical location* (sensor size)
		brain (large)	brain (medium/small)
		shoulder (large)	n/a

Table 12-1 Tissue oximetry sensor locations (continued)

Graphic representation (right)*	Graphic representation (left)*	Adult (≥40 kg) anatomical location* (sensor size)	Pediatric (<40 kg) anatomical location* (sensor size)
		arm (large)	n/a
		flank/abdomen (large)	flank/abdomen (medium/small)
		n/a	abdomen (medium/small)
		leg – quadriceps (large)	leg – quadriceps (medium)
		leg – calf (gastrocnemius or tibialis, large)	leg – calf (gastrocnemius or tibialis, medium)

**All sensor location graphic representations are shown for an adult patient except for the abdomen.*

5 If **StO_2** is not a current key parameter, touch the displayed parameter label located inside of any parameter tile to select **StO_2 <Ch>** as a key parameter from the **Select Parameter** menu, where <Ch> is the sensor channel. The channel options are **A1** and **A2** for ForeSight oximeter cable A and **B1** and **B2** for ForeSight oximeter cable B.

6 The channel and sensor location will appear on the left side of the parameter tile. Touch anywhere on the parameter tile to access the parameter configuration window.

7 To change the sensor location or patient monitoring mode, touch the **Sensor Location** tab.

8 Select the Patient monitoring mode: adult or pediatric .

NOTE The sensor mode selection is automatically selected based on the patient's entered body weight. Adult sensor mode is configured for any body weight ≥40 kg.

9 Select the anatomical location of the sensor. See table 12-1 for a list of available sensor locations. The sensor locations are color coded based on the connection port:

- **Green**: Sensor locations for an ForeSight oximeter cable connected to tissue oximeter port A on HemoSphere Alta monitor

- **Blue**: Sensor locations for an ForeSight oximeter cable connected to tissue oximeter port B on HemoSphere Alta monitor

10 Touch the home icon or the return icon Screen on the navigation bar to return to the monitoring screen.

12.3.1 Attaching Sensors to the Patient

The following sections describe how to prepare the patient for monitoring. For additional information on how to apply a sensor to the patient, see the instructions included in the ForeSight/ForeSight Jr sensor packaging.

12.3.1.1 Selecting a Sensor Site

To ensure patient safety and proper data collection, consider the following items when selecting a sensor site.

WARNING Sensors are not sterile and therefore should not be applied on abraded, cracked, or lacerated skin. Exercise caution when applying sensors to a site with delicate skin. Applying sensors, tape or pressure to such a site may reduce circulation and/or cause skin deterioration.

Do not place sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis, pneumoencephalus, or edema.

If electrocautery procedures will be performed, sensors and electrocautery electrodes should be placed as far apart as possible to prevent unwanted skin burns; a distance of at least 15 cm (6 in) is recommended.

CAUTION Sensors should not be placed on high density hair areas.

The sensor must be able to rest flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the sensor and the skin will affect the validity of the data collected and may result in an alarm message.

NOTE Skin pigmentation does not affect the validity of collected data. The ForeSight oximeter cable compensates automatically for skin pigmentation.

In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or X-ray is recommended.

Table 12-2 provides sensor selection guidelines based on patient monitoring mode, patient weight, and body location.

Table 12-2 Sensor selection matrix

Patient Mode	Sensor	Weight	Body Location				
			Brain	Flank	Abdomen	Legs	Arms/ Deltoids
Adult	Large	≥ 40 kg	•	•		•	•
Pediatric	Medium	≥ 3 kg	•	•	•	•	
Pediatric neonatal	Small	< 8 kg	•				
		< 5 kg	•	•	•		

Table 12-2 Sensor selection matrix (continued)

Patient Mode	Sensor	Weight	Body Location				
			Brain	Flank	Abdomen	Legs	Arms/ Deltoids
Pediatric neonatal	Small, non-adhesive	< 8 kg	•				
		< 5 kg	•	•	•		

NOTE If you connect a sensor that is sized inappropriately for the current patient monitoring mode, that channel displays an alert on the status bar. If this is the only sensor connected, you may be prompted to switch modes (adult or pediatric).

If you connect a sensor that is sized inappropriately for the selected body location, that channel displays an alert on the status bar. If this is the only sensor connected, you may be prompted to select a different body location or use a different sensor size.

WARNING Use only Edwards supplied accessories with the ForeSight oximeter cable. Edwards accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the ForeSight oximeter cable. Connecting a non-Edwards sensor will cause an appropriate alert on that channel and no StO_2 values will be recorded.

Sensors are designed for single-patient use, and are not to be reprocessed – re-used sensors present a risk of cross-contamination or infection.

Use a new sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies.

If a sensor seems damaged in any way, it must not be used.

Always read the sensor packaging.

12.3.1.2 Preparing the Sensor Site

To prepare the patient's skin for sensor placement:

1. Verify that the skin area where the sensor is to be placed is clean, dry, intact, and free of powder, oil, or lotion.
2. If necessary, shave hair from skin at the chosen site.
3. Use an appropriate cleanser to gently clean the intended sensor site.
   The large and medium sensor packages include an alcohol pad. Do not use the alcohol pad on newborn or fragile skin.
   You may use Tegaderm or Mepitel under the sensor in patients with delicate skin or edema.
4. Allow the skin to dry completely before applying the sensors.

12.3.1.3 Applying Sensors

1. Select the appropriate sensor (see table 12-2 on page 208) and remove it from the package.

2 Remove and discard the protective liner from the sensor (figure 12-10).

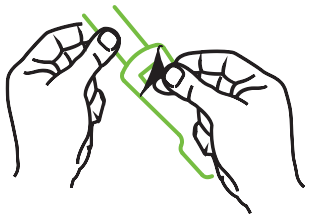


Figure 12-10 Removing protective liner from sensor

NOTE When using the non-adhesive small sensor, you must size and cut the sensor band length to fit the patient.

- Shorten the sensor band away from the patient. Do not cut the sensor band while on the patient, and do not cut any other part of the sensor.
- Attach the sensor band to the patient with the print facing out.
- Do not over-tighten the sensor band, as pressure can be transferred to the baby.

3 Affix the sensor to the patient in the chosen location.

Cerebral Use (figure 12-11): Select the site on the forehead above the eyebrow and just below the hairline where the sensors will be linearly aligned.

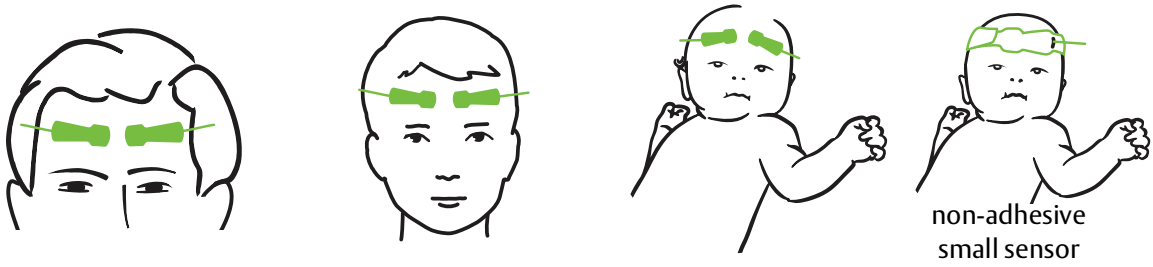


Figure 12-11 Sensor placement (cerebral)

Non-Cerebral Use (figure 12-12): Select the site that provides the ideal access to the desired skeletal muscle tissue (if muscle cannot be palpated, too much adipose or edema may be present).

- Arm: Position sensor over the deltoid (shoulder), biceps (upper arm), or brachioradialis muscle.
- Leg: Position sensor over the quadriceps (upper leg), gastrocnemius (calf), or tibialis (calf) muscle. Apply the sensor with the connector towards the feet.

- Flank/Abdomen: Position Sensor over the Latissimus dorsi (flank) or external oblique (abdomen) muscle.

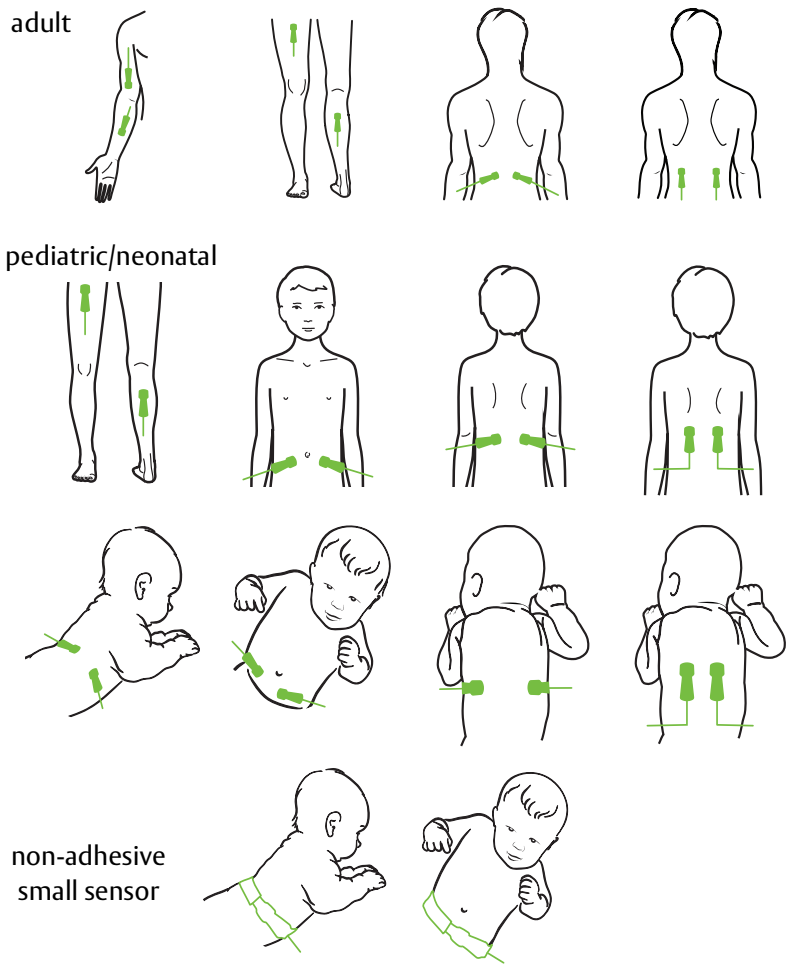


Figure 12-12 Sensor placement (non-cerebral)

NOTE When monitoring muscle tissue, place the sensor centrally over the selected muscle bed (e.g., middle of upper half of the lower leg as diagrammed).

A muscle bed with significant atrophy may not provide enough tissue for monitoring.

When monitoring for the effects of vascular obstruction in a limb, place a sensor on both the limb of concern and in the same location on the opposing limb.

WARNING Exercise extreme care when applying sensors. Sensor circuits are conductive and must not come into contact with other grounded, conductive parts other than EEG or entropy monitors. Such contact would bridge the patient's isolation and cancel the protection provided by the sensor.

Failure to apply sensors properly may cause incorrect measurements. Misapplied sensors or sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

WARNING Do not position a sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the sensor or the patient lying on a sensor) transfers weight from the sensor to the skin, which can injure skin and reduce sensor performance.

The sensor site must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

12.3.1.4 Connecting Sensors to Cables

1. Be sure that ForeSight oximeter cable is connected to the HemoSphere Alta advanced monitoring platform and that sensors are placed correctly on the patient's skin.
2. Use the clips on the sensor cable to secure and prevent the cable from being pulled away from the patient.

WARNING Do not connect more than one patient to the ForeSight oximeter cable. This may compromise the patient's isolation and cancel the protection provided by the sensor.

CAUTION When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection.

Do not lift or pull the ForeSight oximeter cable by any cable connection, or place the ForeSight oximeter cable in any position that might present a risk that the cable may fall on the patient, bystander or operator.

3. Position the sensor connector in front of the sensor cable connector and align the marks on each (figure 12-13).

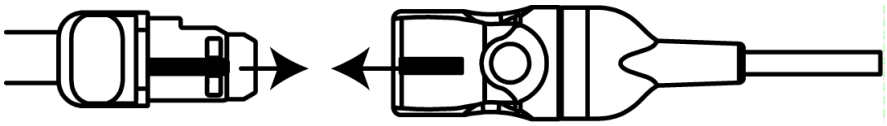


Figure 12-13 Connecting a sensor to the sensor cable connector

4. Gently push the sensor connector straight into the sensor cable connector until it snaps into place.
5. Gently pull back on the sensor to verify the sensor is fully inserted into the connector.

6 Verify that the channel status LED indicator on the ForeSight oximeter cable changes from white to green when the sensor is fully connected. See figure 12-14.

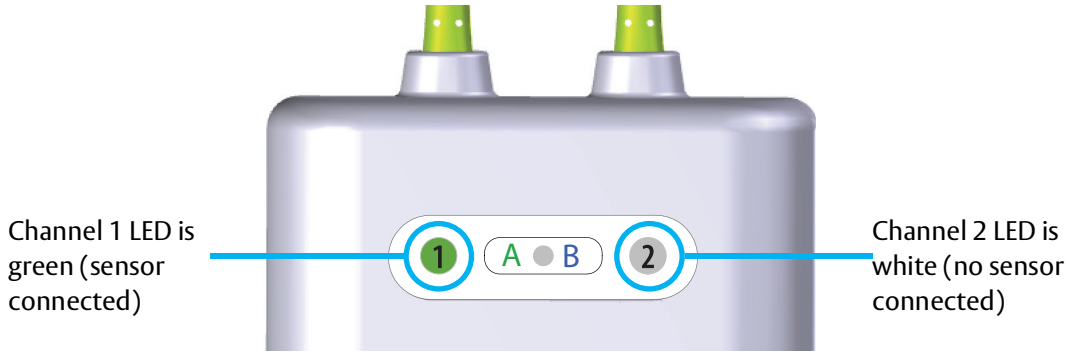


Figure 12-14 Connecting a sensor to the ForeSight oximeter cable – channel status LED

CAUTION Once patient monitoring has started, do not replace the sensor or disconnect the sensor for more than 10 minutes to avoid restarting the initial StO_2 calculation.

NOTE If the ForeSight oximeter cable cannot read sensor data properly after starting a new patient, a message to verify the sensors are properly applied to the patient may be displayed.

Confirm that sensors are properly adhered to the patient and dismiss the message and begin monitoring.

12.3.2 Disconnecting Sensors After Monitoring

Once you are done monitoring a patient, you need to remove the sensors from the patient and disconnect the sensors from the sensor cable as described in the instructions included in the ForeSight/ForeSight Jr/ ForeSight IQ sensor packaging.

12.3.3 Monitoring Considerations

12.3.3.1 ForeSight Oximeter Cable Use During Defibrillation

WARNING The ForeSight oximeter cable has been designed to promote patient safety. All cable parts are "Type BF Defibrillation Proof" and are protected against the effects of the defibrillator discharge and may remain attached to the patient. Cable readings may be inaccurate during defibrillator use and up to twenty (20) seconds thereafter.

No separate actions are required when using this equipment with a defibrillator, but only Edwards-supplied sensors must be used for proper protection against the effects of a cardiac defibrillator.

Do not come into contact with patients during defibrillation, or serious injury or death could result.

12.3.3.2 Interference

CAUTION Measurements may be affected in the presence of strong electromagnetic sources such as electro-surgery equipment, and measurements may be inaccurate during use of such equipment.

Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate or erroneous measurements, as may intravascular dyes or any substance containing dyes that change usual blood pigmentation. Other factors that may affect measurement accuracy include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in the Sensor path, Bilirubinemia, externally applied coloring (tattoos), high levels of HGB or Hct and birthmarks.

When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection.

12.3.3.3 Interpreting StO_2 Values

WARNING If the accuracy of any value displayed on the monitor is questionable, determine the patient's vital signs by alternative means. The functions of the alarm system for patient monitoring must be verified at regular intervals and whenever the integrity of the product is in doubt.

CAUTION When compared to earlier software versions, a ForeSight oximeter cable with a software version of V3.0.7 or later and used with pediatric sensors (small and medium) is more responsive in the display StO_2 values. Specifically, in the range below 60%, StO_2 measurements could be reported lower than in earlier software versions. Clinicians should consider the faster response and potentially modified StO_2 values when using V3.0.7 software, especially if they are experienced with earlier software versions of the ForeSight oximeter cable.

NOTE For patients experiencing complete bilateral external carotid artery (ECA) occlusion, measurements may be lower than expected.

Table 12-3 summarizes the validation methodology associated with the ForeSight oximeter cable.

Table 12-3 StO_2 validation methodology

Patient population	ForeSight sensor	Cerebral reference	Non-cerebral reference	Type measurement	Subject weight range
Adult	Large	Co-oximetry of jugular bulb and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	≥ 40 kg
Pediatric – adolescents, children, infants, and neonates	Medium	Co-oximetry of internal jugular vein and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	≥ 3 kg

Table 12-3 StO_2 validation methodology (continued)

Patient population	ForeSight sensor	Cerebral reference	Non-cerebral reference	Type measurement	Subject weight range
Pediatric – adolescents, children, infants, and neonates	Small	Co-oximetry of internal jugular vein and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	3 to 8 kg
Pediatric – neonates (term, premature, low birth weight, very low birth weight)	Small	FORE-SIGHT MC3010[1]	Co-oximetry of umbilical venous and pulse oximetry samples	StO_2 data averaged in two-minute windows[2]	< 5 kg

[1] Unlike the other ForeSight validation studies, this cerebral validation study did not include invasive measurements because of the challenge for medical centers to obtain consent to insert an internal jugular venous catheter in very small subjects.

[2] StO_2 data was averaged in two-minute windows for term, premature low birth weight (LBW), and very low birth weight (VLBW) neonates for the following reasons: 1) to reduce the influence of acute changes in StO_2 due to changes in body position or touch as the hemodynamics in premature LBW and VLBW neonates are not as stable compared to normal birth weight neonates, and 2) to enable measurements for both FORE-SIGHT MC3010 and ForeSight sensors or across multiple abdominal locations at nominally the same time for the smallest neonates for which only one sensor can be fitted on the head or specific abdominal location at a time.

12.3.4 Skin Check Timer

Tissue oximetry sensor sites must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. The **Skin Check Reminder** displays a reminder every 12 hours, by default. The **Skin Check Reminder** popup is a reminder to assess skin integrity under the sensor and to move the sensor if the blood circulation or skin integrity is compromised at the current sensor site. Touch **OK** after this check is performed and to return to the main monitoring screen. The skin check is logged in the **Events & Intervention** side panel.

The time interval for this reminder can be modified:

1. Touch anywhere in the **StO_2** parameter tile → **Skin Check** tab.
2. Select a time interval between skin check notifications. The options are: **2 Hours**, **4 Hours**, **6 Hours**, **8 Hours** or **12 Hours** (default).
3. To reset the timer, select **Reset** button at the bottom of the Skin check window.

12.3.5 Set Averaging Time

The averaging time used to smooth monitored data points can be adjusted. Faster averaging times will limit the filter of irregular or noisy data points.

1. Touch anywhere in the **StO_2** parameter tile → **Averaging** tab.
2. Select a time interval between skin check notifications. The options are: **Slow (24 seconds)**, **Normal** (default, 16 seconds), **Fast** (8 seconds), and **None** (2 seconds).

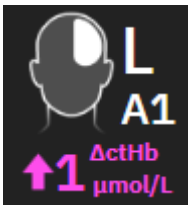
12.3.6 Signal Quality Indicator

The signal quality indicator (SQI), displayed on parameter tiles configured for tissue oximetry is a reflection of the signal quality based on the amount of near-infrared light tissue perfusion. See *Signal Quality Indicator* on page 194.

12.3.7 Relative Change in Total Hemoglobin – ΔctHb

The relative change in total hemoglobin (ΔctHb) is a sub-parameter of StO_2. A trending value, ΔctHb is calculated from the sum of relative changes in oxygenated hemoglobin and deoxygenated hemoglobin (ΔO2Hb and ΔHHb). Each connected tissue oximetry sensor site StO_2 measurement has its own ΔctHb sub-parameter.

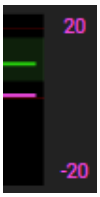
12.3.7.1 ΔctHb Value Display



To display the value of ΔctHb on the StO_2 parameter tile:

1. Touch anywhere in the **StO_2** parameter tile → **ΔctHb Tools** tab.
2. Toggle "**Show ΔctHb Value**" on. The ΔctHb value will be displayed on the StO_2 tile.

12.3.7.2 ΔctHb Trend Display



To display the trend of ΔctHb on the StO_2 parameter trend graph:

1. Touch anywhere in the **StO_2** parameter tile → **ΔctHb Tools** tab.
2. Toggle "**Show ΔctHb Trend Graph**" on. The trend will be plotted in pink with a corresponding y-axis on the right side of the graph.

12.3.7.3 Reset ΔctHb

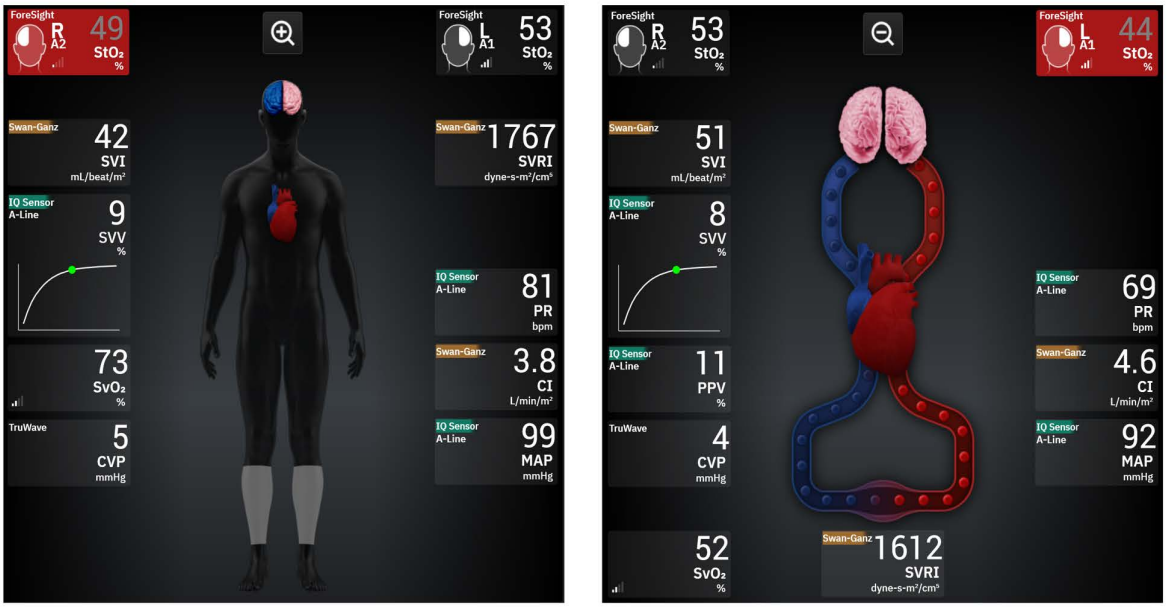
To reset the baseline value of ΔctHb to zero for all channels:

1. Touch anywhere in the **StO_2** parameter tile → **ΔctHb Tools** tab.
2. Touch the **Reset ΔctHb** button.

12.3.8 Tissue Oximetry Physiology Screen

While monitoring with a ForeSight oximeter cable, two physiology screens are available to display the interaction between location specific tissue oximetry values and the cardiovascular system. These two views are shown below in figure 12-15 and are available through the Split monitor view by selecting the physiology icon  . See *Split Screen* on page 89. The default physiology screen while monitoring with the oximeter cable

is the tissue oximetry view, which is shown first in figure 12-15. Touch the magnifying glass to view the just cerebral oximetry and cardiovascular system. To return to the tissue oximetry view, touch the zoom out icon .



① ②

① tissue oximetry

② cerebral oximetry/cardiovascular

Figure 12-15 Tissue Oximetry Physiology Screens

Tissue Oximetry. This view displays monitored tissue oximetry values, including cerebral sensor sites, and any of the monitored cardiovascular parameters displayed on the main physiology screen described in *Split Screen* on page 89.

While a sensor is connected, the color of the location on the body graphic changes color based on the measured value of that connected sensor

- **Red (Upper alarm zone)**. The sensor location (cerebral and somatic) will appear read when the monitored value is above the upper target range limit
- **Blue (lower alarm zone)**. The sensor location (cerebral and somatic) will appear blue when the monitored value is below the lower target range limit
- **Pink (cerebral target zone)**. The cerebral sensor locations appear pink when the monitored values are within target range
- **Gray (somatic target zone)**. Somatic sensor locations appear gray when monitored values are within target range.

Sensor locations on the body graphic are only shaded when a sensor is connected and configured for that location.

Cerebral Oximetry/Cardiovascular. this view is similar to the main physiology screen with the addition of monitored cerebral oximetry values, if available.

12.4 Edwards Algorithm for Measurement of Blood Hemoglobin (tHb Algorithm)

The Edwards algorithm for measurement of blood hemoglobin gives clinicians continuous and non-invasive access to the concentration of total hemoglobin in the blood/circulatory system of patients and can offer many advantages in the assessment of both acute and chronic anemic status in a variety of clinical settings. It can enable clinicians to monitor changes in hemoglobin between invasive blood samples and identify if a patient's blood hemoglobin is stable or increasing/decreasing and consequently allow them to adjust their patient blood management strategies.

The Edwards algorithm for measurement of blood hemoglobin is intended for continuously and non-invasively monitoring total hemoglobin concentration in the blood (tHb). It is derived from the relative changes in tissue hemoglobin (ΔctHb) obtained from the HemoSphere ForeSight oximeter cable and requires an initial calibration. This calibration uses a reference blood hemoglobin measurements obtained from laboratory blood gas analyzers using quality standards for hospital laboratory procedures. After calibration, the algorithm provides the value of total blood hemoglobin (tHb). It relies on the same technological principle for tissue oximetry used by the existing HemoSphere ForeSight oximeter cable.

WARNING tHb measurements should not be used exclusively to treat patients. A review of all of the patient's laboratory blood testing is recommended prior to making clinical decisions. Inconsistent measurements should be supplemented with additional testing to obtain a valid result.

The accuracy of total hemoglobin measurement may be compromised by conditions impacting local blood flow hemodynamics intermittently such as asymmetric carotid stenosis and occurrence of undiagnosed focal stroke during the course of monitoring.

Clinical procedures that inject compounds that have optical absorption characteristics between 660-900 nm, such as indocyanine green (contrast agent) or methylene blue (for treatment of high methemoglobin) may lead to inaccurate or erroneous measurements. A calibration or recalibration of the tHb parameter is recommended after these procedures.

Clinical procedures mitigating elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) or dyshemoglobin through blood transfusion or other means may lead to inaccurate or erroneous measurements. Other factors that may affect measurement accuracy include conditions such as myoglobin, hemoglobinopathies, anemia, sickle cell anemia, pooled blood under the skin, interference from foreign objects in sensor path, bilirubinemia, externally applied coloring, high levels of HGB or Hct and birthmarks. A calibration or recalibration of the tHb parameter is recommended after these procedures.

CAUTION Inaccurate tHb values may be caused by
- Inaccurate relative change in tissue hemoglobin (ΔctHb) measurements
- Inaccurate laboratory blood gas analyzer measurements

12.4.1 Indications for Use

The Edwards algorithm for measurement of blood hemoglobin is indicated for continuously monitoring changes to hemoglobin concentration in the circulating blood of adults ≥40 kg receiving advanced hemodynamic monitoring using HemoSphere ForeSight oximeter cable and non-invasive ForeSight IQ sensors in cerebral locations.

12.4.2 Intended Use

The Edwards algorithm for measurement of blood hemoglobin is intended for use as an adjunct monitor of relative and total hemoglobin concentration of blood in individuals at risk for reduced-flow or no-flow ischemic states in surgical and ICU settings.

NOTE The Edwards algorithm for measurement of Blood Hemoglobin feature has been validated for use in surgical and ICU settings. Device performance outside of these settings has not been validated.

The Edwards algorithm for measurement of Blood Hemoglobin feature can only be used with a compatible Edwards hemodynamic monitoring platform system labeled for use with this software algorithm.

12.4.3 Inputs and Outputs of Edwards Algorithm for Measurement of Blood Hemoglobin

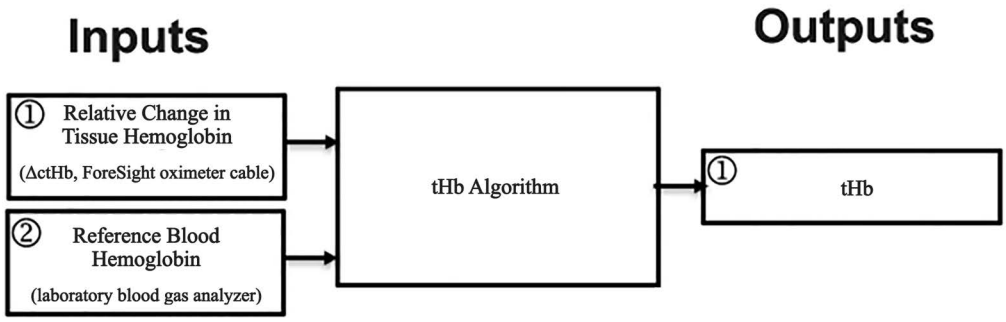


Figure 12-16 Block Diagram of the Edwards algorithm for measurement of blood hemoglobin (tHb Algorithm)

12.4.3.1 Inputs of Edwards tHb Algorithm

The Edwards algorithm for measurement of blood hemoglobin utilizes two inputs:

1 ΔctHb parameter obtained from the ForeSight oximeter cable sampled every 2 seconds. The algorithm will only accept the first input shown from a ForeSight oximeter cable and connected ForeSight IQ large sensors placed in either or both right and left cerebral locations.

2 Reference blood hemoglobin value from a laboratory blood gas analyzer which needs to be inputted for calibration.
This reference value is accepted from any laboratory blood gas analyzer using quality standards for hospital laboratory procedures.

The output of the algorithm is:

1 The total blood hemoglobin (tHb) parameter (after calibrated with reference value)

A higher value of tHb represents a higher concentration of total hemoglobin in the circulatory system of the patient and a lower value indicates a lower hemoglobin concentration. Additionally, the algorithm includes secondary output flags to inform users of the following situations:

- when a calibration should not be performed
- when a new calibration is recommended
- when the input signal (ΔctHb) is unstable.

12.4.4 Total Blood Hemoglobin (tHb) Parameter Display

Total blood hemoglobin (tHb) is selectable as a key parameter for display on the HemoSphere Alta advanced monitoring platform.

1. Connect one or two large ForeSight IQ sensors to the left and/or right cerebral locations. See *Attaching Sensors to the Patient* on page 208.
2. Configure the channel(s) of the ForeSight oximeter cable to left and/or right cerebral locations. See *Connecting the ForeSight Oximeter Cable* on page 203.
3. Touch the **Select Parameter** tab from the parameter configuration menu and select tHb from tissue oximetry section.

Total blood hemoglobin (tHb) is updated every 2 seconds and is provided as a numerical value measured in g/dL of blood. This value is displayed on the monitor as a static numerical value and as a trended value. An example of a calibrated tHb display is shown in figure 12-17.

Figure 12-17 tHb parameter display

Table 12-4 tHb parameter display

Parameter	Specification	
tHb	Units	g/dL
	Update rate	2 seconds
	Accuracy*	A_{RMS}<1 g/dL
	Display range	4.0 to 20.0 g/dL
**Accuracy validated for 6.0 g/dL < tHb < 14.9 g/dL. See Performance Verification Results on page 222.*		

12.4.5 Calibration and Recalibration Steps

The tHb parameter is not displayed at the start of monitoring when configured as key parameter for display. See figure 12-18.

Figure 12-18 tHb parameter display at the start of monitoring

12.4.5.1 Calibration of tHb Parameter

To calibrate tHb:

1. Touch the **Calibrate** icon  on the tHb parameter display.
2. The tHb Calibration screen is displayed. Touch the **Calibrate tHb** button.

NOTE tHb monitoring and calibration can only occur when ΔctHb values are being monitored using one or two large ForeSight IQ sensors configured for left (L) and/or right (R) cerebral locations.

3 Touch the **Draw** button and then draw the blood sample.
4 Send the blood sample to the lab for measured analysis by blood gas analyzer using quality standards for hospital laboratory procedures.
5 When lab values are received enter the patient's hemoglobin or hematocrit. The acceptable input range is from 4.0 to 20.0 g/dL.

NOTE For accurate measurement of total hemoglobin, tHb readings should be calibrated using invasive total hemoglobin values from accurate sources.

6 Touch the **Calibrate** button.
7 A message is displayed after successful initialization to indicate a completed tHb calibration. The parameter display for tHb shows a calibrated tHb value (tHb). See figure 12-17

During monitoring of total blood hemoglobin (tHb), if a recalibration is needed, a calibration recommended Alert appears on the information bar and the calibration exclamation icon will appear on the parameter tile. See figure 12-19.

Figure 12-19 tHB parameter recalibration warning

12.4.5.2 Recalibration of tHb Parameter

To recalibrate tHb:

1 Touch the **Recalibrate** icon on the tHb parameter display.
2 The tHb Recalibration screen is displayed. Touch the **Recalibrate tHb** button.
3 Follow the steps outline for tHb Calibration from baseline (step 3) to successful calibration (step 7).

12.4.6 Algorithm Performance Verification

Retrospective verification testing was performed by comparing simultaneous data from ForeSight and reference blood gas measurements. For each patient, one reference blood hemoglobin measurement was used for deriving and calibrating ForeSight tHb values and the remaining reference values were used for comparison against ForeSight tHb. Accuracy was analyzed using Root Mean Squared Error (RMSE or ARMS) and Bland-Altman analyses. 95% confidence intervals for RMSE were generated based on cluster bootstrapping with resampling of the subjects. 95% confidence intervals for Bland-Altman analyses were calculated using methods that account for between subjects and within subject variation [JM Bland, DG Altman, 1999] and [GY Zou, 2011].

A total of 251 data points (simultaneous ForeSight hemoglobin and reference blood hemoglobin values) were compared from 83 randomly selected surgical patients at 5 different sites (Amsterdam UMC, Amsterdam, The Netherlands; Hospital Universitario Marques de Valdecilla, Santander, Spain; Greenville Memorial Hospital, North Carolina, USA; UC Davis, California, USA; Northwestern University, Illinois USA). Table 12-5 provides the

number of patients for each site as well as the patient demographics including age, gender, height, weight, and race and ethnicity (when not forbidden to collect by local law of the study sites) and the surgery types from all five sites. Full subgroup analyses across other demographic factors, including Race and Ethnicity, are on File at Edwards Lifesciences.

A total of 251 data points (reference blood hemoglobin values from blood gas analyzers) were used for calibration and validation.

Table 12-5 Patient demographics used for verification testing

Site	Number of Patients	Age (years)	Gender	Height (cm)	Weight (kg)	Surgery Type	Race/ethnicity	Reference Device Used*
Amsterdam UMC, Amsterdam, The Netherlands	27	68.7±8	6 Females 21 Males	175.6±9.4	80.5±14	Heart valve replacement (10) Heart valve repair (2) Bentall procedure (2) CABG (12) Other cardiac (1)	Hindustani (1) White (11) Not available (15)	RAPID Point 500 - Siemens Healthcare Diagnostics
Hospital Universitario Marques de Valdecilla, Santander, Spain	8	61.5±14	5 Females 3 Males	163.0±6.7	72.8±12	Heart valve repair (2) Heart valve replacement (5) Other cardiac (1)	Not available (8)	ABL800 flex - Radiometer
Greenville Memorial Hospital, North Carolina, USA	18	60.6±15	4 Females 14 Males	176.5±10.0	90.7±22	Heart valve repair (1) coronary artery disease (6) CABG (8) Open chest heart valve repair (3)	Black or African American (9) White (9)	iSTAT 1 - Abbott
Northwestern University, Chicago, USA	19	58.4±12	5 Females 14 Males	173.7±10.0	84.8±18	Other cardiac (19)	Asian (1) Black or African American (1) Not available (1) Hispanic/Latino (1) White (15)	GEM Premier 5000
UC Davis, Sacramento, USA	11	66.6±12	5 Females 6 Males	168.7±7.2	86.4±25	Vascular (3) Orthopedic (2) Other cardiac (1) Other/ general surgery (5)	Asian (1) Black (1) Hispanic/Latino (1) White (8)	ABL90 - Radiometer

**All reference devices used are FDA cleared for laboratory use and as such, must comply with Clinical Laboratory Improvement Amendments (CLIA) requirements.*

12.4.7 Performance Verification Results

The accuracy of the tHb parameter (RMSE of tHb and ΔtHb when compared to reference blood hemoglobin measurements) was <1 g/dL. The reference hemoglobin values used for comparison ranged from 6.0 to 14.9 g/dL. Results are shown in table 12-6. In addition, Bland-Altman results show bias is close to 0 and precision < 1 g/dL for tHb (table 12-6, figure 12-20). A summary of these results is provided below, with full subgroup analyses across other demographic factors, including Race and Ethnicity, being contained on file at Edwards Lifesciences.

Table 12-6 RMSE and Bland-Altman analysis results comparing tHb with reference blood gas analyzer measurements

	Number of patients	RMSE, g/dL	Bias, g/dL	Precision, g/dL	BA plot
Edwards algorithm for tHb vs. laboratory blood gas analyzer	83	0.77 [0.69, 0.85]	0.07 [-0.03, 0.16]	0.73 [0.66, 0.81]	figure 12-20

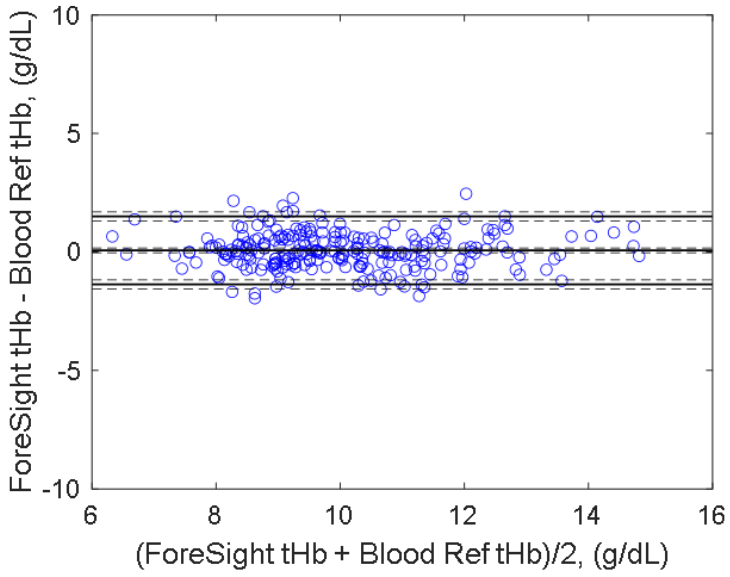


Figure 12-20 Bland-Altman plots of tHb algorithm vs. blood gas analyzer for tHb

The secondary output flags (do not calibrate, recalibrate, or unstable input signal for ΔctHb) were used in the above accuracy analyses to determine when calibration should be performed. In addition, statistical analysis was performed to assess the frequency of when the flag that triggers a "recalibrate" message was set to TRUE and is based on the n=83 patient dataset presented above. As seen in table 12-7, on average, each patient triggered the recalibrate flag 1.5 times during the patient's monitoring time. The average time of the first occurrence of setting the recalibrate flag to TRUE from the first calibration was 78 minutes, and the average time between two consecutive recalibrate flags being set to TRUE was 109 minutes.

Table 12-7 Statistical analysis to assess frequency of the recalibrate flag

	# of times recalibrate flag is set to TRUE per case	First time recalibrate flag is set to TRUE since the first calibration (minutes)	Time between two consecutive ~~R~~recalibrate flags (minutes)
Mean ± Std	1.5 ± 1.5	78 ± 83	109 ± 70
Median [25, 75] percentiles	1 [0.3, 2]	53 [19, 104]	83 [62, 144]

12.4.8 Troubleshooting

The algorithm includes output flags to inform users of the following situations:

- calibration should not be performed
- a new calibration is recommended
- the input signal (ΔctHb) is unstable

The troubleshooting causes and solutions listed in this section are associated with these output flags to inform of common error conditions which are displayed on a compatible monitor's help screens

Table 12-8 tHb calibration and recalibration troubleshooting messages

Message/Icon	Possible causes	Suggested actions
	Total blood hemoglobin (tHb) has not been calibrated	Calibration needed to view total blood hemoglobin (tHb)
	A significant change in ΔctHb monitored by ForeSight oximeter cable detected	Recalibrate tHb to continue accurate monitoring of total blood hemoglobin (tHb)
tHb – Do Not Calibrate	Poor signal quality Calibration is unavailable	Verify patient HGB levels per hospital standard of care Wait for improved signal quality

Clinical Tools and Algorithms 13

Contents

13.1 Acumen Hypotension Prediction Index (HPI) Software Feature

The Acumen Hypotension Prediction Index (HPI) software can be utilized with an Acumen IQ sensor connected or with an Acumen IQ cuff and heart reference sensor (HRS) connected. Due to the differences in performance and indications for use depending up chosen sensor technology, the Acumen Hypotension Prediction Index (HPI) software feature is introduced below based on monitoring technology. Unless otherwise stated, such as the introduction sections below, content in this HPI advanced feature section applies to both monitoring technologies.

13.1.1 Introduction to Acumen Hypotension Prediction Index (HPI) Software in Minimally-Invasive Mode

Acumen Hypotension Prediction Index (HPI) software, when using an Acumen IQ sensor connected to a radial arterial catheter, provides the clinician with information regarding the likelihood of a patient trending towards a hypotensive event and the associated hemodynamics. A hypotensive event is predefined as mean arterial pressure (MAP) < 55, 60, 65, 70, 75, 80, or 85 mmHg for at least one minute. The accuracy of the presented measurements is based upon several factors: the arterial line is reliable (not damped), the connected arterial line pressure sensor is well aligned and properly zeroed, and patient demographics (age, gender, height, and weight) have been accurately entered into the device.

CAUTION The effectiveness of the HPI parameter during minimally-invasive monitoring has been established using radial arterial pressure waveform data. The effectiveness of the HPI parameter using arterial pressure from other sites (e.g., femoral) has not been evaluated.

The Acumen HPI feature is intended for use in surgical and non-surgical patients receiving advanced hemodynamic monitoring. The additional quantitative information provided by using the Acumen HPI feature is for reference only and no therapeutic decisions should be made based solely on the Acumen Hypotension Prediction Index (HPI) parameter.

Precaution. If in the clinician's judgment, a mean arterial pressure (MAP) value of < 55, 60, 65, 70, 75, 80, or 85 mmHg would not be meaningful for an individual patient, the clinician may choose to disable the HPI feature completely from the HPI settings menu, or if the information available on the secondary screen is useful, may choose to silence the HPI alarm from the **Parameter Settings** screen.

When enabled, the HPI smart alerts and smart trends feature can assist clinicians in the identification of potential underlying mechanism(s) that may be possible targets for intervention to prevent or treat hypotension based on review of the patient's complete hemodynamic state before treatment. These mechanisms include preload, contractility, and afterload. See *HPI Smart Alerts and Smart Trends* on page 236 for more information. When HPI alarms, the HPI high alert popup and smart trends screen display smart alerts for linked parameters.

NOTE When using both HPI smart alerts and AFM simultaneously, it is important to consider that HPI smart alert behaviors are based upon identification of potential underlying mechanism(s) to prevent or treat hypotension, while AFM fluid recommendation behavior is based upon a prediction of fluid responsiveness. As such, these two software features are considering different targets and patient hemodynamic conditions, and should be considered independently. Current patient hemodynamics should be reviewed prior to determining the most appropriate course of action. See *Assisted Fluid Management* on page 278 for more information on that feature.

CAUTION Inaccurate FT-CO measurements can be caused by factors such as:

- Improperly zeroed and/or leveled sensor/transducer
- Over- or under-damped pressure lines
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  - Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure, including but not limited to:
  - Extreme peripheral vasoconstriction which results in a compromised radial arterial pressure waveform
  - Hyperdynamic conditions as seen in post liver transplant
- Excessive patient movement
- Electrocautery or electrosurgical unit interference

Aortic valve regurgitation may cause an over estimation of Stroke Volume / Cardiac Output calculated depending on the amount of valvular disease and the volume lost back into the left ventricle.

13.1.2 Introduction to Acumen Hypotension Prediction Index (HPI) Software in Non-Invasive Mode

The Edwards Acumen Hypotension Prediction Index (HPI) feature provides the clinician with physiological insight into a patient's likelihood of future hypotensive events (predefined as mean arterial pressure < 55, 60, 65, 70, 75, 80, or 85 mmHg for at least one minute in duration) and the associated hemodynamics. The Acumen HPI feature is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring. The Acumen HPI feature is considered to be additional quantitative information regarding the patient's physiological condition for reference only and no therapeutic decisions should be made based solely on the Acumen Hypotension Prediction Index (HPI) parameter.

The accuracy of the Acumen Hypotension Prediction Index (HPI) software, when using an Acumen IQ finger cuff and heart reference sensor (HRS), is based upon several factors: the finger cuff has been properly sized and placed, the HRS has been properly zeroed and positioned. and patient demographics (age, gender, height, and weight) have been accurately entered into the device.

NOTE Cuff sizing may not be applicable to all cuffs.

Precaution. If in the clinician's judgment, a mean arterial pressure (MAP) value of < 55, 60, 65, 70, 75, 80, or 85 mmHg would not be meaningful for an individual patient, the clinician may choose to disable the HPI feature completely from the HPI settings menu, or if the information available on the secondary screen is useful, may choose to silence the HPI alarm from the **Parameter Settings** screen.

Clinical validation studies (see *Clinical Validation with Hypotension Threshold in Non-Invasively Monitored Patients* on page 249) demonstrate that ClearSight (NIBP) HPI is accurate and hence useful across the typical range of variation of patient hemodynamics and clinical practice for surgical and non-surgical procedures. The surgery types, surgical characteristics and non-surgical patient conditions studied are identified in table 13-20 on page 249 and table 13-23 on page 251 to inform clinicians of the patient populations studied.

When enabled, the HPI smart alerts and smart trends feature can assist clinicians in the identification of potential underlying mechanism(s) that may be possible targets for intervention to prevent or treat hypotension based on review of the patient's complete hemodynamic state before treatment. These mechanisms include preload, contractility, and afterload. See *HPI Smart Alerts and Smart Trends* on page 236 for more information. When HPI alarms, the HPI high alert popup and smart trends screen display smart alerts for linked parameters.

NOTE When using both HPI smart alerts and AFM simultaneously, it is important to consider that HPI smart alert behaviors are based upon identification of potential underlying mechanism(s) to prevent or treat hypotension, while AFM fluid recommendation behavior is based upon a prediction of fluid responsiveness. As such, these two software features are considering different targets and patient hemodynamic conditions, and should be considered independently. Current patient hemodynamics should be reviewed prior to determining the most appropriate course of action. See *Assisted Fluid Management* on page 278 for more information on that feature.

CAUTION Inaccurate non-invasive measurements can be caused by factors such as:

- Improperly zeroed and/or leveled HRS
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:
  - Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure
- Poor blood circulation to the fingers.
- A bent or flattened finger cuff.
- Excessive patient movement of fingers or hands.
- Artifacts and poor signal quality.
- Incorrect placement of finger cuff, position of finger cuff, or finger cuff too loose.
- Electrocautery or electrosurgical unit interference.

13.1.3 Acumen Hypotension Prediction Index Parameters Overview

The Acumen Hypotension Prediction Index parameter, HPI, which can be configured as a key parameter on all monitoring screens, displays as an integer value ranging from 0 to 100, with higher values indicating a higher likelihood of a hypotensive event. In addition, the Acumen Hypotension Prediction Index (HPI) software provides three additional configurable parameters, dP/dt, Ea_{dyn}, and PPV, which together with SVV, provide decision support based upon preload responsiveness [SVV or PPV], contractility [dP/dt], and afterload [Ea_{dyn}]. Refer to *Acumen Hypotension Prediction Index (HPI) Parameter Display* on page 229, *HPI Algorithm Side Panel* on page 234, and *Clinical Application* on page 238, for additional information regarding SVV, dP/dt and Ea_{dyn}.

Like other monitored parameters, the HPI value updates every 20 seconds. When the HPI value exceeds 85, a high priority alarm is initiated. If the HPI value exceeds 85 for two consecutive readings (total of 40 seconds), an HPI High Alert popup appears on the screen recommending a review of the patient hemodynamics. Hemodynamic information associated with hypotension is available for the user on the HPI secondary screen located on the clinical tools side panel. That information includes several key parameters (MAP, CO, SVR, PR, and SV), as well as more advanced indicators of preload, contractility, and afterload (SVV or PPV, dP/dt, Ea_{dyn}). Additionally, the patient hemodynamics may also be assessed by review of currently configured key parameters, as for example, SVV, PPV, CO and SVR.

Once the Acumen HPI feature is activated, the user can choose to configure Acumen Hypotension Prediction Index (HPI) as a key parameter, display it on the Information Bar, or choose not to display it. dP/dt, Ea_{dyn}, and PPV can also be configured as key parameters.

Refer to the HPI as a Key Parameter and HPI in the Information Bar sections for information about configuring the parameter. See *HPI as a Key Parameter* on page 230 and *HPI on Information Bar* on page 232.

The alarm and alert functions for HPI will differ with the chosen display option for HPI as described in table 13-1.

Table 13-1 HPI display configurations

Display option	Audible and visual alarm	Alert popup
Key Parameter	Yes	Yes
Information Bar	No	Yes
Not displayed	No	No

Unlike other monitored parameters, the HPI alarm limits are not adjustable, as HPI is not a physiologic parameter with a selectable target range (as with cardiac output, for example), but rather a likelihood of physiological state. The alarm limits are displayed to the user in the software, but the controls to change the alarm limits are disabled. The alarm limit for the HPI parameter (>85 for red alarm range) is a fixed value that may not be modified. The yellow target limit for the HPI parameter (50<HPI≤ 85 for yellow target range) is also a fixed value that may not be modified.

The visual and audible cues available to the user when the HPI value is >85 (red alarm range) result from the analysis of multiple variables from an arterial pressure waveform and patient demographic information, and application of a data-driven model developed from retrospectively annotating hypotensive and non-hypotensive episodes. The HPI alarm limit is provided in table 13-2 on page 229 and in table D-4 on page 375. The algorithm performance characteristics for the alarm threshold of 85 are provided in table 13-14 and table 13-15 (minimally-invasive), and table 13-24 and table 13-27 (non-invasive), included in the clinical validation section.

The parameters dP/dt, Ea_{dyn}, and PPV can be configured as key parameters. PPV and dP/dt behave as other monitored parameters, however Ea_{dyn} is not an alarmable parameter. Alarm/target ranges are unavailable for Ea_{dyn} and target status indicators appear white at all times. A dashed line appears at a value of 0.8 on the Ea_{dyn} graphical trend plot for reference.

13.1.4 Acumen Hypotension Prediction Index (HPI) Parameter Display

The HPI value will update every 20 seconds and displays as a value equating to the likelihood that a hypotensive event may occur on a scale from 0 to 100. The higher the value, the higher the likelihood that a hypotensive event (predefined as mean arterial pressure < 55, 60, 65, 70, 75, 80, or 85 mmHg for at least one minute) will occur.

The HPI parameter uses data from the first ten minutes of monitoring to establish a 'base value.' Device performance during these first ten minutes may differ as a result. Table 13-2 provides a detailed explanation and interpretation of HPI graphical display elements (trendline, dial segment [cockpit display], audible alarms, and parameter value [tile display]) and recommended user action when HPI is configured as a key parameter.

WARNING The Acumen Hypotension Prediction Index, HPI, should not be used exclusively to treat patients. A review of the patient's hemodynamics is recommended prior to initiating treatment.

Table 13-2 HPI value graphical and audible display elements

HPI value	Graphical display elements	Audible	General interpretation	Recommended user action
HPI ≤50	White	None	Patient hemodynamics indicate that there is a low to moderate likelihood of a hypotensive event occurring. A low HPI value does not exclude a hypotensive event from occurring for surgical patients in the next 5-15 minutes or non-surgical patients in the next 20-30 minutes (minimally-invasive radial arterial line monitoring only) regardless of MAP value.	Continue monitoring patient hemodynamics. Remain vigilant with respect to changing patient hemodynamics using the primary monitoring screen, HPI secondary screen, HPI, and trends in parameters and vital signs.
50<HPI ≤85	Yellow	None		
HPI >85	Red (flashing)	High priority alarm tone	Surgical patient has a high likelihood of experiencing a hypotensive event within 15 minutes Non-surgical patient has a high likelihood of experiencing a hypotensive event within 20 minutes (minimally-invasive radial arterial line monitoring only)	Check patient hemodynamics using the secondary screen and other primary screen parameters in order to investigate the potential cause of the high likelihood of hypotension in order to inform a potential course of action
HPI >85 and persists for two continuous readings (40 seconds)	Red (flashing) Popup	High priority alarm tone	Surgical patient has a high likelihood of experiencing a hypotensive event within 15 minutes Non-surgical patient has a high likelihood of experiencing a hypotensive event within 20 minutes (minimally-invasive radial arterial line monitoring only)	Acknowledge popup by chosen method Check patient hemodynamics using the secondary screen and other primary screen parameters in order to investigate the potential cause of the high likelihood of hypotension in order to inform a potential course of action
HPI =100	Red (flashing) Popup	High priority alarm tone	Patient is hypotensive	Acknowledge popup by chosen method Check patient hemodynamics using the secondary screen and other primary screen parameters in order to investigate the potential cause of the hypotension in order to inform a potential course of action

NOTE If HPI is displayed on the Information Bar the graphical display element changes will not change color nor alarm. Instead the user will only be notified when HPI exceeds 85 for consecutive updates by displaying the HPI High Alert Popup.

13.1.5 HPI as a Key Parameter

With an Acumen IQ sensor or cuff connected, HPI can be configured as a key parameter using the steps described in *Change Parameters* on page 86.

The display of HPI differs in several ways from other key parameters. Display of other key parameters is described in *Status Indicators* on page 88.

Table 13-3 describe the similarities and differences between HPI and other key parameters.

Table 13-3 HPI versus other key parameters: similarities and differences

Similarities	Differences
• Values update every 20 seconds • Audible alarm when > alarm limit • Visual alarm when > alarm limit • Can display % change, if configured • Audible alarm can be disabled	• HPI key parameter tile does not have green target color in colored font, depending on clinical/alarm indicator status • HPI key parameter tile has shortcut key in top-right corner to provide direct access to HPI Secondary Screen • HPI will display Alert popup when HPI exceeds high alarm limit for two consecutive updates or HPI value is 100 • HPI only available as key parameter if activation key entered • HPI alarm or yellow target limit is not adjustable • HPI does not have a target, green-shaded region with red arrows at the upper and lower limits when displayed as a trend on the main monitoring screen because it is not a physiologic parameter with a target range. Instead HPI is a quantitative indication of physiological status used to inform users of patient likelihood of trending toward a hypotensive event. Specifically: * When HPI is less than or equal to 50, the graphic elements (displayed number trend line or dial segment) are white and clinician should continue monitoring patient hemodynamics using the primary monitoring screen, HPI secondary screen, HPI, and trends in parameters and vital signs. * When HPI is greater than 50 and less than or equal to 85, the graphic elements (displayed number trend line or dial segment) are yellow and clinician should continue monitoring patient hemodynamics using the primary monitoring screen, HPI secondary screen, HPI, and trends in parameters and vital signs. * When HPI exceeds 85, the graphical elements (displayed number, trend line, or dial segment) appear red indicating the user should check patient hemodynamics using the secondary screen and other monitoring screen parameters in order to investigate the potential cause of the high likelihood of hypotension (or hypotension if HPI = 100) in order to inform a potential course of action • HPI has four parameter status colors: gray, white, yellow, and red. See table 13-4.

Figure 13-1 HPI key parameter tile

HPI will be displayed as shown in figure 13-1 when configured as a key parameter in all screens except the cockpit screen (figure 13-2). For more information about the cockpit screen, see *Cockpit Screen* on page 93.

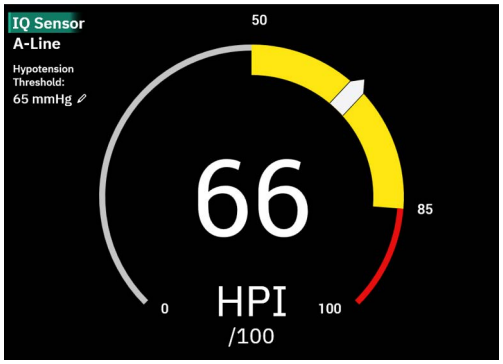


Figure 13-2 HPI key parameter on cockpit screen

On all monitoring screens, the font color of the parameter value denotes parameter status as shown in table 13-4. On the cockpit screen, HPI has the same alarm and target ranges, but it is displayed as shown in figure 13-2.

Table 13-4 Parameter status colors for HPI

Parameter status color	Lower limit	Upper limit
Gray	Fault condition	
White	10	50
Yellow	51	85
Red/Gray Flashing	86	100

13.1.6 HPI Alarm

When HPI is configured as a key parameter and exceeds the upper threshold of 85, a high priority alarm will activate which indicates to the user that the patient may be trending towards a hypotensive event. This includes an alarm tone, red parameter status color, and flashing parameter value. The alarm limit of HPI shown in table 13-4 divides the display range into areas of lower and higher likelihood of hypotension. HPI uses features extracted from Acumen IQ measurements, some compared to an initial base value determined over the first 10 minutes of the patient monitoring session, to a data-driven model developed from retrospective analysis of an arterial waveform database collected from ICU and surgical patients containing annotated hypotensive (predefined as mean arterial pressure < 55, 60, 65, 70, 75, 80, or 85 mmHg for at least 1 minute) and non-hypotensive events. HPI is displayed as an integer value between 0 and 100. The assessment of hypotension likelihood using HPI should consider both the displayed value along the range from 0 to 100 and the associated parameter color (white/red). As with other available alarms on the HemoSphere Alta advanced monitoring

platform, the volume of the HPI available alarm is adjustable. See *Alarms/Targets* on page 123 for information about silencing the alarm and configuring the alarm volume. Occurrence of HPI alarm will be logged in the data download file following an update with HPI exceeding the alarm limit.

CAUTION The HPI parameter may not provide advanced notice of a trend towards a hypotensive event in situations where a clinical intervention results in a sudden non-physiological hypotensive event. If this occurs, the HPI feature will provide the following without delay: a high alert popup, a high priority alarm, and an HPI value of 100 will be displayed indicating that the patient is undergoing a hypotensive event.

13.1.7 HPI on Information Bar

When HPI is not configured as a key parameter, the parameter value is still computed and displayed on the information bar as shown in figure 13-3.

① Computed and displayed HPI value

Figure 13-3 Information bar with HPI

13.1.8 Disable HPI Information Bar Indicator

To disable the HPI information bar indicator:

1. Navigate to the HPI secondary screen on the side panel (see *Navigate to HPI Algorithm Side Panel* on page 235)
2. Touch the HPI settings icon .
3. Disable the **Always Show HPI** option button..

The HPI feature remains available even when HPI is not displayed on the screen. If HPI is configured as a key parameter, the parameter will alarm and alert as described in *HPI Alarm* on page 231.

13.1.9 HPI Algorithm High Alert Notification

When HPI parameter exceeds 85 for two consecutive 20-second updates or reaches 100 at any time, the HPI algorithm high alert notification becomes active. See figure 13-4. This notification covers the side panel section of the screen and recommends a review of patient hemodynamics. It displays either when HPI is configured as a key parameter or appears on the information bar.

WARNING The Acumen Hypotension Prediction Index, HPI, should not be used exclusively to treat patients. A review of the patient's hemodynamics is recommended prior to initiating treatment.

To review patient hemodynamics on the HPI algorithm side panel (see *HPI Algorithm Side Panel* on page 234) and acknowledge the HPI algorithm high alert notification, touch the **Review** button. To acknowledge the HPI high alert notification without reviewing patient hemodynamics on the HPI algorithm side panel, touch the **Acknowledge** button.

Upon acknowledgment, the following will occur:

- The notification will disappear
- The HPI alarm tone will be silenced for as long as the alert is active.
- The HPI high alert is acknowledged.

The **Review** button is enabled when any monitoring screen is displayed. If the **Review** button on the HPI algorithm high alert notification is touched, the HPI algorithm side panel is displayed. When the **Review** button is disabled, the HPI algorithm side panel can still be accessed as described in *Navigate to HPI Algorithm Side Panel* on page 235.

To disable the HPI algorithm high alert side panel, see *Disable HPI Information Bar Indicator* on page 232.

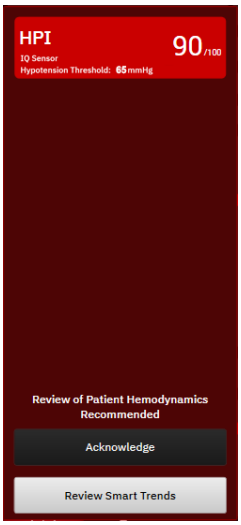


Figure 13-4 HPI high alert notification

13.1.10 Hypotension Threshold Setting

To change the MAP threshold used to determine the HPI parameter value, navigate to the HPI settings screen by touching one of the following:

- the edit icon on the HPI parameter tile

  or

- **Clinical Tools** icon → **Hypotension Prediction Index** button→ settings icon on the bottom of the HPI algorithm side panel

  If another clinical tool is active, use the drop down menu to select **Hypotension Prediction Index**.

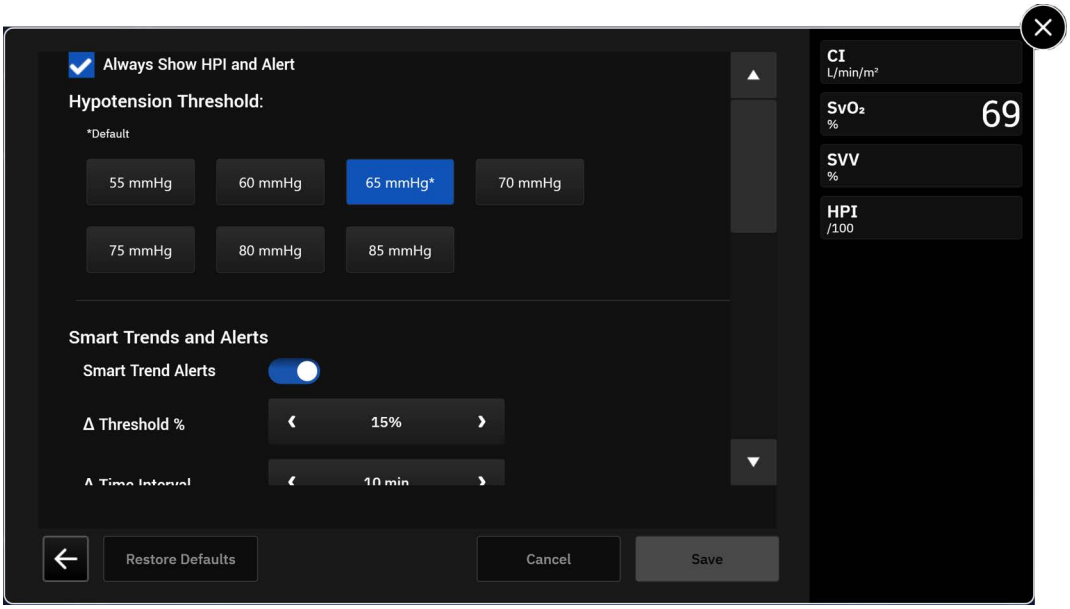


Figure 13-5 HPI parameter hypotension threshold settings screen

Select one of the following Hypotension Threshold menu options: **55**, **60**, **65**, **70**, **75**, **80**, or **85 mmHg**. The default value is **65 mmHg**. Touch **Save** to commit a new hypotension threshold. The selected value will be displayed on the parameter tile (see figure 13-1 on page 231) and on the high alert notification (see figure 13-4 on page 233)

13.1.11 HPI Algorithm Side Panel

The HPI algorithm side panel provides hemodynamic information about the patient. It may be a useful tool to quickly review the patient hemodynamics related to hypotension. This side panel may be accessed at any time during hemodynamic monitoring with an Acumen IQ sensor or Acumen IQ cuff.

The HPI secondary screen has one viewing modes:

- **Minimal**. Displays the three parameter configured for Preload, Afterload and Contractility

Touch the expand icon  to view two additional viewing modes on the secondary screen:

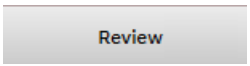
- **Smart Trend**. A graphical display of the three parameters configured for Preload, Afterload, and Contractility along with their current smart alert status
- **Relationship.** A display of all Acumen IQ sensor or cuff monitored hemodynamic parameters categorized by Preload, Afterload, and Contractility or by their relationship to Preload, Afterload or Contractility parameters.

To toggle between these views, touch the arrows () to scroll through and select the secondary screen display option.

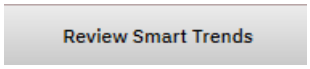
The HPI algorithm side panel, along with other key parameters on the monitoring screen, can be used to provide potential insight into the cause of a high hypotension likelihood or hypotension when such an event occurs.

13.1.11.1Navigate to HPI Algorithm Side Panel

To access the HPI algorithm side panel, touch one of the following:

- **Clinical Tools** icon  → **Hypotension Prediction Index** button. If another clinical tool is active, use the drop down menu to select **Hypotension Prediction Index**.
- **Review** button  on HPI algorithm high alert side notification

  or

  Review Smart Trends button  (Smart Trends enabled) on the HPI high alert popup.
- HPI information bar indicator button  on information bar.

NOTE	The HPI algorithm side panel is also accessible if an Acumen IQ sensor or Acumen IQ cuff is not connected.

13.1.11.2Relationship View

The parameters displayed on the HPI algorithm relationship view secondary screen include the following key parameters:

- cardiac output (CO)/cardiac index (CI)
- pulse rate (PR)
- mean arterial pressure (MAP)
- stroke volume (SV)/ stroke volume index (SVI)
- systemic vascular resistance (SVR)/ systemic vascular resistance index (SVRI)

Additional advanced parameters are arranged visually on the screen by **PRELOAD**, **CONTRACTILITY**, and **AFTERLOAD**. These advanced parameters are:

- stroke volume variation (SVV) or pulse pressure variation (PPV)
- systolic slope (dP/dt)
- dynamic arterial elastance (Ea_{dyn})

To toggle between display of PPV or SVV on the relationship view secondary screen, touch the currently displayed parameter name (PPV or SVV) on the relationship view secondary screen. To toggle between display indexed and non-indexed parameters (CO/CI, SV/SVI, or SVR/SVRI), select the desired parameter as a key parameter. For all of the parameters on the HPI secondary screen, the percent change and direction of change

(via up/down arrow) over a user-selectable time interval and small graphical trend plots are displayed. The arterial blood pressure waveform is also displayed. All parameter boxes are outlined in the current target status color, matching visual indicator functionality of parameter tiles.

Figure 13-6 HPI algorithm relationship view

For parameter derivations, see table C-1 in appendix C, *Equations for Calculated Patient Parameters.*

13.1.11.3HPI Smart Alerts and Smart Trends

The HPI smart alerts and smart trends feature can assist clinicians in the identification of potential underlying mechanism(s) that may be possible targets for intervention to prevent or treat hypotension based on review of the patient's complete hemodynamic state before treatment. These mechanisms include preload, contractility, and afterload. The smart alerts algorithm considers the value and % change in value of parameters in relation to user defined thresholds to assist the user in determining the most appropriate course of action. The clinician can link parameters to each of the three physiological mechanisms (preload, contractility, afterload) and customize factors that affect when the category is triggered.

To disable HPI smart alerts, touch the settings icon on the bottom of the HPI algorithm side panel and touch and disable the **Smart Trend Alerts** toggle button.

Ea_{dyn} parameter value, MAP parameter value, and the HPI trend plot are displayed on this screen along with one parameter related to each of the following mechanisms:

Mechanism	Related parameter choice
PRELOAD	pulse pressure variation (PPV) stroke volume variation (SVV) stroke volume index (SVI)
CONTRACTILITY	systolic slope (dP/dt) cardiac index (CI)
AFTERLOAD	systemic vascular resistance (SVR)

NOTE The CVP value required for SVR calculation can come from pressure cable monitored CVP, or a user entered CVP value. For information on CVP source prioritization, see table 4-1 on page 89. When no source of CVP is detected, the default value assigned is 5 mmHg. To change the default value, see *CVP Settings* on page 129.

With HPI **Smart Trend Alerts** enabled, an HPI algorithm high alert notification appears when HPI alarms. See figure 13-7. The categories are triggered based on the linked parameter's state, which includes the parameter's value and its trend over a user-defined time interval in comparison to defined thresholds.

Triggers for smart alerts are defined by changes in a parameter value beyond a pre-selected parameter target value, and/or % change threshold (10%, 15% or 20%) over a pre-set time interval (5, 10, 15, or 30 minutes) in accordance with user-configurable settings set on the HPI settings screen.

For each parameter, there are specific thresholds that are relevant to the HPI smart alerts decisions. See table 13-5 below. Pre-selected parameter target values are set on the parameter Alarms/Targets screen. See *Alarms/Targets* on page 123. The hard threshold target values listed below are the Edwards default thresholds for parameter warning (yellow) ranges.

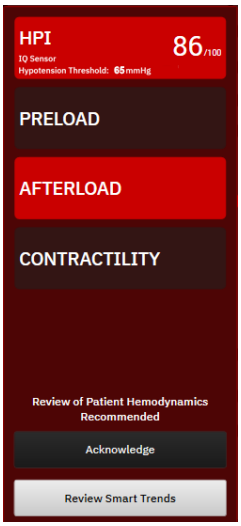


Figure 13-7 HPI smart alert notification

Table 13-5 HPI smart alert parameter default thresholds

Parameter	Default threshold
SVV & PPV (%)	≥ 13
SVI (mL/beat/m^2)	≤ 30
CI (L/min/m^2)	≤ 2
dP/dt (mmHg/s)	≤ 480
SVR (dyne-s/cm^5)	≤ 1970/BSA
MAP (mmHg)*	≤ 72
**Note: Hypotension Threshold + 10% (Not configurable) ≤ 72*	

A smart alert condition is displayed as a shaded region on the trend graph for that parameter. Smart alert settings (% change value and time interval) are configured by the user.

Touch the settings icon on the bottom of the HPI side panel to access the settings menu.

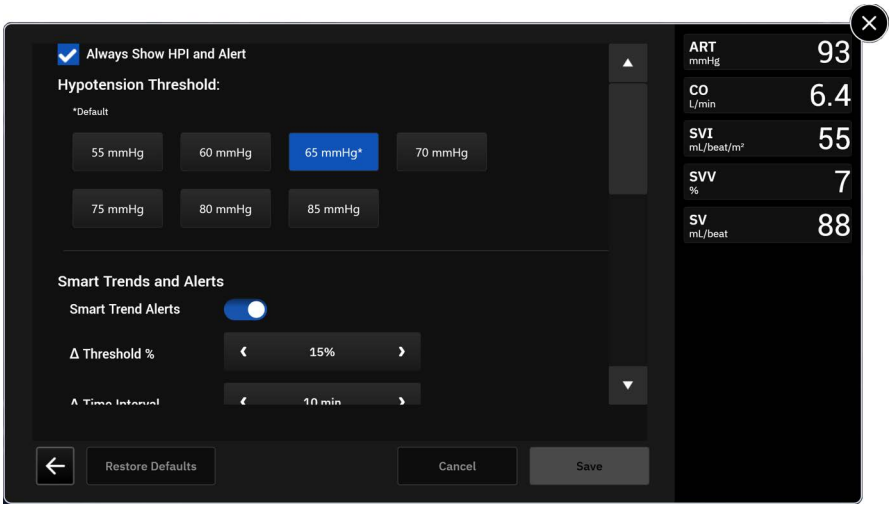


Figure 13-8 HPI algorithm settings menu

Touch the arrows (,)on the settings menu to scroll through and select the desired smart trends and alerts menu option.

Δ Threshold % (10%, 15%, or 20%). This value determines the change in value over the **Δ Time Interval** at which a parameter displays smart alerts

Δ Time Interval (Min) (5, 10, 15 or 20 minutes). This interval determines the time frame in which the **Δ Threshold %** is evaluated for each displayed parameter.

Parameter Selection. Select a **Preload Parameter** (**PPV**, **SVV**, or **SVI**) and **Contractility Parameter** (**dP/dt** or **CI**). The **Afterload Parameter** is always configured to **SVR**.

13.1.12Clinical Application

The Acumen Hypotension Prediction Index parameter, HPI, can be configured as a key parameter on the monitoring screen, or it can be displayed only in the Information Bar at the bottom right of the monitoring screen, as described in *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225.

When HPI is displayed in the Information Bar:

- After a second consecutive HPI value exceeds 85, High Alert popup appears
- Check patient hemodynamics using the HPI secondary screen and other primary screen parameters in order to investigate the potential cause of the high likelihood of hypotension in order to inform a potential course of action.

When HPI is configured as a key parameter, HPI and trend graph appear on the monitoring screen:

- Alarm occurs when HPI exceeds 85.
- Trend line and parameter tile outline appears yellow (warning target zone) when HPI is greater than 50 and less than or equal to 85.
- When HPI is less than or equal to 50:
  - The trend line and value appear white.

- Continue monitoring patient hemodynamics. Remain vigilant with respect to changing patient hemodynamics using the primary monitoring screen, HPI secondary screen, HPI, and trends in parameters and vital signs.
- When HPI exceeds 85, check patient hemodynamics using the HPI secondary screen and other primary screen parameters in order to investigate the potential cause of the high likelihood of hypotension in order to inform a potential course of action.
- Once mean arterial pressure remains below 65 mmHg for three consecutive readings, indicating the occurrence of a hypotensive event:
  - HPI displays 100.
  - Check patient hemodynamics using the HPI secondary screen and other primary screen parameters in order to investigate the potential cause of the hypotension in order to inform a potential course of action.

13.1.13Additional Parameters

- Stroke Volume Variation (SVV) and Pulse Pressure Variation (PPV) – sensitive dynamic measures of fluid responsiveness, which predict whether the preload is increased – by giving more fluid or by reducing the venous unstressed volume via compensatory control mechanisms or drugs – the heart will respond with an increase in stroke volume [1]. Low values of SVV or PPV are an indicator that a patient is not fluid responsive; high values are an indicator that a patient is fluid responsive; and there is a gray zone in between [6].
- Systolic slope (dP/dt) – The maximum upslope of the arterial pressure waveform from a peripheral artery. The arterial pressure dP/dt (by nature of its computation during outflow) will have absolute values lower than the isovolumic LV pressure $dP/dt\text{-}_{max}$, but their changes correlate strongly [1, 2].

NOTE dP/dt measured from the peripheral artery has not been studied as a measure of left ventricular contractility in all patient populations.

- Dynamic arterial elastance (Ea_{dyn}) – a measure of the afterload to the left ventricle by the arterial system (arterial elastance), relative to the left ventricular elastance, computed as the ratio between PPV and SVV [8]. The arterial elastance is an integrative arterial load parameter that incorporates systemic vascular resistance (SVR), total arterial compliance (C) and systolic and diastolic time intervals [9, 10].

The correlation of these parameters to physiological status and their relationship to clinical outcome has been well-studied with a large body of clinical literature.

Most interventions to treat SV (or SVI) and MAP, impact primarily SV and its determinants preload, contractility, afterload. Decision support for treatment decisions should integrally provide information on all three aspects, since they often inter-relate.

SVV is limited as preload measure to patients that are mechanically ventilated with stable ventilation frequency and tidal volumes and that do not have intra-abdominal insufflation [6, 7]. SVV is best used in conjunction with stroke volume or cardiac output assessment.

The trending change in dP/dt is helpful as decision support to assess change in contractility of the left ventricle in conjunction with stroke volume variation and stroke volume or cardiac output assessment.

Table 13-6 demonstrates the improved bias and precision of the trended percentage change of dP/dt when compared to absolute values of dP/dt.

Table 13-6 dP/dt accuracy comparison of minimally invasive and non-invasive monitored surgical patients

Intra-patient bias ± precision of absolute value dP/dt	Bias ± precision of percentage changes of dP/dt	Concordance of percentage changes of dP/dt
-3.6 [-58.9, 51.7], mmHg/s ± 83.6 [69.9, 97.4], mmHg/s	0.02 [-0.00, 0.04] % ± 1.35 [1.34, 1.37] %	88.9% [82.7%, 93.6%]

CAUTION Exercise caution when using the absolute values of dP/dt. Pressure will change distally due to narrowing of vessels and frictional forces within the vessels. While absolute dP/dt may not be an accurate measure of cardiac contractility, trends may be helpful.

Exercise caution when using dP/dt in patients with severe aortic stenosis, since the stenosis may reduce the coupling between the left ventricle and the afterload.

The dP/dt parameter, although predominantly determined by changes in LV contractility, may be impacted by afterload during periods of vasoplegic states (venoarterial decoupling). During these periods, dP/dt may not reflect changes in LV contractility.

By normalizing the arterial elastance by the ventricular elastance, their ratio becomes an index of the matching between the LV and the arterial system. When matching there is an optimal transfer of blood from the LV to the arterial system without loss of energy and with optimal stroke work [3, 8, 9].

Ea_{dyn} has been shown to provide an indication of potential afterload responsiveness to increase MAP by giving volume in preload volume responsive mechanically ventilated patients [4] and spontaneously breathing patients [5]. Afterload responsiveness to increase MAP is greater potentially at values of $Ea_{dyn} > 0.8$ [4, 5, 8].

Ea_{dyn} is not limited to patients that are mechanically ventilated because it is a computation of presented as the ratio of PPV/SVV [5, 8]. Ea_{dyn} is best used in conjunction with stroke volume variation (in ventilated patients) and stroke volume or cardiac output assessment.

SVV or PPV, dP/dt, and Ea_{dyn} share the property that one is seldom independent of one or the other. Giving volume to increase the preload and increase the stroke volume leads to an increase in cardiac output and arterial pressure; therefore, the afterload on the ventricle increases. Increasing afterload (increasing aortic pressure) by increasing systemic vascular resistance, will reduce the stroke volume. The resulting increased end-systolic volume, however, leads to a secondary increase in end-diastolic volume because more blood is left inside the ventricle following ejection and this extra blood is added to the venous return, thereby increasing ventricular filling, which increases contractility (Frank-Starling mechanism) and partially offsets the reduction in stroke volume caused by the initial increase in afterload.

SVV or PPV, dP/dt, and Ea_{dyn} are intended as integrative decision support parameters to guide an interventional treatment of SV or SV and MAP.

To provide the performance of these parameters using NIBP monitored patients (ClearSight) compared with minimally-invasively monitored patients (FloTrac), the bias and limits of agreement (LoA) were calculated for SVV, PPV, and Ea_{dyn}. Results of this analysis with 95% confidence intervals are shown below in

table 13-7. 95% confidence intervals were calculated by accounting for the repeated measurements from the same test subject by using the Bland JM, Altman DG (2007) method. The Bland-Altman plots for these parameters are shown in figure 13-9.

Table 13-7 95% Confidence interval results for bias and limits of agreement (LoA)

Parameter	Bias [95% CI]	Lower LoA [95% CI]	Upper LoA [95% CI]
SVV (%)	-0.18 [-0.25, -0.11]	-3.03 [-3.52, -2.53]	2.66 [2.17, 3.16]
PPV (%)	-0.01 [-0.10, 0.08]	-3.78 [-4.40, -3.17]	3.76 [3.14, 4.38]
Ea_{dyn}	0.04 [0.04, 0.05]	-0.29 [-0.33, -0.25]	0.38 [0.34, 0.42]

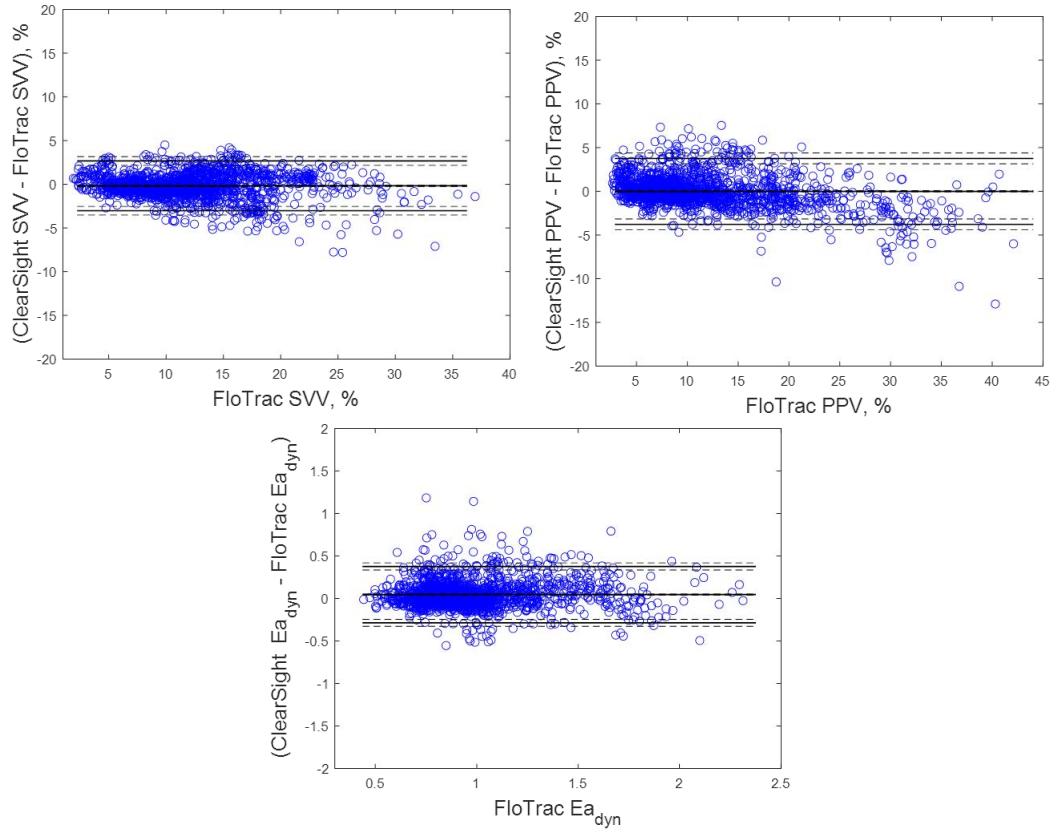


Figure 13-9 Bland-Altman plots for SVV, PPV, and Ea_{dyn}

13.1.14 Clinical Validation with Hypotension Threshold in Minimally-Invasive Monitored Patients

Retrospective clinical validation studies were undertaken to assess the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in minimally-invasive monitored surgical and non-surgical patients.

13.1.14.1 Surgical Patients

A retrospective clinical validation study assessed the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in minimally-invasive monitored surgical patients. Table 13-8 provides the patient demographics of the 1141 surgical patients included in this study. The number of hypotensive event segments included for each MAP target and a summary of patient data lengths (in minutes) are provided below in table 13-9. The 1141 surgical patients can be further stratified as described in table 13-10 below.

Table 13-8 Patient demographics (minimally-invasive monitored surgical patients, N=1141)

Description	Value
# of Patients	1141
Gender (Male/Female)	631/510
Age	58.0 ± 17.0
BSA (m2)	1.9 ± 0.3
Height (cm)	169.1 ± 10.8
Weight (kg)	80.3 ± 22.2

Table 13-9 Analysis dataset length and number of hypotension events (minimally-invasive monitored surgical patients)

Proposed MAP targets	Number of hypotensive events	Median total data length (minutes)	Mean total data length (± Std Dev, minutes)
55 mmHg	6315	331.3	360.0 ± 158.2
60 mmHg	4763		
65 mmHg	6447		
70 mmHg	3858		
75 mmHg	4050		
80 mmHg	3740		
85 mmHg	3336		

Table 13-10 Surgical Patient Characteristics (minimally-invasive, N=1141)

Surgery Type	# patients (% of total)
abdominal	333 (27.1%)
cardiac	120 (9.7%)
cervical	83 (6.7%)
cranial	217 (17.6%)
extremity	126 (10.2%)
spinal	62 (5.0%)
thoracic	92 (7.5%)
other HRS	198 (16.1%)
TOTAL*	**965 (100%)**
*Note: Some patients may have multiple procedures done, thus the total number of procedures are more than the total number of patients	

13.1.14.2Non-Surgical Patients

A retrospective clinical validation study assessed the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in minimally-invasively monitored non-surgical patients. Table 13-11 provides the patient demographics of the 672 non-surgical patients included in this study. The number of hypotensive event segments included for each MAP target and a summary of patient data lengths (in minutes) are provided below in table 13-12.

The 672 non-surgical patients can be further stratified as described in table 13-13 below.

Table 13-11 Patient demographics (minimally-invasive monitored non-surgical patients, N=672)

Description	Value
# of Patients	672
Gender (Male/Female)	430/242
Age	62.2 ± 15.8
BSA (m2)	2.0 ± 0.3
Height (cm)	171.4 ± 11.3
Weight (kg)	88.0 ± 27.4

Table 13-12 Analysis dataset length and number of hypotension events (minimally-invasive monitored non-surgical patients)

Proposed MAP targets	Number of hypotensive events	Median total data length (minutes)	Mean total data length (± Std Dev, minutes)
55 mmHg	5772	1440.0	3321.8 ± 17900.3
60 mmHg	7125		
65 mmHg	11029		
70 mmHg	14845		
75 mmHg	10664		
80 mmHg	11531		
85 mmHg	15508		

Table 13-13 Non-Surgical patient characteristics (minimally-invasive, N=672)

Diagnosis	# patients (% of total)
cardiac ICU	269 (40.0%)
neuro ICU	17 (2.5%)
cardiac surgery floor	4 (0.6%)
medical intensive care unit	9 (1.3%)
surgical intensive care unit	83 (12.4%)
trauma intensive care unit	67 (10%)
cardiology floor	4 (0.6%)
general medical floor	22 (3.3%)
pulmonary floor	8 (1.2%)
surgical floor	138 (20.5%)
transplant floor	11 (1.6%)
unknown	40 (6.0%)
TOTAL	**672 (100%)**

13.1.14.3Hypotension Threshold Clinical Validation Study Results – Minimally-Invasive Monitoring

The results of the receiver operating characteristic (ROC) analyses for surgical and non-surgical patients are summarized below in table 13-14and table 13-15.

A hypotensive event is calculated by identifying a segment of at least 1 minute in length such that all data points in the section have a MAP less than the indicated Variable Map Value (55, 60, 65, 70, 75, 80, and 85). An event (positive) data point is chosen as the sample 5 minutes prior to the hypotensive event. If consecutive hypotension events are less than 5 minutes apart then a positive sample is defined as the first sample immediately following the preceding hypotension event.

A non-hypotensive event is calculated by identifying segments of data points such that the segment is at least 20 minutes away from any hypotensive events and all data points in that segment have MAP less than the indicated Variable Map Value (55, 60, 65, 70, 75, 80, and 85). One non-event (negative) data point is taken for each of the non-hypotensive event segments.

A true positive, as described in table 13-14 and table 13-15, is any event (positive) data point with HPI value greater than or equal to a chosen threshold. Sensitivity is the ratio of true positives to total number of events (positives) with a positive defined as a data point that is at most 5 minutes prior to a hypotensive event. A false negative is any positive data point with HPI value less than the threshold.

A true negative, as described in table 13-14 and table 13-15, is any negative (non-event) data point with HPI value less than a chosen threshold. Specificity is the ratio of true negatives to total number of non-events (negatives) with a negative defined as a data point that is at least 20 minutes away from any hypotensive event. A false positive is any negative data point with HPI value greater than or equal to the threshold.

Positive predictive value (PPV), negative predictive value (NPV), and area under the ROC curve (AUC) are also reported for each variable MAP target in table 13-14 and table 13-15.

Table 13-14 Clinical validation study results* (minimally-invasive monitored surgical patients)

HPI Threshold	Variable MAP Value (mmHg)	PPV [confidence interval]	NPV [confidence interval]	Specificity (%) [95% confidence interval]	Sensitivity (%) [95% confidence interval]	AUC
85	55	99.1 =(5583/5634) [97.7, 99.8]	88.4 =(5586/6318) [86.6, 90.0]	99.1 =(5586/5637) [97.9, 99.8]	88.4 =(5583/6315) [83.1, 91.7]	0.95 [0.93, 0.97]
	60	99.8 =(3958/3964) [99.6, 100.0]	86.5 =(5156/5961) [84.2, 88.5]	99.9 =(5156/5162) [99.8, 100.0]	83.1 =(3958/4763) [75.4, 88.2]	0.94 [0.92, 0.96]
	65	99.8 =(5346/5358) [99.5, 99.9]	76.8 =(3648/4749) [73.1, 80.1]	99.7 =(3648/3660) [99.3, 99.9]	82.9 =(5346/6447) [77.5, 87.1]	0.95 [0.93, 0.96]
	70	98.8 =(2551/2583) [97.8, 99.5]	81.6 =(5784/7091) [79.1, 83.7]	99.4 =(5784/5816) [99.0, 99.8]	66.1 =(2551/3858) [63.7, 68.6]	0.87 [0.86, 0.89]
	75	98.5 =(2715/2755) [97.8, 99.2]	78.7 =(4922/6257) [76.1, 81.2]	99.2 =(4922/4962) [98.8, 99.6]	67.0 =(2715/4050) [64.5, 69.4]	0.87 [0.86, 0.88]
	80	99.3 =(2590/2607) [98.8, 99.8]	78.0 =(4071/5221) [75.1, 80.6]	99.6 =(4071/4088) [99.2, 99.9]	69.3 =(2590/3740) [66.9, 71.5]	0.88 [0.86, 0.89]
	85	97.7 =(2204/2256) [96.1, 99.1]	73.6 =(3164/4296) [70.5, 76.5]	98.4 =(3164/3216) [97.3, 99.4]	66.1 =(2204/3336) [63.7, 68.4]	0.87 [0.85, 0.88]

*Data on File at Edwards Lifesciences

Table 13-15 Clinical validation study results* (minimally-invasive monitored non-surgical patients)

HPI Threshold	Variable MAP Value (mmHg)	PPV [confidence interval]	NPV [confidence interval]	Specificity (%) [95% confidence interval]	Sensitivity (%) [95% confidence interval]	AUC
85	55	98.7 =(5028/5095) [97.0, 99.8]	98.0 =(36308/37052) [97.5, 98.4]	99.8 =(36308/36375) [99.6, 100.0]	87.1 =(5028/5772) [84.7, 89.1]	0.97 [0.96, 0.97]
	60	96.1 =(5729/5963) [90.6, 99.4]	97.0 =(44955/46351) [96.3, 97.6]	99.5 =(44955/45189) [98.7, 99.9]	80.4 =(5729/7125) [76.9, 83.4]	0.95 [0.94, 0.96]
	65	99.0 =(9726/9828) [97.8, 99.8]	95.4 =(27312/28615) [94.1, 96.5]	99.6 =(27312/27414) [99.2, 99.9]	88.2 =(9726/11029) [85.8, 90.2]	0.98 [0.97, 0.98]
	70	99.0 =(13024/13162) [98.0,99.6]	92.9 =(23939/25760) [90.7,94.7]	99.4 =(23939/24077) [98.9,99.8]	87.7 =(13024/14845) [84.8,90.1]	0.98 [0.97, 0.98]
	75	96.8 =(8509/8793) [94.4, 98.6]	94.8 =(38946/41101) [93.2, 96.0]	99.3 =(38946/39230) [98.8, 99.7]	79.8 =(8509/10664) [75.0, 83.8]	0.96 [0.96, 0.97]
	80	95.8 =(9724/10154) [93.0, 98.1]	95.0 =(34611/36418) [94.0, 96.0]	98.8 =(34611/35041) [98.0, 99.4]	84.3 =(9724/11531) [81.6, 86.7]	0.96 [0.95, 0.97]
	85	96.0 =(13189/13741) [93.1, 98.3]	92.9 =(30359/32678) [91.4, 94.2]	98.2 =(30359/30911) [96.9, 99.3]	85.0 =(13189/15508) [82.6, 87.2]	0.96 [0.95, 0.97]

*Data on File at Edwards Lifesciences

Table 13-16 provides the hypotensive event occurrence percentage and time-to-event data for a given HPI range for surgical patients in the clinical validation study. These data are presented using time windows that have been selected based upon how fast hypotensive events developed on average in surgical patients. Therefore based upon the clinical validation study data, table 13-16 presents data for surgical patients for a time-window of 15 minutes. This analysis is performed by taking samples in each patient from the validation dataset and looking forward in time for a hypotensive event within a 15-minute search window. Once a hypotensive event is found for a given sample then the time-to-event is noted, which is the time duration between the sample and the hypotensive event. The time-to-event statistic is the average event time of all samples that have an event within the search window.

Table 13-17 provides the hypotensive event occurrence percentage and time-to-event data for a given HPI range for non-surgical patients in the clinical validation study. These data are presented using time windows that have been selected based upon how fast hypotensive events developed on average in non-surgical patients. Therefore based upon the clinical validation study data, table 13-17 presents data for non-surgical patients for a time-window of 120 minutes. This analysis is performed by taking samples in each patient from the validation dataset and looking forward in time for a hypotensive event within a 120-minute search window. Once a hypotensive event is found for a given sample then the time-to-event is noted, which is the time duration between the sample and the hypotensive event. The time-to-event statistic is the average event time of all samples that have an event within the search window.

The event rates, included in table 13-16 and table 13-17, are the ratio of the number of samples that have an event within the search window to the total number of samples. This is done for samples in each MAP target for each of the individual HPI ranges between 10 to 99 as shown in table 13-16 and table 13-17.

CAUTION The HPI parameter information provided in table 13-16 and table 13-17 is presented as general guidance and may not be representative of individual experience. A review of the patient's hemodynamics is recommended prior to initiating treatment.

Table 13-16 Event rate analysis (surgical minimally-invasive, N=1141)

HPI Range	55 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	60 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	65 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	70 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	75 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	80 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	85 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]
10-14	17.5 9 [3.7, 14]	11.0 9 [3.7, 13.7]	14.4 8 [3.3, 14]	22.9 8.7 [4, 13.7]	31.1 8.3 [3.7, 13.3]	24.8 7.7 [3.7, 13.3]	29.2 8.3 [3.7, 13.7]
15-19	19.9 7.8 [2.7, 13.7]	12.5 9 [3.7, 13.7]	18.2 8.3 [3.7, 13.7]	21.8 8.3 [3.7, 14]	30.9 8.3 [3.7, 13.7]	26.4 8 [3.3, 13.7]	28.1 8.3 [3.3, 13.7]
20-24	17.9 8.3 [3, 13.3]	15.1 8.3 [3.3, 14]	21.0 8.3 [3.7, 14]	26.2 8.3 [3.4, 13.7]	32.9 8.3 [3.3, 14]	28.1 8 [3.3, 13.4]	31.4 8.3 [3.3, 13.7]
25-29	21.6 8.3 [3, 13.7]	18.9 8 [3.3, 13.3]	24.2 8.7 [3.3, 13.3]	27.8 8.3 [3.3, 13.7]	30.3 8.3 [3.3, 13.7]	30.7 8 [3.3, 13.7]	33.4 8 [3, 13.7]
30-34	22.3 7.7 [2.7, 13.7]	23.4 7.3 [3, 13.7]	29.2 7.3 [2.7, 13]	32.9 8 [3, 13.7]	36.3 8.3 [3, 13.7]	30.2 7.7 [3, 13.7]	35.7 8 [3, 13.3]
35-39	24.1 7.3 [2.7, 13.3]	28.8 7.3 [2.7, 13.3]	34.9 6.7 [2.7, 12.7]	36.0 7.7 [2.7, 13.3]	39.5 7.7 [2.7, 13.7]	33.4 7.3 [3, 13.3]	38.2 7 [3, 13.3]
40-44	27.6 7 [2.3, 13]	35.0 7.3 [2.3, 13]	44.8 6.3 [2.3, 12.7]	41.7 7 [2.7, 13.3]	42.9 7 [2.3, 13]	37.1 7.3 [2.7, 13.3]	43.2 7.3 [2.7, 13.3]
45-49	30.0 6 [2, 13]	38.8 6.7 [2.3, 13.3]	47.8 6.7 [2.3, 13]	46.4 7 [2.7, 13.3]	48.6 6.7 [2.3, 13]	38.7 7.3 [2.7, 13.7]	46.9 6.7 [2.7, 13]
50-54	32.9 6.3 [2, 13]	42.3 6 [2, 13.3]	52.6 6 [2, 13.3]	48.9 6.7 [2.3, 12.7]	49.6 6.7 [2.3, 13]	42.3 7 [2.3, 13]	48.2 6.7 [2.3, 12.7]
55-59	37.7 5.7 [1.7, 12.7]	46.3 5.7 [2, 12.7]	57.0 5.8 [2, 13]	52.1 6.7 [2.3, 13]	52.8 6.3 [2, 12.7]	44.2 6.3 [2, 13]	52.8 6.7 [2.3, 13]
60-64	40.2 6 [1.7, 12.7]	54.6 5.7 [1.7, 12.7]	64.6 5.7 [2, 12.3]	56.6 6.7 [2.3, 13]	58.3 6 [2, 12.7]	54.7 6.3 [2, 13]	55.5 6 [2, 12.7]
65-69	48.0 5.7 [1.7, 13]	61.9 4.7 [1.7, 11.3]	68.7 5 [1.7, 12.3]	63.1 6 [2, 12.7]	65.8 6 [2, 12.7]	59.4 6 [2, 13]	62.8 5.3 [2, 12.3]
70-74	60.7 5.3 [1.3, 12.7]	68.7 4.3 [1.7, 12]	79.5 4.7 [1.7, 12]	71.4 5.7 [1.7, 13]	73.6 5 [1.7, 12.3]	69.4 5.3 [1.7, 12.7]	70.6 5 [1.7, 12.3]
75-79	68.5 4.7 [1.3, 12]	78.1 4.3 [1.3, 11.3]	85.5 4.3 [1.3, 11.7]	77.4 5 [1.7, 12.3]	79.2 5 [1.3, 12]	73.5 5 [1.5, 12]	76.0 5 [1.3, 11.7]
80-84	78.7 4.3 [1, 11.7]	84.6 4.3 [1.3, 11]	88.8 4 [1.3, 11]	82.6 4.7 [1.3, 12]	82.6 4.7 [1.3, 12]	78.1 4.7 [1.3, 12]	81.4 4.7 [1.3, 11.3]
85-89	84.5 4 [1, 11.3]	90.2 4 [1, 11]	90.9 3.7 [1.3, 11.3]	85.8 4.3 [1.3, 11.7]	88.1 4 [1.3, 11.7]	86.1 4.7 [1.3, 12]	86.0 4 [1.3, 11.3]
90-94	92.9 3.7 [1, 11]	94.7 3.3 [1, 10.3]	94.5 3 [1, 10.3]	91.4 3.7 [1, 11.3]	90.7 3.3 [1, 11]	90.4 3.7 [1, 12]	88.2 3.3 [1, 10.7]
95-99	96.8 1.3 [0.3, 8.3]	97.3 1.3 [0.3, 8]	98.0 1.3 [0.3, 7.7]	96.9 1.3 [0.3, 8.7]	96.9 1.3 [0.3, 8.7]	96.4 1.3 [0.3, 9]	95.7 1.3 [0.3, 8.7]

Table 13-17 Event rate analysis (non-surgical minimally-invasive, N=672)

HPI Range	55 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	60 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	65 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	70 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	75 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	80 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	85 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]
10-14	20.5 50 [8.7, 101.3]	19.7 44.3 [9.3, 102.3]	9.6 49.3 [9.7, 106]	12.5 45 [9, 101.3]	16.6 47.2 [9, 103]	18.6 48.3 [10, 101.7]	24.7 41 [8.3, 101.2]
15-19	20.6 45.7 [10.3, 103.3]	20.8 44 [8.3, 100.7]	12.6 44.3 [10, 105.6]	17.2 45.7 [8, 104]	21.8 44.3 [9.3, 100]	21.1 50 [10, 104]	29.1 40.7 [8.7, 98]
20-24	22.7 47 [10.7, 104.7]	21.8 43.3 [9, 101.3]	16.8 40.3 [8.3, 102.1]	20.0 45.7 [8.7, 101.7]	24.7 43.7 [8.7, 100.3]	24.1 48.3 [9.7, 104]	31.4 43 [7.7, 101.3]
25-29	22.9 47 [10, 103.3]	24.8 40.3 [8, 101.7]	20.9 39.3 [7.1, 102]	24.6 40.7 [7.7, 100.7]	26.8 42.7 [8, 101]	28.1 44.7 [9.3, 101.7]	33.5 41.7 [7.3, 100.3]
30-34	24.9 46.3 [8, 103.3]	29.1 39.7 [7.3, 100.3]	24.0 37.3 [7, 101]	29.8 36 [6.3, 98]	30.8 37.7 [7, 98.7]	31.4 42 [8.7, 98.7]	37.5 38.3 [6.7, 97.7]
35-39	30.4 42.3 [6.7, 100.3]	32.0 37.7 [6, 100]	31.4 30 [5.7, 93.5]	35.9 29.3 [5.3, 98]	34.6 30.7 [5.3, 96]	35.8 41 [7, 97.3]	44.7 34.7 [5.7, 95.3]
40-44	35.9 36.7 [6.3, 100]	37.5 33.3 [5.3, 98]	38.4 27.3 [5, 90]	41.9 24.7 [4.7, 94.7]	41.1 25.5 [4.3, 92.3]	40.9 35.3 [6.3, 95.3]	51.1 32.3 [5.3, 93]
45-49	39.7 31 [5.3, 96.3]	41.9 26.3 [4.7, 96]	44.5 23.7 [4, 90]	47.8 19 [3.7, 88.3]	43.7 23.7 [4, 94]	42.6 30.7 [5.3, 92.3]	52.3 28 [5, 91]
50-54	42.0 29 [5, 94.7]	46.0 21.3 [4, 92.7]	48.2 19.7 [4, 91]	52.1 17.3 [3.3, 81.3]	47.6 19.7 [3.3, 91]	44.3 30 [5, 94]	52.5 24.7 [3.7, 93]
55-59	46.2 27 [4.7, 93.3]	51.6 18 [3.3, 88.3]	55.9 17 [3.7, 87.9]	62.7 15.7 [3, 78.3]	53.2 17 [3, 85]	47.5 27 [4.3, 93.3]	56.3 20 [3.3, 87.3]
60-64	49.6 20.3 [4, 89]	58.1 15.7 [3, 83.4]	63.3 12.3 [2.7, 72.3]	71.9 12.3 [2.7, 76.3]	60.1 14 [2, 80]	53.5 19 [3, 89.3]	63.3 16 [2.7, 83.3]
65-69	61.1 12.7 [3, 77.7]	66.9 10.3 [2.3, 70.3]	69.7 9 [2, 52.3]	78.3 8.3 [1.7, 51]	69.5 10.3 [1.7, 68.7]	61.6 12.3 [2.3, 79.3]	70.6 11.3 [1.7, 75.1]
70-74	71.4 9 [2, 50.3]	73.9 8 [1.7, 48.3]	81.7 7 [1.7, 25.3]	87.1 6.3 [1.3, 23.7]	76.5 8 [1.3, 52.3]	68.8 9 [1.7, 65.7]	78.1 8.7 [1.3, 62.7]
75-79	83.1 7 [1.7, 18.3]	81.1 6.3 [1.3, 27.7]	88.2 6 [1.3, 17]	93.8 5 [1, 16]	83.9 6.7 [1, 34.7]	76.2 7 [1.3, 54.8]	80.3 6.7 [1, 50]
80-84	90.0 6 [1.3, 16]	88.9 5.3 [1, 17.3]	92.9 5 [1, 15.7]	96.5 4.3 [1, 14.3]	88.4 5.3 [1, 18]	81.8 6 [1, 37]	84.3 5.3 [1, 34]
85-89	95.9 5 [1.3, 14.3]	94.8 4.7 [1, 15]	95.8 4 [1, 13.7]	98.2 3.7 [1, 13]	92.7 4.3 [1, 16]	87.1 5 [1, 18.7]	88.3 4.3 [1, 16.7]
90-94	99.3 3.3 [1, 12.3]	97.7 3.3 [1, 13.3]	98.4 2.7 [1, 11.3]	99.2 2.7 [0.7, 11]	96.7 3.3 [1, 13]	93.1 3.7 [1, 14.7]	92.6 3.3 [1, 14]
95-99	99.9 1.3 [0.3, 8.3]	99.7 1.3 [0.3, 9.3]	99.7 1.3 [0.3, 7.7]	99.9 1 [0.3, 7.3]	99.5 1.3 [0.3, 9]	98.8 1.3 [0.3, 9.3]	99.2 1.3 [0.3, 9]

13.1.15 Clinical Validation with Hypotension Threshold in Non-Invasively Monitored Patients

Retrospective clinical validation studies were undertaken to assess the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in non-invasively monitored surgical and non-surgical patients.

13.1.15.1 Surgical Patients

A retrospective clinical validation study assessed the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in non-invasively monitored surgical patients. Table 13-18 provides the patient demographics of the 927 surgical patients included in this study. The number of hypotensive event segments included for each MAP target and a summary of patient data lengths (in minutes) are provided below in table 13-19.

The 927 surgical patients can be further stratified as described in table 13-20 below.

Table 13-18 Patient demographics (non-invasively monitored surgical patients, N=927)

Description	Value
# of Patients	927
Gender (Male/Female)	468/459
Age	57.9 ± 13.9
BSA (m2)	2.0 ± 0.3
Height (cm)	171.8 ± 12.2
Weight (kg)	86.6 ± 23.7

Table 13-19 Analysis dataset length and number of hypotension events (non-invasively monitored surgical patients)

Proposed MAP targets	Number of hypotensive events	Median total data length (minutes)	Mean total data length (± Std Dev, minutes)
55 mmHg	971	178.3	193.1 ± 104.2
60 mmHg	2219		
65 mmHg	2561		
70 mmHg	2113		
75 mmHg	2894		
80 mmHg	2440		
85 mmHg	3381		

Table 13-20 Surgical patient characteristics (non-invasive, N=927)

Surgery Type	# patients (% of total)
cardiac	110 (11.9%)
colorectal	15 (1.6%)
cranial	7 (0.8%)
ear	14 (1.5%)
esophageal	6 (0.6%)
eye	47 (5.1%)
facial	24 (2.6%)
foot	2 (0.2%)
gastro-intestinal	65 (7.0%)
gynecology	61 (6.6%)

Table 13-20 Surgical patient characteristics (non-invasive, N=927) (continued)

Surgery Type	# patients (% of total)
hand	1 (0.1%)
leg	10 (1.1%)
liver	11 (1.2%)
nose	9 (1.0%)
orthopedic	13 (1.4%)
other Non-Cardiac	367 (39.6%)
pancreas	12 (1.3%)
renal	27 (2.9%)
skin	6 (0.6%)
spinal	1 (0.1%)
thoracic	3 (0.3%)
unknown	92 (9.9%)
urology	24 (2.6%)
TOTAL	**927 (100%)**

13.1.15.2Non-Surgical Patients

A retrospective clinical validation study assessed the diagnostic performance of HPI to predict hypotensive and non-hypotensive events in non-invasive monitored non-surgical patients. Table 13-21 provides the patient demographics of the 424 non-surgical patients included in this study. The number of hypotensive event segments included for each MAP target and a summary of patient data lengths (in minutes) are provided below in table 13-22.

The 424 non-surgical patients can be further stratified as described in table 13-23 below.

Table 13-21 Patient demographics (non-invasive monitored non-surgical patients, N=424)

Description	Value
# of Patients	424
Gender (Male/Female)	286/138
Age	61.8 ± 14.2
BSA (m2)	2.0 ± 0.2
Height (cm)	174.5 ± 9.7
Weight (kg)	83.0 ± 19.4

Table 13-22 Analysis dataset length and number of hypotension events (non-invasive monitored non-surgical patients)

Proposed MAP targets	Number of hypotensive events	Median total data length (minutes)	Mean total data length (± Std Dev, minutes)
55 mmHg	648	417.3	415.8 ± 199.6
60 mmHg	689		
65 mmHg	1672		
70 mmHg	1312		
75 mmHg	2868		
80 mmHg	4375		
85 mmHg	4826		

Table 13-23 Non-surgical patient characteristics (non-invasive, N=424)

Diagnosis	# patients (% of total)
cardiac	211 (49.8%)
cerebral	2 (0.5%)
gastro-intestinal	8 (1.9%)
hypertension	1 (0.2%)
hypotension	5 (1.2%)
hypothermia	1 (0.2%)
internal	8 (1.9%)
intestinal	1 (0.2%)
liver	2 (0.5%)
neurological	69 (16.3%)
orthopedic	1 (0.2%)
post-Surgical	4 (0.9%)
pulmonary	7 (1.7%)
renal	2 (0.5%)
respiratory	40 (9.4%)
sepsis	18 (4.2%)
shock	4 (0.9%)
trauma	8 (1.9%)
vascular	32 (7.5%)
TOTAL	**424 (100%)**

13.1.15.3Hypotension Threshold Clinical Validation Study Results – Non-Invasive Monitoring

The results of the receiver operating characteristic (ROC) analyses for surgical and non-surgical patients are summarized below in table 13-24 and table 13-25.

A hypotensive event is calculated by identifying a segment of at least 1 minute in length such that all data points in the section have a MAP less than the indicated Variable Map Value (55, 60, 65, 70, 75, 80, and 85). An event (positive) data point is chosen as the sample 5 minutes prior to the hypotensive event. If consecutive hypotension events are less than 5 minutes apart then a positive sample is defined as the first sample immediately following the preceding hypotension event.

A non-hypotensive event is calculated by identifying segments of data points such that the segment is at least 20 minutes away from any hypotensive events and all data points in that segment have MAP less than the indicated Variable Map Value (55, 60, 65, 70, 75, 80, and 85). One non-event (negative) data point is taken for each of the non-hypotensive event segments.

A true positive, as described in table 13-24 and table 13-25, is any event (positive) data point with HPI value greater than or equal to a chosen threshold. Sensitivity is the ratio of true positives to total number of events (positives) with a positive defined as a data point that is at most 5 minutes prior to a hypotensive event. A false negative is any positive data point with HPI value less than the threshold.

A true negative, as described in table 13-24 and table 13-25, is any negative (non-event) data point with HPI value less than a chosen threshold. Specificity is the ratio of true negatives to total number of non-events (negatives) with a negative defined as a data point that is at least 20 minutes away from any hypotensive event. A false positive is any negative data point with HPI value greater than or equal to the threshold.

Positive predictive value (PPV), negative predictive value (NPV), and area under the ROC curve (AUC) are also reported for each variable MAP target in table 13-24 and table 13-25.

Table 13-24 Clinical validation study results* (non-invasive monitored surgical patients)

HPI Threshold	Variable MAP Value (mmHg)	PPV [confidence interval]	NPV [confidence interval]	Specificity (%) [95% confidence interval]	Sensitivity (%) [95% confidence interval]	AUC
85	55	97.2 =(693/713) [94.9, 99.1]	94.3 =(4610/4888) [93.0, 95.3]	99.6 =(4610/4630) [99.2, 99.9]	71.4 =(693/971) [67.0, 75.0]	0.88 [0.86, 0.90]
	60	97.9 =(1738/1775) [96.6, 98.9]	89.8 =(4244/4725) [88.2, 91.3]	99.1 =(4244/4281) [98.6, 99.6]	78.3 =(1738/2219) [75.9, 80.6]	0.91 [0.89, 0.92]
	65	98.3 =(2011/2046) [97.1, 99.2]	89.2 =(4533/5083) [87.4, 90.7]	99.2 =(4533/4568) [98.7, 99.6]	78.5 =(2011/2561) [75.7, 81.1]	0.90 [0.89, 0.92]
	70	96.7 =(1457/1506) [94.9, 98.4]	88.7 =(5157/5813) [87.2, 90.1]	99.1 =(5157/5206) [98.5, 99.5]	69 =(1457/2113) [66.4, 71.5]	0.86 [0.85, 0.88]
	75	98.4 =(2075/2109) [97.4, 99.2]	85.6 =(4868/5687) [83.8, 87.1]	99.3 =(4868/4902) [98.9, 99.6]	71.7 =(2075/2894) [69.6, 73.7]	0.87 [0.85, 0.88]
	80	99.2 =(1761/1775) [98.4, 99.8]	81.4 =(2963/3642) [78.5, 83.8]	99.5 =(2963/2977) [99.1, 99.9]	72.2 =(1761/2440) [69.7, 74.4]	0.87 [0.86, 0.88]
	85	99.5 =(2586/2599) [98.9, 99.9]	69 =(1773/2568) [64.9, 72.8]	99.3 =(1773/1786) [98.4, 99.8]	76.5 =(2586/3381) [74.1, 78.6]	0.88 [0.87, 0.89]

*Data on File at Edwards Lifesciences

Table 13-25 Clinical validation study results* (non-invasive monitored non-surgical patients)

HPI Threshold	Variable MAP Value (mmHg)	PPV [confidence interval]	NPV [confidence interval]	Specificity (%) [95% confidence interval]	Sensitivity (%) [95% confidence interval]	AUC
85	55	99.2 =(486/490) [97.5, 100.0]	98.2 =(8963/9125) [97.7, 98.6]	100 =(8963/8967) [99.9, 100.0]	75 =(486/648) [67.9, 80.7]	0.88 [0.85, 0.91]
	60	99.4 =(541/544) [98.0, 100.0]	97.9 =(6931/7079) [97.2, 98.5]	100 =(6931/6934) [99.9, 100.0]	78.5 =(541/689) [73.4, 82.7]	0.90 [0.87, 0.92]
	65	99.8 =(1422/1425) [99.4, 100.0]	97 =(8012/8262) [95.9, 97.8]	100 =(8012/8015) [99.9, 100.0]	85 =(1422/1672) [82.0, 87.6]	0.92 [0.91, 0.94]
	70	99.2 =(1033/1041) [98.5, 99.8]	97.1 =(9367/9646) [96.5, 97.7]	99.9 =(9367/9375) [99.8, 100.0]	78.7 =(1033/1312) [74.7, 82.1]	0.9 [0.87, 0.91]
	75	98.2 =(2499/2544) [95.8, 99.7]	95.3 =(7449/7818) [94.1, 96.3]	99.4 =(7449/7494) [98.6, 99.9]	87.1 =(2499/2868) [84.8, 89.3]	0.94 [0.93, 0.95]
	80	98.8 =(3866/3913) [97.7, 99.6]	90.8 =(5048/5557) [88.5, 92.8]	99.1 =(5048/5095) [98.3, 99.7]	88.4 =(3866/4375) [86.1, 90.3]	0.94 [0.94, 0.95]
	85	99.5 =(4218/4241) [98.8, 99.9]	84.2 =(3238/3846) [79.8, 87.7]	99.3 =(3238/3261) [98.4, 99.9]	87.4 =(4218/4826) [85.0, 89.5]	0.94 [0.94, 0.95]

*Data on File at Edwards Lifesciences

Table 13-26 provides the hypotensive event occurrence percentage and time-to-event data for a given HPI range for surgical patients in the clinical validation study. These data are presented using time windows that have been selected based upon how fast hypotensive events developed on average in surgical patients. Therefore based upon the clinical validation study data, table 13-26 presents data for surgical patients for a time-window of 15 minutes. This analysis is performed by taking samples in each patient from the validation dataset and looking forward in time for a hypotensive event within a 15-minute search window. Once a hypotensive event is found for a given sample then the time-to-event is noted, which is the time duration between the sample and the hypotensive event. The time-to-event statistic is the average event time of all samples that have an event within the search window.

Table 13-27 provides the hypotensive event occurrence percentage and time-to-event data for a given HPI range for non-surgical patients in the clinical validation study. These data are presented using time windows that have been selected based upon how fast hypotensive events developed on average in non-surgical patients. Therefore based upon the clinical validation study data, table 13-27 presents data for non-surgical patients for a time-window of 120 minutes. This analysis is performed by taking samples in each patient from the validation dataset and looking forward in time for a hypotensive event within a 120-minute search window. Once a hypotensive event is found for a given sample then the time-to-event is noted, which is the time duration between the sample and the hypotensive event. The time-to-event statistic is the average event time of all samples that have an event within the search window.

The event rates, included in table 13-26 and table 13-27, are the ratio of the number of samples that have an event within the search window to the total number of samples. This is done for samples in each MAP target for each of the individual HPI ranges between 10 to 99 as shown in table 13-26 and table 13-27.

CAUTION The HPI parameter information provided in table 13-26 and table 13-27 is presented as general guidance and may not be representative of individual experience. A review of the patient's hemodynamics is recommended prior to initiating treatment.

Table 13-26 Event rate analysis (surgical non-invasive, N=927)

HPI Range	55 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	60 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	65 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	70 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	75 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	80 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	85 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]
10-14	13.1 9.3 [4.9, 14]	25.0 8.7 [4, 13]	9.1 8.7 [3.7, 14]	15.1 9 [4, 14]	22.8 8 [4, 13.7]	29.3 8.7 [3.3, 13.7]	34.0 7.7 [3.3, 13]
15-19	9.4 9 [4.3, 14]	25.0 8.7 [3.5, 12.9]	10.9 9 [3.7, 14]	14.0 8.3 [3.7, 13.3]	21.6 8.3 [3.7, 13.6]	26.3 8 [3.3, 13.3]	41.1 8 [3.3, 13.7]
20-24	9.2 8.7 [4, 14.1]	23.0 9 [4, 13.7]	11.2 8.7 [3.4, 13.7]	15.8 8.3 [3.7, 13.7]	20.8 9 [3.7, 14]	24.5 8 [3.3, 13.7]	42.7 7.3 [2.3, 13.3]
25-29	11.4 8.7 [3.7, 13.6]	24.5 8.3 [3.7, 14]	13.8 8 [3.3, 13.3]	17.2 8.3 [3.3, 13.7]	23.0 8.7 [3.7, 14]	24.4 7.7 [3, 13.3]	37.8 7.7 [3, 13.7]
30-34	9.5 9 [4, 13.7]	23.1 9 [4.3, 14]	16.0 8.3 [3.3, 13.5]	19.3 8 [3.3, 13.7]	25.6 8.3 [3.7, 14]	26.4 7.7 [3, 13.3]	41.1 7.3 [2.7, 13.3]
35-39	12.3 8 [3.3, 13.7]	27.8 8.3 [3, 13.3]	18.8 8 [3, 14]	21.7 8 [3, 13.7]	29.5 8.7 [3.3, 14]	28.3 7.7 [3, 13.7]	41.3 7.3 [2.7, 13.7]
40-44	16.0 8.3 [3.7, 13]	30.3 8.7 [3, 13.7]	23.1 7.7 [3, 13.3]	24.8 8 [3, 13.3]	36.1 8.3 [3, 13.7]	30.0 7.7 [3.3, 13.7]	41.3 6.7 [2.3, 13]
45-49	20.0 7.7 [2.7, 13.7]	32.2 8 [3, 13.3]	29.9 7.7 [2.6, 13.7]	29.4 7.7 [2.7, 13.3]	39.0 7.7 [2.7, 13.3]	35.0 7.7 [3, 13.3]	45.0 6.7 [2, 13]
50-54	21.3 7.7 [2.3, 13.7]	35.8 7.3 [2.7, 13.3]	33.9 7.3 [2.7, 13.3]	33.9 7.3 [2.3, 13.7]	42.5 7.7 [2.7, 13.3]	37.7 7 [2.5, 13]	49.4 7 [2.3, 13.3]
55-59	22.2 7.3 [2.3, 13.3]	38.8 8.3 [2.3, 13.3]	33.9 7.7 [2.3, 13.7]	34.4 7.3 [2.3, 13.7]	43.9 7.7 [2.7, 13]	41.2 7.3 [2.3, 13]	53.1 7 [2.3, 13.3]
60-64	23.9 6.7 [2.3, 13.3]	44.9 6.7 [2.3, 12.7]	40.4 7.3 [2.3, 13.3]	39.4 7.3 [2, 13.7]	45.0 7.7 [2.7, 13]	43.1 7 [2.3, 12.7]	55.6 6.7 [2.3, 13]
65-69	32.9 6.3 [2, 13.3]	45.6 6.7 [2, 12.3]	44.5 6.7 [2.3, 13]	42.0 6.7 [2, 13.3]	50.0 7.3 [2.3, 13]	45.9 7 [2.3, 13.3]	61.0 7 [2.3, 13.3]
70-74	37.7 6 [1.7, 12.3]	52.1 6.7 [2, 13.3]	49.4 6.7 [2, 13]	47.1 6.7 [2, 13.3]	51.2 7 [2, 12.8]	52.0 6.7 [2, 13.3]	67.1 7 [2, 13]
75-79	45.3 5.7 [1.7, 11.7]	58.1 6 [2, 12.7]	56.9 6.3 [1.7, 12.7]	55.1 6 [2, 12.7]	63.0 6.3 [2, 12.7]	62.5 6.3 [1.7, 13.3]	70.6 6.3 [2, 13]
80-84	58.8 5.3 [1.7, 11.7]	69.4 6 [1.7, 12.7]	61.3 6.2 [1.7, 13]	63.8 5.7 [1.7, 12.7]	71.2 6 [2, 12.7]	66.5 5.7 [1.7, 12.7]	76.8 5.3 [1.7, 13]
85-89	83.4 4.3 [1.3, 11.3]	86.0 4.7 [1.3, 12.3]	82.2 5 [1.3, 12.3]	81.6 5 [1.3, 12.3]	84.0 5 [1.3, 12.7]	83.3 4.7 [1.3, 12]	87.9 5 [1.3, 12]
90-94	95.3 3 [1, 10.7]	93.8 3.3 [1, 11]	93.4 3.3 [1, 10.7]	93.6 4 [1, 11.7]	92.5 3.7 [1, 11.7]	91.6 3.7 [1, 11.3]	92.9 3.7 [1, 11]
95-99	97.3 1 [0.3, 7.3]	96.9 1.3 [0.3, 7.7]	97.7 1.3 [0.3, 8]	97.0 1.3 [0.3, 8.7]	96.7 1.3 [0.3, 8.3]	96.5 1.3 [0.3, 8.3]	96.6 1.3 [0.3, 8]

Table 13-27 Event rate analysis (non-surgical non-invasive, N=424)

HPI Range	55 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	60 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	65 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	70 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	75 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	80 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]	85 mmHg MAP target Event rate (%); Time-to-Event in minutes: Median [10th percentile, 90th percentile]
10-14	16.1 63.3 [21, 103.7]	8.9 53.3 [10.1, 99.1]	14.6 60.3 [13.3, 107.5]	13.3 47.5 [9.3, 95.4]	17.7 26.5 [9, 95.5]	16.8 44.8 [11, 101.6]	28.7 35.7 [6.3, 95]
15-19	15.0 58 [14, 105.3]	8.7 46.3 [10, 97.7]	15.4 52 [11, 99]	15.1 44 [8.7, 105.5]	18.6 41 [8.4, 96.3]	18.6 32 [9, 91.8]	33.4 34.3 [8.6, 97.7]
20-24	12.7 54.3 [8.6, 98]	9.8 51 [10, 102.7]	15.7 42.5 [8.3, 102]	18.3 47 [8.5, 101.8]	21.8 44.3 [6.9, 98.3]	23.0 35.3 [9.9, 100.3]	31.0 28.5 [7.3, 76.7]
25-29	11.2 49.6 [8, 99.8]	10.6 43 [7.7, 103.9]	15.0 46.2 [11, 103.7]	21.7 42.7 [8.4, 100.9]	22.1 39 [6.8, 95.3]	25.2 32.7 [8.7, 97]	32.3 28.7 [7.7, 90.8]
30-34	11.1 40.7 [11.3, 99.6]	12.8 37.7 [8.7, 98.9]	17.2 41.3 [9.3, 102.3]	25.3 37.5 [8, 100]	27.4 35.7 [7.3, 94.3]	28.7 34.9 [6.7, 95.3]	34.4 26.4 [7.7, 93.1]
35-39	14.6 36.3 [8.7, 99.3]	13.7 39.8 [10.3, 104.4]	19.5 37.2 [6.7, 100.3]	29.5 36.6 [8.6, 96.7]	32.3 33.7 [6.3, 93.3]	29.1 30.5 [6.3, 84.8]	40.0 28 [7.7, 81]
40-44	17.0 34.8 [7, 102.1]	14.9 41 [6.3, 105.4]	22.8 26.3 [6.3, 96.4]	33.6 32.3 [7.7, 98]	39.2 29.7 [6, 98.4]	36.1 25.7 [5, 81.6]	45.1 22.3 [5, 87.1]
45-49	21.7 32.3 [6.3, 97.7]	18.5 27.7 [6.3, 94.7]	27.3 23.3 [5.7, 92.3]	34.0 29.2 [6, 91.3]	44.3 24 [4.7, 86.9]	43.5 25.9 [4.3, 85.3]	50.1 23 [4.7, 81.9]
50-54	25.1 27.3 [5.7, 92.6]	23.2 20 [5.7, 91.4]	33.2 27 [6, 94.4]	37.9 28.7 [6, 93.6]	49.9 21.3 [5.7, 86.3]	46.5 22.7 [4.3, 83.8]	49.8 19.7 [4.7, 85.7]
55-59	28.3 24 [5.4, 85.7]	25.9 16.7 [4.3, 78.3]	32.4 22.8 [5, 96.7]	43.5 28.2 [5.9, 99.4]	53.8 20.7 [5.3, 84.4]	50.5 21.7 [5.3, 82.3]	52.6 18 [3, 78]
60-64	28.2 18 [4.3, 82.8]	28.2 16 [4.7, 79.1]	34.6 16.3 [4.7, 89.7]	46.4 26 [4.3, 93.3]	55.4 20.7 [5.3, 85.3]	53.6 22.7 [4.7, 80.3]	58.1 16.3 [3.3, 81.2]
65-69	33.1 14.7 [3.7, 60]	29.3 13.8 [4, 80.7]	42.3 14.3 [4, 78.5]	51.3 20.3 [4.3, 90.9]	61.7 18 [4.3, 83.8]	60.3 20.3 [3.7, 80.7]	66.6 13.3 [2.7, 69.8]
70-74	38.2 13 [3.3, 58.1]	34.3 11.5 [3, 72.4]	46.0 12 [3, 61.3]	54.3 17.7 [3.3, 81.8]	70.0 14.7 [3, 79.3]	68.4 16 [2.7, 80.7]	66.6 12.3 [1.7, 57.3]
75-79	51.5 9.3 [2.3, 24.5]	49.8 9.3 [3, 30.6]	60.7 11 [2.7, 63.6]	64.5 12 [3, 60.7]	77.7 10 [2, 44.9]	74.3 10 [1.7, 59.8]	75.6 8.3 [1.3, 39.3]
80-84	73.9 8.3 [2.3, 18.7]	73.5 9.3 [2.3, 19.2]	79.6 8 [2, 19.3]	76.7 9 [2, 35.1]	82.9 8.3 [1.4, 22.4]	83.8 7.7 [1.3, 43.7]	80.9 6.7 [1, 25.7]
85-89	95.8 7.3 [1.7, 16.7]	93.1 8 [1.7, 17.3]	96.3 5.3 [1.3, 15.4]	95.7 6.7 [1.3, 17.2]	95.6 6 [1.3, 15.7]	94.3 5.7 [1, 17.3]	92.4 5 [1, 16]
90-94	99.5 4.7 [1, 14.3]	100 5.7 [1, 16]	99.7 3.7 [1, 12.3]	99.7 4.3 [1, 15.3]	99.8 3.7 [1, 13]	99.7 3.7 [1, 13.7]	99.3 3 [1, 12]
95-99	100 1 [0.3, 9.7]	100 1.3 [0.3, 10.9]	99.8 1 [0.3, 8]	99.9 1.3 [0.3, 9.3]	99.9 1.3 [0.3, 8.7]	99.8 1 [0.3, 7.7]	99.7 1 [0.3, 8]

13.1.16Additional Clinical Data

13.1.16.1Study Design

A prospective, single-arm, open-label, multicenter study of the hypotension prevention and treatment in patients receiving arterial pressure monitoring with Acumen Hypotension Prediction Index Feature (HPI study) was undertaken to further understand the impact that the Acumen Hypotension Prediction Index (HPI) feature with its available patient hemodynamic data may have in the detection of hemodynamic instability and the reduction of intraoperative hypotension in non-cardiac surgery. The comparison group was a retrospective historical control group (N=22,109) with patient-level data from a non-profit academic consortium group, the Multicenter Perioperative Outcomes Group (MPOG), that collects perioperative data from hospitals across United States. All subjects in this study were treated with an arterial line.

The primary objective of the HPI study was to determine whether the use of the Acumen HPI feature to guide intraoperative hemodynamic management in non-cardiac surgery reduces the duration of intraoperative hypotension (IOH, defined as MAP < 65 mmHg for at least 1 minute) as compared with a historic retrospective control group. The duration of IOH was measured in the same way for the MPOG control cohort and the HPI study prospective cohort. All IOH events were measured and reported. For a subject with multiple IOH events, the events were individually measured and combined across the total surgery time for each patient to obtain a measure of the total duration of IOH. The only difference is that the data for the MPOG cohort were provided in one-minute intervals and for the prospective cohort were provided in 20-second intervals.

The HPI study was a single-arm, unblinded study conducted in 485 eligible subjects (460 pivotal subjects with an additional 25 roll-in cases) at 11 study sites in the United States. No more than 97 subjects (20% of the total population) were enrolled per site. The same sites that contributed to this historical control group were studied prospectively to determine if using the Acumen HPI feature to predict hypotension within 15 minutes of an actual event could reduce the mean duration of IOH by at least 25%.[11]

Inclusion and Exclusion Criteria. Potential subjects were excluded from study participation if during the screening and enrollment process it was determined that the following inclusion and exclusion criteria were met. Table 13-28 and table 13-29 list the inclusion and exclusion criteria applied during the study. Due to the available data for the MPOG groups subjects, there are slight differences in the inclusion and exclusion criteria for the HPI and MPOG groups. Specifically, the differences between the inclusion criteria are the investigator determination of moderate- or high-risk non-cardiac surgery and the identification of planned overnight hospitalization. The relevant specific differences between the two listed exclusion criteria are: patients who are confirmed to be pregnant/nursing, known clinically important intra-cardiac shunts, and known moderate to severe aortic and mitral valve disease.

Table 13-28 HPI prospective subject selection criteria

Inclusion criteria	Exclusion criteria
1 Written informed consent 2 Age ≥ 18 years 3 American Society of Anesthesiologists (ASA) physical status 3 or 4 4 Moderate- or high-risk non-cardiac surgery (for example, orthopedic, spine, urology, and general surgery) 5 Planned pressure monitoring with an arterial line 6 General anesthesia 7 Surgery duration expected to last ≥ 3 hours from induction 8 Planned overnight hospitalization	1 Participating in another (interventional) study 2 Contraindication to the invasive blood pressure monitoring 3 Patient who is confirmed to be pregnant and/or nursing mothers; 4 Emergency surgery 5 Known clinically important intra-cardiac shunts 6 Patient in whom an intraoperative MAP target will be <65 mmHg; 7 Known aortic stenosis with valve area ≤ 1.5 cm^2 8 Known moderate to severe aortic regurgitation 9 Known moderate to severe mitral regurgitation 10 Known moderate to severe mitral stenosis 11 Patient or surgical procedure type known as an SVV limitation (e.g. tidal volume <8 mL/kg of theoretical ideal weight, spontaneous ventilation, persistent cardiac arrhythmia, known atrial fibrillation, open chest surgery, Heart Rate/Respiratory Rate (HR/RR) ratio <3.6) 12 Current persistent atrial fibrillation 13 Known acute congestive heart failure 14 Craniotomy 15 Burn surgeries 16 Patients with intra-aortic balloon pump (IABP) or ventricular assist device(s) 17 Patient transfer from ICU requiring multiple vasoactive agents and known diagnosis of ongoing active sepsis

Table 13-29 MPOG historical control patient selection criteria

Inclusion criteria	Exclusion criteria
1 Receiving care at an Institution planning on participating in the prospective study of Hypotension Prediction Index software 2 Surgery date between January 1 2017 to December 31 2017 3 Adult patients 18 years of age or greater 4 Elective same day admission or inpatient; 5 American Society of Anesthesiologists (ASA) physical status 3 or 4 6 General anesthesia 7 Blood pressure monitoring using an invasive arterial line monitoring for >75% case (to account for arterial lines placed post induction) 8 Case duration (as defined as patient in room time to patient out of room time) ≥180 minutes	1 Baseline mean arterial pressure <65 mmHg (A blood pressure measurement obtained in the immediate preoperative period, or the first valid blood pressure intraoperatively, was determined to be the baseline) 2 Use of more than one vasoactive infusion intraoperatively (phenylephrine, norepinephrine, vasopressin, dopamine, dobutamine, or epinephrine) 3 Emergency surgery 4 Cardiac (on or off pump), burn debridement, or intracranial surgery

The incidence of IOH in the MPOG group was 88% (n=19,445/22,109) and the dates of treatment were between January 1, 2017 and December 31, 2017. The dates of enrollment for the HPI group were May 16, 2019 to February 24, 2020. The secondary effectiveness endpoint was the determination of total area under the curve of the time and MAP for all time periods for which MAP < 65 mmHg in each subject. This endpoint is correlated with the duration and a descriptive analysis of this endpoint was presented with the mean, standard deviation (SD), median, minimum and maximum.

The primary safety endpoint was the percentage of serious adverse events to include perioperative events, postoperative complications, and device-related serious adverse events. The secondary objective for this study (secondary safety endpoint) was to determine if the guidance provided by the Acumen HPI feature reduced a composite measure of complications as indicated below.

- Post-operative episodes of non-fatal cardiac arrest
- In-hospital death
- Stroke
- Acute Kidney Injury (AKI) within 30 days of the procedure
- Myocardial Injury in non-cardiac surgery (MINS) within 30 days of the procedure

13.1.16.2Patient Demographics

Table 13-30 and table 13-31 provide a summary of the available patient demographic information for the prospective clinical cohort (HPI) and the historical control cohort (MPOG) as well as the procedure types undergone by the subjects in the HPI cohort.

Table 13-30 Patient demographics (MPOG study)

Description		HPI (Intent-to-treat)	HPI (Full analysis set)	MPOG (Full analysis set)
# of patients		460	406*	22,109
Gender	Male	51.7 (n=238)	53.0 (n=215)	57.8 (n=12,779)
	Female	48.3 (n=222)	47.0 (n=191)	42.2 (n=9,330)
Age (year)	Mean±SD	63.0±12.97	62.8±13.0	65.3±13.8
	Median (min - max)	65 (19 - 94)	65 (19 - 89)	65 (18 - 90)
BMI	Median (25^{th} and 75^{th} percentile)	28.09 (24.37, 32.81)	28.09 (24.41, 32.86)	28.1 (24.2, 32.9)
ASA score	II**	0.2 (n=1)	0.25 (n=1)	0.0 (n=0)
	III	91.5 (n=421)	92.1 (n=374)	80.83 (n=17,870)
	IV	8.0 (n=37)	7.6 (n=31)	19.17 (n=4,239)
	Not Specified	0.2 (n=1)	0.0 (n=0)	0.0 (n=0)
Surgery duration (minutes, N=458)	Mean±SD	338.1±145.4	363.6±134.0	355.2±145.8
	Median (25^{th} and 75^{th} percentile)	315.5 (235, 416) (n=458)	336 (262, 430)	317 (245, 427)

*The Full Analysis Set (FAS) represents those subjects from the Intent-to-Treat (ITT) population that had a surgery duration of ≥3 hours.
**ASA II subject was identified as a protocol deviation, though not excluded from ITT and FAS populations as this subject met the defined criteria (surgery >3 hours and hemodynamic monitoring data). This subject was included in the efficacy and safety analyses, although by inclusion/exclusion criteria should not have been enrolled in the study.

Table 13-31 Procedure type (HPI)

Procedure type	% (n/N)
Spine surgery	18.5 (85/460)
Hepatectomy	13.7 (63/460)
Whipple	10.0 (46/460)
Vascular (major)	8.5 (39/460)

Table 13-31 Procedure type (HPI) (continued)

Procedure type	% (n/N)
Other	8.5 (39/460)
Nephrectomy	5.7 (26/460)
Other genitourinary surgery	5.4 (25/460)
Cystectomy	5.0 (23/460)
Pancreatectomy	5.0 (23/460)
Renal transplant	4.3 (20/460)
Head & neck surgery	3.9 (18/460)
Complex combined oncologic surgery (including 2 or more distinct organs)	3.0 (14/460)
Exploratory laparotomy	3.0 (14/460)
Colectomy	2.8 (13/460)
Adrenalectomy	2.6 (12/460)
Gastrectomy	2.0 (9/460)
Other gastrointestinal surgery	2.0 (9/460)
Hip revision	1.7 (8/460)
Prostatectomy	1.7 (8/460)
HIPEC	1.3 (6/460)
Hysterectomy with debulking	1.3 (6/460)
Cholecystectomy	0.9 (4/460)
Reoperative orthopedic surgery	0.9 (4/460)
Splenectomy	0.9 (4/460)
Bariatric surgery	0.4 (2/460)
Liver transplant	0.4 (2/460)
Sigmoidectomy	0.4 (2/460)
Not specified	0.2 (1/460)

MPOG group surgery types were determined by Current Procedural Terminology (CPT) grouping. The MPOG group included head and neck; thorax extra- and intra-thoracic; spine and spinal cord; abdomen upper or lower; urology; gynecologic; male reproductive system; pelvis; hip/leg/foot; shoulder/arm/hand; radiologic; obstetrics; and, other procedure.

Table 13-32 presents comparison of surgery types for the HPI and MPOG group surgery types as determined by CPT grouping.

Table 13-32 Surgery type by CPT grouping

Surgery type	HPI		MPOG	
	Number of Patients	Percentage of Total	Number of Patients	Percentage of Total
Head and neck	18	3.4	2024	10.2
Thorax surgery	0	0	3257	16.5

Table 13-32 Surgery type by CPT grouping (continued)

Surgery type	HPI		MPOG	
	Number of Patients	Percentage of Total	Number of Patients	Percentage of Total
Spine surgery	85	16.2	3331	16.8
Upper abdomen	157	29.9	3838	19.4
Lower abdomen	40	7.6	1314	6.6
Urologic	114	21.7	2017	10.2
Gynecologic/obstetric	20	3.8	190	1.0
Orthopedic	12	2.3	2224	11.2
Major vascular	39	7.4	0	0
Other	40	7.6	1596	8.1

Note: IOH duration by surgery type is not available for the MPOG population.

13.1.16.3Study Results

Table 13-33 provides the results of the receiver operating characteristics (ROC) analysis for all HPI subjects with available data for analysis (N=482). The ROC analysis presented in table 13-33 is identical to the analysis performed for the clinical validation studies, presented earlier in table 13-14 and table 13-15. For a detailed description of how hypotensive events, non-hypotensive events, sensitivity, and specificity are defined and calculated for table 13-33, see *Hypotension Threshold Clinical Validation Study Results – Minimally-Invasive Monitoring* on page 244.

Table 13-33 Receiver operating characteristics (ROC) for HPI subjects (N=482)*

HPI Threshold	PPV [95% confidence interval]	NPV [95% confidence interval]	Specificity (%) [95% confidence interval]	Sensitivity (%) [95% confidence interval]	AUC
85	98.4 (=821/834) [97.6, 99.3]	90.3 (=6782/7507) [89.7, 91.0]	99.8 (=6782/6795) [99.7, 99.9]	53.1 (=821/1546) [50.6, 55.6]	0.84

*Data on File at Edwards Lifesciences

Effectiveness. The HPI study was designed to evaluate the ability of the Acumen HPI feature, as a decision support tool, to reduce the duration of IOH by at least 25% in surgical patients that require advanced hemodynamic monitoring. An episode of intraoperative hypotension (IOH) was defined as a mean arterial pressure (MAP) below 65 for three (3) or more consecutive 20 second events for each subject, across all sites.

The primary effectiveness endpoint is a weighted average of site means and standard deviations combined in the same proportion of subjects that were included in the MPOG cohort. This weighted average and its properly computed standard deviation was compared to the estimates obtained from the subjects of the MPOG cohort.

The HPI study met its primary effectiveness endpoint. The HPI pivotal subjects of the full analysis set experienced a mean IOH duration of 11.97 ± 13.92 minutes compared with the MPOG historical control mean IOH of 28.20 ± 42.60 minutes. Table 13-34 demonstrates that this result was a reduction of 57.6% compared to the MPOG historical control (p<0.0001). When considering instances where there were zero episodes of IOH experienced during surgery, there was a 65% reduction of IOH (p<0.0001).

Table 13-34 Mean IOH duration – Primary effectiveness endpoint

Statistics	HPI (subject=406	MPOG (subject=22,109)	p value
Sample size (n)	293	19,446	--
Total IOH minutes	3,508	548,465	--
IOH mean (mins)**	11.97	28.20	<0.0001*
IOH STD	13.92	42.60	--

Note: IOH estimated with stand method; STD estimated with pooled method (pivotal subject with IOH episode in test arm).
Standard Method - IOH episode is defined with at least three consecutive observations having MAP<65. FAS pivotal subjects, with at least 3-hour surgery time.
*One-sided unequal variances t-test was used in analysis. Nominal alpha for the test is 0.025.
**When the HPI cohort data are analyzed using 60-second interval the mean IOH duration increased slightly from 11.97 to 12.59 which remains statistically significantly different from the MPOG 28.20 IOH Mean with a p value <0.0001.

The results of the secondary effectiveness endpoint, determination of total area under the curve (AUC) of the time, and MAP for all time periods for which MAP < 65 mmHg in each Subject, are included in table 13-35.

Table 13-35 Intraoperative hypotension AUC - ITT, pivotal subjects

Study category	Subject	AUC mean (min*mmHg)	AUC SD (min*mmHg)	AUC median (min*mmHg)	AUC range (min*mmHg)	AUC Q3-Q1 (min*mmHg)
All pivotal subjects	457	46.38	82.75	16.67	833.00	54.00
All pivotal subjects with at least one episode	328	64.63	91.46	32.33	832.00	68.00
All pivotal subjects with ≥3 hours surgery duration	406	47.07	85.30	16.83	833.00	51.00
All pivotal subjects with ≥3 hours surgery duration and at least one IOH episode	293	65.23	94.36	32.00	832.00	62.67
All pivotal subjects with <3 hours surgery duration	51	40.89	58.94	12.33	291.00	71.33
All pivotal subjects with <3 hours surgery duration and at least one IOH episode	35	59.58	62.94	37.00	290.00	73.33

Note: Standard Method - IOH episode is defined with at least three consecutive observations having MAP<65. ITT pivotal subjects, with valid surgery time.

An analysis was undertaken to assess the effectiveness of HPI in the reduction of IOH when stratified by MAP level. The duration of IOH was compared between the HPI group and the MPOG group stratified by MAP level between 50 and 70 mmHg, using the standard calculation method. Table 13-36 shows that at all MAP levels, except for MAP <50, the mean IOH duration in HPI Study Subjects was statistically significantly smaller than that reported for each MPOG MAP level.

Table 13-36 Effectiveness stratified by MAP level, HPI study versus MPOG historical control

MAP value	Statistic	HPI (subject=406)	MPOG (subject=22,109)	p value
MAP<50	Sample size (n)	28	8,555	--
	Total IOH minutes	97	35,790	--
	IOH mean (minutes)	3.45	4.20	0.1967
	IOH STD	3.56	13.10	--
MAP<55	Sample size (n)	84	12,484	--
	Total IOH minutes	341	80,115	--
	IOH mean (minuntes)	4.06	6.40	<0.0001
	IOH STD	4.30	15.40	--
MAP<60	Sample size (n)	188	16,561	--
	Total IOH minutes	1,098	212,362	--
	IOH mean (minutes)	5.84	12.80	<0.0001
	IOH STD	7.31	24.10	--
MAP<65	Sample size (n)	293	19,446	--
	Total IOH minutes	3,508	548,465	--
	IOH mean (minutes)	11.97	28.20	<0.0001
	IOH STD	13.92	42.60	--
MAP<70	Sample size (n)	375	20,986	--
	Total IOH minutes	10,241	1,185,983	--
	IOH Mean (minutes)	27.31	56.50	<0.0001
	IOH STD	28.79	70.40	--

Note: Standard Method - IOH episode defined as at least three consecutive observations with MAP<MAP value defining IOH. FAS pivotal subjects with surgery duration at least 3 hours are included. Student's t-test was applied as specified in the SAP.

During the clinical study, the reduction in the duration of intraoperative hypotension was dependent upon clinical judgement as to when, what and how treatment was administered with guidance from the HPI parameter and HPI secondary screen. Intervention types included: colloid, crystalloid, blood products, vasopressors, and inotropes. Of particular interest was a comparison of frequency pattern of subjects and intervention by HPI threshold, meaning when the HPI parameter was predicting a hemodynamic instability (HPI >85). See table 13-37. These data suggest that HPI added value by providing an alert and providing insight through the secondary screen that allowed the clinician to implement more timely and appropriate interventions.

Table 13-37 Frequency pattern of subjects and intervention instances by HPI threshold

Intervention type	HPI group	Study subject				Intervention instance			
		N	n	n/N (%)	p value[a]	N	n	n/N (%)	p value[b]
Colloid	HPI>85	78	58	74.4	0.0004	134	87	64.9	<0.0001
	HPI≤85	78	36	46.2		134	47	35.1	
Crystalloid	HPI>85	163	134	82.2	<0.0001	360	250	69.4	<0.0001
	HPI≤85	163	80	49.1		360	110	30.6	
Blood products	HPI>85	24	18	75.0	0.0781	56	34	60.7	0.0245
	HPI≤85	24	12	50.0		56	22	39.3	
Vasopressor	HPI>85	307	277	90.2	<0.0001	1604	1156	72.1	<0.0001
	HPI≤85	307	189	61.6		1604	448	27.9	
Inotrope	HPI>85	87	72	82.8	<0.0001	187	131	70.1	<0.0001
	HPI≤85	87	39	44.8		187	56	30.0	

a, b: p value from logistic regression model with HPI≤85 as the reference, a - subject, b - intervention instance. N = total subjects or total intervention instances, n = subjects or instances with intervention.

Safety. The Acumen HPI feature was shown to be safe when used in surgical patients that require advanced hemodynamic monitoring.

- There were no subjects with events adjudicated to have any relationship to the Acumen HPI feature.
- There were no ADEs or SADEs adjudicated as related to the Acumen HPI feature.
- There were no unanticipated ADEs (0%) related to the HPI feature.
- There were no deaths that occurred whether related/unrelated to HPI feature.

The secondary safety endpoint is a descriptive statistic that was a composite of 30-day post-operative AEs in the completed cases (CC) population. Table 13-38 shows the components of the 30-Day post-operative composite endpoint for the Completed Cases (CC) population. The results demonstrate that the composite event rate was 4.75% (composite events =19 [95% CI: 2.88, 7.32]), with one subject experiencing more than one of the individual composite elements). The safety data collected for the MPOG arm included mortality (375, 1.83%); AKI Stage 1 (2068, 9.35%); AKI Stage 2 (381, 1.72%); AKI Stage 3 (152, 0.69%); and, Myocardial Injury [MINS] (178, 0.81%).

Table 13-38 HPI study - 30 days post-operative composite endpoint components - CC analysis population (pivotal subjects, n=400)

Analysis endpoint	AE event		POD post-surgery days		
	Events n (%)	95% CI	Mean	Median	Range
Postoperative non-fatal cardiac arrest	1 (0.25)	0.01, 1.38	2.00	2.00	2, 2
In-hospital death	0 (0.00)	0.00, 0.92	N/A	N/A	N/A
Stroke	0 (0.00)	0.00, 0.92	N/A	N/A	N/A
Acute kidney injury - overall	16 (4.00)	2.30, 6.41	5.94	1.00	0, 27
Acute kidney injury - stage 1	11 (2.75)	1.38, 4.87	6.82	1.00	0, 27
Acute kidney injury - stage 2	3 (0.75)	0.15, 2.18	6.33	7.00	2, 10
Acute kidney injury - stage 3	2 (0.50)	0.06, 1.79	0.50	0.50	0, 1
Myocardial injury (MINS)	3 (0.75)	0.15, 2.18	1.67	1.00	0, 4

CC=complete (evaluable) group, CI=confidence interval, post-surgery days (POD)=AESTDT-SGDT

Analysis of in the intent-to-treat population (n=460) yielded 3 (0.066%) instances of myocardial injury (MINS) and 17 (3.7%) incidents of acute kidney injury (AKI).

Length of stay in the hospital and the ICU for the HPI cohort is in table 13-39.

Table 13-39 Length of stay

Endpoint	n	Mean	Median	Range		95% exact CI	
				Min	Max	Lower	Upper
Hospital length of stay (LOS) days	455	6.8	5.3	0.3	50.5	6.2	7.3
ICU length of stay (LOS) days	151	2.7	2.0	0.1	27.0	2.2	3.1

13.1.16.4Study Summary

These results demonstrate a substantial reduction in mean intraoperative hypotension (IOH), that was consistent across most sites; most sites had a > 25% reduction in its mean duration of IOH, with all sites but one exceeding 35%; ranging from a 23% to 72% mean IOH reduction. The findings of the study showed a reduction of the duration of IOH to 11.97 mins (SD 13.92), representing a 57.6% reduction ($p<0.0001$). This reduction is clinically relevant, as IOH lasting at least 1-minute has been associated with perioperative complications and morbidity such as AKI, MINS and stroke [12].

Sensitivity analyses, including review of pooling of study sites, confounding factors and subjects excluded from the intent-to-treat cohort did not materially change this clinically relevant finding of reduction in mean intraoperative hypotension (IOH).

The results demonstrate that Acumen HPI feature was shown to be safe when used in surgical patients that require advanced hemodynamic monitoring, with no device-related adverse events. Additionally, the composite event rate of 4.75% (composite events =19 [95% CI: 2.88, 7.32]) is low when considering that the subjects were ASA Physical Status 3 and 4 undergoing non-cardiac surgery.

In this unblinded prospective-to-historical comparison study design, IOH was demonstrated to be reduced with the use of the HPI software feature. This study has limitations secondary to potential bias associated with clinician awareness in the prospective arm and the comparison to a historical cohort.

13.1.16.5Conclusion

The results of this study are robust and provide valid scientific evidence that the Acumen HPI feature is safe and provided a statistically and clinically significant reduction in mean IOH. Therefore, Acumen HPI is effective in detecting hemodynamic instability and substantially reducing the amount of intraoperative hypotension when used in surgical patients who require intraoperative hemodynamic monitoring during non-cardiac surgery.

13.1.17References

1 De Hert et al, Evaluation of Left Ventricular Function in Anesthetized Patients Using Femoral Artery dP/dtmax. Journal of Cardiothoracic and Vascular Anesthesia 2006; 20(3): 325-330.

2 Tartiere et al, Non-invasive radial pulse wave assessment for the evaluation of left ventricular systolic performance in heart failure. Eur Journal of Heart Failure 2007; 9: 477-483.

3 Monge Garcia MI, Orduna PS, Cecconi M. Understanding arterial load. Intensive Care Med 2016; 42: 1625-1627.

4 Monge Garcia MI, Manuel Gracia Romero MG, Cano AG, Aya HD, Rhodes A, Grounds RM, Cecconi M. Dynamic arterial elastance as a predictor of arterial pressure response to fluid administration: a validation study. Critical Care 2014; 18: 626-637.

5 Cecconi M, Monge Garcia MI, Romero MG, Mellinghof J, Caliandro F, Grounds RM, Rhodes A. 2015. The Use of Pulse Pressure Variation and Stroke Volume Variation in Spontaneously Breathing Patients to Assess Dynamic Arterial Elastance and to Predict Arterial Pressure Response to Fluid Administration. Anesth Analg 2015; 120: 76-84.

6 Cannesson M, Le Manach Y, Hofer CK, Goarin JP, Lehot JJ, Vallet B, Tavernier B. Assessing the diagnostic accuracy of pulse pressure variations for the prediction of fluid responsiveness. A “gray zone” approach. Anesthesiology 2011; 115: 231-241.

7 Cannesson M, Musard H, Desebbe O, Boucau C, Simon R, Henaine R, Lehot JJ. The Ability of Stroke Volume Variations Obtained with Vigileo/FloTrac System to Monitor Fluid Responsiveness in Mechanically Ventilated. Anesth Analg 2009; 108: 513-517.

8 Pinsky MR. Protocolized Cardiovascular Management Based on Ventricular-arterial Coupling. In: Functional Hemodynamic Monitoring. Update in Intensive Care and Emergency Medicine (44). Springer-Verlag, Berlin, 2004, pp. 381-395.

9 Sunagawa K, Maughan WL, Burkhoff D, Sagawa K. Left ventricular interaction with arterial load studied in isolated canine ventricle. Am J Physiol, Heart Circ Physiol 1983; 245: H773-H780.

10 Chantler PD, Lakatta EG, Najjar S. Arterial-ventricular coupling: mechanistic insights into cardiovascular performance at rest and during exercise. J Appl Physiol 2008; 105: 1342-1351.

11 Shah NJ, Mentz G, Kheterpal S. The incidence of intraoperative hypotension in moderate to high risk patients undergoing non-cardiac surgery: A retrospective multicenter observational analysis. J Clin Anest. 2020: 66; 109961.

12 Salmasi V, Maheshwari K, Yang D, Mascha EJ, Singh A, Sessler DI, Kurz A. Relationship between intraoperative hypotension, defined by either reduction from baseline or absolute thresholds, and acute kidney and myocardial injury after noncardiac surgery: A retrospective cohort analysis. Anesthesiology. 2017 Jan;126(1):47-65.

13.2 Global Hypoperfusion Index (GHI) Algorithm Feature

The global hypoperfusion index (GHI) algorithm can be activated with a connected Swan-Ganz catheter and oximetry cable. The GHI algorithm uses inputs from the CCO algorithm (STAT CO [sCO]) or RVCO algorithm (CO_{RV}) and oximetry algorithm (SvO_2) to determine the GHI value. The global hypoperfusion index (GHI) algorithm provides the clinician with physiological insight into a patient's likelihood of future hemodynamic instability. The GHI algorithm is intended for use in surgical or non-surgical patients receiving advanced hemodynamic monitoring with the Swan-Ganz catheter. The GHI algorithm is considered to provide additional information regarding the patient's predicted future risk for clinical deterioration, as well as identifying patients at low risk for deterioration. The product predictions are for reference only and no therapeutic decisions should be made based solely on the GHI algorithm predictions. Future hemodynamic instability correlates to when mixed venous oxygen saturation (SvO_2) drops to 60% or less for one minute.

Precaution. If in the clinician's judgment, the prediction of global hypoperfusion events, defined as a mixed venous oxygen saturation (SvO_2) value of ≤ 60% would not be meaningful for an individual patient, the clinician may choose to deselect GHI as a key parameter.

CAUTION Inaccurate GHI values may be caused by:

- Inaccurate cardiac output measurements
- Inaccurate SvO_2 measurements
- Incorrect placement or position of the catheter
- Excessive variations in pulmonary artery blood temperature. Some examples that cause BT variations include, but are not limited to:
  * status post cardiopulmonary bypass surgery
  * centrally administered cooled or warmed solutions of blood products
  * use of sequential compression devices
- Clot formation on the thermistor
- Anatomical abnormalities (for example, cardiac shunts)
- Excessive patient movement
- Electrocautery or electrosurgical unit interference
- Rapid changes in cardiac output

The accuracy of the Global Hypoperfusion Index (GHI) algorithm, when using an advanced Swan-Ganz catheter and HemoSphere oximetry cable, is based upon several factors: the catheter has been properly placed, the patient CCO cable or pressure cable has been correctly connected, the oximetry cable has been properly connected, and oximetry algorithm calibrated.

Clinical validation studies (see *Clinical Validation* on page 270) demonstrate that GHI is accurate and hence useful across the typical range of variation of patient hemodynamics and clinical practice for surgical and non-surgical procedures. The non-surgical procedure types and surgery types studied are identified in table 13-44 and table 13-45 to inform clinicians of the patient populations studied.

13.2.1 Global Hypoperfusion Index Parameter Overview

The global hypoperfusion index parameter, GHI, which can be configured as a key parameter on all monitoring screens, displays as an integer value ranging from 0 to 100, with higher values indicating a higher likelihood of future hemodynamic instability.

Like the venous oximetry parameter, the GHI value updates every 2 seconds. When the GHI value exceeds or equals 75, the GHI parameter tile is highlighted in red. If the GHI value exceeds or equals 75 for 3 consecutive readings (total of 6 seconds), a medium alarm is initiated.

The alarm and alert functions for GHI will differ with the chosen display option for GHI as described in table 13-40.

Table 13-40 GHI display configurations

Display option	Audible and visual alarm	Information bar alarm messaging
Key Parameter	Yes	Yes
Key Parameter (audible alarm silenced)	No	Yes
Not displayed	No	No

Unlike other monitored parameters, the GHI alarm limits are not adjustable, as GHI is not a physiologic parameter with a selectable target range (as with cardiac output, for example), but rather a likelihood of physiological state. The alarm limits are displayed to the user in the software, but the controls to change the alarm limits are disabled. The alarm limit for the GHI parameter (≥75 for red alarm range) is a fixed value that may not be modified. Although the alarm limits for GHI are not adjustable, the GHI parameter alarm can be silenced similar to key parameters with adjustable alarm/target ranges. See *Configure Targets and Alarms for One Parameter* on page 128.

The GHI alarm limit is provided in table 13-41 on page 267 and in table D-4 on page 375. The algorithm performance characteristics for the alarm threshold of 75 are provided in table 13-48, included in the clinical validation section.

13.2.2 Global Hypoperfusion Index (GHI) Parameter Display

The GHI value will update every 2 seconds and displays as a value equating to the likelihood that a hypoperfusion event may occur on a scale from 0 to 100. The higher the value, the higher the likelihood that a hypoperfusion event (SvO_2 ≤ 60% for at least one minute) will occur.

Table 13-41 provides a detailed explanation and interpretation of GHI graphical display elements (trendline, dial segment [cockpit display], audible alarms, and parameter value [tile display]) and recommended user action when GHI is configured as a key parameter.

WARNING The global hypoperfusion index, GHI, should not be used exclusively to treat patients. A review of all of the patient's hemodynamics is recommended prior to initiating treatment.

Table 13-41 GHI value graphical and audible display elements

GHI value	Graphical display elements	Audible	General interpretation	Recommended user action
GHI<75	White	None	Patient hemodynamics indicate that there is a low to moderate likelihood of a hypoperfusion event occurring. A low GHI value does not exclude a hypoperfusion event from occurring in the future	Continue monitoring patient hemodynamics. Remain vigilant with respect to changing patient hemodynamics using the primary monitoring screen, GHI, and trends in parameters and vital signs.
GHI≥75	Red (flashing)	None	Surgical patient has a high likelihood of experiencing a future hypoperfusion event within the next 15 minutes	Check patient hemodynamics and blood flow in order to investigate the potential cause of the high likelihood of hypoperfusion in order to inform a potential course of action

Table 13-41 GHI value graphical and audible display elements (continued)

GHI value	Graphical display elements	Audible	General interpretation	Recommended user action
GHI≥75 and persists for three continuous readings (6 seconds)	Red (flashing)	Medium priority alarm tone	Surgical patient has a high likelihood of experiencing a future hypoperfusion event	Check patient hemodynamics using the other primary screen parameters in order to investigate the potential cause of the high likelihood of hypoperfusion in order to inform a potential course of action
GHI =100	Red (flashing)	Medium priority alarm tone	Patient is experiencing hypoperfusion and at risk for ischemia	Check patient hemodynamics and other primary screen parameters in order to investigate the potential cause of the hypoperfusion in order to inform a potential course of action

13.2.3 GHI as a Key Parameter

GHI can be configured as a key parameter using the steps described in *Change Parameters* on page 86.

The display of GHI differs in several ways from other key parameters. Display of other key parameters is described in *Status Indicators* on page 88.

Figure 13-10 GHI key parameter tile

GHI will be displayed as shown in figure 13-10 when configured as a key parameter in all screens except the cockpit screen (figure 13-11). For more information about the cockpit screen, see *Cockpit Screen* on page 93.

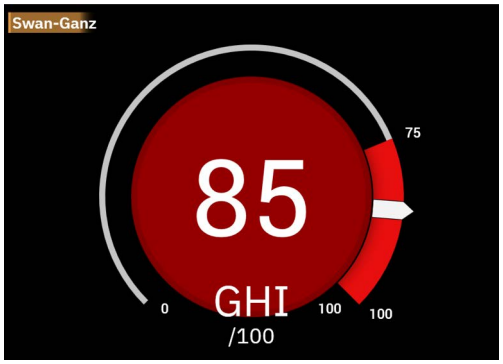


Figure 13-11 GHI key parameter on cockpit screen

On all monitoring screens except the cockpit screen, the font color of the parameter value denotes parameter status as shown in table 13-42. On the cockpit screen, GHI has the same alarm and target ranges, but it is displayed as shown in figure 13-11.

Table 13-42 Parameter status colors for GHI

Parameter status color	Lower limit	Upper limit
Gray	Fault condition	
White	0	74
Red/Gray Flashing	75	100

13.2.4 GHI Alarm

When GHI is configured as a key parameter and exceeds or equals the upper threshold of 75 for three consecutive readings, a medium priority alarm will activate which indicates to the user that the patient may be trending towards hemodynamic instability and a hypoperfusive event. This includes an alarm tone, yellow visual alarm indicator, red parameter status color, and flashing parameter value. The alarm limit of GHI shown in table 13-42 divides the display range into areas of lower and higher likelihood of hypoperfusion. GHI uses features extracted from sCO or CO_{RV} and SvO_2 measurements to a data-driven model developed from retrospective analysis of a database collected from surgical and non-surgical patients containing annotated hypoperfusion (defined as SvO_2 ≤60% for at least 1 minute) and non-hypoperfusive events. GHI is displayed as an integer value between 0 and 100. The assessment of hypoperfusion likelihood using GHI should consider both the displayed value along the range from 0 to 100 and the associated parameter color (white/red). As with other available alarms on the HemoSphere advanced monitoring platform, the volume of the GHI available alarm is adjustable. See *Alarms/Targets* on page 123 for information about silencing the alarm and configuring the alarm volume. Occurrence of GHI alarm will be logged in the data download file following an update with GHI exceeding the alarm limit.

Silence Audible GHI Alarm. The GHI alarm will be silenced for 15 minutes when silence audible alarm icon on the navigation bar is touched. A countdown timer will appear on the parameter tile. Alarms will resume sounding after the pause period has elapsed. If GHI drops below 65 before 15 minutes have elapsed, the alarm pause will end and the alarm can be re-activated if GHI alarms again.

CAUTION The GHI parameter may not provide advanced notice of a trend towards a global hypoperfusive event in situations where a clinical intervention results in a sudden non-physiological hypoperfusive event. If this occurs, the GHI feature will provide the following without delay: a medium priority alarm, and an GHI value of 100 will be displayed indicating that the patient is undergoing a hypoperfusive event.

13.2.5 Clinical Application

The global hypoperfusion parameter, GHI, can be configured as a key parameter on the monitoring screen.

When GHI is configured as a key parameter, GHI and trend graph appear on the monitoring screen:

- Alarm occurs when GHI exceeds or equals 75.
- When GHI is less than 75:
  - The trend line and value appear white.
    - Continue monitoring patient hemodynamics. Remain vigilant with respect to changing patient hemodynamics using the primary monitoring screen, GHI, and trends in parameters and vital signs.

- When GHI exceeds 75, check patient hemodynamics using other primary screen parameters in order to investigate the potential cause of the high likelihood of hypoperfusion in order to inform a potential course of action.
- Once mixed oxygen saturation remains below 60% for 6 consecutive readings (12 seconds), indicating the occurrence of a hypoperfusive event:
  * GHI displays 100.
  * Check patient hemodynamics using other primary screen parameters in order to investigate the potential cause of the hypoperfusion in order to inform a potential course of action.

13.2.6 Clinical Validation

A total of 4 retrospective datasets were performed to validate the algorithm and assess the diagnostic performance of GHI. Two of the datasets contain both OR (surgical) and ICU (non-surgical) data, one of the datasets is only ICU, and one dataset is only OR. Table 13-43 provides the patient numbers for each dataset.

Table 13-43 Patient numbers in GHI algorithm clinical validation datasets

Dataset	OR	ICU
Dataset 1 (N=67)	66	63
Dataset 2 (N=25)	25	25
Dataset 3 (N=20)	0	20
Dataset 4 (N=98)	98	0
Total = 297	189	108

Table 13-44 provides the patient demographics and ICU diagnosis for the ICU patients.

Table 13-44 Patient demographics and ICU diagnosis (ICU patients, N=108)

Description		ICU patients, all datasets
# of Patients		108
Age (years)		61.7 ± 13
BSA (m^2)		2.1 ± 0.33
Gender (% male)		76 [70.4]
Pulmonary Hypertensive (# of patients [% of total patients])		32 [29.6%]
Admission diagnosis (number of patients [% of total patients])	acute renal failure	1 [0.9%]
	cardiac disease	88 [81.5%]
	fluid shifts	2 [1.9%]
	multi-system organ failure	1 [0.9%]
	pneumonia	1 [0.9%]
	pulmonary edema hypotension	2 [1.9%]
	sepsis	12 [11.1%]
	not reported	1 [0.9%]

Table 13-45 provides the patient demographics and surgery type for the surgical patients (N=189).

Table 13-45 Patient demographics and surgery types (surgical patients, N=189)

Description	Surgical patients, all datasets
# of Patients	189
Age (years)	60.4 ± 13.2

Table 13-45 Patient demographics and surgery types (surgical patients, N=189) (continued)

Description		Surgical patients, all datasets
BSA (m^2)		2.02 ± 0.31
Gender (% male)		123 [65.1%]
Pulmonary Hypertensive (# of patients [% of total patients])		54 [28.6%]
Surgery type (number of patients [% of total of patients])	cardiac surgery (CABG, valve replacement, etc.)	134 [70.9%]
	lung transplant	28 [14.8%]
	heart transplant	8 [4.2%]
	ventricular assistive device placement	3 [1.6%]
	aortic arch aneurysm repair	6 [3.2%]
	Bentall procedure	1 [0.5%]
	Craniectomy	1 [0.5%]
	tumor removal	1 [0.5%]
	laparotomy	1 [0.5%]
	thoracic aneurysm repair	1 [0.5%]
	ventricular septal defect closure	1 [0.5%]
	not reported	4 [2.3%]

An additional clinical validation study was performed using 7 retrospective datasets to validate the algorithm and assess the diagnostic performance of GHI for patients using the RVCO algorithm (CO_{RV}) instead of the CCO algorithm. Three of the datasets contain both OR (surgical) and ICU (non-surgical) data, and four of the datasets is only OR. Table 13-46 provides the patient numbers for each dataset.

Table 13-46 Patient numbers in GHI algorithm clinical validation datasets using the RVCO algorithm

Dataset	OR	ICU
Dataset 1 (N=59)	59	0
Dataset 2 (N=23)	23	0
Dataset 3 (N=19)	19	19
Dataset 4 (N=92)	92	0
Dataset 5 (N=24)	24	24
Dataset 6 (N=23)	23	23
Dataset 7 (N=13)	13	0
Total = 253	253	66

Table 13-47 provides the patient demographics and surgery type for the surgical patients in clinical validation data sets using CCO algorithm input (N=238) and RVCO algorithm input (N=253).

Table 13-47 Patient demographics and surgery types (RVCO validation datasets, N=253)

Description	Validation datasets with RVCO algorithm input
# of Patients	253
Age (years)	60.3 ± 12.8
BSA (m^2)	1.98± 0.24
Gender (% male)	68.4%

Table 13-47 Patient demographics and surgery types (RVCO validation datasets, N=253) (continued)

Description		Validation datasets with RVCO algorithm input
Surgery type (% of total of patients)	cardiac surgery	64.8%
	pulmonary thromboendarterectomy	25.3%
	heart/liver/lung transplant	9.9%
	not reported	0%

13.2.6.1 Clinical Validation Study Results

A hypoperfusion event is calculated by identifying a segment of at least 1 minute in length such that all data points in the section have a SvO_2 ≤60%. A positive data point is any point during this global hypoperfusion event or during the global hypoperfusion progression window that occurs before the start of the global hypoperfusion event.

The global hypoperfusion window is the time it takes SvO_2 to progress physiologically into global hypoperfusion and was found to be 30 minutes based on the clinical validation datasets listed in table 13-43. Negative data points are all points not labeled as positive and have an SvO_2 greater than 60%

To validate and assess the performance of the GHI algorithm all positive and negative labeled data points for the validation patients described in table 13-44 and table 13-45 were combined and the following performance metrics were calculated:

- Sensitivity: The ratio of true positives to total number of positive data points. True positive samples are alarms generated during samples labeled as positive.
- Specificity: The ratio of true negatives to total number of negative data points. True negative samples are data points with no alarm generated that area also labeled as negative.
- Positive Predictive Value (PPV): The ratio of true positives to total positive predictions.
- Negative Predictive Value (NPV): The ratio of true negatives to total negative predictions.
- Receiver Operator Curve Area Under the Curve (ROC AUC): Measure of how well the algorithm can separate the positive and negative samples.
- F1 Score: Harmonic mean between sensitivity (recall) and PPV (precision)

Performance of the GHI algorithm can be seen in table 13-48 for all patients in the clinical validation datasets.

Table 13-48 Clinical validation study results - all patients*

GHI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	PPV [95% confidence interval]	NPV [95% confidence interval]	ROC AUC [95% confidence interval]	F1 Score [95% confidence interval]
75	84.4 [84.2, 84.6]	89.0 [88.9, 89.1]	83.3 [83.1, 83.5]	89.7 [89.6, 89.8]	94.3 [94.23, 94.37]	83.85 [83.73, 83.97]

*Data on File at Edwards Lifesciences

Performance of the GHI algorithm can be seen in table 13-48 for all patients in the clinical validation datasets using the RVCO algorithm input.

Table 13-49 Clinical validation study results - all patients using RVCO algorithm input*

GHI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	PPV [95% confidence interval]	NPV [95% confidence interval]	ROC AUC [95% confidence interval]
75	66.84 [66.36, 67.33]	97.05 [96.78, 97.32]	95.83 [95.47, 0.962]	74.58 [74.3, 74.86]	94.32 [94.03, 94.61]

*Data on File at Edwards Lifesciences

13.3 Cerebral Autoregulation Index (CAI) Algorithm

The Cerebral Autoregulation Index (CAI) is a derived parameter that quantifies the dynamic relationship between Mean Arterial Pressure (MAP) and the Absolute Levels of Blood Oxygenation Saturation (StO_2) in the cerebral tissue. CAI is intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence between MAP (as surrogate of cerebral perfusion pressure) and cerebral StO_2 (as surrogate of cerebral blood flow). CAI is not available in pediatric mode. For information on monitoring StO_2 with a ForeSight IQ sensor in cerebral tissue, see *Connecting the ForeSight Oximeter Cable* on page 203.

The CAI algorithm receives inputs from the StO_2 algorithm and uses that data in conjunction with MAP data from the APCO algorithm to calculate the coherence between the two parameters and outputs CAI as a derived parameter via a trended graph and an index value.

The CAI parameter can enhance clinician's understanding of the underlying hemodynamic changes behind cerebral desaturation events. It helps the clinician recognize/identify possible causes of, for example, decrease in StO_2 and clinical events related to StO_2 decrease (e.g., hypotension as opposed to inadequate oxygen content).

The parameter does not have any alarm ranges and is represented as a number with a range between 0 to 100.

A high CAI value means that MAP and StO_2 have a greater coherence and informs the clinician that alterations in MAP may result in concomitant changes in cerebral oxygen saturation as cerebral autoregulation is likely impaired. Whereas a low CAI value means there is lesser coherence between the two parameters and therefore alterations in MAP may not result in concomitant changes in cerebral oxygen saturation as cerebral autoregulation is likely intact.

CAUTION Inaccurate CAI values may be caused by:
- Inaccurate Mean Arterial Pressure (MAP) measurements
- Inaccurate cerebral StO_2 measurements

Clinical validation studies (see Clinical Validation) demonstrate that CAI is accurate and hence, may be useful across the typical range of variation of patient hemodynamics and clinical practice for surgical procedures. The surgery types studied are identified in Table 13-51 to inform clinicians of the patient populations studied.

13.3.1 Indications for Use

Cerebral Autoregulation Index (CAI) Algorithm is an informational index intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between Mean Arterial Pressure (MAP) and the

Absolute Levels of Blood Oxygenation Saturation (StO_2) in patient's cerebral tissue. MAP is acquired by the HemoSphere pressure cable and StO_2 is acquired by the ForeSight oximeter cable. CAI is intended for use in patients over 18 years of age receiving advanced hemodynamic monitoring. CAI is not indicated to be used for treatment of any disease or condition and no therapeutic decisions should be made based solely on the Cerebral Autoregulation Index (CAI) Algorithm.

13.3.2 Intended Use

Cerebral Autoregulation Index (CAI) Algorithm is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. The algorithm is intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between MAP and cerebral StO_2.

13.3.3 Cerebral Autoregulation Index (CAI) Parameter Display

The CAI value updates every 20 seconds and displays a value on a scale from 0 to 100. This value equates to the level of coherence between Mean Arterial pressure (MAP) and the Absolute Levels of Blood Oxygenation Saturation (StO_2) in the cerebral tissue. A high CAI value (CAI ≥ 45) means that MAP and StO_2 have a greater coherence and informs the clinician that alterations in MAP may result in concomitant changes in cerebral oxygen saturation because cerebral autoregulation is likely impaired. Whereas a low CAI value (CAI < 45) means there is lesser coherence between the two parameters and therefore alterations in MAP may not result in concomitant changes in cerebral oxygen saturation because cerebral autoregulation is likely intact.

The MAP source is shown on the parameter tile as shown in figure 13-12

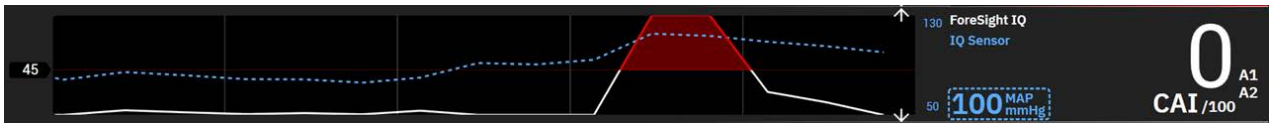


Figure 13-12 CAI key parameter trend display and parameter tile

Table 13-50 provides a detailed explanation and interpretation of CAI parameter value and the recommended user action.

WARNING The Cerebral Autoregulation Index (CAI), should not be used exclusively to treat patients. A review of all of the patient's hemodynamics is recommended prior to initiating treatment.

Table 13-50 General interpretations and recommended actions for CAI values

CAI value	General interpretation	Recommended user action
CAI < 45	MAP and StO_2 are weakly/moderately associated. Potential changes in MAP are likely not associated with changes in StO_2. Cerebral autoregulation is likely intact.	None
CAI ≥ 45	MAP and StO_2 are strongly associated. Potential changes in MAP are likely associated with concomitant changes in StO_2. Cerebral autoregulation is likely impaired.	Review individual MAP and StO_2 trends. Be aware that potential changes in MAP are likely associated with concomitant changes in StO_2 (e.g., a drop in MAP may likely be associated with a drop in StO_2) and that cerebral autoregulation capability is likely impaired.

13.3.4 Clinical Validation

A total of 50 clinical cases (cardiac surgery and general surgery) from three different sites (Northwestern University, Chicago, USA; UC Davis, Sacramento, USA; University of Minnesota, Minneapolis, USA; Amsterdam UMC, Amsterdam, The Netherlands) were used for this analysis. Table 13-51 provides the patient numbers for each site as well as the patient demographics and the surgery types from all three sites.

Table 13-51 Patient Demographics

Site	Number of Patients	Age (years)	Gender	Height (cm)	Weight (kg)	Surgery Type
Northwestern University, Chicago, USA	18	66±10	4 Females 14 Males	173±13	89±30	Cardiac surgery (N=12) General surgery (N=6)
UC Davis, Sacramento, USA	9	61±17	4 Females 5 Males	169±9	79±20	General surgery
Amsterdam UMC, Amsterdam, The Netherlands	23	58±16	7 Females 16 Males	180±11	83±15	Cardiac surgery (N = 16) General surgery (N = 7)

13.3.5 Clinical Validation Results

To validate CAI, a Receiver Operating Characteristic (ROC) analysis was performed to assess its capability to discriminate states of Intact Cerebral Autoregulation (Class I) from states of Impaired Cerebral Autoregulation (Class II). Gold-standard labels of the two classes were obtained via retrospective analysis of Cerebral Blood Flow (CBF) vs MAP curves for the utilized time-series clinical data.

Using this data, the following performance metrics were calculated:

- Sensitivity: The true positive rate; ratio of true positives to total number of positive events. TP/P=TP/(TP+FN). True positives (TP) are defined as Class II (Impaired Cerebral Autoregulation) data points with a corresponding CAI value greater or equal than a given threshold. False negatives (FN) are defined as Class II (Impaired Cerebral Autoregulation) data points with a corresponding CAI value less than a given threshold.

- Specificity: The true negative rate; ratio of true negatives to total number of negative events. TN/N=TN/(TN+FP). True Negatives (TN) are defined as Class I (Intact Cerebral Autoregulation) data points with a corresponding CAI value less than a given threshold. False Positives (FP) are defined as Class I (Intact Cerebral Autoregulation) data points with a corresponding CAI value greater than or equal to a given threshold.
- ROC AUC: the area under the ROC curve (AUC) summarizes the performance as a single number (0.5 to 1) with a higher AUC associated with a better performing algorithm.

The performance goals for CAI algorithm are defined as follows:

Sensitivity and Specificity ≥ 80% at the threshold of 45.

The performance of CAI for the chosen threshold of 45 is reported in Table 13-52 below.

Table 13-52 ROC analysis results for clinical data (N=50)

CAI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	ROC AUC [95% confidence interval]
45	82 [75, 88]	94 [91, 96]	0.92 [0.89, 0.94]

Table 13-53 provides the confusion matrix that was used to calculate sensitivity/specificity for CAI threshold of 45.

Table 13-53 Confusion matrix for CAI at the chosen threshold of 45

		Cerebral Autoregulation	
		Positive (Impaired)	Negative (Intact)
CAI	Positive (CAI ≥ 45)	1862 (TP)	493 (FP)
	Negative (CAI < 45)	392 (FN)	7851 (TN)

Additionally, Table 13-54 provides the percentage of time when CAI<45 and the percentage of time when CAI≥45 for the datasets included in the external validation studies presented in Table 13-52.

Table 13-54 Percentage of time when CAI<45 and CAI≥45 for clinical data

Dataset	Percentage of time when CAI<45	Percentage of time when CAI≥45
External clinical validation (N=50)	78.15	21.85

To evaluate potential site effects on CAI performance, the ROC analysis was also repeated for each site individually. The results are summarized in Table 13-55,Table 13-56, and Table 13-57 . The results demonstrate that CAI performance is consistent across different sites, as shown by the almost identical AUCs. The confidence intervals of AUCs and the sensitivity and specificity vary across sites due to different number of patients enrolled in different sites, and different number of positive events and/or negative events in these patients.

Table 13-55 ROC analysis results for UC Davis clinical data (N=9)

CAI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	ROC AUC [95% confidence interval]
45	82 [66, 93]	89 [67, 98]	0.90 [0.77, 0.96]

Table 13-56 ROC analysis results for Northwestern University clinical data (N=18)

CAI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	ROC AUC [95% confidence interval]
45	74 [61, 87]	93 [89, 98]	0.87 [0.79, 0.95]

Table 13-57 ROC analysis results for Amsterdam UMC clinical data (N=23)

CAI Threshold	Sensitivity (%) [95% confidence interval]	Specificity (%) [95% confidence interval]	ROC AUC [95% confidence interval]
45	84 [74, 89]	96 [94, 97]	0.93 [0.89, 0.96]

NOTE The clinically optimal threshold of 45 for the CAI algorithm was defined using datasets completely separate and independent of the external clinical validation datasets. As shown in Table 13-52, at the chosen threshold of 45, CAI can accurately discriminate moderatestates of impaired autoregulation from states of intact autoregulation.

Benefit-Risk Analysis

CAI is intended to represent a surrogate measurement of whether cerebral autoregulation is likely intact or is likely impaired as expressed by the level of coherence or lack thereof between two existing hemodynamic parameters, MAP and StO2 in the cerebral tissue. The ROC analysis against gold-standard labels of impaired and intact cerebral autoregulation demonstrates that CAI can accurately differentiate states of impaired cerebral autoregulation from states of intact cerebral autoregulation at the chosen threshold of 45. The agreement between CAI and the goldstandard labels of intact vs. impaired cerebral autoregulation is strong but not perfect. However, the benefits outweigh the risks, as CAI can enhance clinician's understanding of the potential impacts of MAP changes on cerebral perfusion.

While CAI will be shown on the monitor as an index value and a trended graph, both StO_2 and MAP trends will still be individually displayed on the monitor for review by the clinician and to aid them make treatment decisions based on these individual values. CAI is not indicated to be used for treatment of any disease or condition and no therapeutic decisions should be made based solely on the Cerebral Autoregulation Index (CAI) value.

13.4 Assisted Fluid Management

The Acumen assisted fluid management (AFM) software feature provides clinical decision support for the management of patient fluids.

13.4.1 Introduction

WARNING The Assisted Fluid Management feature should not be used exclusively to treat the patient. A review of the patient's hemodynamics is recommended throughout the monitoring session to assess fluid responsiveness.

The assisted fluid management (AFM) feature cycles through various states during a session. Table 13-59 describes each of these states.

Table 13-58 AFM algorithm states

State	AFM dashboard notification	Definition
Prompted	Bolus Suggested/ Test Bolus Suggested	A notification that has prompted the user to either (1) accept and inform the monitor that fluid administration has started or (2) decline the suggestion.
Not Prompted	Fluid Not Suggested	Fluid is not suggested.
Decline	AFM Suggestions Suspended	An action by the user to decline the AFM prompt which places the AFM feature in a 5-minute quiet period with no new notifications.
Accepted	Bolus in Progress	A fluid bolus that the User has accepted and elected to start. "**Bolus in Progress**" may also appear after initiating a User Bolus.
Analysis declined		A fluid bolus that the user has declined to analyze and will not be presented to the AFM software for analysis.
Completed	Bolus Complete	A fluid bolus that the user has completed.
Analyzing	Bolus Complete; Analyzing Hemodynamic Response	A fluid bolus that has been analyzed by the AFM algorithm. It was delivered within the prescribed rate and volume limits and has the required information to assess the hemodynamic response to the fluid.

13.4.2 Principle of Operation

The AFM software feature has been designed to guide optimal intravenous fluid administration. It includes a rule-based algorithm to make fluid management suggestions by recognizing patterns of fluid responsiveness using a patient's hemodynamic data and past responses to fluid administration. Its inputs are:

- User settings (i.e., **Fluid Strategy** [desired change in stroke volume: 10%, 15% or 20%], **Surgery Mode** [**Open** or **Laparoscopic/Prone**], and **Fluid Tracking** [**Fluid Meter** or **Manual**]).
- Hemodynamic data from arterial pressure-based analysis (pulse rate [PR], mean arterial pressure [MAP], stroke volume [SV], stroke volume variation [SVV], systemic vascular resistance [SVR], and the rate of SV change over the past two minutes).
- Fluid delivery data (start time and stop time of the fluid bolus and the fluid bolus volume).

Fluid responsiveness is derived from stroke volume changes as measured by the Acumen IQ sensor, and AFM algorithm fluid suggestions are derived from the predicted increase in stroke volume computed in part by measure of fluid responsiveness. This prediction is based upon a combination of the information derived from:

1. **Patient population model**. This utilizes data on the relationship between percent increase in stroke volume (%ΔSV) and stroke volume variation (SVV) from patient responses to the administration of 500 mL fluid at different SVV levels (N = 413 patients).[1]
2. **Individual patient bolus history.** This utilizes the fluid administration response of the currently monitored patient.

The combined information allows the algorithm to determine a delta stroke volume by identifying boluses that were given in a similar hemodynamic state and aggregating their responses, taking into account systematic biases (i.e., the model is over-estimating or under-estimating the patient's actual response to fluid) and weighting the prediction by the quality of the information in the patient bolus history to provide a final prediction.

The final prediction is compared to the chosen fluid strategy to determine if a fluid suggestion should be generated. If the predicted delta stroke volume is greater that the selected fluid strategy, then the output of the algorithm is a fluid suggestion prompt on the hemodynamic monitor. If the predicted stroke volume is not greater than the selected fluid strategy, the algorithm either does not output a fluid suggestion, or if there is limited information in the patient bolus history the algorithm may prompt a test bolus. For further information regarding possible AFM algorithm status, please refer to table 13-60 on page 284.

The fluid suggestions generated by the AFM software feature are focused on SV and CO and independent of MAP. Therefore, AFM may suggest fluid when a patient is normotensive. A full review of the patient's hemodynamic status is recommended prior to accepting an AFM algorithm recommendation or AFM algorithm test suggestion.

CAUTION The Assisted Fluid Management software feature relies on information provided by the clinician to accurately assess fluid responsiveness.

It is important to select the correct **Surgery Mode** and desired **Fluid Strategy**. The selected **Surgery Mode** and **Fluid Strategy** influences AFM fluid suggestions. Selecting the incorrect **Surgery Mode** or **Fluid Strategy** can impact the frequency of AFM suggestions. It is also important that fluid administration information (volume and duration) is accurately entered into the system. See *Assisted Fluid Management Settings* on page 282 for more information about **Fluid Strategy** and **Surgery Mode**. See *Managing Fluids with the AFM Software Feature* on page 285 for more information about fluid administration.

If the AFM software feature estimates that a patient will be fluid responsive, it will provide a message suggesting fluid administration may improve the hemodynamic status of the patient. If the AFM software feature estimates that a patient will not be responsive to fluid, the system will not suggest fluid administration.

The AFM feature includes the display of relevant hemodynamic parameters and provides real-time tracking of current patient status and total fluid volume administered for each individual patient. The AFM feature is available when an Acumen IQ sensor is connected to a radial arterial catheter.

1. Cannesson M, Le Manach Y, Hofer CK, Goarin JP, Lehot JJ, Vallet B, Tavernier B. Assessing the diagnostic accuracy of pulse pressure variations for the prediction of fluid responsiveness: a "gray zone" approach. Anesthesiology. 2011 Aug; 115(2): 231-41.

CAUTION Fluid management suggestions provided by the AFM feature can be compromised by factors such as:

- Inaccurate FT-CO measurements
- Acute changes in FT-CO measurements secondary to vasoactive medication administration, patient repositioning or surgical interventions
- Bleeding at rates similar to, or greater than, the rate of fluid delivery
- Arterial line interference

Always review patient hemodynamic status before complying with AFM suggestions.

Accurate stroke volume variation (SVV) measurement is necessary for the AFM software feature to make fluid management suggestions. Patients must be:

- mechanically ventilated
- have a tidal volume of ≥8 mL/kg

NOTE When using both AFM algorithm and HPI parameter smart alerts simultaneously, it is important to consider that AFM algorithm fluid recommendation behavior is based upon a prediction of fluid responsiveness, while HPI parameter smart alert behaviors are based upon identification of potential underlying mechanism(s) to prevent or treat hypotension. As such, these two software features are considering different targets and patient hemodynamic conditions, and should be considered independently. Current patient hemodynamics should be reviewed prior to determining the most appropriate course of action. See *Acumen Hypotension Prediction Index (HPI) Software Feature* on page 225 for more information on that feature.

13.4.3 Help Screens for AFM Software Feature

AFM software help screens are available to support many common user questions. To access AFM algorithm help screens, touch the help icon at the top of the AFM dashboard after a session is initialized. The AFM dashboard is located on the Assisted Fluid Management Side Panel.

The AFM algorithm help screens include content about getting started, using the AFM feature, and common questions about how the system works. On each AFM algorithm help screen, touch the question that interests you to see a brief answer. For additional information, contact your Edwards representative.

13.4.4 Starting or Restarting the AFM Software Feature

1 The Acumen IQ sensor must be zeroed to atmospheric pressure to ensure accurate monitoring.

Touch the **Zero** icon 

located on the navigation bar

OR

Press the physical zero button 

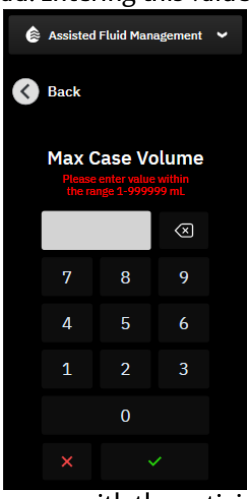
directly on the pressure cable (HEMPSC100 only) and hold for three seconds (see figure 9-1 on page 153).
For more details on monitoring with the HemoSphere pressure cable and an Acumen IQ sensor see *FloTrac Sensor, FloTrac Jr Sensor, and Acumen IQ Sensor Monitoring* on page 155.

2 Touch the **Clinical Tools** icon  → **Assisted Fluid Management** button. If another clinical tool is active, use the drop down menu to select **Assisted Fluid Management**.

NOTE If Assisted Fluid Management is started during an active GDT tracking session, the user will be notified that this will end their current tracking session.

3 Set the desired AFM settings for **Surgery Mode** (**Laparoscopic/Prone** or **Open**), and **Fluid Strategy** (**10%**, **15%**, or **20%**). See *Assisted Fluid Management Settings* on page 282.

4 Enter the **Max Case Volume** on the keypad. Entering this value is required to start an AFM session.



The **Maximum Case Volume** provides the user with the anticipated fluid volume for the entire case based upon available information at the start of the case. A patient's fluid needs may change over the course of the case and therefore this value should be considered as a guide and not the absolute threshold between optimal and excessive fluid delivery.

During an active AFM session an alert is displayed on the status bar when the total fluid delivered through the AFM feature approaches (within 500 mL) or exceeds the pre-set **Maximum case volume** to guard against potential fluid overload. The **Maximum case volume** value does not limit the functionality of the AFM feature or influence AFM fluid suggestions. This value may be changed from AFM settings screen at any time during an active AFM session by touching the settings icon  on the AFM dashboard.

NOTE In the event of power loss during an AFM session, it must be re-initialized upon return of power. If monitoring with the same patient is resumed after powering back on the monitor, the history of boluses given to the current patient is cleared; however, the total volume delivered through the AFM feature and the **Maximum case volume** value remain.

5 Touch **Initialize** button on the AFM dashboard.

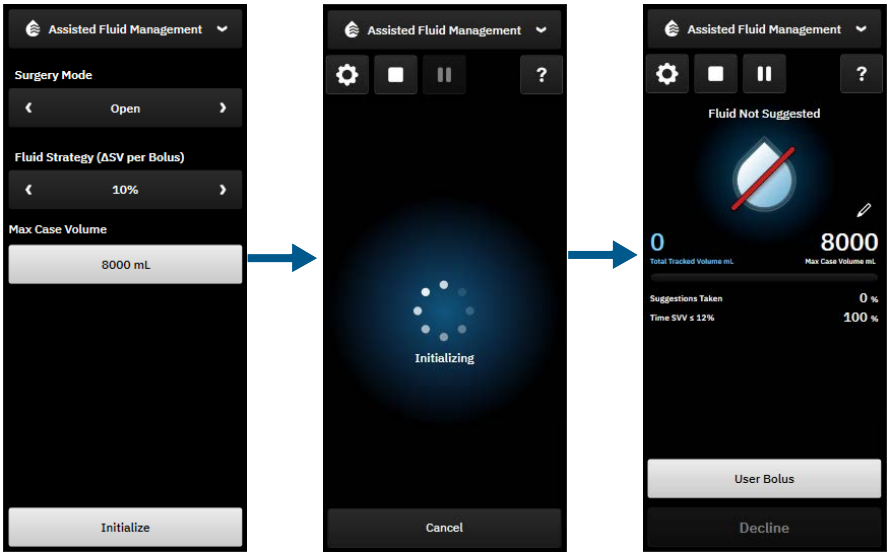


Figure 13-13 AFM algorithm dashboard - Session initialization

13.4.5 AFM Dashboard Display

The AFM dashboard (shown in Figure 13-13) can be displayed on the side panel while an AFM session is active.

The AFM dashboard can be minimized at any time by touching the **Clinical Tools** icon on the navigation bar.

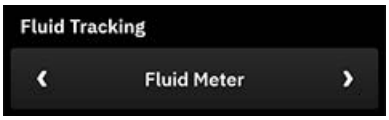
When the AFM dashboard is minimized, the fluid status icon is displayed on the information bar. To restore the AFM dashboard on the side panel, touch the fluid status icon on the information bar or access it through the side panel. See table 13-60 on page 284 for information bar icons.

13.4.6 Assisted Fluid Management Settings

Review all settings before starting an AFM session. An AFM session cannot be started without zeroing the connected Acumen IQ sensor or without setting the **Maximum case volume**. To adjust settings related to the Assisted Fluid Management feature, touch the settings icon at the right edge of the AFM dashboard.

13.4.6.1 Fluid Tracking

For **Fluid Tracking**, select either **Fluid Meter** or **Manual** using the arrows to switch through menu options.



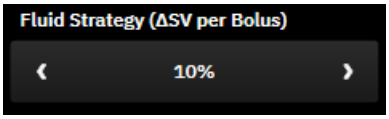
During **Manual** mode, the user is responsible for entering the fluid bolus volume delivered. With a fluid meter, the user enters a target volume for the bolus and the fluid meter will track the start, end, and flow rate of fluid delivery after the user opens and closes the fluid line.

NOTE By default, the AFM feature requires a fluid meter connection to initialize. Using the AFM feature in Manual mode is optional. For more information on changing this advanced setting, contact your Edwards representative.

13.4.6.2 Fluid Strategy

It is important to correctly select the desired **Fluid Strategy**. The selected fluid strategy influences AFM fluid suggestions. Selecting a **Fluid Strategy** that is not aligned to the clinician's fluid management strategy will lead to undesired fluid suggestions (e.g., clinician desires a restrictive fluid strategy but chooses a **Fluid Strategy** of **10%** in AFM Settings) or a lack of fluid suggestions (e.g., clinician desires liberal fluid strategy but chooses a **Fluid Strategy** of **20%** in AFM settings).

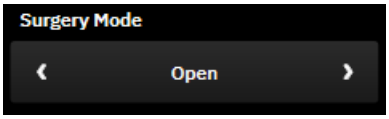
For **Fluid Strategy**, select either **10%**, **15%**, or **20%** using the arrows to switch through menu options.



NOTE **Fluid Strategy** can be used to adjust the AFM algorithm to be more liberal (**10%**) or restrictive (**20%**) in suggesting fluid. The default setting is **15%**. This percentage is the percent change in stroke volume in response to a 500 mL bolus of fluid. It is not necessary to administer a 500 mL bolus of fluid to use the AFM software feature. The percent change is adjusted to align with the volume of fluid delivered. A lower percentage indicates a lower threshold for suggesting fluid, and is therefore a more liberal setting.

13.4.6.3 Surgery Mode

For **Surgery Mode**, select either **Open** or **Laparoscopic/Prone** using the arrows to switch through menu options.

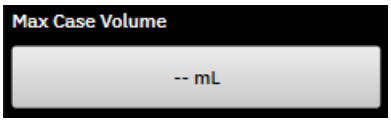


NOTE It is important to select the correct **Surgery Mode**. The selected surgery mode influences how the AFM algorithm interprets SVV. Selecting the incorrect **Surgery Mode** can lead to inappropriate fluid suggestions. If the patient is undergoing a laparoscopic procedure or is in the prone position and **Open** is selected as the **Surgery Mode**, AFM may produce additional fluid suggestions. If the patient is undergoing an **Open** procedure and **Laparoscopic/Prone** is selected as the **Surgery Mode**, the AFM algorithm may withhold fluid suggestions.

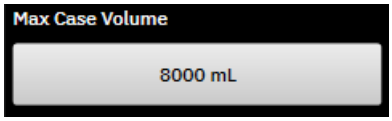
13.4.6.4 Maximum Case Volume

The **Maximum case volume** provides the user with the anticipated target fluid volume for the entire case and is set by the clinician at the start of the case based upon available clinical data at that point. A patient's fluid needs may change over the course of the case and therefore this value should be considered as a guide and not the absolute threshold between optimal and excessive fluid delivery. During an active AFM session a visual notification is provided when the total fluid delivered through the AFM feature approaches (within 500 mL) or exceeds the pre-set **Maximum case volume** to guard against potential fluid overload. The **Maximum case**

volume value does not limit the functionality of the AFM feature or influence AFM fluid suggestions. Entering this value is required to start an AFM session, and this value may be changed from the notification or through the AFM settings screen at any time during an active AFM session. To set the **Maximum case volume** when the AFM session has not been started, select the **Max Case Volume** button and enter the volume for the AFM session on the keypad.



If the **Maximum case volume** has already been entered, the current **Maximum case volume** value will appear on the settings screen. To change the **Maximum case volume**, touch the button and enter the new value on the keypad.

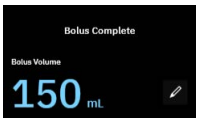
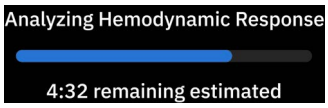


NOTE If making a change to the **Maximum case volume**, the new value must be greater than the total volume displayed on the AFM dashboard.

Table 13-59 AFM algorithm fluid status icons

AFM fluid status icon on information bar display	AFM fluid status icon on AFM dashboard	Meaning
		AFM session is initializing.
		Fluid is suggested. The estimated % change in stroke volume exceeds the threshold defined by the **Fluid Strategy** setting (10%, 15%, 20%). When the AFM algorithm recommends fluid, the final prediction is based on input from both the population model and the individual patient bolus history.
		A test bolus is suggested. To learn about the patient's fluid responsiveness, a test bolus is suggested. When the AFM algorithm suggests a test bolus, the final prediction contains little to no input from the individual patient bolus history and relies primarily on the patient population model and will trigger a test bolus suggestion if SVV > 9% in **Open** surgery mode or SVV > 12% in **Laparoscopic/Prone** surgery mode.
		Fluid is not recommended The AFM software feature will not suggest fluid (neither AFM recommendation nor test bolus) when specific physiology indicates that fluid is not recommended. This status display will appear when the AFM software feature has learned that the patient has not responded to fluid in this hemodynamic state in the past through the individual patient bolus history. If it does not have information in the Individual patient bolus history, it relies on SVV and will not suggest fluid if SVV ≤ 9% in **Open** surgery mode or SVV ≤ 12% in **Laparoscopic/Prone** surgery mode.

Table 13-59 AFM algorithm fluid status icons (continued)

AFM fluid status icon on information bar display	AFM fluid status icon on AFM dashboard	Meaning
		A bolus has completed. Review the information on the AFM dashboard and make an analysis decision.
		AFM Mode is paused. The AFM software feature will not suggest fluid in this state. A paused state is entered if the AFM software is waiting on a user response (total tracked volume approaching or exceeding maximum case volume), the system detects unstable pressure measurements, or the pressure cable has been disconnected.
		AFM Mode is suspended. A fluid bolus suggestion has been declined. A five minute timer is initiated and the AFM software feature will not suggest fluid during this time period.
		A bolus has completed and is being analyzed. The AFM algorithm is analyzing the hemodynamic response of a bolus. The estimated time left is displayed on the information bar and on the AFM dashboard. While the bolus is being analyzed by the algorithm, the User Bolus button will be unavailable and the user will not receive any fluid suggestions from the algorithm.
		A bolus is in progress. This icon will cycle through various fluid levels to indicate that a bolus is actively being administered (manually or with the fluid meter).

13.4.7 Managing Fluids with the AFM Software Feature

Once the AFM algorithm is initialized, the AFM feature will support fluid optimization in two ways: suggesting fluid or not suggesting fluid. An icon is displayed on the navigation bar or AFM dashboard to indicate the software's suggestion (see table 13-60 on page 284).

To administer fluid when the AFM feature is not suggesting fluid, open the fluid line (**Fluid Meter**) or touch the **User Bolus** button (**Manual**).

When following an AFM fluid suggestion or selecting **User Bolus**, a prompt will appear and the fluid administration workflow will commence.

The fluid administration workflow is used to gather the fluid administration information used by the AFM algorithm to analyze the hemodynamic response to the fluid bolus. The following workflows are followed for both an AFM algorithm fluid suggestion and a requested **User Bolus**. The following workflows outline steps for the user in **Fluid Meter** mode or **Manual** mode.

NOTE By default, the AFM feature requires a fluid meter connection to initialize. Using the AFM feature in Manual mode is optional. For more information on changing this advanced setting, contact your Edwards representative.

13.4.7.1 Fluid Administration Workflow – Acumen IQ Fluid Meter

Use the following AFM software workflow when an Acumen IQ fluid meter is connected. The Acumen IQ fluid meter is a sterile, single-use device that tracks the flow rate of fluid delivered to a patient through the intravenous line to which it has an in line connection. For instructions on using the AFM software feature without a fluid meter, see *Fluid Administration Workflow – Manual Mode* on page 290. Refer to the directions for use provided with the Acumen IQ fluid meter for specific instructions on placement and use, and for relevant warnings, cautions and notes. The Acumen IQ fluid meter is compatible with a HemoSphere Alta AFM cable. The HemoSphere Alta AFM cable plugs into a common cable port on the HemoSphere Alta monitor.

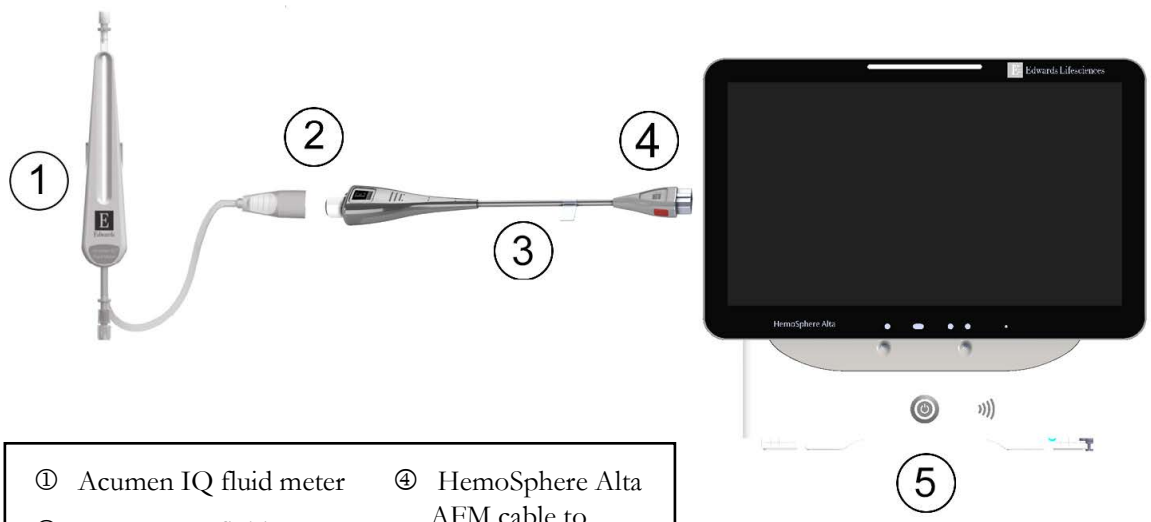


Figure 13-14 Acumen IQ fluid meter and HemoSphere Alta AFM cable connection overview

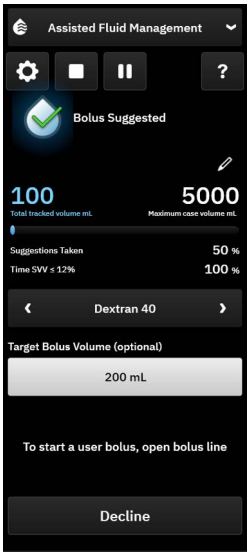
Acumen IQ Fluid Meter Connection Steps

Refer to the Acumen IQ fluid meter instructions for use for full connection instructions.

1. Refer to the Acumen IQ fluid meter instructions for use for detailed instructions on setup and in line connection of the fluid meter to the intravenous line.
2. Ensure proper orientation, then plug the HemoSphere Alta AFM cable into one of the five common cable ports on the right panel of the HemoSphere Alta monitor.
3. Connect the Acumen IQ fluid meter to the end of the Acumen AFM cable indicated by ② in Figure 13-14.

Acumen IQ Fluid Meter Fluid Administration Workflow

1 An audible chime is heard and the "**Bolus Suggested**" message appears on the AFM dashboard when the algorithm suggests a fluid bolus.



NOTE If 40 seconds have elapsed when the AFM algorithm does not recommend fluid for the patient, the "**Bolus Suggested**" message will be removed from the dashboard.

2 The fluid delivery message prompts the user to review patient hemodynamics and begin a fluid bolus if they agree with the suggestion. To decline the suggestion, touch the **Decline** button. Fluid suggestions will be paused for five minutes. To proceed with administering a bolus, continue to step 3.

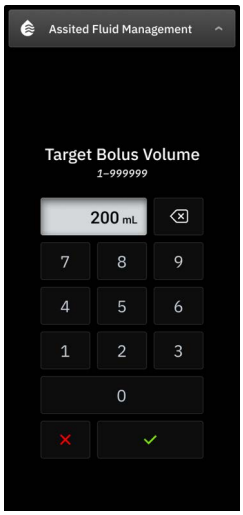
3 Specify the **Fluid Type** by using the arrows to switch through menu options.
Options are: Sodium Chloride Injection 0.9% (NaCl 0.9%), Ringer's lactate solution (RL - also known as sodium lactate solution and Hartmann's solution, PlasmaLyte, Dextran 40, Albumin 5%, Hetastarch 6%.

CAUTION Use of any fluids not listed in the specified **Fluid Type** list or choosing the incorrect fluid type may result in measurement inaccuracies.

NOTE With a fluid meter connected, the **Fluid Type** must be specified.

NOTE It may be appropriate to decline an AFM algorithm suggestion if review of patient hemodynamics does not suggest administration of fluid or in surgical situations where is it inappropriate to administer fluid. Note that constantly declining bolus suggestions may limit the usefulness of the AFM algorithm to determine future fluid responsiveness. Touch the **Decline** button to decline the bolus suggestion.

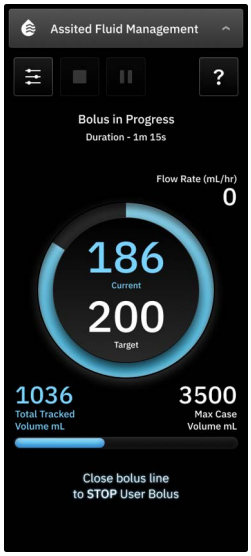
4 Touch the **Target Bolus Volume** button to enter the desired volume. This step is optional.



NOTE The AFM software feature can only analyze fluid boluses that are of volumes between 100 and 500 mL and delivered at a rate between 1 and 10 L per hour. If analysis of the fluid bolus by the AFM feature is desired, ensure that the volume and rate of delivery are within the required ranges.

5 Open the fluid line to begin bolus delivery.

6 Once a bolus is started, the "**Bolus in Progress**" message is displayed on the AFM dashboard and a meter appears to indicate the current volume of bolus delivered.



The color around the volume meter will turn green when the target volume has been reached.

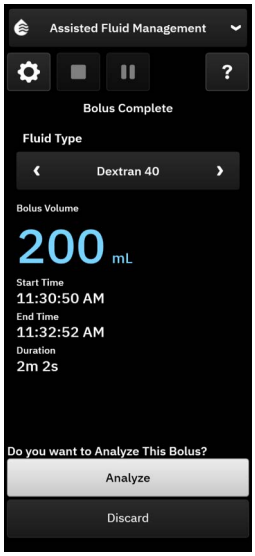
7 Close the fluid line when the desired bolus volume has been delivered.

NOTE The bolus delivery rate is dependent upon stopping the bolus when fluid administration is complete. Incorrect bolus delivery rate can impact the accuracy of the hemodynamic response assessment to a fluid bolus and the reliability of the future AFM algorithm suggestions.

CAUTION The presence of confounding factors during bolus delivery may lead to an incorrect fluid recommendation by the AFM software. Therefore, boluses delivered in the presence of confounding factors should be discarded. Potential confounding factors include but are not limited to:

- Vasoactive agent was administered during bolus administration
- Additional fluid given after primary bolus administered
- Subject repositioning
- Ventilatory changes
- Surgical manipulation
- Arterial line interference
  - External compression (i.e., leaning on A-line)
  - ABG draw, fast flush
  - Overdamping of line
- Vascular clamping
- Additional line of fluid simultaneously opened during bolus administration
- Known acute hemorrhage during fluid administration
- Inaccurate FT-CO measurements

8 Verify if **Fluid Type** displayed on the AFM algorithm dashboard is correct. If incorrect, touch on the **Fluid Type** button to edit.



If changing the **Fluid Type**, verify that the **Bolus Volume** shown is still accurate. If necessary, adjust the volume by touching the edit icon next to the **Bolus Volume**.

9 Upon fluid bolus completion, if the total volume delivered through AFM is approaching (within 500 mL) or exceeding the **Maximum case volume**, the AFM session will pause and one of the following messages will appear:
A. Total tracked volume is approaching the maximum case volume
B. Total tracked volume has exceeded the maximum case volume

If one of these notifications appears, re-assess the **Maximum case volume** to ensure it meets the patient's fluid needs and end the AFM session if appropriate. The total volume delivered is available at

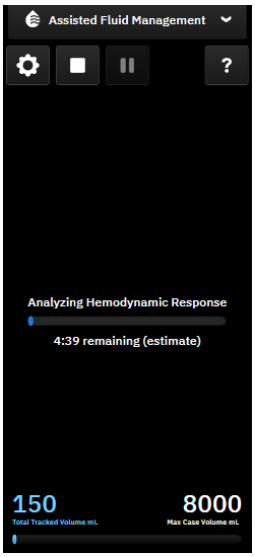
all times on the AFM dashboard and the **Maximum case volume** can be reviewed or changed at any time through the AFM settings by touching the settings icon on the AFM dashboard. For more information, see *Approaching/Exceeding Maximum Case Volume Workflow* on page 294.

NOTE If an additional AFM algorithm session for the same patient is desired after the previous session has ended, refer to *Starting or Restarting the AFM Software Feature* on page 280. All initial AFM settings, with the exception of the **Maximum case volume**, will be maintained. Refer to *Assisted Fluid Management Settings* on page 282 to access and modify these settings, as necessary.

10 Touch **Analyze** to accept the current bolus for analysis.
While the bolus is being analyzed by the algorithm, the **User Bolus** button will be unavailable and the user will not receive any fluid suggestions from the algorithm.

The AFM algorithm will only analyze fluid boluses within the following ranges:

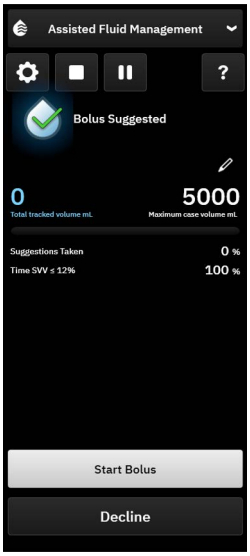
- Bolus Volume: 100 - 500 mL
  Bolus Rate: 1 - 10 L/hr



13.4.7.2 Fluid Administration Workflow – Manual Mode

NOTE It is important that fluid administration information (volume and duration) is accurately entered into the system.

1 An audible chime is heard and **Bolus Suggested** message appears on the AFM dashboard when the algorithm suggests a fluid bolus.



NOTE If 40 seconds have elapsed when the AFM algorithm does not recommend fluid for the patient, the "**Bolus Suggested**" message will be removed from the dashboard.

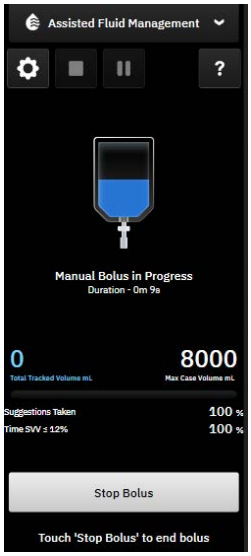
2 The fluid delivery message prompts the user to review patient hemodynamics and begin a fluid bolus if they agree with the suggestion.

If a fluid bolus is started, touch **Start Bolus** to indicate the timing of the start of the bolus.

NOTE It may be appropriate to decline an AFM algorithm suggestion if review of patient hemodyamics does not suggest administration of fluid or in surgical situations where is it inappropriate to administer fluid. Note that constantly declining bolus suggestions may limit the usefulness of the AFM algorithm to determine future fluid responsiveness. Touch the **Decline** button to decline the bolus suggestion.

NOTE The AFM software feature can only analyze fluid boluses that are of volumes between 100 and 500 mL and delivered at a rate between 1 and 10 L per hour. If analysis of the fluid bolus by the AFM feature is desired, ensure that the volume and rate of delivery are within the required ranges.

3 Once a bolus is started, then the "**Manual Bolus in Progress**" message along with the fluid bolus duration is displayed on the AFM dashboard.
When the bolus is completed, touch the **Stop Bolus** button and the **Bolus Volume** keypad will display.

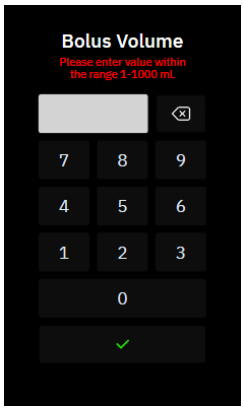


NOTE The bolus delivery rate is dependent upon stopping the bolus when fluid administration is complete. Incorrect bolus delivery rate can impact the accuracy of the hemodynamic response assessment to a fluid bolus and the reliability of the future AFM algorithm suggestions.

CAUTION The presence of confounding factors during bolus delivery may lead to an incorrect fluid recommendation by the AFM software. Therefore, boluses delivered in the presence of confounding factors should be discarded. Potential confounding factors include but are not limited to:

- Vasoactive agent was administered during bolus administration
- Additional fluid given after primary bolus administered
- Subject repositioning
- Ventilatory changes
- Surgical manipulation
- Arterial line interference
  - External compression (i.e., leaning on A-line)
  - ABG draw, fast flush
  - Overdamping of Line
- Vascular clamping
- Additional line of fluid simultaneously opened during bolus administration
- Known acute hemorrhage during fluid administration
- Inaccurate FT-CO measurements

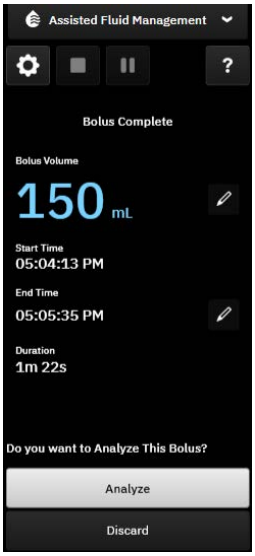
4 Enter the fluid bolus volume on the **Bolus Volume** keypad. Touch enter key when complete.



Precaution. When estimating the amount of fluid delivered and entering the information into the system for analysis, it is important to ensure that the fluid bolus volume entered into the system is as accurate as possible.

- If the bolus volume entered into the system is greater than what was actually given, it could be interpreted as less effective causing subsequent bolus suggestions to be suppressed if the patient returns to a similar hemodynamic state.
- If the bolus volume entered into the system is less than what was actually given, it could be interpreted as more effective causing subsequent bolus suggestions to be made if the patient returns to a similar hemodynamic state.

5 Verify if information on the AFM dashboard is correct. If incorrect, touch the edit icon next to **End Time** or **Bolus Volume** value to edit.



NOTE The prompt to analyze the hemodyanic response after a fluid bolus times out after 90 seconds. If analysis is available (**Analyze** is selectable), this will automatically be chosen.

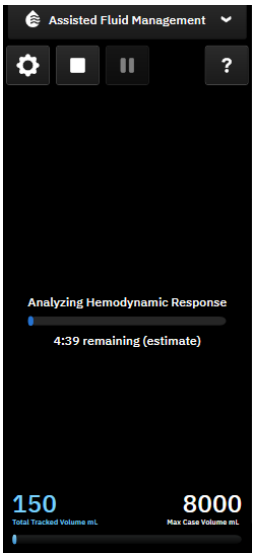
6 Upon fluid bolus completion, if the total volume delivered through AFM is approaching (within 500 mL) or exceeding the **Maximum case volume**, the AFM session will pause and one of the following messages will appear:
A. Total tracked volume is approaching the maximum case volume

B. Total tracked volume has exceeded the maximum case volume

If one of these notifications appears, re-assess the **Maximum case volume** to ensure it meets the patient's fluid needs and end the AFM session if appropriate. The total volume delivered is available at all times on the AFM dashboard and the **Maximum case volume** can be reviewed or changed at any time through the AFM settings by touching the settings icon on the AFM dashboard. For more information, see *Approaching/Exceeding Maximum Case Volume Workflow* on page 294.

NOTE If an additional AFM session for the same patient is desired after the previous session has ended, refer to *Starting or Restarting the AFM Software Feature* on page 280. All initial AFM algorithm settings, with the exception of the **Maximum case volume**, will be maintained. Refer to *Assisted Fluid Management Settings* on page 282 to access and modify these settings, as necessary.

7 Touch **Analyze** to accept the current bolus for analysis. Touch **Discard** to exclude the current bolus from further analysis by the AFM algorithm.
If the user accepts the current bolus and the bolus volume and rate fits within the AFM algorithm's criteria, the bolus will be analyzed by the algorithm.



While the bolus is being analyzed by the algorithm, the **User Bolus** button will be unavailable and the user will not receive any fluid suggestions from the algorithm.
The AFM algorithm will only analyze fluid boluses within the following ranges:
Bolus Volume: 100 - 500 mL
Bolus Rate: 1 - 10 L/hr

NOTE Due to insufficient data, analysis is not available if any Acumen IQ sensor or AFM software feature related technical faults occurred immediately before or after bolus delivery or are still active.

13.4.7.3 Approaching/Exceeding Maximum Case Volume Workflow

Upon fluid bolus completion, if the total volume delivered through AFM is approaching (within 500 mL) or exceeding the **Maximum case volume**, the AFM session will pause. If one of the notifications listed below appears, re-assess the **Maximum case volume** to ensure it meets the patient's fluid needs and end the AFM session if appropriate. The AFM feature will remain paused until one of the two choices are made. The total

volume delivered is available at all times on the AFM dashboard (AFM suggestions/statistics, bolus in progress and analysis in progress side panels) and the **Maximum case volume** can be reviewed or changed at any time through the AFM settings by touching the settings icon on the AFM dashboard.

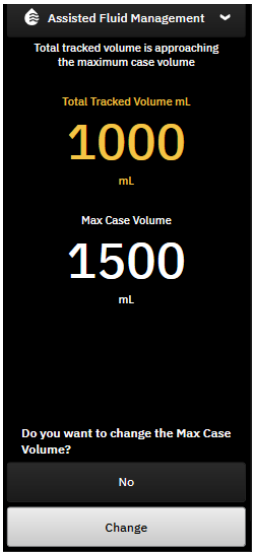
A. Total tracked volume is approaching the maximum case volume

If approaching the pre-set volume, touch:

- **Change** to enter a new value through the keypad if patient fluid needs have changed. A notification will appear again if the total volume delivered through AFM is approaching (within 500 mL) the **Maximum Case Volume**;

  or

- **No** to continue the AFM session without changing the **Maximum case volume**. If acknowledged, the next notification to appear will indicate that the **Maximum case volume** has been exceeded.



The AFM session will continue once a selection has been made. The session can also be ended through the AFM settings menu at any time as described in *Pausing and Ending an AFM Algorithm Session* on page 296.

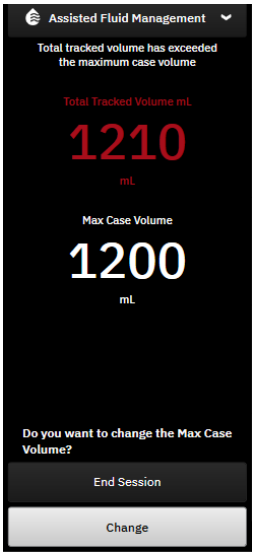
B. Total tracked volume has exceeded the maximum case volume

If exceeding the pre-set volume, touch:

- **Change** to enter a new volume amount if the decision is made to intentionally exceed the pre-set volume because patient fluid needs have changed and continue the AFM session;

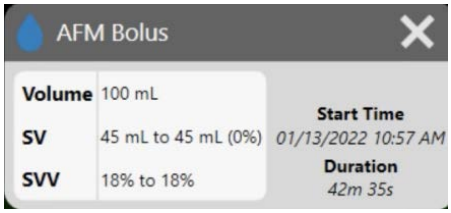
  or

- **End Session** to discard the history of boluses given to the patient through the AFM feature and discontinue the AFM session as described in *Pausing and Ending an AFM Algorithm Session* on page 296.



13.4.8 Fluid Bolus Information Popup

Information on previously delivered fluid boluses and a session summary can be reviewed after an AFM session is ended on the AFM algorithm side panel or through the **Events & Intervention** side panel. To view information on a previously delivered fluid bolus during an active AFM session view the **AFM Bolus** or **User Bolus** information popup. The fluid bolus popup contains the bolus volume, bolus start time, bolus duration, fluid type (Fluid Meter only), change in SV, and change in SVV from beginning to end of the bolus. To view this popup during or after an AFM session has ended, touch the blue shaded region on the plot for which the AFM bolus was delivered.



13.4.9 Pausing and Ending an AFM Algorithm Session

An active AFM session can be paused at any time, causing the AFM algorithm to suspend new fluid suggestions. While the AFM algorithm is paused, the AFM dashboard will display the total tracked volume, maximum case volume, percentage of suggestions taken and GDT statistics (SVV parameter time-in-target) for the current session.

To pause the current AFM session, touch the AFM pause button in the AFM dashboard.

To resume AFM session after being paused, touch the AFM start button.

Each AFM session can be ended by the user. The HemoSphere Alta advanced monitoring platform will end the AFM session if a new patient is selected or the user switches to a different monitoring technology. AFM is only available with a connected pressure cable and Acumen IQ sensor. When the AFM session ends, monitoring continues without AFM prompts and display features. To end the current AFM session, use the following steps:

1 Touch the stop button  .

2 Confirm on the AFM dashboard by touching the **Finish** button.

If a Fault occurs while an AFM session is active, AFM will be suspended until the Fault condition is cleared.

NOTE If an additional AFM session for the same patient is desired after the previous session has ended, refer to *Starting or Restarting the AFM Software Feature* on page 280. All initial AFM settings will be maintained. Refer to *Assisted Fluid Management Settings* on page 282 to access and modify these settings, as necessary.

13.4.10GDT Tracking During an AFM Algorithm Session

By touching the start AFM icon on the AFM dashboard, a GDT tracking session is automatically started with the following settings:

Parameter	Target
SVV	≤ 12%

The GDT parameter and target are non-configurable during an AFM session. When the AFM session is paused or ended, the GDT tracking session is paused or ended as well. For additional information about the GDT Tracking feature, refer to *Enhanced Parameter Tracking* on page 308.

The current **Time-In-Target Range** value for SVV ≤ 12% is displayed on the SVV parameter tile. 

13.4.11Clinical Validation

A prospective, multicenter, clinical study with 330 subjects allocated to a single arm across 9 US clinical sites was carried out to evaluate the performance of the Acumen Assisted Fluid Management (AFM) software feature in its ability to predict a patient's fluid responsiveness.

NOTE This study was conducted using a previous version of the graphical user interface software. There are differences in the graphical user interface of AFM on previous user interfaces and the user interface presented here for the HemoSphere Alta advanced monitoring platform. Relevant differences have been noted where necessary.

Subjects included in the study were ≥18 years of age, with planned non-cardiac/non-thoracic surgery (e.g., abdominal surgery, combined abdominal/pelvic surgery, major peripheral vascular surgery) expected to last >2 hours post-anesthesia induction and had an American Society of Anesthesiologists (ASA) Score of 3 or 4. Table 13-61 provides a summary of the subject demographics.

Table 13-60 Subject demographics

Type	AFM IDE study
# of Patients	330
Age	64.2 ± 12.9

Table 13-60 Subject demographics

Type	AFM IDE study
BMI	26.3 ± 4.5
ASA 3	91.8%
ASA 4	8.2%

The primary objective of the study was to evaluate the performance of the AFM feature in its ability to predict a patient's fluid responsiveness. The primary objective is based upon the performance of the AFM feature and the clinical decision making that occurred during the clinical study. The validity of the fluid responsiveness was measured by reporting the number of recommendations followed by delivered boluses that did and did not have a stroke volume (SV) response meeting the set fluid strategy (for example, for 15% fluid strategy, 500 cc of fluid should increase the patient's stroke volume by 15% if the patient is fluid responsive).

NOTE An AFM algorithm recommendation in this study is equivalent to a fluid bolus suggestion on the HemoSphere Alta advanced monitoring platform. An AFM algorithm test/test bolus is equivalent to a test bolus suggestion on the HemoSphere Alta advanced monitoring platform.

The AFM software feature showed that 66.1% [62.1%, 69.7%] of the time a bolus was administered after an AFM recommendation (based primarily on the subject's previous SV response), there was an increase in stroke volume per set fluid strategy. Additionally, the AFM software feature showed that 60.5% [57.8, 63.2] of the time a bolus was administered after a test bolus suggestion (based primarily on SVV) there was an increase in stroke volume per set fluid strategy. (table 13-62).

Table 13-61 AFM algorithm response rates by bolus type

Type of bolus event*	Mean response rate (%) [confidence interval]
AFM algorithm recommendation	66.1% [62.1, 69.7]
AFM algorithm test	60.5% [57.8, 63.2]
**Note: An AFM recommendation in this study is equivalent to a fluid bolus suggestion on the HemoSphere Alta advanced monitoring platform. An AFM test is equivalent to a test bolus suggestion on the HemoSphere Alta advanced monitoring platform.*	

An analysis of the response rate at the subject level demonstrates that the mean response rate was 65.62% and the median [interquartile range] per-subject response is 75% [50%, 100%] with a range from 0% to 100%.

Out of the 330 subjects enrolled in the study, 307 subjects were assigned to the per-protocol pivotal cohort and included in the effectiveness evaluation for the primary endpoint. In the per-protocol pivotal cohort, 94% (289/307) and 54% (165/307) of the subjects received AFM test suggestions and AFM recommended suggestions, respectively, and 6% of the subjects (18/307) did not receive any AFM suggestions. Therefore, it should be noted that the primary effectiveness endpoint is based on the 54% that received AFM recommended boluses.

User boluses during the study were recorded whenever fluid was given outside of an AFM test or recommendation while the AFM feature was in use. When the clinician administered a user bolus, there was an increase in stroke volume 40.9% [37.4, 44.1] of the time. The user boluses were not given exclusively as part of a manually administered fluid management protocol.

A secondary analysis provided the AFM algorithm performance stratified by delivered bolus volume (see table 13-63). The results demonstrate that AFM algorithm performance can depend on the bolus volume used.

Table 13-62 AFM algorithm performance by bolus volume (mL)

Bolus volume (mL)	Mean response (%)	(2.5% LCL, 97.5% UCL)	Number of boluses	Number of subjects
≤100	77.26%	(72.60, 81.81)	147	76
>100-200	59.92%	(54.61, 65.13)	152	76
>200-250	57.73%	(50.63, 64.94)	79	49
>250-300	65.27%	(59.18, 69.39)	49	39
All Boluses	66.04%	(61.56, 71.13)	424	207

Accuracy of the AFM software feature was analyzed at the bolus level; this includes sensitivity and specificity, and positive and negative predictive values.

Sensitivity is the ratio of true positives to the total number of responders (positives). A true positive is any event with an increase in stroke volume per the predetermined fluid strategy when a bolus is given (within 5 minutes) after AFM recommendation. Sensitivity of the AFM feature was 77.7%.

Specificity is the ratio of true negatives to the total number of non-responders (negatives). In the context of the clinical study, a true negative is any bolus given outside of the AFM recommendations to which the patient did not respond. Specificity of the AFM feature was 40.6%.

Positive predictive value (PPV) is the probability that a patient will be responsive to a bolus recommended by AFM. PPV of the AFM feature was 62.7%.

Negative predictive value (NPV) is the probability that a patient will be non-responsive to a bolus given outside of AFM recommendations. NPV of the AFM feature was 58.9%.

Table 13-63 Accuracy results of the AFM feature (bolus level)

Measurement	Value (%) [95% confidence interval]
PPV	62.7 [59.6, 65.3]
NPV	58.9 [54.4, 63.2]
Specificity	40.6 [37.1, 44.3]
Sensitivity	77.7 [74.9, 80.3]

13.4.11.1Fluid Bolus Activity

The AFM software feature uses the current hemodynamic state and past response to fluid given in similar states to determine if a fluid recommendation should be generated. Therefore, it is possible to receive several AFM suggestions in a one-hour period. Post-hoc analysis of the clinical validation study determined that the number of recommendations can range from 0-6 AFM recommendations per hour, with no AFM recommendations for

the majority of the time (see table 13-65). It is also possible for an AFM suggestion to immediately follow the completion of a non-responsive fluid bolus if current hemodynamic state has changed since the prior non-responsive bolus.

Table 13-64 Frequency of AFM algorithm recommendations per hour**

AFM algorithm recommendations per hour	Frequency of occurrence*
0	73.8% (784/1062)
1	10.9% (116/1062)
2	6.7% (71/1062)
3	5.3% (56/1062)
4	2.4% (26/1062)
5	0.6% (6/1062)
6	0.3% (3/1062)

**The frequency of occurrence is based upon the number of hours with a given number of AFM algorithm recommendations divided by the total number of hours.*
***The frequency of AFM algorithm recommendations per hour is presented as general guidance and may not be representative of individual experience.*

As a clinical decision support system, AFM algorithm suggestions can be declined or discarded by the user. In the clinical validation study, 47% (1209/2550) of the total AFM algorithm suggestions were declined by the user which included 40% (324/803) of the AFM algorithm recommendations and 51% (885/1747) of AFM algorithm test suggestions. In addition, out of the 1341 AFM algorithm prompts that were accepted by the users, 13% (168/1341) were discarded which included 11% (52/479) of the AFM algorithm recommended boluses and 13% (116/862) of AFM algorithm test boluses.

Although post-hoc analysis revealed no difference in performance based on compliance to AFM algorithm suggestions, the clinical validation study was not designed to directly address this question. Therefore, the AFM algorithm performance may be affected by the compliance to AFM algorithm suggestions. Table 13-66 includes a complete accounting of the fluid boluses in the clinical validation study.

Table 13-65 Complete accounting of fluid boluses

Bolus originator	Prompted	Suggestion declined	Accepted	Discarded (analysis declined)	Completed	Analyzed
AFM algorithm	2550	1209	1341	168	1173	1165
- Recommended	803	324	479	52	427	424
- Test	1747	885	862	116	746	741
User	606	14	592	81	511	508
Total	3156	1223	1933	249	1684	1673

During the clinical validation study, the boluses were discarded 13% of the time (analysis declined). The reasons for discarded boluses during the study are included in table 13-67.

Table 13-66 Reasons boluses were discarded (analysis declined) in the per protocol pivotal subjects

Fluid demographics Reasons bolus discarded (analysis declined)	%(n/N)
Administered vasoactive agent with fluids	35.0% (89/254)
Other	18.1% (46/254)
ABG draw / fast flush	11.8% (30/254)
Subject repositioning	11.8% (30/254)
Arterial line interference	10.2% (26/254)
Ventilatory changes	4.7% (12/254)
Additional fluid given after primary bolus administered	3.5% (9/254)
Overdamping of line	1.6% (4/254)
Surgical manipulation	0.8% (2/254)
Unknown	0.8% (2/254)
Additional line of fluid simultaneously opened up during bolus	0.4% (1/254)
Known acute hemorrhage during fluid administration (blood loss >= 250cc in 7 min period)	0.4% (1/254)
Vascular clamping	0.4% (1/254)
Total	100.0% (254/254)
**Note: More than one Reason for Discarding a Bolus could be provided and as a result there are 254 reasons documented for 249 discarded boluses.* *Denominators are based on the total number of available data captured for each parameter.*	

During the clinical validation study, the AFM algorithm suggestions (recommendations and test) were declined 47% of the time. The reasons for decline identified during the study are provided in table 13-68.

Table 13-67 Reasons suggestions were declined in the per protocol pivotal subjects

Fluid demographics Reasons AFM algorithm prompt not accepted	% (n/N)
The subject is normotensive at this time	42.3% (592/1399)
Fluid is contraindicated by the procedure at present	7.2% (101/1399)
Clinician prefers to use a vasoactive agent instead; at this time	7.0% (98/1399)
Clinician does not think subject will be fluid responsive	6.3% (88/1399)
Other	4.4% (62/1399)
This bolus recommendation is suspect; based on recent bad data (i.e.; artifact in BP signal)	3.6% (50/1399)
We are starting to close the case now	3.5% (49/1399)
Busy engaging in other tasks	3.5% (49/1399)
ABG / ~~L~~lab draw	2.7% (38/1399)
Clinician believes the hemodynamic changes are temporary and due to surgical manipulation	2.6% (36/1399)
Currently hypertensive	2.4% (34/1399)
Clinician is administering fluid (blood or other) outside of AFM	2.4% (34/1399)
Waiting for RBC administration	2.1% (29/1399)
There was a change in subject position and clinician would like to wait and see	1.9% (26/1399)
Fluid recently administered; now observing	1.9% (26/1399)
Subject recently received fluid but was not responsive	1.2% (17/1399)
Clinician hit decline to remove AFM popup prompt so that hemodynamics could be further reviewed before deciding on giving fluid	1.1% (15/1399)

Table 13-67 Reasons suggestions were declined in the per protocol pivotal subjects

Fluid demographics Reasons AFM algorithm prompt not accepted	% (n/N)
Managing BP	1.1% (15/1399)
Questionable pressure tracing	1.0% (14/1399)
There was a brief period of arrhythmia and the clinician doesn't believe that the patient needs a bolus	0.8% (11/1399)
Clinician is concerned about dilutional anemia at this time	0.5% (7/1399)
Clinician mistakenly declined AFM recommendation.	0.3% (4/1399)
There was an expected change with insufflation which is anticipated to be brief	0.2% (3/1399)
Clinician is concerned about right ventricular dysfunction	0.1% (1/1399)
We had a temporary change in ventilation strategy (i.e.: recruitment maneuver)	0.1% (1/1399)
Total	100.0% (1399/1399)
**Note: More than one reason for a declined AFM algorithm prompt could be provided and as a result there are 1399 reasons documented for 1223 declined boluses.* *Denominators are based on the total number of available data captured for each parameter.*	

In the clinical validation study, 66% of the AFM algorithm recommended boluses produced the desired change in SV that met the Fluid Strategy as reported in Table 13-62. However, a study limitation was that fluid was not delivered when the user declined an AFM recommendation and, as such, the SV responses of the declined AFM algorithm suggestions are unknown. If each declined AFM recommendation was categorized as a negative response, the response rate could be as low as 37%. Reasons for these declines included normotension, fluid contraindicated by the procedure at the present time, and clinician preference to use a vasopressor. The complete list of reasons and their prevalence are provided in table 13-68 on page 301.

13.4.12Fluid Meter Only Mode

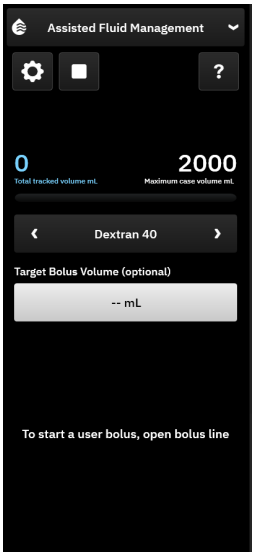
The Acumen IQ fluid meter can be connected (see figure 13-14 on page 286) to track fluid without initializing the AFM algorithm. Enabling the "**Fluid Meter Only Mode**" is an advanced setup feature. For additional information, contact your Edwards representative.

1 Touch the settings icon → **Advanced Settings** button and enter the **Secure User** password. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
2 Touch the **AFM** software button.
3 Toggle the "**Fluid Meter Only Mode**" switch on.

NOTE Active AFM algorithm sessions will end when **Fluid Meter Only Mode** is entered. Total accumulated fluid volume delivered during all previous AFM algorithm sessions from the current patient session will continue to be tracked.

4 Connect the fluid meter by following connections steps outlined in *Fluid Administration Workflow – Acumen IQ Fluid Meter* on page 286.
5 Touch the **Clinical Tools** icon → **Assisted Fluid Management** software button. If another clinical tool is active, use the drop down menu to select **Assisted Fluid Management** software.
6 Set the desired fluid meter settings for **Fluid Type** and **Maximum case volume**.

7 Touch the start icon  .



8 Enter the target bolus volume (optional).

9 Open the fluid line to begin bolus delivery.

10 The total tracked volume will be recorded and displayed on the Assisted Fluid Management software side panel.

13.5 Right Ventricular Cardiac Output Algorithm

The right ventricular cardiac output algorithm (RVCO algorithm) calculates right ventricular cardiac output (CO_{RV}) and stroke volume (SV_{RV}) using the right ventricular pressure (RVP) waveform monitored with a pressure cable and Swan-Ganz IQ catheter. The RVCO algorithm can utilize iCO values from an iCO thermodilution set as an optional input for calculating RVCO parameters. See *Intermittent Cardiac Output* on page 143 for steps. After an iCO measurement is made and accepted, RVCO parameters will display "**CAL**" on the parameter tile to indicate they have been calibrated.

CAUTION Inaccurate RVCO values may be caused by:
- Inaccurate or noisy right ventricular pressure
- Incorrect placement of position of the catheter
- Excessive patient movement
- Inaccurate Intermittent Cardiac Output (iCO) values

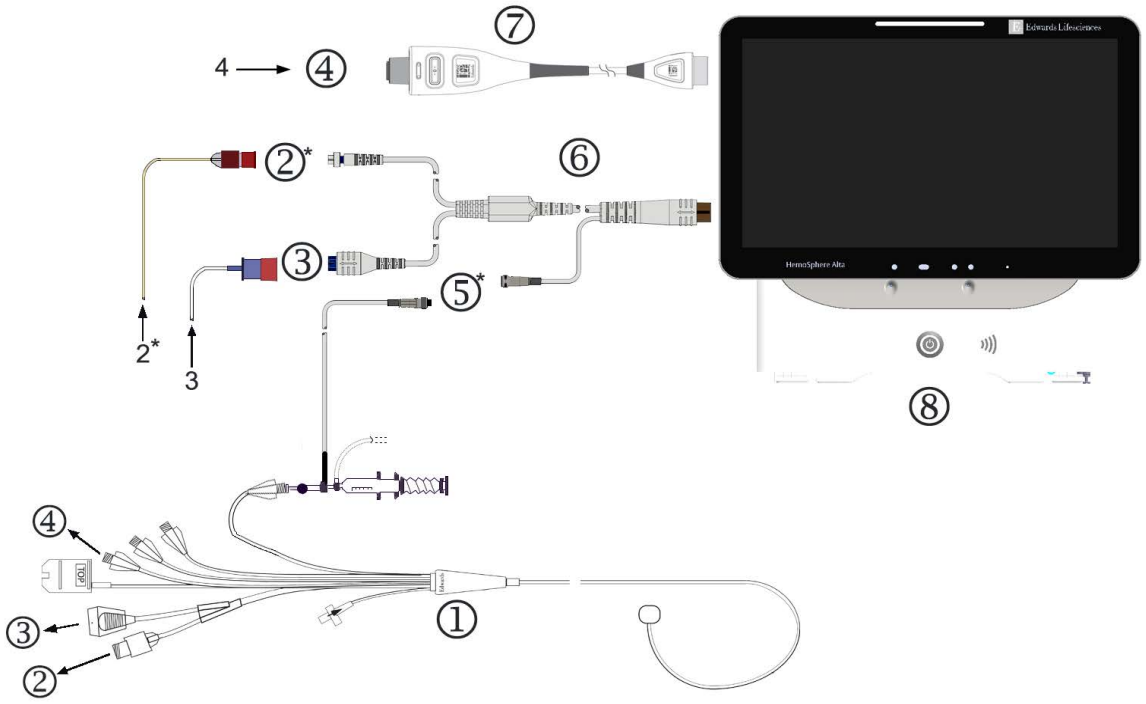
13.5.1 Indications for Use

When used in combination with the HemoSphere Pressure Cable connected to a compatible Swan-Ganz catheter, the Right Ventricular Cardiac Output (RVCO) feature provides the clinician with physiological insight into the hemodynamic status of the right ventricle of the heart. The RVCO algorithm is intended for use in surgical or non-surgical patients over 18 years of age that require advanced hemodynamic monitoring. The Right Ventricular Cardiac Output provides a continuous cardiac output and derived parameters.

13.5.2 Connecting Patient Cables

1. Connect the HemoSphere Alta Swan-Ganz patient cable to the monitor as previously described in section 8.1.
2. Connect EEPROM connector of the catheter to the thermal filament connection of th eHemoSphere Alta Swan-Ganz patient cable (as shown by ③ in figure 13-15).
3. Connect the RV port of the Swan-Ganz IQ catheter to TruWave transducer and pressure cable (as shown by ④ in figure 13-15). See *Pressure Cable Monitoring with a TruWave pressure transducer (DPT)* on page 158.
4. (Optional for iCO thermodilution): Attach the catheter end of the patient cable to the thermistor connector on the Swan-Ganz IQ catheter as shown by ② in figure 13-15.
5. (Optional for iCO thermodilution): Connect the injectate temperature probe (in-line or bath) to the injectate temperature probe connector on the patient CCO cable illustrated by ③ in figure 13-15.

6 Verify that the catheter is properly inserted into the patient. Refer to details in catheter IFU.



① Swan-Ganz IQ catheter
② thermistor connection*
③ catheter EEPROM connection to HemoSphere Alta Swan-Ganz patient cable
④ RV port to TruWave transducer / pressure cable
⑤ injectate temperature probe connection*
⑥ HemoSphere Alta Swan-Ganz patient cable
⑦ pressure cable
⑧ HemoSphere Alta advanced monitor

*optional

Figure 13-15 Swan-Ganz IQ catheter connection overview

13.5.3 RVCO Calibration (Optional)

When available, the RVCO algorithm can utilize iCO values from an iCO thermodilution set as additional input for calculating RVCO algorithm parameters. This additional input is optional. See *Intermittent Cardiac Output* on page 143. While monitoring RVCO algorithm parameters with a

Swan-Ganz IQ catheter and an iCO thermodilution set is performed, a confirmation popup window will appear to confirm Swan-Ganz IQ catheter parameter calibration. Touch the **Continue** button to confirm calibration. "CAL" will appear on any parameter to indicate calibration. See figure 13-16.

Figure 13-16 RVCO calibrated key parameter tile

13.5.4 RVCO Clinical Validation

A total of 9 retrospective datasets were performed to validate the algorithm and assess the performance of RVCO. The data collected over these sites included both surgical and non-surgical data including cardiac surgery, liver transplant surgery, chronic thromboembolic pulmonary hypertensive (CTEPH), and patients undergoing invasive cardiopulmonary exercise testing in the cardiac catheterization laboratory (Cath Lab). Table 13-69 provides the patient numbers for each dataset.

Table 13-68 Patient numbers in RVCO algorithm clinical validation datasets

Dataset	Patients (#)	iCO measurements (#)	Surgical (#)	Non-Surgical (#)
Dataset 1 (N=95)	95	360	95	0
Dataset 2 (N=19)	19	68	19	0
Dataset 3 (N=100)	100	145	0	100
Dataset 4 (N=24)	24	183	24	24
Dataset 5 (N=23)	23	92	23	0
Dataset 6 (N=37)	37	232	37	37
Dataset 7 (N=23)	23	103	23	0
Dataset 8 (N=59)	59	380	59	0
Dataset 9 (N=17)	17	114	17	0
Total = 397	397	1677	297	161

Table 13-70 provides the types of critically ill patients used in the validation dataset.

Table 13-69 Patient characteristics (validation dataset, N=397)

Patient characteristic	# patients* (% of total)
Aortic valve replacement/repair	39 (9.8%)
Mitral valve replacement/repair	43 (10.8%)
Tricuspid valve replacement/repair	5 (1.3%)
Coronary revascularization	81 (20.4%)
Aorta surgery	20 (5.0%)
CTEPH or PTE	66 (16.6%)
Lung transplant	1 (0.3%)
LVAD	17 (4.3%)
Right heart catheterization	100 (25.2%)

Table 13-69 Patient characteristics (validation dataset, N=397) (continued)

Patient characteristic	# patients* (% of total)
Liver transplant	54 (13.6%)
*Note: Some patients may have multiple procedures done, thus the total number of procedures are more than the total number of patients	

13.5.5 RVCO Clinical Validation Study Results

The Right Ventricular Cardiac Output (RVCO) algorithm calculates continuous cardiac output using the right ventricular pressure (RVP) waveform. The RVP waveform is measured using an existing Edwards FloTrac (Acumen IQ) sensor, or Edwards disposable pressure transducer (DPT) sensor connected through a fluid-filled catheter-tubing system to the right-ventricular lumen/port of an existing compatible Swan-Ganz catheter. The intermittent cardiac output (iCO) measurement by using the bolus thermodilution technique is *an optional input* to the RVCO algorithm that is not required for the RVCO algorithm to provide the cardiac output parameter; if available, the RVCO algorithm will use it as a calibration point.

To validate and assess the performance of the RVCO algorithm, the algorithm was evaluated to confirm that it meets the pre-specified performance acceptance criteria in both the non-calibrated (no iCO, table 13-71) and calibrated (with iCO, table 13-72) states.

Table 13-70 Clinical validation study results – (non-calibrated state)*

Bias (L/min)	Precision (L/min)	Percent precision (%)	Sample size (# iCOs)	Number of patients
0.290	1.243	20.173	1677	397

**Data on file at Edwards Lifesciences*

Table 13-71 Clinical validation study results – (calibrated with iCO)*

Bias (L/min)	Precision (L/min)	Percent precision (%)	Sample size (# iCOs)	Number of patients
0.165	1.064	17.601	1235	290

**Data on file at Edwards Lifesciences*

NOTE

The RVCO algorithm has different performance when calibrated against a reference. Clinicians should consider the risks and benefits when determining the appropriate cardiac output methodology for the patient.

Refer to the caution listed at the start of this section, *Right Ventricular Cardiac Output Algorithm* on page 304 for conditions that cause RVCO measurement errors. Ensure that the catheter is placed correctly and the right ventricular waveform is accurate.

13.6 Enhanced Parameter Tracking

The HemoSphere Alta advanced monitoring platform provides tools for performing **Goal Directed Therapy** (**GDT**), enabling a user to track and manage key parameters in the optimal range. With enhanced parameter tracking, clinicians have the ability to create and monitor customized protocols.

13.6.1 GDT Tracking

13.6.1.1 Key Parameter and Target Selection

1 Touch the **Clinical Tools** icon → **Goal Directed Therapy** button. If another clinical tool is active, use the drop down menu to select **Goal Directed Therapy**.

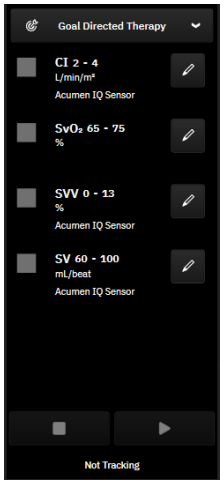


Figure 13-17 GDT menu screen – parameter selection

2 The parameters shown match the key parameters selected on the trend monitoring screen. See *Change Parameters* on page 86 to change the key parameters. Touch the edit icon to change the displayed target range. The default values are the target ranges set for that parameter. See *Configure Targets and Alarms for One Parameter* on page 128.

3 Use the arrow keys to change the target ranges or touch in the value box to use the keypad to change target range values. If left unedited, parameter values will be tracked in the default range.

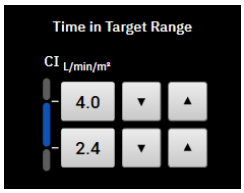


Figure 13-18 GDT menu screen – target selection

4 Touch on the boxes next to parameters to select and designate those parameters for tracking.

5 Touch the play icon to begin GDT tracking.

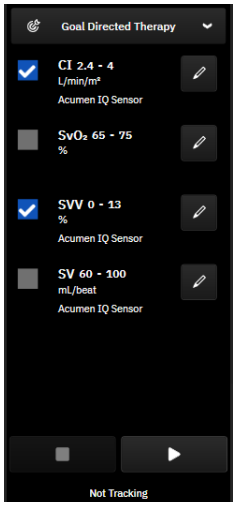


Figure 13-19 GDT – start active tracking

13.6.1.2 Active GDT Tracking

During active GDT tracking, the plot area of the parameter trend graph within targeted range appears shaded in blue. See figure 13-20.

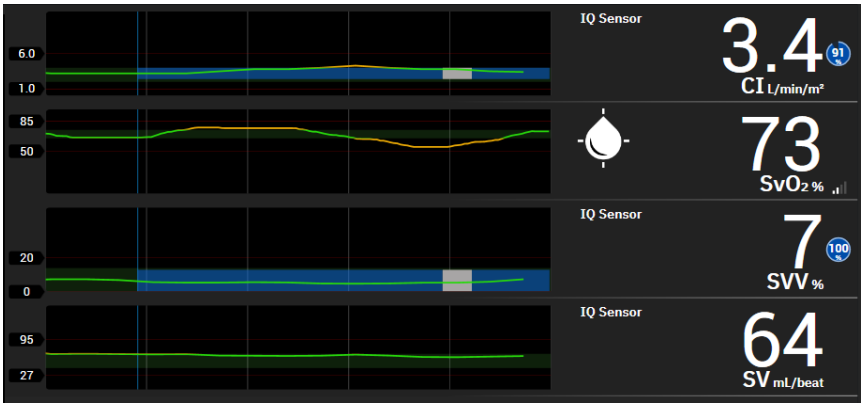


Figure 13-20 GDT – sctive tracking

GDT Tracking Side Panel. Touch the **Clinical Tools** icon → **Assisted Fluid Management** button to access the GDT side panel at any time. Touch the stop icon to stop tracking or the pause icon to pause tracking. While tracking is paused, the plot area within target range on the parameter graph appears shaded in gray.

Time-In-Target™ Value. This is the primary output of enhanced parameter tracking. It is displayed on the upper right corner of the parameter's tile and next to that parameter on the GDT side panel. This value represents the accumulated percentage of time a parameter has been within target during an active tracking session.

Parameter Tile Target Indicator Colors. Table 13-73 defines clinical target indicator colors during GDT tracking.

Table 13-72 GDT target status indicator colors

Color	Indication
Blue	Tracked parameter is currently within the configured target range.
Black	Tracked parameter is currently outside of the configured target range.
Red	Tracked parameter is currently below the low alarm limit or above the high alarm limit.
Gray	Tracked parameter is unavailable, in a fault state, GDT tracking is paused, or a target has not been selected.

NOTE While viewing active GDT tracking on the Graphical Trend Screen, parameter selection menus are disabled.

13.6.1.3 Historical GDT

Touch the **Clinical Tools** icon → **Events & Intervention** to view previous GDT tracking sessions. Scroll through the list of events to locate and select the desired tracking session. The summary of that tracking session is displayed on the side panel.

13.6.2 SV Optimization

During SV Optimization mode, the SV/SVI target range for GDT tracking is selected based on recent SV trends. This allows the user to identify the optimal SV value during active monitoring of fluid management.

1. Select **SV** or **SVI** as a key parameter.
2. Use the edit key to view the target values for SV/SVI. Toggle the **SV Optimization** to **On**.
3. Select the toggle for 10% optimization.
4. Touch the play icon to begin GDT tracking.
5. Observe the SV trend while administering necessary fluid management to achieve an optimal value. The trend line appears blue. In place of the time-in-target value, a light gray "n/a" icon appears on the SV/SVI parameter tile and GDT side panel.
6. Touch within the plot area until the add target icon appears on the SV/SVI trend graph along with optimized target values.
7. Touch the target icon to accept the values or the exit icon to continue to monitor SV/SVI values.
8. After the displayed target range is accepted, GDT tracking is initiated and plot area will turn blue. The values are now configured for SV/SVI in the GDT side panel parameter settings and can be adjusted using the edit icon .

9 The GDT side panel can be accessed at anytime when GDT mode is active to end the GDT tracking session by touching the stop icon .

13.6.3 GDT Report Download

The **Export Data** screen allows a user to export GDT reports to a USB drive. See *GDT Report* on page 132.

13.7 Fluid Responsiveness Test

With the **Fluid Responsiveness Test** (**FRT**), clinicians have the ability to assess preload responsiveness. Preload responsiveness is assessed by tracking the changes in **SV, SVI, CO** or **CI** in response to a fluid challenge (**Passive Leg Raise** or **Fluid Bolus**).

To begin the test:

1 Touch the **Clinical Tools** icon → **Fluid Responsiveness Test** button. If another clinical tool is active, use the drop down menu to select **Fluid Responsiveness Test**.

2 Use the arrows (,) to scroll through and select FRT menu options.

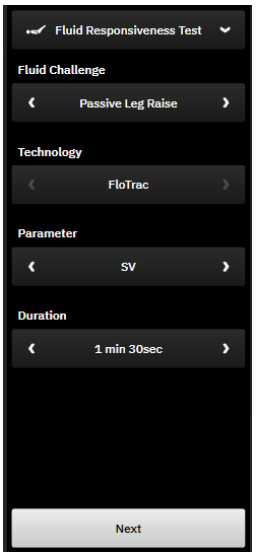


Figure 13-21 Fluid Responsiveness Test side panel – main menu screen

3 Select the **Fluid Challenge** type as: **Passive Leg Raise** or **Fluid Bolus**.

For more continued instructions for the selected Fluid Challenge type, follow the steps below.

NOTE Interpretation of the Fluid Responsiveness Test (FRT) is directly correlated with the response time of the parameter being monitored. Response times of monitored parameters can vary depending on the monitoring mode and are dictated by the connected technology. Update rates for FRT selected parameters while in minimally-invasive mode are based on CO averaging time (see table 5-4 on page 122).

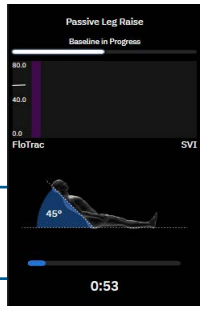
13.7.1 Passive Leg Raise Test

The **Passive Leg Raise** is a sensitive noninvasive method for assessing a patient's fluid responsiveness. During this test, venous blood transferred from the lower body to the heart simulates a fluid challenge. Use the arrows (❮ , ❯) to scroll through and select menu options.

1 Select the Fluid Challenge type as: **Passive Leg Raise**.
2 Select the **Technology** type. This determines which connected technology and monitored parameter data will be used for analysis.
3 Select the **Parameter** to be analyzed:
   - **SV**, **SVI**, **CO**, or **CI** (**FloTrac** and **ClearSight** technology types)
   - **SV_{20s}**, **SVI_{20s}**, **CO_{20s}**, or **CI_{20s}** (**Swan-Ganz** technology type with PAP signal; see *20-Second Flow Parameters* on page 142)
4 Select the **Duration**: **1 min**, **1 min 30 sec**, or **2 min** (**FloTrac** and **ClearSight** technology types) or **3 min** (**Swan-Ganz** technology type).
5 Touch the **Next** button when all menu selections have been made.
6 Place the patient in a semi-recumbent position. Touch the **Start Baseline** button to begin the baseline measurement.

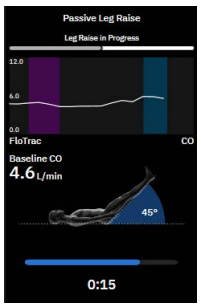
NOTE The baseline value is averaged from multiple readings. Ensure that the patient remains still and stays in the same position during this measurement period. The baseline measurement duration is 1 minute. Once measurement of the baseline has commenced, the side panel is locked until the passive leg raise challenge is completed or the process is canceled and you have returned to the FRT menu screen.

7 A trend graph of the selected parameter and a countdown timer displaying the amount of time remaining for the baseline measurement appears on the FRT side panel.



NOTE To abort the baseline measurement, touch the **Cancel** button and return to the FRT menu screen.

8 At the conclusion of the baseline measurement, the baseline value will appear below the trend graph. Touch **Next** to continue to the passive leg challenge. To remeasure the baseline value, touch **Cancel** to return to the FRT menu screen to restart baseline measurement process. In certain cases, the system will detect an unstable baseline. Touch **Restart** to remeasure the baseline.
9 To continue to the **Passive Leg Raise** measurement, place the patient in supine position and touch the **Start** button. Passively raise the patient's legs to a 45 degree angle within five seconds. A five second countdown clock will appear to indicate time remaining until the start of the challenge measurement.
10 A new countdown timer will appear starting at the selected challenge duration time. Ensure that the patient remains still during the measurement period.



NOTE Before sufficient measurements have been taken, the **Cancel** button can be touched to abort the test. A confirmation popup window will appear. Touch **Yes** to return to the FRT menu screen.

After sufficient measurements have been taken, the **Cancel** button is no longer available. To stop the test and analyze measured data before the full time of the test has been reached touch **End Now**.

11 At the conclusion of the test, the change in the selected **Parameter** value as a response to the fluid challenge will be displayed. See Figure 13-22. Touch the **Back to Main** button to perform another test, or the hide side panel by touching **Clinical Tools** icon Clinical Tools on the navigation bar to return to full display of the main monitoring screen.

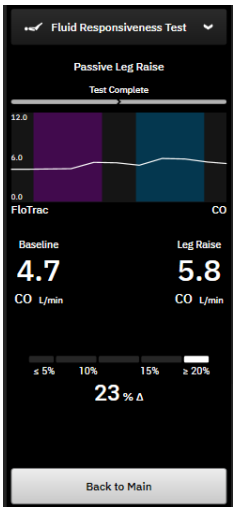


Figure 13-22 Fluid Responsiveness Test – results screen

13.7.2 Fluid Bolus Test

The **Fluid Bolus** test is a sensitive method for assessing a patient's fluid responsiveness. During this test, a fluid bolus is administered to the patient and preload responsiveness may be assessed by tracking the value of SV, SVI, CO, or CI. Use the arrows (〈 , 〉) to scroll through and select menu options.

1 Select the Fluid Challenge type as: **Fluid Bolus**.
2 Select the **Technology** type. This determines which connected technology and monitored parameter data will be used for analysis.
3 Select the **Parameter** to be analyzed:
   - **SV**, **SVI**, **CO**, or **CI** (**FloTrac** and **ClearSight** technology types)
   - **SV_{20s}**, **SVI_{20s}**, **CO_{20s}**, or **CI_{20s}** (**Swan-Ganz** technology type with PAP signal; see *20-Second Flow Parameters* on page 142)
4 Select the **Duration**: **5 min**, **10 min**, or **15 min**.
5 Touch the **Next** button when all menu selections have been made.
6 Touch the **Start Baseline** button to begin the baseline measurement.

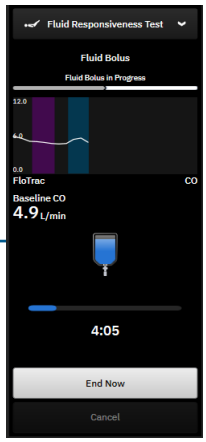
NOTE The baseline value is averaged from multiple readings. Ensure that the patient remains still and stays in the same position during this measurement period. The baseline measurement duration is 1 minute. Once measurement of the baseline has commenced, the side panel is locked until the fluid bolus challenge is completed or the process is canceled and you have returned to the FRT menu screen.

7 A trend graph of the selected parameter and a countdown timer displaying the amount of time remaining for the baseline measurement appears on the FRT side panel.

NOTE To abort the baseline measurement, touch the **Cancel** button and return to the FRT menu screen.

8 At the conclusion of the baseline measurement, the baseline value will appear below the trend graph. Touch **Next** to continue to the fluid bolus challenge.

To remeasure the baseline value, touch **Cancel** to return to the FRT menu screen to restart baseline measurement process. In certain cases, the system will detect an unstable baseline. Touch **Restart** to remeasure the baseline.



9 Administer the fluid bolus and touch **Start** when the bolus begins.

10 A new countdown timer will appear starting at the selected challenge **Duration** time. Ensure that the patient remains still during the measurement period.

NOTE Before sufficient measurements have been taken, the **Cancel** button can be touched to abort the test. A confirmation popup window will appear. Touch **Yes** to return to the FRT menu side panel.

After sufficient measurements have been taken, the **Cancel** button is no longer available. To stop the test and analyze measured data before the full time of the test has been reached touch **End Now**. Touch **Back to Main** to return to the FRT menu side panel.

11 At the conclusion of the test, change in the selected **Parameter** value as a response to the fluid challenge will be displayed. See Figure 13-22. Touch the return icon to perform another test, or the home icon to return to the main monitoring screen.

13.7.3 Historical Test Results

The user can view previous test results on **Events & Intervention** side panel. Touch the **Clinical Tools** icon  → **Events & Intervention** to view previous FRT sessions. A list of all fluid responsiveness tests for the current patient is shown within the events list. Use the scroll buttons to highlight a specific test and select the desired FRT session. The summary of that session is displayed on the side panel.

Troubleshooting 14

Contents

14.1 On Screen Help

The help topics outlined in this chapter and displayed on monitor help screens are associated with common error conditions. In addition to these error conditions, a list of unresolved anomalies and troubleshooting steps are available at eifu.edwards.com. This list is associated with the HemoSphere Alta advanced monitor model numbers (beginning with "ALTA") and software version indicated on the startup page (see "Start Up Procedure" on page 76). These issues are continually updated and compiled as a result of ongoing product improvements.

The main help screen allows the user to navigate to specific help for HemoSphere Alta advanced monitoring platform issues. Faults, alerts and warnings notify the user of error conditions affecting parameter measurements. Faults are technical alarm conditions that suspend parameter measurement. The category help screen provides specific assistance for faults, warnings, alerts, and troubleshooting.

1. Touch the help icon on the navigation bar  .
2. Touch the **Version** button to display software versions and serial numbers for the monitor and connected cable(s).
3. Touch the **Guide** button to see a list of **Faults**, **Alerts**, **Warnings**, or **Troubleshooting** categorized based on monitoring technology**.**
4. Touch the plus icon to see an expanded window detailing the **Possible Causes** and **Suggested Actions** related to the selected notification message.

14.2 Monitor Status Lights

The HemoSphere Alta advanced monitoring platform has a visual alarm indicator to alert the user to alarm conditions. See "Alarm Priorities" on page 376 for more information on medium and high priority physiological alarm conditions. The monitor power button has an integrated LED to indicate the power status at all times.

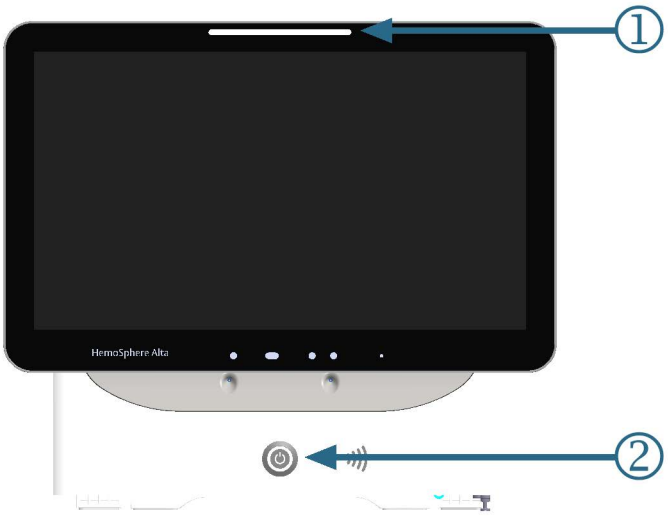


Figure 14-1 HemoSphere Alta advanced monitoring platform LED indicators

① visual alarm indicator ② monitor power status

Table 14-1 HemoSphere Alta advanced monitoring platform visual alarm indicator

Alarm status	Color	Light pattern	Suggested action
High-priority physiological alarm	Red	Flashing ON/OFF	This physiological alarm condition needs immediate attention Refer to the status bar for specific alarm condition
High-priority technical faults and alerts	Red	Flashing ON/OFF	This alarm condition requires immediate attention and will remain active during an alarm pause If a particular technical alarm condition is unrecoverable, restart system If problem persists, contact Edwards Technical Support
Medium-priority technical faults and alerts	Yellow	Flashing ON/OFF	This alarm condition needs prompt attention Refer to the status bar for specific alarm condition
Medium-priority physiological alarm	Yellow	Flashing ON/OFF	This alarm condition needs prompt attention Refer to the status bar for specific alarm condition
Low-priority technical alert	Yellow	Solid ON	This alarm condition requires non-urgent attention Refer to the status bar for specific alarm condition

Table 14-2 HemoSphere Alta advanced monitoring platform power light

Monitor status	Color	Light pattern	Suggested action
Monitor power ON	Green	Solid ON	None
Monitor power OFF Monitor connected to AC mains Battery charging	Yellow	Flashing ON/OFF	Wait for battery to be charged before unplugging from AC mains.
Monitor power OFF Monitor connected to AC mains Battery not charging	Yellow	Solid ON	None

Table 14-2 HemoSphere Alta advanced monitoring platform power light

Monitor status	Color	Light pattern	Suggested action
Monitor power OFF	No light	Solid OFF	None

14.3 Pressure Cable Communication

The pressure cable LED indicates the status of the pressure sensor or transducer. LED functionality only applies to the HEMPSC100 model pressure cable.

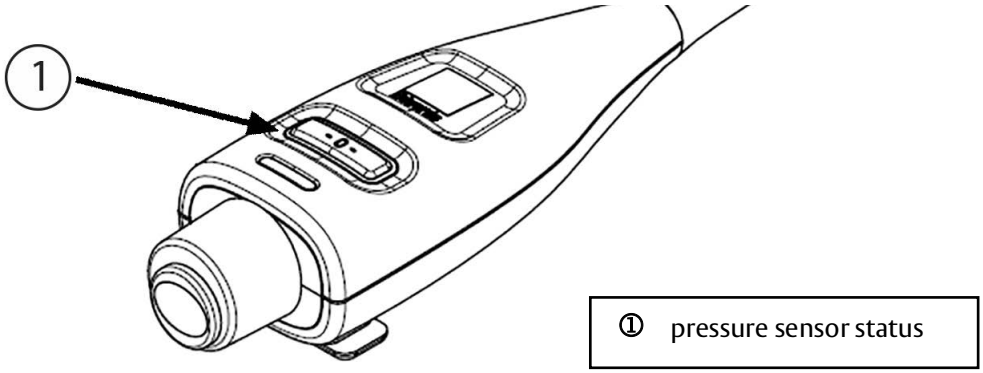


Figure 14-2 Pressure cable LED indicator (HEMPSC100 only)

Table 14-3 Pressure cable communication light (HEMPSC100 only)

Condition	Color	Light Pattern	Suggested Action
No pressure sensor/transducer connected	No light	Solid OFF	None
Pressure sensor/transducer connected but not yet zeroed	Green	Flashing ON/OFF	Zero the pressure sensor to begin monitoring
Pressure sensor/transducer zeroed	No light	Solid OFF	None. The connected pressure sensor can actively monitor pressure signal.
Pressure sensor/transducer medium priority technical alarm	Yellow	Flashing ON/OFF	Refer to the screen to ascertain the type of technical fault. Use the help menu or tables below for the appropriate suggested action.

14.4 ForeSight Oximeter Cable Sensor Communication

The ForeSight oximeter cable LED indicates the status of the tissue oximetry sensor channels.

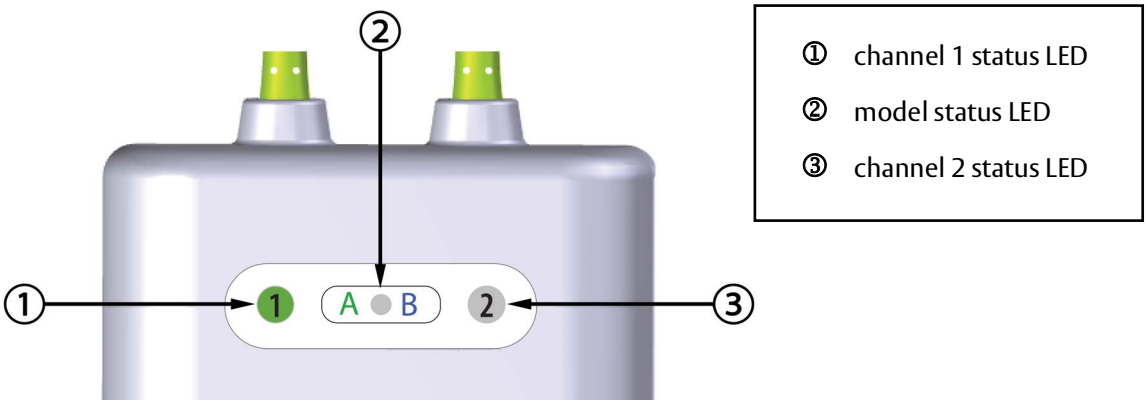


Figure 14-3 ForeSight oximeter cable LED indicators

Table 14-4 ForeSight oximeter cable LED communication lights

LED indicator	Color	Indication
Channel 1 status	White	No sensor connected
	Green	Sensor connected
Channel 2 status	White	No sensor connected
	Green	Sensor connected
Module status	Green	Channels are associated with port A on HemoSphere Alta monitor
	Blue	Channels are associated with port B on HemoSphere Alta monitor

CAUTION If any of the ForeSight oximeter cable LEDs fail to turn on, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical Support. There is a risk that damaged parts could reduce the performance of the cable.

14.5 Pressure Controller Communication

The pressure controller lights indicate the status of the finger cuff(s) and heart reference sensor.

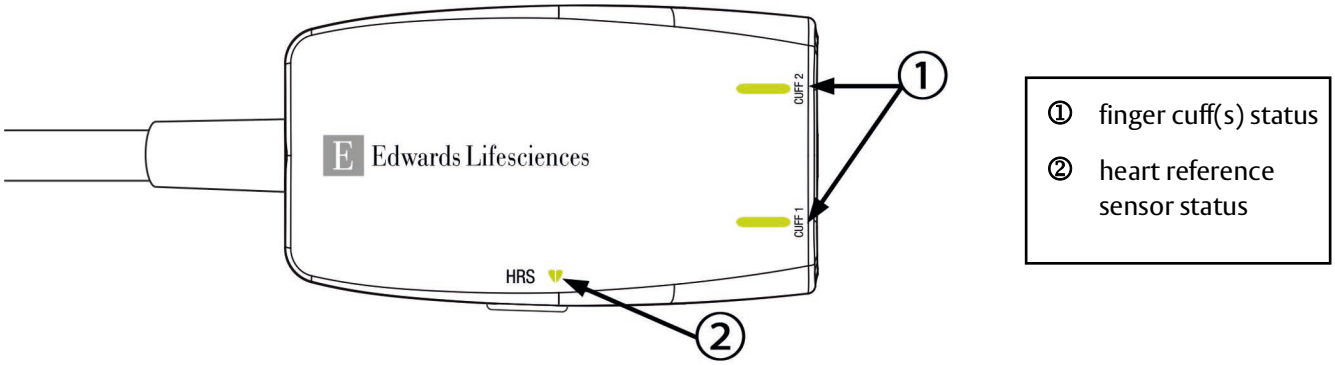


Figure 14-4 Pressure Controller LED Indicators

Table 14-5 Pressure controller communication lights*

Condition	Color	Light Pattern	Suggested Action
CUFF STATUS LIGHT			
No finger cuff connected	No light	Solid OFF	None
Finger cuff connected	Green	Solid ON	None. The connected cuff is detected, authenticated, and not expired.
Active monitoring	Green	Flashing ON/OFF	None. The connected finger cuff is actively monitoring.
Defective finger cuff connected Expired finger cuff connected Non-compatible Edwards finger cuff connected	Amber	Flashing ON/OFF	Verify that a compatible Edwards finger cuff has been used. Disconnect and reconnect the finger cuff. Replace the finger cuff with a compatible Edwards finger cuff. Restart the measurement. If the problem persists, contact Edwards Technical Support.
HEART REFERENCE SENSOR STATUS LIGHT			
No heart reference sensor connected	No light	Solid OFF	None
Heart reference sensor connected	Green	Solid ON	None. The system is ready to start a measurement.
Defective heart reference sensor connected Non Edwards heart reference sensor detected	Amber	Flashing ON/OFF	Verify that an Edwards heart reference sensor has been used. Disconnect and reconnect the heart reference sensor. Replace the heart reference sensor with a genuine heart reference sensor. Restart the measurement. If the problem persists, contact Edwards Technical Support.
**Finger cuff error may also be indicated by software. See table 14-24 on page 338.*			

14.6 HemoSphere Alta Advanced Monitoring Platform Error Messages

14.6.1 System/Monitoring Faults/Alerts

Table 14-6 Monitoring faults/alerts

Message	Possible causes	Suggested actions
Fault: Cable Port {0} Error – Check Cable Connection Points for Damage*	Cable is not inserted properly Connection points on cable or port are damaged	Reinsert the cable Check for bent or broken pins Try switching to other cable port If problem persists, contact Edwards Technical Support
Fault: Cable Port {0} Software Error – Replace Cable or Call Tech Support*	There is a software error with the cable inserted in cable port X	Contact Edwards Technical Support
Fault: Internal System Failure	Internal system malfunction	Power cycle the system If problem persists, contact Edwards Technical Support
Fault: System Recovering, Please Wait...	An unexpected event has occurred Diagnosis is in progress	Please allow 60 seconds for the system to diagnose the issue If problem persists, contact Edwards Technical Support
Fault: Battery Depleted	The battery is depleted and the system will shut down in 1 minute if not plugged in	Connect the HemoSphere Alta advanced monitor to an alternate source of power to avoid loss of power and resume monitoring
Fault: System Temperature Too High – Shutdown Imminent	The internal temperature of the monitor is at a critically high level Monitor ventilation openings are obstructed	Reposition the monitor away from any heat sources Ensure that the monitor ventilation openings are unobstructed and clear of dust If problem persists, contact Edwards Technical Support
Fault: Monitor – Incompatible Software Version – Software Update Required	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Wi-Fi Connection Lost	Wi-Fi hardware not functioning properly, may be unavailable or not setup	Contact Edwards Technical Support
Alert: Wireless Certificate Expires < 4 Weeks	Wireless certificate expires in less than 4 weeks	Navigate to Wireless Connectivity settings from the Advanced Setup menu and upload a valid certificate If problem persists, contact Edwards Technical Support
Alert: Wireless Certificate Expires < 2 Weeks	Wireless certificate expires in less than 2 weeks	Navigate to Wireless Connectivity settings from the Advanced Setup menu and upload a valid certificate If problem persists, contact Edwards Technical Support
Alert: Wireless Certificate Expired	Wireless certificate is expired	Navigate to Wireless Connectivity settings from the Advanced Setup menu and upload a valid certificate If problem persists, contact Edwards Technical Support
Alert: Low Battery	The battery has less than 20% charge remaining or will be depleted within 8 minutes	Connect the HemoSphere Alta advanced monitor to an alternate source of power to avoid loss of power and continue monitoring
Alert: Battery Disconnected	Previously inserted battery not detected Poor battery connection	Confirm the battery is properly seated in the battery bay *Remove and re-insert the battery pack* Change battery pack If the problem persists, contact Edwards Technical Support
Alert: Battery Error – Servicing Required	Internal battery fault occurred Battery can no longer sustain the system adequately on a full charge	Power cycle the system If condition persists, replace the battery *pack*

Table 14-6 Monitoring faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: Battery Needs Conditioning	Gas gauge is not synched to actual battery capacity status	To ensure uninterrupted measurement, make certain the HemoSphere Alta advanced monitor is connected to an electrical outlet Condition the battery (ensure a measurement is not active): • Connect monitor to an electrical outlet to fully charge battery • Allow the battery to rest in a fully charged state for at least two hours • Disconnect the monitor from the electrical outlet and continue to run the system on battery power • The HemoSphere Alta advanced monitor will power down automatically when the battery is fully depleted • Allow the battery to rest in a fully depleted state for five hours or more • Connect monitor to an electrical outlet to fully charge the battery If the condition battery message persists, replace the battery pack
Alert: System Temperature Too High	The internal temperature of the monitor is reaching a critically high level Monitor ventilation openings are obstructed	Reposition the monitor away from any heat sources Ensure that the monitor ventilation openings are unobstructed and clear of dust If problem persists, contact Edwards Technical Support
Alert: System LED Indicators Inoperable	Visual alarm indicator hardware or communication error Visual alarm indicator malfunction	Power cycle the system If problem persists, contact Edwards Technical Support
Alert: System Buzzer Inoperable	Speaker hardware or software communication error Mainboard speaker malfunction	Power cycle the system If problem persists, contact Edwards Technical Support
Alert: Voice – Internal Error – Servicing Required	Internal system malfunction	Power cycle the system Perform a software update If problem persists, contact Edwards Technical Support
Alert: Gesture – Internal Error – Servicing Required	Internal system malfunction	Power cycle the system Perform a software update If problem persists, contact Edwards Technical Support
**Note: {0} is the port number: 1, 2, 3, 4, or 5.*		

14.6.2 Monitoring Troubleshooting – Numeric Keypad Errors

Table 14-7 Numeric keypad errors

Message	Possible causes	Suggested actions
Value out of range (xx-yy)	The entered value is either higher or lower than the allowed range	Displayed when the user enters a value that is out of range. The range is displayed as part of the notification replacing the xx and yy.
Value must be ≤ xx	The entered value is in range, but is higher than the high value setting such as the high scale setting. xx is the associated value.	Enter a lower value
Value must be ≥ xx	The entered value is in the range, but is lower than the low value setting such as the low scale setting. xx is the associated value.	Enter a higher value
Incorrect password entered	The password entered is incorrect	Enter the correct password

Table 14-7 Numeric keypad errors

Message	Possible causes	Suggested actions
Please enter valid time	The time entered is invalid, i.e. 25:70	Enter the correct time in 12- or 24-hour format
Please enter valid date	The date entered is invalid, i.e. 33.13.009	Enter the correct date

14.6.3 HemoSphere Remote Application Connectivity Errors

Table 14-8 HemoSphere Remote application connectivity errors

Message	Possible causes	Suggested actions
Alert: HemoSphere Remote App – HemoSphere Remote Application	An issue with HemoSphere Remote App Wrong HemoSphere Remote App hostname or port	Check the network connection Check the HemoSphere Remote App server Verify and re-enter the HemoSphere Remote App hostname and port Contact your local IT If problem persists, contact Edwards Technical Support
Alert: HemoSphere Remote App – HemoSphere Remote Application Not Reachable	An issue with HemoSphere Remote App Wrong HemoSphere Remote App hostname or port	Check the network connection Check the HemoSphere Remote App server Verify and re-enter the HemoSphere Remote App hostname and port Contact your local IT If problem persists, contact Edwards Technical Support
Alert: HemoSphere Remote App Connectivity – System Error	Client certificate invalid or unavailable	Contact Edwards Technical Support
Alert: HemoSphere Remote App – Certificate Expires < 4 Weeks	HemoSphere Remote App certificate expires in less than 4 weeks	Navigate to HemoSphere Remote App Connectivity settings from the Advanced Setup menu and upload a valid certificate If the problem persists, contact Edwards Technical Support
Alert: HemoSphere Remote App – Certificate Expires < 2 Weeks	HemoSphere Remote App certificate expires in less than 2 weeks	Navigate to HemoSphere Remote App Connectivity settings from the Advanced Setup menu and upload a valid certificate If the problem persists, contact Edwards Technical Support
Alert: HemoSphere Remote App – Certificate Expired	HemoSphere Remote App certificate is expired	Navigate to HemoSphere Remote App Connectivity settings from the Advanced Setup menu and upload a valid certificate If problem persists, contact Edwards Technical Support

14.7 HemoSphere Alta Swan-Ganz Patient Cable Error Messages

14.7.1 CO Faults/Alerts

Table 14-9 HemoSphere Alta Swan-Ganz patient cable CO faults/alerts

Message	Possible causes	Suggested actions
Fault: Swan-Ganz System – Blood Temp Out of Range*	Monitored blood temperature is <31 °C or >41 °C	Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Resume CO monitoring when blood temperature is within range
Fault: Swan-Ganz System – Cardiac Output < 1.0 L/min*	Measured CO < 1.0 L/min	Follow hospital protocol to increase CO Resume CO monitoring
Fault: Swan-Ganz System – Thermal Filament Positioning Error*	Flow around thermal filament may be reduced Thermal filament may be against vessel wall Catheter not in patient	Flush catheter lumens Verify proper catheter positions in the pulmonary artery: • Confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • Confirm appropriate catheter placement for patient's height, weight, and insertion site • Consider chest x-ray for evaluation of proper placement Resume CO monitoring
Fault: Swan-Ganz System – CO –Thermal Signal Loss*	Thermal signal detected by monitor is too small to process Sequential compression device interference	Verify proper catheter position in the pulmonary artery: • Confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • Confirm appropriate catheter placement for patient's height, weight, and insertion site • Consider chest x-ray for evaluation of proper placement Temporarily turn off sequential compression device per hospital procedure Resume CO monitoring
Fault: Swan-Ganz System – Incompatible Software – Software Update Required	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: GHI Error – Restart CO Monitoring	The GHI Algorithm or its inputs have become invalid	Ensure SvO2 and sCO values are nominal Attempt to restart the GHI Algorithm by restarting Continuous Cardiac Output monitoring. If problem persists, contact Edwards Technical Support
Fault: Swan-Ganz System – Data Processing Error*	Data processing error	Resume CO monitoring Power monitor off and on to restore system Use Bolus CO mode
Fault: Swan-Ganz System – Catheter Error*	Poor catheter thermal filament connection Catheter CO error Patient CCO cable malfunction Auto QA failure Catheter connected is not an Edwards CCO catheter	Change patient CCO cable Use Bolus CO mode Verify catheter is an Edwards CCO catheter

Table 14-9 HemoSphere Alta Swan-Ganz patient cable CO faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: Swan-Ganz System – Thermal Filament or Thermistor Connection Not Detected	Catheter thermal filament connection not detected Patient CCO cable malfunction Catheter connected is not an Edwards CCO catheter Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C	Verify patient CCO cable and catheter connections Disconnect thermistor and/or thermal filament connections and check for bent/missing pins Change patient CCO cable Verify that catheter thermal filament and/or catheter thermistor are connected securely to patient CCO cable Verify catheter is an Edwards CCO catheter Use Bolus CO mode Verify that blood temperature is between 15 - 45 °C
Fault: Swan-Ganz System – Subsystem Malfunction – Servicing Required	Electrocautery interference Internal system malfunction	Disconnect patient CCO cable during electrocautery use Power monitor off and on to restore platform If problem persists, contact Edwards Technical Support
Fault: Swan-Ganz System – Recovery in Process – Please Wait	An unexpected event has occurred Diagnosis is in progress	Please allow 60 seconds for the system to diagnose the issue If problem persists, contact Edwards Technical Support
Alert: Swan-Ganz System – Catheter Error	Poor catheter thermal filament connection Patient CCO cable malfunction Catheter CO error Auto QA failure Catheter connected is not an Edwards CCO catheter	Verify secure thermal filament connection Check catheter/ patient CCO cable thermal filament connections for bent/missing pins Change patient CCO cable Replace catheter for CO measurement Use Bolus CO mode Replace catheter for CO measurement
Alert: Swan-Ganz System – Catheter Thermal Filament or Thermistor Connection Not Detected	Catheter thermal filament connection not detected Patient CCO cable malfunction Catheter connected is not an Edwards CCO catheter Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C	Verify that catheter thermal filamentis connected securely to patient CCO cable Disconnect thermal filament connection and check for bent/missing pins Change patient CCO cable Verify that catheter is an Edwards CCO catheter Verify that catheter thermistor is connected securely to patient CCO cable Verify that blood temperature is between 15 – 45 °C Disconnect thermistor connection and check for bent/ missing pins
Alert: Swan-Ganz System – Retrieving Measurement	Large pulmonary artery blood temperature variations detected Sequential compression device interference Catheter thermal filament not properly positioned	Allow more time for monitor to measure and display CO Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Wait for CO measurement to be updated Minimizing patient discomfort may reduce temperature variations Temporarily turn off the sequential compression device per hospital procedure

**These are latching faults. Touch the silence icon to silence. To clear, restart monitoring.*

Note: While GHI is selected as a key parameter, Swan-Ganz technology CO faults/alerts will always be displayed, regardless of whether CO is selected as a key parameter

14.7.2 EDV and SV Faults/Alerts

Table 14-10 HemoSphere Alta Swan-Ganz patient cable EDV and SV faults/alerts

Message	Possible causes	Suggested actions
Alert: Swan-Ganz System – EDV – Retrieving Measurement	Patient's respiratory pattern may have changed Sequential compression device interference Catheter thermal filament not properly positioned	Allow more time for monitor to measure and display EDV Temporarily turn off sequential compression device per hospital procedure Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement
Alert: Swan-Ganz System – EDV – Heart Rate Signal Out of Range	Patient's time-averaged heart rate out of range (HR_{avg} <30 or >200 bpm) No heart rate detected ECG interface cable connection not detected	Wait until the average heart rate is within range Select appropriate lead configuration to maximize heart rate triggers Verify cable connection between HemoSphere Alta advanced monitor and bedside monitor is secure Change the ECG interface cable

14.7.3 iCO Faults/Alerts

Table 14-11 HemoSphere Alta Swan-Ganz patient cable iCO faults/alerts

Message	Possible causes	Suggested actions
Fault: Swan-Ganz System – iCO – Injectate Temperature Out of Range	Injectate temperature < 0 °C, > 30 °C or > BT Injectate temperature probe malfunction Patient CCO cable malfunction	Verify injectate fluid temperature Check injectate probe connections for bent/missing pins Change injectate temperature probe Change patient CCO cable
Fault: Swan-Ganz System – Injectate Probe Connection Error	Injectate temperature probe not detected Injectate temperature probe malfunction Patient CCO cable malfunction	Verify connection between patient CCO cable and injectate temperature probe Change injectate temperature probe Change patient CCO cable
Fault: Swan-Ganz System – Thermal Filament or Thermistor Connection Not Detected	Catheter thermal filament connection not detected Patient CCO cable malfunction Catheter connected is not an Edwards CCO catheter Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C	Verify patient patient CCO cable and catheter connections Disconnect thermistor and thermal filament connectiosn and check for bent/missing pins Change patient CCO cable Verify that catheter thermistor is connected securely to patient CCO cable Verify catheter is an Edwards CCO catheter Use Bolus CO mode Verify that blood temperature is between 15 – 45 °C Disconnect thermistor connection and check for bent/missing pins Change patient CCO cable
Fault: Swan-Ganz System – iCO – Blood Temp Out of Range	Monitored blood temperature is <31 °C or >45 °C	Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Resume bolus injections when blood temperature is within range

Table 14-11 HemoSphere Alta Swan-Ganz patient cable iCO faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: Swan-Ganz System – iCO – Injectate Volume Not Valid	In-line probe injectate volume must be 5 mL or 10 mL	Change injectate volume to 5 mL or 10 mL Use a bath type probe for an injectate volume of 3 mL
Alert: Swan-Ganz System – iCO – Unstable Baseline	Large pulmonary artery blood temperature variations detected	Allow more time for blood temperature baseline to stabilize Use Manual mode
Alert: Swan-Ganz System – iCO – Curve Not Detected	No bolus injection detected for >4 minutes (Automatic mode) or 30 seconds (Manual mode)	Restart Bolus CO monitoring and proceed with injections
Alert: Swan-Ganz System – iCO – Extended Curve	Thermodilution curve slow to return to baseline Injectate port in introducer sheath Possible cardiac shunt	Verify correct injection technique Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight and insertion site • consider chest x-ray for evaluation of proper placement Ensure injectate port location is outside of the introducer sheath Use "iced" injectate and/or 10 mL injectate volume to create a larger thermal signal
Alert: Swan-Ganz System – iCO – Irregular Curve	Thermodilution curve has multiple peaks	Verify correct injection technique Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Use "iced" injectate and/or 10 mL injectate volume to create a larger thermal signal
Alert: Swan-Ganz System – iCO – Warm Injectate	Injectate temperature within 8 °C of blood temperature Injectate temperature probe malfunction Patient CCO cable malfunction	Use cooler injectate fluid Change injectate temperature probe Change patient CCO cable
Alert: Swan-Ganz System – Thermal Filament or Thermistor Connection Not Detected	Catheter thermal filament connection not detected Patient CCO cable malfunction Catheter connected is not an Edwards CCO catheter Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C	Verify that catheter thermal filament is connected securely to patient CCO cable Disconnect thermal filament connection and check for bent/missing pins Change patient CCO cable Verify that catheter is an Edwards CCO catheter Verify that catheter thermistor is connected securely to patient CCO cable Verify that blood temperature is between 15 – 45 °C Disconnect thermistor connection and check for bent/missing pins

14.7.4 20-Second Parameters Faults/Alerts

Table 14-12 HemoSphere Alta Swan-Ganz patient cable 20s parameters faults/alerts

Message	Possible causes	Suggested actions
Fault: Swan-Ganz System – 20s Parameters – PA Pressure Compromised	Pulmonary artery pressure waveform is inadequate to measure 20s parameters accurately Pressure waveform has shifted or is measuring negative signals due to change in phlebostatic axis or other related movement impacting pressure signal	Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the pulmonary artery pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero pulmonary artery pressure transducer
Alert: Swan-Ganz System – 20s Parameters – PA Pressure Compromised	Pulmonary artery pressure waveform is inadequate to measure 20s parameters accurately Pressure waveform has shifted or is measuring negative signals due to change in phlebostatic axis or other related movement impacting pressure signal	Verify proper catheter position in the pulmonary artery: • confirm wedge pressure balloon inflation volume of 1.25 - 1.50 mL • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the pulmonary artery pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero pulmonary artery pressure transducer

14.7.5 General Troubleshooting

Table 14-13 HemoSphere Alta Swan-Ganz patient cable general troubleshooting

Message	Possible causes	Suggested actions
Swan-Ganz System – Connect patient CCO cable for CO monitoring	Connection between the monitor and patient CCO cable has not been detected	Verify the connection between the patient CCO cable and the monitor Disconnect the patient's CCO cable and check for bent/missing pins Change patient CCO cable
Swan-Ganz System – Connect thermistor for CO monitoring	Connection between patient CCO cable and catheter thermistor has not been detected Patient CCO cable malfunction	Verify that catheter thermistor is connected securely to patient CCO cable Disconnect thermistor connection and check for bent/missing pins Change patient CCO cable
Swan-Ganz System – Connect thermal filament for CO monitoring	Connection between patient CCO cable and catheter thermal filament has not been detected Patient CCO cable malfunction Catheter connected is not an Edwards CCO catheter	Verify that catheter thermal filament is connected securely to patient CCO cable Disconnect thermal filament connection and check for bent/missing pins Change patient CCO cable Verify catheter is an Edwards CCO catheter
Swan-Ganz System – Connect pulmonary artery pressure sensor for 20s parameter monitoring	CO_{20s}, CI_{20s}, SV_{20s} or SVI_{20s} is configured as a key parameter Connection between the pressure cable and a pulmonary artery pressure sensor has not been detected	Verify connection between pressure cable and monitor Disconnect pressure cable and check for bent/missing pins Change pressure cable

Table 14-13 HemoSphere Alta Swan-Ganz patient cable general troubleshooting (continued)

Message	Possible causes	Suggested actions
Swan-Ganz System – Zero pulmonary artery pressure for 20s parameter monitoring	The pulmonary artery pressure signal was not zeroed prior to monitoring	Touch the “Zero” icon on the navigation bar
Swan-Ganz System – Connect injectate probe for iCO monitoring	Connection between patient CCO cable and catheter injecate temperature probe has not been detected Injectate temperature probe malfunction Patient CCO cable malfunction	Verify the connection between the patient CCO cable and injectate temperature probe Change injectate temperature probeChange patient CCO cable
Swan-Ganz System – Connect pressure cable for 20s parameter monitoring	Connection between the monitor and pressure cable has not been detected	Verify connection between pressure cable and monitor Disconnect pressure cable and check for bent/missing pins Change pressure cable
Swan-Ganz System – Connect CCOmbo V Swan-Ganz Catheter for 20s parameter monitoring	The Swan-Ganz catheter is incompatible with CO_{20s}, CI_{20s}, SV_{20s} or SVI_{20s}	Replace the Swan-Ganz catheter with one that has a reference number starting with either 774 or 777
Swan-Ganz System – Connect ECG Input for EDV or SV monitoring	ECG interface cable connection not detected	Verify that cable connection between the panel and bedside monitor is secure Change the ECG interface cable
CI > CO	Incorrect patient BSA BSA < 1	Verify units of measure and values for patient's height and weight
CO ≠ iCO	Incorrectly configured bolus information Faulty thermistor or injectate probe Unstable baseline temperature affecting bolus CO measurements	Verify that computation constant, injectate volume, and catheter size have been correctly selected Use “iced” injectate and/or 10 mL injectate volume to create a large thermal signal Verify correct injection technique Change injectate temperature probe
SVR > SVRI	Incorrect patient BSA BSA <1	Verify units of measure and values for patient’s height and weight
HemoSphere Alta Advanced Monitor HRavg ≠ External Monitor HR	External monitor not optimally configured for ECG signal output External monitor malfunction ECG interface cable malfunction Elevated patient heart rate HemoSphere Alta advanced monitor uses up to 3 minutes of HR data to calculate HRavg	Stop CO monitoring and verify heart rate is the same for HemoSphere Alta advanced monitor and external monitor Select appropriate lead configuration to maximize heart rate triggers and minimize atrial spike sensing Verify signal output from an external monitoring device Wait for the patient's HR to stabilize Change the ECG interface cable

14.7.6 Smart Wedge Algorithm Faults/Alerts

Table 14-14 Smart Wedge faults/alerts

Message	Possible causes	Suggested actions
Alert: Smart Wedge – Artifact Detected – Check Lines	Abnormally high systolic PAP pressure (systolic PAP pressure > 100 mmHg) Abnormally low diastolic PAP pressure (diastolic PAP pressure < -20 mmHg) Pressure waveform is inadequate to measure PAOP accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Patient Motion PAP line flushing	Assess pressure monitoring system starting from patient leading to pressure bag Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned Make sure pressure sensor is aligned with the patient's phlebostatic axis Zero the pressure transducer on the hemodynamic patient monitor to zero transducer and confirm pressure cable connection Make sure the pressure bag is inflated and flush bag is at least ¼ full Manually make the PAOP pressure measurement
Alert: Smart Wedge – No Wedge Detected	No wedge detected for >30 seconds Pressure waveform is inadequate to measure PAOP accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low	Assess pressure monitoring system starting from patient leading to pressure bag Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned Make sure pressure sensor is aligned with the patient's phlebostatic axis Zero the pressure transducer on the hemodynamic patient monitor to zero transducer and confirm pressure cable connection Make sure the pressure bag is inflated and flush bag is at least ¼ full Manually make the PAOP pressure measurement
Alert: Smart Wedge – Wedge Too Long	The Smart Wedge algorithm has been engaged for a prolonged period (> 60 seconds)	Deflate the balloon catheter Verify the correct wedging technique
Alert: Smart Wedge – Smart Wedge Is Not Supported For Pediatric Patients	Smart Wedge technology is not validated for patients under 18 years of age	Measurement with alternate technology recommended

14.7.7 Right Ventricular Cardiac Output (RVCO) Algorithm Faults/Alerts

Table 14-15 RVCO faults/alerts

Message	Possible causes	Suggested actions
Fault: RVCO – Failed to Run – Poor RVP Quality, Check Catheter	Right Ventricle Pressure waveform is inadequate for CO evaluation Too much noise due to movement of patient or transducer setup Pressure waveform has shifted or is measuring negative signals due to change in phlebostatic axis or other related movement impacting pressure signal	Verify proper catheter position in the right ventricle: • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the right ventricle pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero right ventricular pressure transducer at heart height Flush right ventricle pressure transducer Replace right ventricle pressure transducer
Fault: RVCO – Failed to Run, Check RVP	Poor right ventricle waveform definition Pulse detection from waveform is inadequate for processing Internal Processing Error	Verify proper catheter position in the right ventricle: • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the right ventricle pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero right ventricular pressure transducer at heart height Flush right ventricle pressure transducer Replace right ventricle pressure transducer
Alert: RVCO – Poor RVP Quality	Right ventricle waveform is inadequate to measure 20s parameters accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Pressure waveform has shifted or is measuring negative signals due to change in phlebostatic axis or other related movement impacting pressure signal	Verify proper catheter position in the right ventricle: • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the right ventricle pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero right ventricular pressure transducer at heart height Flush right ventricle pressure transducer Replace right ventricle pressure transducer
Alert: RVCO – Failed to Calibrate	Poor iCO bolus Time between last iCO and first valid RVCO is too long	Re-perform iCO

Table 14-15 RVCO faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: RVCO – PA Systolic Higher than RA Systolic	Systolic peak of Pulmonary Artery pressure is measuring higher than the systolic peak of the Right Atrium Pressure	Verify proper catheter position for both Pulmonary Artery and Right Ventricle: • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Make sure the right ventricle pressure line is not kinked Make sure there are no loose connections Perform Square Wave Test to assess the frequency response of the system Re-zero right ventricular pressure transducer at heart height Re-zero pulmonary artery pressure transducer at heart height Flush right ventricle pressure transducer Flush pulmonary artery pressure transducer Replace right ventricle pressure transducer Replace pulmonary artery pressure transducer

Table 14-16 RVCO warnings

Message	Possible causes	Suggested actions
New Patient Session Required for RVCO	A Swan IQ catheter has been connected during the active patient session and a TPTD set has been attempted.	If TPTD is desired, begin a new patient session If no TPTD is desired, navigate away from the TPTD tool

14.8 Pressure Cable Error Messages

14.8.1 General Pressure Cable Faults/Alerts

Table 14-17 Pressure cable general faults/alerts

Message	Possible causes	Suggested actions
Fault: Port {0} – Pressure Cable – Incompatible Software Version	The software version on this cable is incompatible with this monitor	Replace the pressure cable Contact Edwards Technical Support
Fault: Port {0} – Pressure Cable Recovery in Process – Please Wait	An unexpected event has occurred Diagnosis is in process	Please allow 60 seconds for the system to diagnose the issue If problem persists, contact Edwards Technical Support
Fault: Port {0} – Pressure Cable Malfunction – Servicing Required	Possible electrocautery interference Internal system malfunction	Disconnect and reconnect pressure cable Reposition the cable away from any heat sources or insulating surfaces If the cable body feels warm, allow it to cool before operating it again Power monitor off and on to restore platform If problem persists, contact Edwards Technical Support
Fault: Port {0} – Pressure Cable Disconnected	Pressure cable disconnected during monitoring Pressure cable not detected Bent or missing pressure cable connector pins	Confirm that pressure cable is connected Verify that connection between pressure cable and sensor/transducer is secure Check pressure cable connector for bent/missing pins Disconnect and reconnect pressure cable Try switching to other cable port If problem persists, contact Edwards Technical Support
Fault: Pressure – Port {0} – Pressure Sensor Disconnected*	Pressure sensor disconnected during monitoring Cable connections not detected Edwards pressure cable or sensor malfunction Internal system malfunction	Verify catheter connection Verify pressure cable and sensor and check for missing pins Verify that connection between pressure cable and sensor/transducer is secure Change Edwards pressure cable Change Edwards CO/pressure sensor If problem persists, contact Edwards Technical Support
Fault: Port {0} – Pressure Sensor Error*	A non-Edwards sensor has been detected Cable or sensor malfunction Damaged or defective sensor	Verify that an Edwards pressure sensor has been used Disconnect sensor and check for bent/missing contacts Change pressure sensor Change pressure cable If problem persists, contact Edwards Technical Support
Alert: Cable Port {0}*– Incompatible Pressure Sensor	Incompatible pressure sensor connected for configured monitoring mode	Disconnect sensor Use minimally-invasive monitoring mode
Alert: Port {0} – Pressure Sensor Error	A non-Edwards sensor has been detected Cable or sensor malfunction Damaged or defective sensor	Verify that an Edwards pressure sensor has been used Disconnect sensor and check for bent/missing contacts Change pressure sensor Change pressure cable If problem persists, contact Edwards Technical Support
Alert: Port {0} – One Too Many Pressure Cables Detected – Please Disconnect	More than 4 pressure cables are connected	Disconnect excess pressure cables Verify no more than 4 pressure cables are connected
Alert: Pressure – Port {0} – Release Pressure Cable Zero Button*	The pressure cable zero button has been depressed for more than 10 seconds Pressure cable malfunction	Release the pressure cable zero button Check that the button releases properly Replace the pressure cable
**Note: {0} is the port number: 1, 2, 3, 4, or 5.*		

14.8.2 Arterial and Right Ventricular Pressure Faults/Alerts

Table 14-18 HemoSphere pressure cable ART and RVP faults/alerts

Message	Possible causes	Suggested actions
Fault: Pressure – Port {0} – Arterial Waveform Compromised	Edwards pressure cable or sensor malfunction Internal system malfunction Arterial waveform is inadequate to measure blood pressure accurately Poor pressure waveform over extended period of time Patient condition results in a low pulse pressure Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low Patient condition results in a low pulse pressure Fluid line is being flushed	Assess Edwards pressure monitoring system starting from patient leading to pressure bag Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the arterial catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned Make sure Edwards pressure sensor/transducer is aligned with the patient's phlebostatic axis Zero the Edwards pressure sensor/transducer on HemoSphere Alta advanced monitoring platform to zero transducer and confirm pressure cable connection Make sure the pressure bag is inflated and flush bag is at least ¼ full Enter Non-Pulsatile Mode Perform Square Wave Test to assess Edwards pressure monitoring system frequency response Verify Edwards pressure cable and sensor and check for missing pins Change Edwards pressure cable Change Edwards CO/pressure sensor If problem persists, contact Edwards Technical Support
Fault: Pressure – Port {0} – Arterial Pressure Disconnected	Arterial pressure low and non-pulsatile Arterial catheter disconnected Cable connections not detected Edwards pressure cable or sensor malfunction Internal system malfunction	Verify arterial catheter connection Verify connection between pressure cable and sensor and check for missing pins Change Edwards pressure cable Change Edwards pressure sensor If problem persists, contact Edwards Technical Support
Fault: Pressure – Port {0} – Right Ventricular Waveform Compromised	Edwards pressure cable or sensor malfunction Internal system malfunction Right Ventricular waveform is inadequate to measure blood pressure accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low Patient condition results in a low pulse pressure Fluid line is being flushed	Assess Edwards continuous pressure monitoring system starting from patient leading to pressure bag Check the right ventricular waveform for motion artifact Make sure the catheter is not kinked or clotted Make sure all right ventricular pressure lines are patent and stopcocks are properly positioned Make sure Edwards pressure sensor/transducer is aligned with the patient's phlebostatic axis Zero the Edwards pressure sensor/transducer on the monitor to zero transducer and confirm pressure cable connection Make sure the pressure bag is inflated and flush bag is at least ¼ full Perform Square Wave Test to assess the Edwards pressure monitoring system frequency response Change Edwards pressure cable Change Edwards CO/pressure sensor If problem persists, contact Edwards Technical Support

Table 14-18 HemoSphere pressure cable ART and RVP faults/alerts

Message	Possible causes	Suggested actions
Alert: Pressure – Port {0} – Arterial Waveform Compromised	Edwards pressure cable or sensor malfunction Internal system malfunction Arterial waveform is inadequate to measure blood pressure accurately Poor pressure waveform over extended period of time Patient condition results in a low pulse pressure Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low Patient condition results in a low pulse pressure Fluid line is being flushed	Assess Edwards pressure monitoring system starting from patient leading to pressure bag Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the arterial catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned Make sure Edwards pressure sensor/transducer is aligned with the patient's phlebostatic axis Zero the Edwards pressure sensor/transducer on HemoSphere Alta advanced monitoring platform to zero transducer and confirm pressure cable connection Make sure the pressure bag is inflated and flush bag is at least ¼ full Enter Non-Pulsatile Mode Perform Square Wave Test to assess Edwards pressure monitoring system frequency response Verify Edwards pressure cable and sensor and check for missing pins Change Edwards pressure cable Change Edwards CO/pressure sensor If problem persists, contact Edwards Technical Support
Alert: Pressure – Port {0} –SVV Calculation Impaired	High degree of pulse rate variability could affect the SVV value	Assess Edwards continuous pressure monitoring system starting from patient leading to pressure bag Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact
**Note: {0} is the port number: 1, 2, 3, 4, or 5.*		

14.8.3 Assisted Fluid Management Faults/Alerts

Table 14-19 HemoSphere pressure cable AFM faults/alerts

Message	Possible causes	Suggested actions
Fault: AFM Error – Please Restart Session	Data processing error while initializing Assisted Fluid Management Aalgorithm Internal system malfunction Integrity of pressure monitoring line is compromised	Assess arterial waveform and continuous CO system Restart AFM session If problem persists, contact Edwards Technical Support
Fault: Port {0} – Acumen AFM Cable Error – Recovery in Process – Please Wait	System is restarting due to an error	Allow the system to automatically resolve the issue If the problem persists, contact Edwards Technical Support
Fault: Acumen AFM Cable Malfunction – Servicing Required	Internal system malfunction	Disconnect and reconnect Acumen AFM cable Replace Acumen AFM cable If problem persists, contact Edwards Technical Support
Fault: Port {0} – AFM Cable – Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Port {0} – Acumen AFM Cable Disconnected	Acumen AFM Cable has become disconnected	Connect Acumen AFM Cable to HemoSphere Alta monitor Continue AFM in Manual Fluid Tracking mode
Fault: Acumen IQ Fluid Meter Disconnected	Acumen IQ Fluid Meter has become disconnected	Connect Acumen IQ Fluid Meter to Acumen AFM cable Continue AFM in Manual Fluid Tracking mode

Table 14-19 HemoSphere pressure cable AFM faults/alerts

Message	Possible causes	Suggested actions
Fault: Acumen IQ Fluid Meter Error	Damaged or defective Acumen IQ Fluid meter	Disconnect Acumen IQ fluid meter and check for bent/ missing contacts Replace Acumen IQ fluid meter If problem persists, contact Edwards Technical Support
Alert: Port {0} – Multiple Acumen AFM Cables Detected – Disconnect Cable	Multiple Acumen AFM Cable connections detected	Disconnect one of the Acumen AFM Cables
Alert: AFM – Acumen IQ Fluid Meter Error	Damaged or defective Acumen IQ fluid meter Non-Edwards fluid meter in use	Disconnect Acumen IQ Fluid Meter and check for bent/ missing contacts Replace Acumen IQ Fluid Meter Verify that an Edwards fluid meter is being used Disconnect and reconnect Acumen IQ Fluid Meter Replace the fluid meter with an Edwards Acumen IQ Fluid Meter If problem persists, contact Edwards Technical Support
Alert: Exceeded Maximum Case Volume	Tracked volume has exceeded configured Maximum Case Volume	Set a new Maximum Case Volume limit End the AFM session
Alert: Detected Flow Rate Too High	Tracked bolus flow rate through fluid meter has exceeded 8.0 L/hr	Reduce bolus flow rate to below 8.0 L/hr Continue AFM session in Manual fluid tracking mode
Alert: Bolus Detected During Initialization	Fluid bolus detected during initialization of AFM session	Close bolus line and retry AFM initialization
Alert: Acumen IQ Fluid Meter Detected	AFM is in Manual fluid tracking mode but Acumen IQ Fluid Meter is connected	Disconnect Acumen IQ fluid meter Select to continue AFM algorithm session in fluid meter mode
Alert: Bolus Detected During AFM Analysis	Additional fluid bolus detected during ongoing AFM bolus analysis	When possible, deliver fluids after bolus analysis is complete
**Note: {0} is the port number: 1, 2, 3, 4, or 5.*		

Table 14-20 HemoSphere pressure cable AFM warnings

Message	Possible causes	Suggested actions
Port {0} – Acumen AFM Cable Disconnected	Acumen AFM ɕCable has become disconnected	Connect Acumen AFM Cable to HemoSphere Alta monitor Continue AFM algorithm in Manual Fluid Tracking mode
Acumen IQ Fluid Meter Disconnected	Acumen IQ Fluid Meter has become disconnected	Connect Acumen IQ Fluid Meter to Acumen AFM cable Continue AFM in Manual Fluid Tracking mode
AFM Session Paused	AFM session has been paused	Resume the AFM session in the side panel
AFM Suggestion Suspended (Bolus Declined)	Previous AFM suggestion was declined	Open the bolus line and start bolus when needed Suggestions will resume after <#> timer
**Note: {0} is the port number: 1, 2, 3, 4, or 5.*		

14.8.4 Cerebral Adaptive Index (CAI) Algorithm Faults/Alerts

Table 14-21 HemoSphere pressure cable CAI faults/alerts

Message	Possible causes	Suggested actions
Fault: CAI – Internal Failure	A processing error has occurred in the calculation of CAI	Disconnect and reconnect the ForeSight oximeter cable Disconnect and reconnect the pressure cable Replace the ForeSight oximeter cable Replace the pressure cable If problem persists, contact Edwards Technical Support

Table 14-21 HemoSphere pressure cable CAI faults/alerts

Message	Possible causes	Suggested actions
Fault: CAI – Poor Signal Quality	CAI is being monitored and tissue oximetry sensor or MAP measurement is no longer valid	Verify correct placement of StO_2 sensor Check that StO_2 sensor is in direct contact with the skin and that the clear liner has been removed Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the arterial catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned
Fault: CAI – MAP Not Valid for CAI	CAI is active and MAP source is not from HemoSphere pressure cable CAI is active and there is a poor MAP signal quality	Check MAP input is from TruWave/FloTrac/AcumenIQ sensor Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the arterial catheter is not kinked or clotted Make sure all arterial pressure lines are patent and stopcocks are properly positioned
Fault: CAI – StO_2 Not Valid for CAI	CAI is active and there is a poor StO_2 signal quality	Verify correct placement of StO_2 sensor
Alert: CAI – Cannot Be Initialized – Multiple Sensors Configured to Left Cerebral Location	CAI is monitoring and multiple StO_2 sensors are configured to the left cerebral location	Verify only one ForeSight sensor is attached to each cerebral location. Switch one of the ForeSight sensors to the Right cerebral location.
Alert: CAI – Cannot Be Initialized – Multiple Sensors Configured to Right Cerebral Location	CAI is monitoring and multiple StO_2 sensors are configured to the right cerebral location	Verify only one ForeSight sensor is attached to each cerebral location. Switch one of the ForeSight sensors to the Left cerebral location.

Table 14-22 HemoSphere pressure cable CAI warnings

Message	Possible causes	Suggested actions
CAI – Arterial Pressure Required For CAI Monitoring	CAI is being monitored and MAP is not valid	Verify the connection between the pressure sensor and pressure cable Touch the "Zero" icon on the navigation bar to verify the pressure type is ART and zero pressure Disconnect pressure cable and check for bent or missing pins Change Edwards pressure sensor Change pressure cable
CAI – Connect ForeSight IQ Sensor To Cerebral Location For CAI Monitoring	CAI is being monitored and StO_2 is not valid	Verify a ForeSight IQ sensor is connected and the ForeSight IQ sensor location is cerebral Connect a ForeSight oximeter cable to the indicated port on the monitor Reconnect the ForeSight oximeter cable
CAI – Monitoring Is Not Supported In Pediatric Mode	Pediatric mode is on before the algorithm starts to calculate A switch to pediatric mode is made after CAI monitoring has already started	Switch to Adult mode to measure tissue oximetry Stay on Adult mode to measure tissue oximetry
CAI – Calculating – Please Wait	Valid MAP and L/R cerebral StO_2 sensors are connected and calculation of algorithm has started but up to 5 minutes to display first CAI value is needed	Wait up to 5 minutes

14.8.5 General Troubleshooting

Table 14-23 HemoSphere pressure cable general troubleshooting

Message	Possible causes	Suggested actions
Pressure - Connect pressure cable	A pressure-dependent key parameter is configured The connection between the monitor and the pressure cable has not been detected	Verify connection between the pressure cable and monitor Disconnect pressure cable and check for bent/missing pins Change pressure cable
Pressure - Connect Acumen IQ Sensor	An Acumen IQ dependent key parameter is configured The connection between the pressure cable and the Acumen IQ pressure sensor has not been detected The incorrect pressure sensor type is connected	Verify the connection between pressure cable and catheter Verify that the pressure sensor connected is for Acumen IQ monitoring Disconnect pressure cable and check for missing pins Change Edwards Acumen IQ sensor Change pressure cable
Pressure - Port {0} - Connect pressure sensor	A pressure-dependent key parameter is configured The connection between the pressure cable and pressure sensor has not been detected	Verify connection between pressure cable and catheter Verify that the pressure sensor is connected Disconnect pressure cable and check for missing pins Change Edwards pressure sensor Change pressure cable
Pressure – Port {0} – Zero sensor for pressure monitoring	The pressure signal was not zeroed prior to pressure monitoring	Touch the “Zero” icon on the navigation bar to zero pressure
CI > CO	Incorrect patient BSA BSA <1	Verify units of measure and values for patient's height and weight
SVR > SVRI	Incorrect patient BSA BSA <1	Verify units of measure and values for patient’s height and weight

14.9 ClearSight Monitoring Error Messages

14.9.1 Faults/Alerts

Table 14-24 ClearSight monitoring faults/alerts

Message	Possible causes	Suggested actions
Fault: ClearSight System – Finger Cuff {0} – BP Measurement Error*	Blood pressure measurement failed due to movement or poor measurement conditions	Allow system to automatically resolve the issue Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Fault: ClearSight System - Finger Cuff {0} - Poor Signal Quality	Light signal too high	Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size Restart measurement†
Fault: ClearSight System – Finger Cuff {0} – No Signal Detected – Low Perfusion	No measurable Plethysmogram detected on startup Possibly contracted arteries	Allow system to automatically resolve the issue Warm the hand Apply finger cuff to a different finger
Fault: ClearSight System – Finger Cuff {0} – No Pressure Waveforms Detected	The system failed to detect pressure waveforms Pressure pulsations in the finger diminished due to pressure applied to the upper arm, elbow or wrist	Allow system to automatically resolve the issue Check if the blood flow in the arm of the patient is free of obstructions Check the blood pressure waveforms Reapply finger cuff(s) Restart measurement
Fault: ClearSight System - Finger Cuff {0} - Check Cuff Cable Air Supply*	Finger cuff air tube kinked Finger cuff leaking The cable between the HemoSphere Alta monitor and pressure controller is kinked or leaking Defective pressure controller Defective ClearSight system	Check finger cuff Replace finger cuff Replace pressure controller Restart measurement
Fault: ClearSight System – Finger Cuff Disconnected	Previously connected finger cuff(s) not detected	Disconnect and reconnect Edwards finger cuff(s) Replace finger cuff(s) Restart measurement
Fault: ClearSight System – Accumulated Single Cuff Monitoring Has Reached The Duration Limit	Cumulative measurement time on the same finger exceeded maximum duration of 8 hours	Place the cuff on another finger and restart monitoring
Alert: ClearSight System - Finger Cuff 1 Has Expired - Replace Cuff Alert: ClearSight System - Finger Cuff 2 Has Expired - Replace Cuff	Finger cuff <#> has exceeded maximum use time*	Replace finger cuff <#>* Restart measurement
Alert: ClearSight System - Finger Cuff 1 or Finger Cuff Connector Error Alert: ClearSight System - Finger Cuff 2 or Finger Cuff Connector Error	Finger cuff <#> detected The cuff connector on Pressure Controller is damaged or defective*	Disconnect and reconnect Edwards finger cuff <#>* Replace finger cuff <#> Replace Pressure Controller Restart measurement*

Table 14-24 ClearSight monitoring faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: ClearSight System - HRS Value Out of Physiological Range	Heart end of HRS is loose and may no longer be at heart level HRS detached from finger cuff HRS incorrectly calibrated HRS is defective	Verify HRS placement. Finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis Vertically align the two ends of HRS and calibrate Replace HRS Restart Measurement If problem persists, contact Edwards Technical Support
Fault: ClearSight System - HRS Disconnected	Heart Reference Sensor (HRS) disconnected during monitoring HRS connection not detected	Verify HRS connection Disconnect and reconnect Edwards HRS Replace HRS If problem persists, contact Edwards Technical Support
Fault: ClearSight System - HRS Detected	Measurement without HRS chosen but HRS is connected	Disconnect HRS Or select to measure with HRS
Alert: ClearSight System - HRS or HRS Connector Error	Non Edwards HRS detected HRS is defective	Verify that an Edwards HRS has been used Disconnect and reconnect Edwards HRS Replace HRS with a genuine Edwards HRS Restart Measurement If problem persists, contact Edwards Technical Support
Fault: ClearSight System - HRS or HRS Connector Error	HRS is defective HRS connector on pressure controller is damaged	Disconnect and reconnect Edwards HRS Replace HRS Replace pressure controller Restart measurement If problem persists, contact Edwards Technical Support
Alert: ClearSight System - HRS Has Expired - Replace HRS	HRS has expired as it is past useful life	Disconnect and reconnect Edwards HRS Replace HRS Restart Measurement If problem persists, contact Edwards Technical Support
Fault: ClearSight System - Pressure Controller Disconnected	Pressure controller connection not detected	Disconnect and reconnect Edwards pressure controller Replace pressure controller If problem persists, contact Edwards Technical Support
Alert: ClearSight System - Pressure Controller Error	Incompatible pressure controller detected Non Edwards pressure controller detected Defective pressure controller connected	Verify that an Edwards pressure controller has been used Disconnect and re-connect Edwards pressure controller Replace pressure controller with a genuine Edwards pressure controller If problem persists, contact Edwards Technical Support
Fault: ClearSight System- Pressure Controller Error	Unresponsive pressure controller Pressure controller authentication failure Defective pressure controller	Disconnect and reconnect Edwards pressure controller Power cycle the system Replace pressure controller If Problem Persists, contact Edwards Technical Support
Fault: ClearSight System - Pressure Controller Error	Defective pressure controller Poor connection between Edwards pressure controller and HemoSphere ClearSight subsystem	Disconnect and reconnect Edwards pressure controller Replace pressure controller If problem persists, contact Edwards Technical Support
Fault: ClearSight System - Pressure Controller Power Failure - Servicing Required	Defective HemoSphere ClearSight subsystem Defective Edwards pressure controller	Disconnect and reconnect Edwards pressure controller Replace pressure controller Replace HemoSphere ClearSight module If Problem Persists, contact Edwards Technical Support
Fault: ClearSight System - Incompatible Pressure Controller Software	Unsuccessful software upgrade or incompatible software version detected	Replace pressure controller with a genuine Edwards pressure controller If problem persists, contact Edwards Technical Support

Table 14-24 ClearSight monitoring faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: ClearSight System - Continuous Monitoring Has Reached the 72 Hour Limit	Continuous measurement on the same hand exceeded maximum duration of 72 hours	Place the cuffs on fingers of opposite hand and resume monitoring
Fault: ClearSight System -Air Supply Error - Insufficient Pressure Build Up	Kinked or damaged pressure controller cable Damaged finger cuff System malfunction Defective pressure controller	Power cycle the system Replace pressure controller Replace finger cuff If problem persists, contact Edwards Technical Support
Alert: ClearSight System – Arterial Waveform Compromised	The system failed to detect pressure waveforms Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow, or wrist	Check if the blood flow in the arm of the patient is free of obstructions Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis Check the blood pressure waveforms Reapply finger cuff(s) Restart measurement If problem persists, contact Edwards Technical Support
Fault: Second Cuff Connected During Single Cuff Monitoring	A second finger cuff connection is detected	Disconnect one of the finger cuffs and restart measurement Restart measurement in double cuff monitoring mode
Alert: Cuff Pressure Release Mode – Monitoring Suspended	Finger cuff pressure has been released	Monitoring will automatically resume when the countdown clock on the status bar reaches 00:00 To resume monitoring, touch the countdown clock and select "Postpone Release"
Alert: ClearSight System - Finger Cuff 1 – Blood Pressure Measurement Error Alert: ClearSight System - Finger Cuff 2 – Blood Pressure Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions	Allow system to automatically resolve issue Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size[†]
Alert: ClearSight System - Finger Cuff 1 – No Pressure Waveforms Detected Alert: ClearSight System - Finger Cuff 2 – No Pressure Waveforms Detected	The system failed to detect pressure waveforms Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist	Allow System to automatically resolve issue Check if the blood flow in the arm of the patient is free of obstructions Check the blood pressure waveforms Reapply finger cuff(s)
Alert: HRS Value Out of Physiological Range	Heart end of HRS is loose and may no longer be at heart level HRS detached from finger cuff HRS incorrectly calibrated HRS is defective	Verify HRS placement. Finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis Vertically align the two ends of HRS and calibrate Replace HRS If problem persists, contact Edwards Technical Support
Alert: No HRS Connected – Verify Patient Positioning Alert: Current Offset: Finger <offset amount> Above Heart Alert: Current Offset: Finger at Heart Level Alert: Current Offset: Finger <offset amount> Below Heart	The patient positioning mode is "Patient Sedated and Stationary" and an HRS is not connected	Verify that the displayed offset is still accurate If the patient has been re-positioned, update the offset value on the "Zero" screen
Alert: ClearSight - Servicing Recommended	ClearSight subsystem pump lifetime expired - display message for every measurement when pump lifetime is 100%+	Contact Edwards Technical Support

Table 14-24 ClearSight monitoring faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: Updated Calibration Might Be Required	Updated calibration may be required due to changes to hemodynamic state	Perform new calibration Keep calibration Clear BP Calibration
**Note: {0} is the CUFF port number: 1 or 2.* ***Note: {0} is the user entered vertical offset from finger to heart level.* *†Cuff sizing may not be applicable to all cuffs.*		

Table 14-25 ClearSight monitoring warnings

Message	Possible causes	Suggested actions
HRS Out of Range!	HRS pressure offset exceeded limit during the calibrating process HRS is defective	Vertically align the two ends of Heart Reference Sensor and re-calibrate.
HRS Calibration Unsuccessful! No Movement Detected	Prior to calibration, no HRS movement detected HRS is defective Defective pressure controller	Move heart end of HRS up and down. Next, keep both ends at same level, wait 1-2 seconds, and then re-calibrate while keeping both ends steady.
HRS Calibration Unsuccessful!Excessive Movement Detected	During calibration, HRS movement detected Defective pressure controller	Move heart end of HRS up and down. Next, keep both ends at same level, wait 1-2 seconds, and then re-calibrate while keeping both ends steady.
Severe Vasoconstriction	Very small arterial volume pulsations detected, possibly contracted arteries	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Moderate Vasoconstriction	Very small arterial volume pulsations detected, possibly contracted arteries	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
ClearSight - Finger Cuff 1 - Blood Pressure Measurement Error ClearSight - Finger Cuff 2 - Blood Pressure Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions	Allow system to automatically resolve issue Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Finger Cuff 1 Expiration in < 5 Minutes Finger Cuff 2 Expiration in < 5 Minutes	Finger cuff <#> approaching maximum use time*	Replace finger cuff <#> to ensure uninterrupted measurement*
Finger Cuff 1 Approaching Maximum Use Time Finger Cuff 2 Approaching Maximum Use Time	Finger cuff <#> approaching maximum use time*	Replace finger cuff <#> to ensure uninterrupted measurement*
ClearSight System – HRS Expires in <2 weeks	HRS will expire in less than <#> weeks*	Replace HRS to prevent delay in start of monitoring
ClearSight System – Servicing Recommended	ClearSight subsystem pump lifetime will expire soon	Contact Edwards Technical Support
**Note: <#> is the CUFF port number (1 or 2) or the time left until cuff expires.* *†Cuff sizing may not be applicable to all cuffs.*		

Table 14-26 ClearSight monitoring general troubleshooting

Message	Possible causes	Suggested actions
Pressure Difference: ClearSight BP vs. Other BP	HRS detached from finger cuff or phlebostatic axis HRS not properly calibrated Possibly contracted arteries (due to cold fingers) Finger cuff too loose Other BP measurement device not zeroed Other BP measurement sensor incorrectly applied	Verify HRS placement -The finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis In case of invasive BP reference, HRS heart end and the transducer should be at the same level Calibrate HRS Warm the hand Reapply finger cuff (to a different finger) or replace finger cuff with proper size Re-zero other BP measurement device Remove and reapply other BP measurement sensor†
Connect Acumen IQ Cuff for HPI	Acumen IQ Cuff is not detected and HPI or HPI key parameter is configured	Connect Acumen IQ cuff Replace Acumen IQ cuff
Connect Acumen IQ Cuff in CUFF 1 for HPI	CUFF 1 connection is not an Acumen IQ Cuff and HPI or HPI key parameter is configured	Replace ClearSight Cuff for Acumen IQ Cuff in CUFF 1
Connect Acumen IQ Cuff in CUFF 2 for HPI	CUFF 2 connection is not an Acumen IQ cuff and HPI or HPI key parameter is configured	Replace ClearSight Cuff for Acumen IQ Cuff in CUFF 2
Connect HRS for HPI	HRS is not detected and HPI or HPI key parameter is configured	Connect HRS Replace HRS

†*Cuff sizing may not be applicable to all cuffs.*

14.10Venous Oximetry Error Messages

14.10.1Venous Oximetry Faults/Alerts

Table 14-27 Venous oximetry faults/alerts

Message	Possible causes	Suggested actions
Fault: Venous Oximetry – Recovery in Process – Please Wait	An unexpected event has occurred Diagnosis is in progress	Please allow 60 seconds for the system to diagnose the issue If problem persists, contact Edwards Technical Support
Fault: Venous Oximetry – IR or Light Range Error	Poor oximetry cable/catheter connection Debris or film obstructing oximetry cable/ catheter connector lens Oximetry cable malfunction Catheter kinked or damaged	Verify secure oximetry cable /catheter connection Clean oximetry cable /catheter connectors with 70% isopropyl alcohol and swab, let air-dry, and recalibrate Change oximetry cable and recalibrate Replace catheter if damage is suspected and recalibrate Power monitor off and on to restore platform
Fault: Venous Oximetry – Value Out of Range	Incorrectly entered $ScvO_2/SvO_2$, HGB or Hct values Incorrect HGB units of measure Calculated $ScvO_2/SvO_2$ value is outside of the 0-99% range	Verify correctly entered $ScvO_2/SvO_2$, HGB, and Hct values Verify correct HGB units of measure Obtain updated $ScvO_2/SvO_2$ lab values and recalibrate
Fault: Venous Oximetry – Input Signal Unstable	Poor oximetry cable/catheter connection Debris or film obstructing oximetry cable/ catheter connector lens Oximetry cable malfunction Catheter kinked or damaged	Verify secure oximetry cable /catheter connection Clean oximetry cable /catheter connectors with 70% isopropyl alcohol and swab, let air-dry and recalibrate Change oximetry cable and recalibrate Replace catheter if damage is suspected and recalibrate

Table 14-27 Venous oximetry faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: Venous Oximetry – Cable Malfunction – Servicing Recommended	Signal processing malfunction Oximetry cable memory malfunction Internal malfunction detected in oximetry cable	Power monitor off and on to restore platform Disconnect and then reconnect the cable Change oximetry cable and recalibrate If the cable is wrapped in fabric or sitting on an insulating surface such as a pillow, place it on a smooth surface that allows it to readily dissipate heat If problem persists, contact Edwards Technical Support
Fault: Venous Oximetry– Cable Temperature	Internal Malfunction detected in Oximetry Cable	Power monitor off and on to restore platform If the cable is wrapped in fabric or sitting on an insulating surface such as a pillow, place it on a smooth surface that allows it to readily dissipate heat If the cable body feels warm, allow it to cool before operating again If problem persists, contact Edwards Technical Support
Fault: Port {0} – Venous Oximetry Cable Disconnected	No oximetry cable detected by monitor	If intentionally disconnected, select the alarm silence button to clear the cable status Ensure oximetry cable is connected to monitor Disconnect and reconnect oximetry cable Change oximetry cable to a different cable port
Fault: Port {0} – Multiple Oximetry Cables Detected, Please Disconnect	More than one oximetry cable is connected	Disconnect all secondary oximetry cables
Fault: Port {0} Venous Oximetry – Incompatible Software Version	SW Version on Cable is incompatible with this monitor	Upgrade the Cable SW
Alert: Venous Oximetry – Cable Malfunction – Servicing Recommended	Oximetry cable memory malfunction Internal malfunction detected in oximetry cable	Disconnect and then reconnect the cable Change oximetry cable and recalibrate Power monitor off and on to restore platform If the cable is wrapped in fabric or sitting on an insulating surface such as a pillow, place it on a smooth surface that allows it to readily dissipate heat If problem persists, contact Edwards Technical Support
Alert: Venous Oximetry– Cable Temperature	Internal malfunction detected in oximetry cable	Power monitor off and on to restore platform If the cable is wrapped in fabric or sitting on an insulating surface such as a pillow, place it on a smooth surface that allows it to readily dissipate heat If the cable body feels warm, allow it to cool before operating again If problem persists, contact Edwards Technical Support

Table 14-27 Venous oximetry faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: Venous Oximetry – Poor Signal Quality	Low blood flow at catheter tip or catheter tip against vessel wall Significant change in HGB/Hct values Catheter tip clotted Catheter kinked or damaged Catheter is not connected to oximetry cable	If the cable is wrapped in fabric or sitting on an insulating surface such as a pillow, place it on a smooth surface that allows it to readily dissipate heat If the cable body feels warm, allow it to cool before operating again Verify proper catheter position (for SvO_2, verify proper catheter position in the pulmonary artery): • Confirm wedge pressure balloon inflation volume of 1.25-1.50 ml (for SvO_2 only) • Confirm appropriate catheter placement for patient's height, weight, and insertion site • Consider chest x-ray evaluation of proper placement Aspirate then flush distal lumen per hospital protocol Update HGB/Hct values using update function Check catheter for kinking and recalibrate Replace catheter if damage is suspected and recalibrate Ensure catheter is connected to oximetry cable
Alert: Venous Oximetry – Unstable Signal	Changing $ScvO_2/SvO_2$, HGB/Hct, or unusual hemodynamic values	Stabilize patient per hospital protocol and perform in vivo calibration
Alert: Venous Oximetry – Wall Artifact or Wedge Detected	Low blood flow at catheter tip Catheter tip clotted Catheter tip wedged in vessel or against vessel wall	Aspirate then flush distal lumen per hospital protocol. Verify proper catheter position (for SvO_2, verify proper catheter position in the pulmonary artery): • confirm wedge pressure balloon inflation volume of 1.25-1.50 ml (For SvO_2 only) • confirm appropriate catheter placement for patient's height, weight, and insertion site • consider chest x-ray for evaluation of proper placement Perform in vivo calibration.
Alert: Port {0} – Multiple Oximetry Cables Detected, Please Disconnect	More than one oximetry cable is connected	Disconnect all secondary oximetry cables
Note: While GHI is selected as a key parameter, venous oximetry faults/alerts will always be displayed, regardless of whether SvO_2 is selected as a key parameter **Note 2: {0} is the port number: 1, 2, 3, 4, or 5.*		

14.10.2Venous Oximetry General Troubleshooting

Table 14-28 Venous oximetry general troubleshooting

Message	Possible causes	Suggested actions
Venous Oximetry – In Vitro Calibration Error	Poor oximetry cable and catheter $ScvO_2$/SvO_2 connection Calibration cup wet Catheter kinked or damaged Oximetry cable malfunction Catheter tip is not in catheter calibration cup	Verify secure oximetry cable / catheter connection Straighten any visible kinks; replace catheter if damage is suspected Change oximetry cable and recalibrate Verify catheter tip is securely seated in calibration cup Perform In vivo calibration
Venous Oximetry – Cable Not Calibrated	Oximetry cable has not been calibrated (in vivo or in vitro) Recall venous oximetry data function has not been performed Oximetry cable malfunction	Run in-vitro calibration Run in-vivo calibration Recall calibration values
Venous Oximetry – Patient data in oximetry cable more than 24 hours old — Recalibrate	Last oximetry cable calibration > 24 hours old Date and time on Edwards' monitors at facility differ	Perform in vivo calibration Synchronize date and time on all Edwards' monitors at facility
Venous Oximetry – Connect oximetry cable for venous oximetry monitoring	Oximetry cable connection at HemoSphere Alta advanced monitoring platform not detected Bent or missing oximetry cable connector pins	Verify secure oximetry cable connection Check oximetry cable connector for bent/missing pins

14.11Tissue Oximetry Error Messages

14.11.1Tissue Oximetry Faults/Alerts

Table 14-29 Tissue oximetry faults/alerts

Message	Possible causes	Suggested actions
Fault: Tissue Oximetry – Subsystem Malfunction – Servicing Required	Internal system malfunction	Servicing Required – Use a Different Monitor
Fault: Tissue Oximetry – Recovery in Process – Please Wait	An unexpected event has occurred Diagnosis is in progress	Please allow 60 seconds for the system to diagnose the issue If problem persists, contact Edwards Technical Support
Fault: Tissue Oximetry – ForeSight Oximeter Cable {0} Disconnected*	FSOC <A/B> has become disconnected	Connect the ForeSight oximeter cable to port <A/B> of the HemoSphere Alta monitor
Fault: Tissue Oximetry – {0} Sensor Disconnected*	ForeSight sensor on the indicated channel has become disconnected	Connect sensor to ForeSight oximeter cable
Fault: Tissue Oximetry – ForeSight Oximeter Cable {0} Error*	The HemoSphere Alta monitor has lost communication with the indicated ForeSight oximeter cable	Reconnect the cable Check for bent or broken pins Try switching the ForeSight oximeter cable to another tissue oximetry port on the monitor If the problem persists, contact Edwards Technical Support
Fault: Tissue Oximetry – Incompatible Software – Software Update Required	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support

Table 14-29 Tissue oximetry faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: Tissue Oximetry – {0} Sensor Ambient Light Too High*	Sensor is not in correct contact with the patient	Check that sensor is in direct contact with skin Apply a light blocker or drape over the sensor to limit exposure to light
Fault: Tissue Oximetry – {0} Sensor Temperature High*	Temperature under sensor is > 45 °C (Adult Mode) or > 43 °C (Pediatric/ Neonatal Mode)	Cooling of patient or environment may be required
Fault: Tissue Oximetry – {0} Signal Level Too Low*	Insufficient light detected from patient Tissue under the sensors may have conditions such as excessive skin pigmentation, elevated hematocrit, birth marks, hematoma, or scar tissue A large (adult) sensor is being used on a pediatric patient (<18 years of age)	Verify that sensor is well adhered to patient's skin Move sensor to a location where SQI is 3 or 4 In the case of edema, remove the sensor until tissue condition returns to normal Replace large sensor with medium or small sensor in pediatric patients (<18 years of age)
Fault: Tissue Oximetry – {0} Signal Level Too High*	Very unusual condition that is likely caused by optical shunting, where most of the light emitted is directed to the detectors Certain non-physiological materials, anatomical characteristics or scalp edema may trigger this message	Check that sensor is in direct contact with skin and that the clear liner has been removed
Fault: Tissue Oximetry – {0} Check Tissue Under Sensor*	Tissue under sensor may have fluid accumulation/edema	Check patient for edema under sensor When tissue condition returns to normal range (e.g., patient is no longer edematous) the sensor may be reapplied
Fault: Tissue Oximetry – {0} Stool Interference High*	The sensor is interrogating primarily stool versus perfused tissue and StO_2 cannot be measured	Move the sensor to a location where the relative amount of intestinal tissue is less, such as the flank
Fault: Tissue Oximetry – {0} Sensor Off*	Computed StO_2 not in valid range or sensor placed on an inappropriate object	Sensor may need to be repositioned
Fault: Tissue Oximetry – {0} StO_2 not in Physiological Range*	The measured value is out of physiological range Sensor malfunction	Verify correct placement of sensor Check sensor connection
Fault: Tissue Oximetry – {0} Algorithm Fault*	A processing error has occurred in the calculation of StO_2 for the indicated channel	Disconnect and reconnect the indicated sensor channel Replace the FSOC If problem persists, contact Edwards Technical Support
Fault: Tissue Oximetry – {0} ΔctHb not in Physiological Range*	The measured value is out of the physiological range Sensor malfunction	Verify correct placement of sensor Check sensor connection
Alert: Tissue Oximetry – {0} Incorrect Sensor Size*	The sensor size is incompatible with either the Patient Mode or body location	Use a different sensor size (Refer to Sensor Instructions for Use for sensor size table) Change the Patient Mode or body location on the tile configuration menu accordingly
Alert: Tissue Oximetry – {0} Sensor Error*	Sensor is defective or Non-Edwards sensor in use	Replace with Edwards sensor
Alert: Tissue Oximetry – {0} Inadequate Signal Level*	Interference from an outside source	Move sensor away from interfering source
Alert: Tissue Oximetry – {0} Sensor Ambient Light Too High*	Ambient light approaching the maximum value	Check that sensor is in direct contact with skin Apply a light blocker or drape over the sensor to limit exposure to light

Table 14-29 Tissue oximetry faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: Tissue Oximetry – {0} Stool Interference High*	Stool Interference is approaching the maximum acceptable level The sensor is interrogating some perfused tissue to make a StO_2 measurement, but there is also a high concentration of stool in the sensor's interrogation path	Consider moving the sensor to a different abdominal location with less stool interference
Alert: Tissue Oximetry – {0} Sensor Temperature Low*	Temperature under sensor < -10 °C	Warming of patient or environment may be required
Alert: Tissue Oximetry – {0} Configure location for tissue oximetry sensor*	An anatomical location on the patient has not been configured for the connected sensor	Use the tissue oximetry configuration menu to select a body location for the indicated sensor channel
Alert: Tissue Oximetry – {0} ΔctHb Reset Failed*	ctHb cannot reset due to instability of StO_2	Address StO_2 instability
**Note: {0} is the sensor channel. The channel options are A1 and A2 for ForeSight oximeter cable A and B1 and B2 for ForeSight oximeter cable B.* *The following components may have alternative labeling conventions:* *ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).* *ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.*		

14.11.2Tissue Oximetry General Troubleshooting

Table 14-30 Tissue oximetry general troubleshooting

Message	Possible causes	Suggested actions
Tissue Oximetry – Connect ForeSight Oximeter Cable <A or B> for StO_2 monitoring	Connection between the HemoSphere Alta monitor and FSOC at the indicated port has not been detected	Connect a FSOC to the indicated port of the HemoSphere Alta monitor Reconnect the FSOC
Tissue Oximetry – Connect tissue oximetry sensor for StO_2 monitoring – {0}*	Connection between the FSOC and tissue oximetry sensor has not been detected on the channel for which StO_2 has been configured	Connect a tissue oximetry sensor to the indicated channel Reconnect the tissue oximetry sensor on the indicated channel
Tissue Oximetry – {0} Sensor Temperature Below Expected Range	Temperature out of physiological range	
Tissue Oximetry – ΔctHb reset in progress	ctHb reset in progress	
**Note: {0} is the sensor channel. The channel options are A1 and A2 for ForeSight oximeter cable A and B1 and B2 for ForeSight oximeter cable B.* *The following components may have alternative labeling conventions:* *ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).* *ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.*		

14.11.3Total Hemoglobin Faults/Alerts

Table 14-31 Total hemoglobin faults/alerts

Message	Possible causes	Suggested actions
Fault: tHb – Multiple Left Sensors Connected	Multiple sensors configured to the same cerebral location	Configure only one sensor to L and R cerebral locations prior to starting calibration
Fault: tHb – Multiple Right Sensors Connected	Multiple sensors configured to the same cerebral location	Configure only one sensor to L and R cerebral locations prior to starting calibration
Fault: tHb – Initialization Error	Cable/Sensor connections unstable prior to initialization Cerebral data unstable prior to initialization Pediatric mode is selected on the monitor	Check cable connections/sensors for ambient light Disconnect and reconnect cable/sensors Wait for cerebral data to stabilize Change patient mode to Adult
Fault: tHb – Not Supported in Pediatric Mode	Pediatric mode is selected on the monitor	Change patient mode to Adult
Alert: Total Hemoglobin Advanced Feature Not Enabled	System detects ForeSight IQ sensor is connected without tHb Advanced Features enabled	Contact Edwards Lifesciences service representative to enable tHb
Alert: tHb – Recalibration Recommended	Calibrated tHb value is unsteady from changes in hemodynamic state. Extended period of time has passed without recalibration	Navigate to the recalibration tab to enter Hgb or Hct
Alert: tHb - Multiple Left Sensors Connected	Sensor configuration changed to the same cerebral location	Re-configure only one sensor to L and R cerebral locations
Alert: tHb - Multiple Right Sensors Connected	Sensor configuration changed to the same cerebral location	Re-configure only one sensor to L and R cerebral locations
Alert: tHb – Unstable Signal	Unstable tHb signal detected	Check cable connections/sensors for ambient light Disconnect and reconnect cable/sensors Wait for cerebral data to stabilize
Alert: tHb – Calibration Recommended	tHb has not been calibrated	Navigate to the calibration tab to enter Hgb or Hct

Table 14-32 Total hemoglobin warnings

Message	Possible causes	Suggested actions
tHb – Do Not Calibrate	Invalid StO_2 from cerebral sensor prior to calibration	Wait for the StO_2 value to stabilize

Appendix A

Specifications and Device Characteristics

Contents

A.1 Essential Performance Characteristics

Under normal and single fault conditions either the essential performance listed in table A-1 below is provided or failure to provide this performance is readily identifiable by the user (e.g., no display of parameter values, technical alarm, distorted waveforms or delay in parameter value update, complete failure of the monitor, etc.).

Table A-1 represents the minimum performance when operating under non-transient electromagnetic phenomena, such as radiated and conducted RF, according to IEC 60601-1-2. Table A-1 also identifies the minimum performance for transient electromagnetic phenomena, such as electrical fast transients and surges, according to IEC 60601-1-2.

Table A-1 HemoSphere Alta advanced monitoring platform essential performance – transient and non-transient electromagnetic phenomena

Cable	Parameter	Essential Performance
General: all monitoring modes and parameters		No interruption of current monitoring mode. No unexpected reboots or halting of operation. No spontaneous triggering of events that require user interaction to initiate. Patient connections provide defibrillator protection. Following exposure to defibrillation voltages, the system shall return to an operational state within 10 seconds. After the transient electromagnetic phenomena, the system shall return to an operational state within 30 seconds. If Swan-Ganz continuous cardiac output (CO) was active during the event, the system will automatically re-initiate monitoring. The system shall exhibit no loss of any stored data following the transient electromagnetic phenomena. When used with HF Surgical Equipment, the monitor shall return to operational mode within 10 seconds without loss of stored data after exposure to the field produced by the HF Surgical Equipment.
HemoSphere Alta Swan-Ganz patient cable	Continuous Cardiac Output (CO), and associated parameters, both indexed and non-indexed (SV, SVR, RVEF, EDV)	Monitors the filament surface temperature and time at temperature. If a time and temperature threshold is exceeded (above 45 °C), monitoring halts and alarm triggered. Measurement of blood temperature within specified accuracy (±0.3 °C). Alarm if blood temperature outside of monitoring range. Alarm if CO and related parameters outside of alarm ranges. Alarm delay based on a variable averaging time. Typical averaging time is 57 seconds.
	intermittent cardiac output (iCO) and associated parameters, both indexed and non-indexed (SV, SVR)	Measurement of blood temperature within specified accuracy (±0.3 °C). Alarm if blood temperature outside monitoring range.
HemoSphere Alta Swan-Ganz patient cable and pressure cable	20-second flow parameters (CO_{20s}, CI_{20s}, SV_{20s}, SVI_{20s})	Alarm if 20-second parameters outside of alarm ranges. Alarm delay based on a 20 second averaging time.
HemoSphere pressure cable	arterial blood pressure (SYS, DIA, MAP), central venous blood pressure (CVP), pulmonary artery blood pressure (MPAP), right ventricular pressure (RVP)	Measurement of blood pressure within specified accuracy (±4% or ±4 mmHg, whichever is greater). Alarm if blood pressure outside of alarm ranges. Alarm delay of 7 seconds based on averaging time of 2 seconds and 5 consecutive seconds outside of alarm ranges. The device supports detection of invasive pressure transducer and transducer cable fault. The device supports detection of disconnected catheter.

Table A-1 HemoSphere Alta advanced monitoring platform essential performance – transient and non-transient electromagnetic phenomena (continued)

Cable	Parameter	Essential Performance
HemoSphere pressure controller	noninvasive blood pressure (SYS, DIA, MAP)	Measurement of blood pressure within specified accuracy (±1% of full scale with a maximum of ±3 mmHg). Alarm if blood pressure outside alarm ranges. Alarm delay of approximately 10 seconds based on averaging window of 5 heartbeats (at 60 bpm this would be 5 seconds but will vary based on heart rate) and 5 consecutive seconds outside of alarm ranges.
HemoSphere oximetry cable	oxygen saturation (mixed venous SvO_2 or central venous oximetry$ScvO_2$)	Measurement of oxygen saturation within specified accuracy (±2% oxygen saturation). Alarm if oxygen saturation outside of alarm ranges. Alarm delay of 7 seconds based on averaging time of 2 seconds and 5 consecutive seconds outside of alarm ranges.
ForeSight oximeter cable	tissue oxygen saturation (StO_2)	The ForeSight oximeter cable shall recognize attached Sensor and issue an appropriate equipment status if inoperable or disconnected. When a sensor is properly positioned on the patient and connected to the ForeSight Elite module, the ForeSight oximeter cable shall measure StO_2 values within system specifications (refer to table A-16 on page 358) and correctly output values to HemoSphere Alta monitor. In response to a defibrillation event, the ForeSight oximeter cable shall not be electrically damaged. In response to an external noise event, the values may continue to report as pre-event values or may be reported as indeterminate value (dashed). The ForeSight oximeter cable shall automatically recover and resume reporting appropriate values within 20 seconds after the noise event.
Acumen AFM cable	fluid delivery tracking (flow rate)	When used with a compatible fluid meter, measurement of flow rate within specified accuracy (±20% or ±1 mL/min, whichever is greater). During transient electromagnetic phenomena, flow rate values may continue to report as pre-event values. The Acumen AFM cable shall automatically recover and resume reporting appropriate values within 30 seconds after the noise event.

A.2 HemoSphere Alta Advanced Monitoring Platform Characteristics and Specifications

Table A-2 HemoSphere Alta advanced monitor physical and mechanical characteristics

HemoSphere Alta advanced monitor		
Weight	21.57 lbs (9.78 kg)	
Dimensions	Height	13.45 in (342 mm)
	Width	15.26 in (388 mm)
	Depth	8.20 in (208 mm)
Footprint	Width	12.5 in (318 mm)
	Depth	7.9 in (201 mm)
Ingress protection	IPX1	
Display	Active Area	15.6 in diagonal (396 mm)
	Resolution	1920 x 1080
Operating system	Windows 10	
Speaker count	1	

Table A-3 HemoSphere Alta advanced monitoring platform environmental specifications

Environmental specification		Value
Temperature	Operational	10 to 37 °C
	Non-operational/storage*	-18 to 45 °C
Relative humidity	Operational	10 to 90% non-condensing 10 to 70% non-condensing (using ClearSight technology)
	Non-operational/storage	ambient to 90% non-condensing
Altitude (Pressure)	Operational	0 to 3000m (70.1 to 101.3 kPa)
	Non-operational/storage	up to 6,000 m
**Note: Battery capacity starts to degrade with extended exposure above 35 °C*		

Table A-4 HemoSphere Alta advanced monitoring platform transportation environmental specifications

Environmental specification	Value
Temperature*	-18 to 45 °C
Relative humidity*	20 to 90% RH non-condensing
Altitude	maximum of 20,000 feet (6096 m) for up to 8 hours
Standard	ASTM D4169, DC13
*Note: Pre-conditioning temperature and humidity	

NOTE Unless otherwise stated, all compatible HemoSphere Alta advanced monitoring platform accessories, components, and cables have the environmental specifications listed in table A-3 and table A-4.

MRI Information. Do not use the HemoSphere Alta advanced monitoring platform or platform modules and cables in an MR environment. The HemoSphere Alta advanced monitoring platform, including all compatible connecting cables, is MR unsafe since the device contains metallic components, which can experience RF-induced heating in the MRI environment.

Table A-5 HemoSphere Alta advanced monitoring platform technical characteristics

Input/Output	
Touch screen	Projective capacitive touch
RS-232 serial port (2)	Edwards proprietary protocol; Maximum data rate = 57.6 kilo baud
USB ports (3)	three USB 2.0 on rear panel
RJ-45 Ethernet port	One
HDMI port	One
Pressure output (1)	DPT pressure out signal from ClearSight technology is compatible with monitors and accessories intended to interface with Edwards non-invasive pressure signal
ECG monitor input	ECG sync line conversion from ECG signal: 1V/mV; Input voltage range ±10V full scale; Resolution = ±1 BPM; Accuracy = ±10% or 5 BPM of the input, whichever is greater; Range = 30 to 200 BPM; 1/4 in. stereo jack, tip at positive polarity; analog cable **Pacemaker pulse rejection capabilities.** Instrument rejects all pacemaker pulses having amplitudes from ±2 mV to ±5 mV (assumes 1V/mV ECG sync line conversion) and pulse widths from 0.1 ms to 5.0 ms, both with normal and ineffective pacing. Pacemaker pulses with overshoot of ≤7% of pulse amplitude (Method A of EN 60601-2-27:2014, subclause 201.12.1.101.13) and overshoot time constants from 4 ms to 100 ms are rejected. **Maximum T-wave rejection capability.** Maximum T-wave amplitude that can be rejected by instrument: 1.0 mV (assumes 1V/mV ECG sync line conversion). **Irregular Rhythm**. Figure 201.101 of EN 60601-2-27:2014. * Complex A1: Ventricular bigeminy, system displays 80 BPM * Complex A2: Slow alternating ventricular bigeminy, system displays 60 BPM * Complex A3: Rapid alternating ventricular bigeminy, system displays 60 BPM * Complex A4: Bidirectional systoles, system displays 104 BPM
HRavg display	**CO Monitoring Off.** Averaging time: 57 seconds; Update rate: Per beat; Response time: 40 seconds for step increase from 80 to 120 BPM, 29 seconds for step decrease from 80 to 40 BPM. **CO Monitoring On.** Averaging time: Time between CO measurements (3 to 21 minutes); Update rate: Approximately 1 minute; Response time: 175 seconds for step increase from 80 to 120 BPM, 176 seconds for step decrease from 80 to 40 BPM.
Electrical	
Rated supply voltage	100 to 240 Vac; 50/60 Hz
Rated input	1.5 to 2.0 Amps
Fuses	T 2.5AH, 250V; High breaking capacity; Ceramic
Alarm	
Sound pressure level	45 to 85 dB(A)
Wireless	
Type	Supports dual stream Wi-Fi in the 2.4GHz, 5GHz and 6Ghz bands

A.3 HemoSphere Alta Monitor Battery Characteristics and Specifications

Table A-6 HemoSphere Alta Monitor battery technical characteristics

Specification	Value
Output voltage (nominal)	14.4 V
Maximum discharge current	4.096 A (8.5 A at 25°C)
Cells	8 x Li-Ion (Lithium Ion)

A.4 HemoSphere Alta Swan-Ganz Patient Cable Characteristics and Specifications

Table A-7 HemoSphere Alta Swan-Ganz patient cable physical characteristics

HemoSphere Alta Swan-Ganz patient cable	
Weight	approximately 0.81 lb (0.37 kg)
Length	120 ± 6 in (305 ± 15 cm)
Ingress protection at monitor connection	IPX1
Ingress protection at catheter connection	IPX4
Applied part classification	Type CF defibrillation proof

NOTE For HemoSphere Alta Swan-Ganz patient cable environmental specifications, see table A-3, *HemoSphere Alta advanced monitoring platform environmental specifications*, on page 352.

Table A-8 HemoSphere Alta Swan-Ganz patient cable parameter measurement specifications

Parameter	Specification	
Continuous Cardiac Output (CO)	Range	1 to 20 L/min
	Reproducibility[1]	±6% or 0.1 L/min, whichever is greater
	Average response time[2]	<10 mins (for CCO catheters) <14 mins (for CCO volumetric catheters)
	Maximum thermal filament surface temperature	48 °C
Intermittent (Bolus) Cardiac Output (iCO)	Range	1 to 20 L/min
	Reproducibility[1]	±3% or 0.1 L/min, whichever is greater
Blood Temperature (BT)	Range	15 to 45 °C (59 to 113 °F)
	Accuracy	±0.3 °C
Injectate Temperature (IT)	Range	0 to 30 °C (32 to 86 °F)
	Accuracy	±1 °C
Average Heart Rate for EDV/ RVEF Determination (HRavg)	Acceptable input range	30 to 200 bpm

Table A-8 HemoSphere Alta Swan-Ganz patient cable parameter measurement specifications

Parameter	Specification	
Continuous Right Ventricular Ejection Fraction (RVEF)	Range	10 to 60%
	Reproducibility[1]	±6% or 3 efu, whichever is greater
[1] Coefficient of variation — measured using electronically generated data [2] 90% change under conditions of stable blood temperature		

NOTE It is recommended that after3 years from the date of purchase, a replacement HemoSphere Alta Swan-Ganz patient cable may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

Table A-9 HemoSphere Alta Swan-Ganz patient cable 20-second flow parameter measurement specifications*

Parameter	Specification	
CO_{20s}	Range	1 to 20 L/min
	Update rate	20 ±1 seconds
CI_{20s}	Range	0 to 20 L/min/m^2
	Update rate	20 ±1 seconds
SV_{20s}	Range	0 to 300 mL/b
	Update rate	20 ±1 seconds
SVI_{20s}	Range	0 to 200 mL/b/m^2
	Update rate	20 ±1 seconds
**20-second flow parameters only available when monitoring pulmonary artery pressure with a connected HemoSphere pressure cable and TruWave DPT. For more information on these parameters, see "20-Second Flow Parameters" on page 142.*		

Table A-10 HemoSphere Alta Swan-Ganz patient cable RVCO algorithm parameter measurement specifications

Parameter	Specification	
right ventricular cardiac output (CO_{RV})	display range	1.0 to 20.0 L/min
	update rate	10 ± 1 seconds

A.5 HemoSphere Pressure Cable Characteristics and Specifications

Table A-11 HemoSphere and HemoSphere Alta pressure cable physical characteristics

HemoSphere pressure cable	HEMPSC100	HEMAPSC200
Weight	approximately 0.64 lbs (0.29 kg)	approximately 0.57 lbs (0.26 kg)
Length	10 ft (3.0 m)	15 ft (4.6 m)
Ingress protection	IPX4	
Applied part classification	Type CF defibrillation proof	

NOTE For HemoSphere pressure cable and HemoSphere Alta pressure cable environmental specifications, see table A-3, *HemoSphere Alta advanced monitoring platform environmental specifications*, on page 352.

Table A-12 HemoSphere and HemoSphere Alta pressure cable parameter measurement specifications

Parameter	Specification	
FloTrac cardiac output (CO)	Display range	1.0 to 20 L/min
	Reproducibility[1]	±6% or 0.1 L/min, whichever is greater
Blood pressure[2]	Live pressure display range	-34 to 312 mmHg
	MAP/DIA/SYS display range	0 to 300 mmHg
	CVP display range	0 to 50 mmHg
	MPAP display range	0 to 99 mmHg
	MRVP display range	0 to 99 mmHg
	PAOP tested range[4]	3.7 to 34.7 mmHg
	PAOP accuracy[5]	±4 mmHg
	Accuracy	±4% or ±4 mmHg, whichever is greater, from -30 to 300 mmHg
	Bandwidth	1-10Hz
	Pressure-out accuracy[6]	±4% or ± 4 mmHg, whichever is greater between -20 and 280 mmHg (post zeroing as viewed on connected monitor)
Pulse rate (PR)	Accuracy[3]	A_{rms} ≤3 bpm

[1]Coefficient of variation - measured using electronically generated data.

[2]Parameter specifications compliant with IEC 60601-2-34 standards. Testing performed under laboratory conditions.

[3]Accuracy tested under laboratory conditions.

[4]PAOP measurement using the Smart Wedge algorithm and Swan-Ganz catheter with PA pressure monitored with TruWave transducer.

[5]Accuracy is the mean absolute error and was tested under clinical conditions

[6]HemoSphere Alta pressure cable only (HEMAPSC200)

NOTE It is recommended that after 5 years from the date of purchase, a replacement HemoSphere pressure cable may be considered depending on its condition and functionality at that time. It is recommended that after 3 years from the date of purchase, a replacement HemoSphere Alta

pressure cable may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

A.6 HemoSphere Oximetry Cable Characteristics and Specifications

Table A-13 HemoSphere oximetry cable physical characteristics

HemoSphere oximetry cable		
Weight	approximately 0.54 lbs (0.24 kg)	
Dimensions	Length	9.6 ft (2.9 m)
Ingress protection	IPX4	
Applied part classification	Type CF defibrillation proof	

NOTE For HemoSphere oximetry cable environmental specifications, see table A-3, *HemoSphere Alta advanced monitoring platform environmental specifications*, on page 352.

Table A-14 HemoSphere oximetry cable parameter measurement specifications

Parameter	Specification	
$ScvO_2/SvO_2$ Oximetry (Oxygen Saturation)	Range	0 to 99%
	Precision[1]	±2% at 30 to 99%
	Update rate	2 seconds
[1] Precision tested under laboratory conditions.		

NOTE It is recommended that after 3 years from the date of purchase, a replacement oximetry cable may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

A.7 HemoSphere Tissue Oximetry Characteristics and Specifications

NOTE For ForeSight oximeter cable environmental specifications, see table A-3, *HemoSphere Alta advanced monitoring platform environmental specifications*, on page 352.

Table A-15 ForeSight oximeter cable physical characteristics

ForeSight oximeter cable		
Weight	mounting clip	0.1 lbs (0.05 kg)
	case, cables, and clip	2.3 lbs (1.0 kg)
Dimensions	monitor cable length	15 ft (4.6 m)[1]
	sensor cable length (2)	4.9 ft (1.5 m)[1]
	cable housing (H × W × D)	6.0 in (15.24 cm) × 3.75 in (9.52 cm) × 2.75 in (6.00 cm)
	mounting clip (H × W × D)	2.4 in (6.2 cm) × 1.75 in (4.47 cm) × 3.2 in (8.14 cm)
Ingress protection	IPX4	
Applied part classification	Type BF defibrillation proof	
[1] *The length of the monitor and sensor cables are nominal lengths*		

Table A-16 ForeSight oximeter cable parameter measurement characteristics

Parameter	**Measurement**	
StO_2 and ΔctHb		
Cerebral StO_2 and Non-cerebral StO_2 (somatic)	Range	1 to 99%
	Minimum resolution	1%
Relative change in total hemoglobin (ΔctHb)	Range	-100 to 100µM
	Minimum resolution	1
StO_2	**Accuracy***	
Cerebral StO_2	large sensors	46% to 88%: -0.06 ± 3.25% at 1 SD
		46% to 88%: -0.06 ± 3.28% at 1 SD†
	medium sensors	44% to 91%: 0.97 ± 5.43% at 1 SD
		44% to 91%: 1.21 ± 5.63% at 1 SD†
		44% to 91%: 1.27 ± 4.93% at 1 SD‡
	small sensors	44% to 90%: -0.74 ± 5.98% at 1 SD
Non-cerebral StO_2 (somatic)	large sensors	51% to 92%: -0.12 ± 4.15% at 1 SD
		51% to 92%: -0.12 ± 4.17% at 1 SD†
	medium sensors	52% to 88%: -0.14 ± 5.75% at 1 SD
	small sensors	66% to 96%: 2.35 ± 5.25% at 1 SD

Table A-16 ForeSight oximeter cable parameter measurement characteristics (continued)

ΔctHb	Accuracy*		
Relative change in total hemoglobin (ΔctHb)	Sensor size	Bland-Altman Bias ± Precision, RSME (Arms)	Method of evaluation^
	large	0.22 ± 2.53 µM at 1 SD, 2.53 µM	Under isovolumic hemodilution human study
		-0.26 ± 2.04 µM at 1 SD, 2.04 µM	Under mild hypoxia human study
	medium	-1.10 ± 5.27 µM at 1 SD, 5.39 µM	Blood phantom study
	small	-0.02 ± 5.96 µM at 1 SD, 5.96 µM	Blood phantom study
		-0.50 ± 2.09 µM at 1 SD, 2.15 µM	Under hemoglobin level desaturation blood phantom study

*Accuracy (Bias ± Precision) not determined outside of the listed ranges

†Dependent Data Bland-Altman

‡Brain StO_2 values averaged versus REF CX bias and precision

^Differential Pathlength factor = 5

Note: StO_2 accuracy is determined based on 30:70% (arterial: venous) reference measurement for REF CX

Method of evaluation for all StO_2 sensor size accuracy measurements under human clinical evaluation studies

NOTE It is recommended that after 5 years from the date of purchase, a replacement ForeSight oximeter cable may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

A.8 HemoSphere Alta ClearSight Technology Characteristics and Specifications

Table A-17 HemoSphere Alta ClearSight technology parameter measurement specifications

Parameter	Specification	
arterial blood pressure	display range	0 to 300 mmHg
	accuracy[1]	Bias systolic pressure (SYS) ≤ ±5.0 mmHg Bias diastolic pressure (DIA) ≤ ±5.0 mmHg Precision (1σ) systolic pressure (SYS) ≤ 8.0 mmHg Precision (1σ) diastolic pressure (DIA) ≤ 8.0 mmHg
	pressure-out accuracy	4 mmHg or 4%, whichever is greater between -20 and 280 mmHg
finger cuff pressure	range	0 to 300 mmHg
	accuracy	1% of full scale (max 3 mmHg), zeroing automatically
cardiac output (CO)	display range	1.0 to 20.0 L/min
	accuracy[2]	Bias ≤ ±0.6 L/min or ≤ 10% (whichever is greater). Precision (1σ) ≤ ±23.75% over the range of cardiac output from 2 to 20 L/min
	reproducibility[3]	±6%
	update rate	20 seconds
pulse rate (PR)	accuracy[4]	A_{rms} ≤ 3 bpm

[1] Accuracy tested under laboratory conditions compared to a calibrated pressure gauge

[2] When compared to a predicate device (FloTrac sensor or pulmonary artery intermittent cardiac output (PA-iCO)

[3] Coefficient of variation – measured using electronically generated data

[4] Accuracy tested under laboratory conditions

Table A-18 Edwards finger cuff characteristics

Finger cuff	
Maximum weight	11 g (0.02 lbs)
LED spectral irradiance	See figure A-1
Max optical output	0.013 mWatts
Max variation of output over treatment area	50%

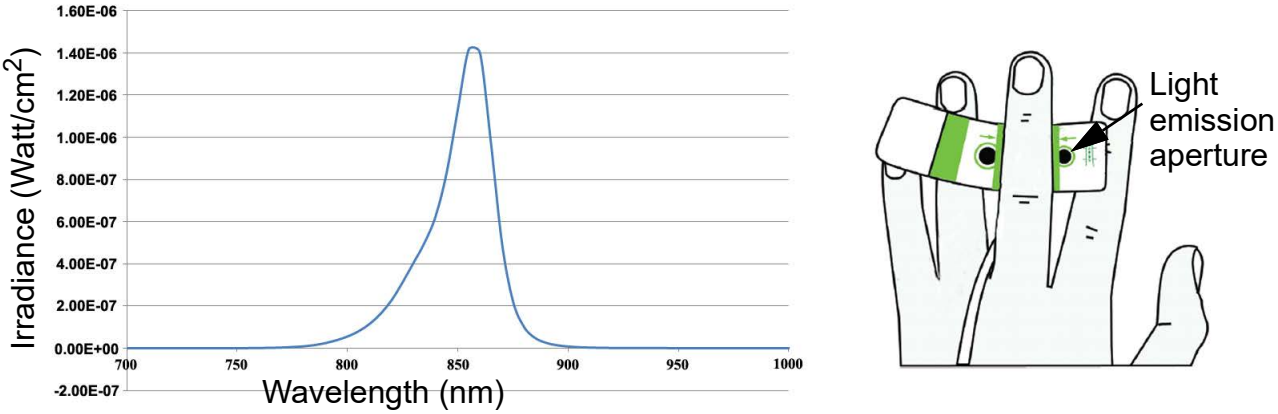


Figure A-1 Spectral Irradiance and location of light emission aperture

A.9 HemoSphere Alta AFM Cable Characteristics and Specifications

Table A-19 HemoSphere Alta AFM cable physical characteristics

HemoSphere oximetry cable		
Weight	approximately 1 lbs (0.45 kg)	
Dimensions	Length	15 ft (4.5 m)
Ingress protection	IPX4	
Applied part classification	Type BF defibrillation proof	

Table A-20 HemoSphere Alta AFM cable operational environmental specifications

Environmental specifications	Value
Temperature	10 to 37 °C
Relative humidity	20 to 90% non-condensing
Altitude	0 to 10,000 feet (3048 m)

Table A-21 HemoSphere Alta AFM cable transportation environmental specifications

Environmental specifications	Value
Temperature*	18 to 45 °C
Relative humidity*	20 to 90% non-condensing at 45 °C
Altitude	0 to 20,000 feet (6096 m)
**Note: Pre-conditioning temperature and humidity*	

NOTE It is recommended that after 3 years from the date of purchase, a replacement HemoSphere Alta AFM cable may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

Table A-22 HemoSphere Alta AFM cable parameter measurement specifications

Parameter	Specification	
Bolus volume	range	100 to 500 mL
	accuracy	±9%*
**Accuracy tested under laboratory conditions*		

Appendix B

Accessories

Contents

B.1 Accessories List

WARNING Only use approved HemoSphere Alta advanced monitoring platform accessories, cables and or components that have been supplied and labeled by Edwards. Using unapproved accessories, cables and or components may affect patient safety and measurement accuracy.

Table B-1 HemoSphere Alta advanced monitoring platform components

Description	Model number
HemoSphere Alta advanced monitor	
HemoSphere Alta Cardiac monitor	ALTACR1
HemoSphere Alta Smart Recovery monitor	ALTASR1
HemoSphere Alta All-On-One monitor	ALTAALL1
HemoSphere Alta Swan-Ganz monitoring	
HemoSphere Alta Swan-Ganz patient cable	HEMA70CC2
Edwards Swan-Ganz/Swan-Ganz IQ/ Swan-Ganz Jr catheters	*
In-line temperature probe (CO-SET+ closed injectate delivery system)	93522
Bath temperature injectate probe	9850A
HemoSphere Alta pressure cable monitoring	
HemoSphere pressure cable	HEMPSC100
HemoSphere Alta pressure cable	HEMAPSC200
Edwards FloTrac, FloTrac Jr, or Acumen IQ sensor	*
Edwards TruWave pressure monitoring transducer	*

Table B-1 HemoSphere Alta advanced monitoring platform components (continued)

Description	Model number
HemoSphere Alta venous oximetry monitoring	
HemoSphere oximetry cable	HEMOXSC100
HemoSphere oximetry cradle	HEMOXCR1000
Edwards oximetry catheter	*
HemoSphere Alta tissue oximetry monitoring	
ForeSight oximeter cable *(May also be labeled as FORE-SIGHT ELITE tissue oximeter module)*	HEMFSM10
ForeSight Jr sensors (size: non-adhesive small and small) *(May also be labeled as FORE-SIGHT ELITE oximetry sensors)*	*
ForeSight oximetry sensors (sizes: medium and large) *(May also be labeled as FORE-SIGHT ELITE oximetry sensors)*	*
HemoSphere Alta ClearSight technology monitoring	
Pressure controller kit	PC2K HEMPC2K

Table B-1 HemoSphere Alta advanced monitoring platform components (continued)

Description	Model number
Pressure controller	PC2 HEMPC
Pressure controller band multi pack	PC2B
Pressure controller cover	PCCVR
Heart reference sensor	EVHRS
ClearSight cuff	*
ClearSight Jr cuff	*
Acumen IQ cuff	*
HemoSphere Alta advanced monitoring platform cables	
Alta AFM cable	HEMAFM100
Acumen IQ fluid meter	AIQFM
Mains power cord	*
Analog ECG monitor cables	**
Additional HemoSphere Alta advanced monitoring platform accessories	
HemoSphere monitor roll stand	HEMRLSTD1000
HemoSphere Alta monitor roll stand bracket	HEMABRKT1000
HemoSphere Alta monitor battery	*

* Please contact your Edwards representative for model and ordering information.

** Edwards Lifesciences analog input cables are bedside monitor specific; they are available for a family of bedside monitor companies such as Philips (Agilent), GE (Marquette) and Spacelabs (OSI Systems). Please contact your Edwards representative for specific model and ordering information.

B.2 Additional Accessories Description

B.2.1 Roll Stand

The HemoSphere monitor roll stand is compatible with the HemoSphere Alta advanced monitor with a roll stand bracket. The HemoSphere Alta roll stand bracket (HEMBRKT1000) comes pre-installed on the HemoSphere Alta monitor and is available for purchase. Contact your Edwards representative for ordering information. To remove the bracket, remove the four screws shown in Figure 3-3 on page 71. Follow included instructions for roll stand assembly and warnings. Place the assembled roll stand on the floor, ensuring that all wheels are in contact with the floor, and securely mount the monitor to the roll stand plate as indicated in the directions.

B.2.2 Oximetry Cradle

The HemoSphere oximetry cradle is a reusable accessory intended to properly secure the HemoSphere oximetry cable while monitoring with the HemoSphere Alta advanced monitoring platform. Follow included instructions for proper cradle mounting directions.

B.2.3 Pressure Controller Cover

The pressure controller cover secures the heart reference sensor into the pressure controller. The pressure controller cover is intended for limited reuse. The operator shall assess whether reuse is appropriate. When reused, follow the platform cleaning instruction listed in *Cleaning the Monitor and Cables* on page 381. Replace if damaged.

To apply the pressure controller cover:

1. Ensure the heart reference sensor (HRS) is attached prior to attaching the pressure controller cover to the pressure controller.
2. Place the pressure controller cover's back mounting notch around the pressure controller cable. See step 1 in figure B-1.
3. Snap the pressure controller cover over the pressure controller, making sure that the pressure controller cover does not interfere with the heart reference sensor (HRS) connection. See step 2 in figure B-1.

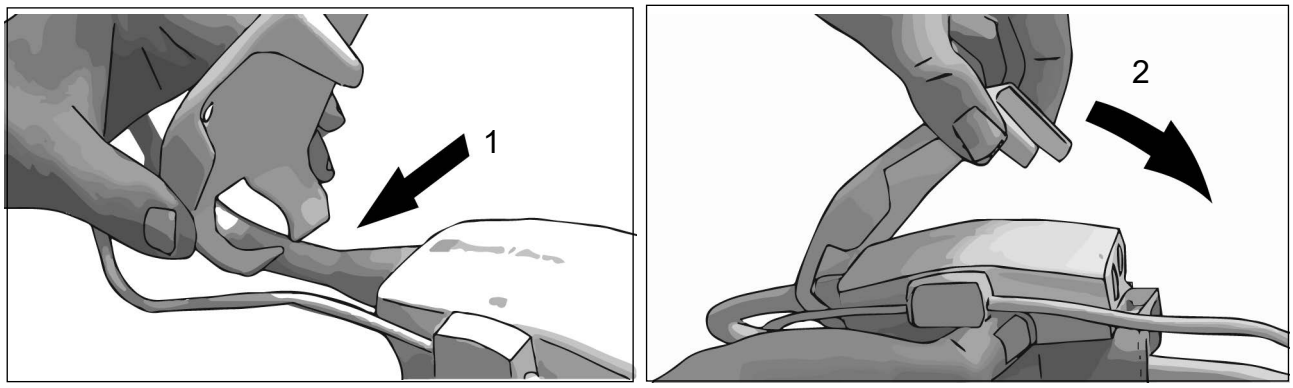


Figure B-1 Applying pressure controller cover

4. To remove the pressure controller cover, pull upwards from the front tab. This is indicated by the arrows symbol . Do not remove the pressure controller cover from the side by HRS connection indicated by the do not remove symbol .

CAUTION Do not pinch any heart reference sensor tubes or wires under the pressure controller cover during application. Be careful the only wire between the back mounting notch is the pressure controller cable.

Do not lift PCCVR from any other point than the front tab.

Appendix C

Equations for Calculated Patient Parameters

This section describes the equations used to calculate continuous and intermittent patient parameters displayed on the HemoSphere Alta advanced monitoring platform.

NOTE Patient parameters are calculated to more decimal places than are displayed on the screen. For example, a screen CO value of 2.4 may actually be a CO of 2.4492. Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.

For all calculations that include SvO_2, $ScvO_2$ will be substituted when the user selects $ScvO_2$.

Subscript SI = Standard International Units

Table C-1 Cardiac and oxygenation profile equations

Parameter	Description and formula	Units
BSA	Body Surface Area (DuBois formula) $BSA = 71.84 \times (WT^{0.425}) \times (HT^{0.725}) / 10{,}000$ where: WT – Patient Weight, kg HT – Patient Height, cm	m^2
CaO_2	Arterial Oxygen Content $CaO_2 = (0.0138 \times HGB \times SaO_2) + (0.0031 \times PaO2)$ (mL/dL) $CaO_2 = [0.0138 \times (HGB_{SI} \times 1.611) \times SaO_2] + [0.0031 \times (PaO_{2SI} \times 7.5)]$ (mL/dL) where: HGB – Total Hemoglobin, g/dL HGB_{SI} – Total Hemoglobin, mmol/L SaO_2 – Arterial O_2 Saturation,% PaO_2 – Partial Pressure of Arterial Oxygen, mmHg PaO_{2SI} – Partial Pressure of Arterial Oxygen, kPa	mL/dL

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
CvO_2	Venous Oxygen Content $CvO_2 = (0.0138 \times HGB \times SvO_2) + (0.0031 \times PvO_2)$ (mL/dL) $CvO_2 = [0.0138 \times (HGB_{SI} \times 1.611) \times SvO_2] + [0.0031 \times (PvO_{2SI} \times 7.5)]$ (mL/dL) where: HGB – Total Hemoglobin, g/dL HGB_{SI} – Total Hemoglobin, mmol/L SvO_2 – Venous O_2 Saturation, % PvO_2 – Partial Pressure of Venous Oxygen, mmHg PvO_{2SI} – Partial Pressure of Venous Oxygen, kPa and PvO_2 can be entered by the user in Invasive monitoring mode and is assumed to be 0 during all other monitoring modes	mL/dL
$Ca\text{-}vO_2$	Arteriovenous Oxygen Content Difference $Ca\text{-}vO_2 = CaO_2 - CvO_2$ (mL/dL) where: CaO_2 – Arterial Oxygen Content (mL/dL) CvO_2 – Venous Oxygen Content (mL/dL)	mL/dL
CI	Cardiac Index CI = CO/BSA where: CO – Cardiac Output, L/min BSA – Body Surface Area, m^2	L/min/m^2
CPI	Cardiac Power Index CPI = MAP× CI × 0.0022	W/m^2
CPO	Cardiac Power Output CPO = CO × MAP × *K* where: cardiac power output (CPO) (W) was calculated as MAP × CO/451 *K* is the conversion factor (2.22×10^{-3}) into watts MAP in mmHg CO L/min	W
DO_2	Oxygen Delivery $DO_2 = CaO_2 \times CO \times 10$ where: CaO_2 – Arterial Oxygen Content, mL/dL CO – Cardiac Output, L/min	mL O_2/min
DO_2I	Oxygen Delivery Index $DO_2I = CaO_2 \times CI \times 10$ where: CaO_2 – Arterial Oxygen Content, ml/dl CI – Cardiac Output, L/min/m^2	mL O_2/min/m^2
dP/dt	Systolic slope calculated as maximal first derivative of arterial pressure waveform with respect to time dP/dt = max(P[n+1]-P[n])/ts, for n=0 to N=1 where: P[n] – current sample of the arterial pressure signal, mmHg ts – sampling time interval, second N – total number of samples in a given cardiac cycle	mmHg/sec

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
Ea_{dyn}	Dynamic Arterial Elastance Ea_{dyn} = PPV/SVV where: SVV – Stroke Volume Variation,% PPV – Pulse Pressure Variation,%	none
EDV	End Diastolic Volume EDV = SV/EF where: SV – Stroke Volume (mL) EF – Ejection Fraction, % (efu)	mL
EDVI	End Diastolic Volume Index EDVI = SVI/EF where: SVI – Stroke Volume Index (mL/m^2) EF – Ejection Fraction, % (efu)	mL/m^2
ESV	End Systolic Volume ESV = EDV – SV where: EDV – End Diastolic Volume (mL) SV – Stroke Volume (mL)	mL
ESVI	End Systolic Volume Index ESVI = EDVI – SVI where: EDVI – End Diastolic Volume Index(mL/m^2) SVI – Stroke Volume Index (mL/m^2)	mL/m^2
LVSWI	Left Ventricular Stroke Work Index LVSWI = SVI x (MAP – PAWP) x 0.0136 $LVSWI = SVI \times (MAP_{SI} - PAWP_{SI}) \times 0.0136 \times 7.5$ where: SVI – Stroke Volume Index, $ml/beat/m^2$ MAP – Mean Arterial Pressure, mmHg MAP_{SI} – Mean Arterial Pressure, kPa PAWP – Pulmonary Artery Wedge Pressure, mmHg $PAWP_{SI}$ – Pulmonary Artery Wedge Pressure, kPa	$g\text{-}m/m^2/beat$
O_2EI	Oxygen Extraction Index $O_2EI = \{(SaO_2 - SvO_2) / SaO_2\} \times 100$ (%) where: SaO_2 – Arterial O_2 Saturation, % SvO_2 – Mixed Venous O_2 Saturation, %	%
O_2ER	Oxygen Extraction Ratio $O_2ER = (Ca\text{-}vO_2 / CaO_2) \times 100$ (%) where: CaO_2 – Arterial Oxygen Content, mL/dL $Ca\text{-}vO_2$ – Arteriovenous Oxygen Content Difference, mL/dL	%

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
PPV	Pulse Pressure Variation PPV= 100 **x** (PPmax-PPmin) / mean(PP) where: PP – Pulse Pressure, mmHg calculated as: PP=SYS - DIA SYS – systolic pressure DIA – diastolic pressure	%
PVR	Pulmonary Vascular Resistance PVR = {(MPAP - PAWP) x 80} /CO PVR = {($MPAP_{SI}$ - $PAWP_{SI}$) x 60} /CO where: MPAP – Mean Pulmonary Artery Pressure, mmHg $MPAP_{SI}$ – Mean Pulmonary Artery Pressure, kPa PAWP – Pulmonary Artery Wedge Pressure, mmHg $PAWP_{SI}$ – Pulmonary Artery Wedge Pressure, kPa CO – Cardiac Output, l/min	dyne-s/cm^5 kPa-s/L
PVRI	Pulmonary Vascular Resistance Index PVRI = {(MPAP – PAWP) x 80} /CI PVRI = {($MPAP_{SI}$ – $PAWP_{SI}$) x 60} /CI where: MPAP – Mean Pulmonary Artery Pressure, mmHg $MPAP_{SI}$ – Mean Pulmonary Artery Pressure, kPa PAWP – Pulmonary Artery Wedge Pressure, mmHg $PAWP_{SI}$ – Pulmonary Artery Wedge Pressure, kPa CI – Cardiac Index, L/min/m^2	dyne-s-m^2/cm^5 kPa-s-m^2/L
RVSWI	Right Ventricular Stroke Work Index RVSWI = SVI x (MPAP – CVP) x 0.0136 RVSWI = SVI x (MPAPSI – CVP_{SI}) x 0.0136 x 7.5 where: SVI – Stroke Volume Index, ml/beat/m2 MPAP – Mean Pulmonary Artery Pressure, mmHg $MPAP_{SI}$ – Mean Pulmonary Artery Pressure, kPa CVP – Central Venous Pressure, mmHg CVP_{SI} – Central Venous Pressure, kPa	g-m/m^2/beat
StO_2	Tissue oxygen saturation $StO_2 = [HbO_2/(HbO_2 + Hb)] \times 100$ where: HbO_2 – Oxygenated Hemoglobin Hb – De-Oxygenated Hemoglobin	%
SV	Stroke Volume SV = (CO/PR) x 1000 where: CO – Cardiac Output, L/min PR – Pulse rate, beats/min	mL/beat

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
SVI	Stroke Volume Index SVI = (CI/PR) x 1000 where: CI – Cardiac Index, L/min/m^2 PR – Pulse rate, beats/min	mL/beat/m^2
SVR	Systemic Vascular Resistance SVR = {(MAP - CVP) x 80} /CO (dyne-sec/cm^5) SVR = {(MAP_{SI} – CVP_{SI}) x 60} /CO where: MAP – Mean Arterial Pressure, mmHg MAP_{SI} – Mean Arterial Pressure, kPa CVP – Central Venous Pressure, mmHg CVP_{SI} – Central Venous Pressure, kPa CO – Cardiac Output, L/min	dyne-s/cm^5 $(kPa\text{-}s/L)_{SI}$
SVRI	Systemic Vascular Resistance Index SVRI = {(MAP - CVP) x 80} /CI SVRI = {(MAP_{SI} - CVP_{SI}) x 60} /CI where: MAP – Mean Arterial Pressure, mmHg MAP_{SI} – Mean Arterial Pressure, kPa CVP – Central Venous Pressure, mmHg CVP_{SI} – Central Venous Pressure, kPa CI – Cardiac Index, L/min/m^2	dyne-s-m^2/cm^5 $(kPa\text{-}s\text{-}m^2/L)_{SI}$
SVV	Stroke Volume Variation SVV = 100 × (SV_{max} - SV_{min}) / mean(SV)	%
VO_2	Oxygen Consumption VO_2 = Ca-vO_2 x CO x 10 (mL O_2/min) where: Ca-vO_2 – Arteriovenous Oxygen Content Difference, mL/dL CO – Cardiac Output, L/min	mL O_2/min
VO_2e	Estimated Oxygen Consumption when $ScvO_2$ is being monitored VO_2e = Ca-vO_2 x CO x 10 (mL O_2/min) where: Ca-vO_2 – Arteriovenous Oxygen Content Difference, mL/dL CO – Cardiac Output, L/min	mL O_2/min
VO_2I	Oxygen Consumption Index VO_2 / BSA	mL O_2/min/m^2

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
VO_2Ie	Estimated Oxyen Consumption Index when $ScvO_2$ is being monitored VO_2e/ BSA	mL O_2/min/m^2
VQI	Ventilation Perfusion Index $VQI = \frac{\{1.38 \times HGB \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100$ $VQI = \frac{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SaO_2/100)) + (0.0031 \times PAO_2)\}}{\{1.38 \times HGB_{SI} \times 1.611344 \times (1.0 - (SvO_2/100)) + (0.0031 \times PAO_2)\}} \times 100$ where: HGB – Total Hemoglobin, g/dl HGB_{SI} – Total Hemoglobin, mmol/l SaO_2 – Arterial O_2 Saturation, % SvO_2 – Mixed Venous O_2 Saturation, % PAO_2 – Alveolar O_2 Tension, mmHg and: $PAO_2 = ((PBAR - PH_20) \times FiO_2) - PaCO_2 \times (FiO_2 + (1.0 - FiO_2)/0.8)$ where: FiO_2 – Fraction of Inspired Oxygen PBAR – 760 mmHg PH_2O – 47 mmHg $PaCO_2$ – 40 mmHg	%

Appendix D

Monitor Settings and Defaults

D.1 Patient Data Input Range

Table D-1 Patient information

Parameter	Minimum	Maximum	Available units
Gender	**M** (Male) / **F** (Female)	N/A	N/A
Age	2	120	years
Height	12 in / 30 cm	98 in / 250 cm	inches (in) or cm
Weight	2 lbs / 1.0 kg	881 lbs / 400.0 kg	lbs or kg
BSA	0.08	5.02	m^2
ID	0 digits	40 characters	None

D.2 Trend Scale Default Limits

Table D-2 Graphical trend parameter scale defaults

Parameter	Units	Minimum default value	Maximum default value	Setting increment	Minimum Gap
ART (live waveform display)	mmHg	50	130	1	1
CVP/PAP/RVP (live waveform display)	mmHg	0	30	1	1
CO/iCO/sCO/CO_{RV}	L/min	0.0	12.0	0.1	1
CI/iCI/sCI	L/min/m^2	0.0	12.0	0.1	1
CPO/CPO_{RV}	W	0.0	9.99	0.01	1
CPI/CPI_{RV}	W/m^2	0.0	9.99	0.01	1
CVP	mmHg	0	20	1	1
DIA_{ART}	mmHg	50	110	1	5
DIA_{PAP}	mmHg	0	35	1	1
DIA_{RVP}	mmHg	0	35	1	1
dP/dt	mmHg/sec	0	2000	20	100
Ea_{dyn}	none	0.2	1.5	0.1	0.1

Table D-2 Graphical trend parameter scale defaults

Parameter	Units	Minimum default value	Maximum default value	Setting increment	Minimum Gap
EDV/sEDV	mL	0	800	10	25
EDVI/sEDVI	mL/m^2	0	400	5	25
GHI	none	0	100	1	10
HPI	none	0	100	1	10
MAP	mmHg	50	130	1	5
MPAP	mmHg	0	45	1	5
MRVP	mmHg	0	45	1	5
PPV	%	0	50	1	10
PR	bpm	40	130	1	5
PR_{RVP}	bpm	40	130	1	5
RV dP/dt	mmHg/sec	100	700	1	50
RV EDP	mmHg	0	25	1	1
RVEF/sRVEF	%	0	100	1	10
StO_2	%	0	99	1	10
$SV/SV_{20s}/SV_{RV}$	mL/b	0	160	5	20
SVI/SVI_{20s}	$mL/b/m^2$	0	80	5	20
SVR/iSVR	$dyne\text{-}s/cm^5$	500	1500	20	100
SVRI/iSVRI	$dyne\text{-}s\text{-}m^2/cm^5$	500	3000	50	200
$SvO_2/ScvO_2$	%	0	99	1	10
SVV	%	0	50	1	10
SYS_{ART}	mmHg	80	160	1	5
SYS_{PAP}	mmHg	0	55	1	1
SYS_{RVP}	mmHg	20	55	1	5
$\Delta ctHb$	none	-20	20	1	5

NOTE The HemoSphere Alta advanced monitoring platform will not accept a setting of an upper scale setting that is less than the lower scale setting. Nor will it accept a lower scale setting that is higher than the upper scale setting.

D.3 Parameter Display and Configurable Alarm/Target Ranges

Table D-3 Configurable parameter alarm and display ranges

Parameter	Units	Display Range	Configurable Alarm/ Target Range
CO/CO_{RV}	L/min	1.0 to 20.0	1.0 to 20.0
iCO	L/min	0.0 to 20.0	0.0 to 20.0
sCO	L/min	1.0 to 20.0	1.0 to 20.0
CO_{20s}	L/min	1.0 to 20.0	1.0 to 20.0
CI	$L/min/m^2$	0.0 to 20.0	0.0 to 20.0
iCI	$L/min/m^2$	0.0 to 20.0	0.0 to 20.0
sCI	$L/min/m^2$	0.0 to 20.0	0.0 to 20.0
CI_{20s}	$L/min/m^2$	0.0 to 20.0	0.0 to 20.0
CPO/CPO_{RV}	W	0.0 to 9.99	0.0 to 9.99
CPI/CPI_{RV}	W/m^2	0.0 to 9.99	N/A
SV/SV_{RV}	mL/b	0 to 300	0 to 300
SV_{20s}	mL/b	0 to 300	0 to 300
SVI	$mL/b/m^2$	0 to 200	0 to 200
SVI_{20s}	$mL/b/m^2$	0 to 200	0 to 200
SVR	$dyne\text{-}s/cm^5$	0 to 5000	0 to 5000
SVRI	$dyne\text{-}s\text{-}m^2/cm^5$	0 to 9950	0 to 9950
iSVR	$dyne\text{-}s/cm^5$	0 to 5000	0 to 5000
iSVRI	$dyne\text{-}s\text{-}m^2/cm^5$	0 to 9950	0 to 9950
SVV	%	0 to 99	0 to 99
Venous oximetry ($ScvO_2/SvO_2$)	%	0 to 99	0 to 99
Tissue oximetry (StO_2)*	%	0 to 99	0 to 99
ΔctHb*	none	-100 to 100	N/A^
CAI*	none	0 to 100	N/A†
EDV	mL	0 to 800	0 to 800
sEDV	mL	0 to 800	0 to 800
EDVI	mL/m^2	0 to 400	0 to 400
sEDVI	mL/m^2	0 to 400	0 to 400
RVEF	%	0 to 100	0 to 100
sRVEF	%	0 to 100	0 to 100
CVP*	mmHg	0 to 50	0 to 50
MAP*	mmHg	0 to 300	10 to 300
ART/PAP/CVP/RVP* (live waveform display)	mmHg	-34 to 312	0 to 300†
MPAP*	mmHg	0 to 99	0 to 99
MRVP	mmHg	0 to 99	N/A†

Table D-3 Configurable parameter alarm and display ranges (continued)

Parameter	Units	Display Range	Configurable Alarm/ Target Range
SYS_{ART}*	mmHg	0 to 300	10 to 300
SYS_{PAP}*	mmHg	0 to 99	0 to 99
SYS_{RVP}	mmHg	0 to 200	N/A†
DIA_{ART}*	mmHg	0 to 300	10 to 300
DIA_{PAP}*	mmHg	0 to 99	0 to 99
DIA_{RVP}	mmHg	-10 to 99	N/A†
PPV	%	0 to 99	0 to 99
PR	bpm	0 to 220	0 to 220
PR_{RVP}	bpm	0 to 220	N/A†
RV dP/dt	mmHg/sec	0 to 999	N/A†
RVEDP	mmHg	0 to 99	N/A†
HPI	none	0 to 100	N/A†
GHI	none	0 to 100	N/A†
dP/dt	mmHg/sec	0 to 3000	0 to 3000
Ea_{dyn}	none	0.0 to 3.0	N/A†

**Parameter is available in Non-Pulsatile mode. Blood pressure parameters are only available in Non-Pulsatile mode with minimally-invasive and invasive monitoring. ART waveform, MAP, DIA_{ART}, and SYS_{ART} are not available in Non-Pulsatile mode during non-invasive monitoring.*

†Parameter alarm range for HPI, GHI, CAI, RVP parameters, and RVP waveform are non-configurable.

^Ea_{dyn} and ΔctHb are non alarming parameters. Ranges shown here are for display only.

D.4 Alarm and Target Defaults

Table D-4 Parameter alarm red zone and target defaults

Parameter	Units	EW default lower alarm (red zone) setting	EW default lower target setting	EW default upper target setting	EW default upper alarm (red zone) setting
CI/iCI/sCI/CI_{20s}	$L/min/m^2$	1.0	2.0	4.0	6.0
CPO	W	0.6	0.8	9.99	9.99
SVI/SVI_{20s}	$mL/b/m^2$	20	30	50	70
SVRI/iSVRI	$dyne\text{-}s\text{-}m^2/cm^5$	1000	1970	2390	3000
SVV	%	0	0	13	20
$ScvO_2$/SvO_2	%	50	65	75	85
StO_2	%	50	60	85	90
EDVI/sEDVI	mL/m^2	40	60	100	200
RVEF/sRVEF	%	20	40	60	60
CVP	mmHg	2	2	8	10

Table D-4 Parameter alarm red zone and target defaults

Parameter	Units	EW default lower alarm (red zone) setting	EW default lower target setting	EW default upper target setting	EW default upper alarm (red zone) setting
SYS_{ART}	mmHg	90	100	130	150
SYS_{PAP}	mmHg	10	14	23	34
DIA_{ART}	mmHg	60	70	90	100
DIA_{PAP}	mmHg	0	4	13	16
MAP	mmHg	60	70	100	120
MPAP	mmHg	5	9	18	25
HGB	g/dL	7.0	11.0	17.0	19.0
	mmol/L	4.3	6.8	10.6	11.8
PPV	%	0	0	13	20
PR	bmp	60	70	100	120
HPI	none	0	N/A	N/A	85
dP/dt	mmHg/sec	380	480	1300	1800
CAI	none	0	N/A	N/A	45

NOTE Non-indexed ranges are based on indexed ranges and entered BSA values.

D.5 Alarm Priorities

Table D-5 Parameter alarms, faults, and alerts priorities

Physiologic parameter (alarms)/ message type	Lower physiological alarm (red zone) priority	Upper physiological alarm (red zone) priority	Message type priority
CO/CI/sCO/sCI/CO_{20s}/ CI_{20s}	High	Medium	
CPO/CPI/CPO_{RV}/CPI_{RV}	Medium	N/A	
SV/SVI/SV_{20s}/SVI_{20s}	High	Medium	
SVR/SVRI	Medium	Medium	
SVV	Medium	Medium	
SvO_2	High	Medium	
StO_2	High	Medium	
EDV/EDVI/sEDV/sEDVI	Medium	Medium	
RVEF/sRVEF	Medium	Medium	
SYS_{ART}/SYS_{PAP}	High	High	
SYS_{RVP}	N/A	N/A	
DIA_{ART}/DIA_{PAP}	High	High	
DIA_{RVP}	N/A	N/A	

Table D-5 Parameter alarms, faults, and alerts priorities

Physiologic parameter (alarms)/ message type	Lower physiological alarm (red zone) priority	Upper physiological alarm (red zone) priority	Message type priority
MAP	High	High	
MPAP	Medium	Medium	
MRVP	N/A	N/A	
PR	High	High	
PR_{RVP}	N/A	N/A	
MPAP	Medium	Medium	
CVP	Medium	Medium	
PPV	Medium	Medium	
HPI	N/A	High	
dP/dt	Medium	Medium	
Ea_{dyn}	N/A	N/A	
RV EDP	N/A	N/A	
RV dP/dt	N/A	N/A	
Fault			Medium/High
Alert			Low

NOTE

The alarm signal generation delay is parameter dependent. For oximetry associated parameters, the delay is less than 2 seconds after the parameter is out of range continuously for 5 or more seconds. For HemoSphere Alta Swan-Ganz patient cable continuous CO and associated parameters, the delay is less than 360 seconds, although typical delay due to parameter calculation is 57 seconds. For HemoSphere pressure cable continuous CO and associated FloTrac system parameters, the delay is 2 seconds for 5 second parameter averaging (after the parameter is out of range continuously for 5 or more seconds for a total of 7 seconds), and 20 seconds for 20 second and 5 minute parameter averaging (see table 5-4 on page 122). For HemoSphere pressure cable with TruWave DPT measured parameters, the delay is 2 seconds, after the parameter is out of range continuously for 5 or more seconds (total of 7 seconds). For HemoSphere ClearSight module noninvasive continuous CO and associated hemodynamic parameters, the delay is 20 seconds. For real-time blood pressure waveform display while monitoring with the HemoSphere ClearSight module, the delay is 5 heartbeats after the parameter is out of range continuously for 5 or more seconds.

The parameter value will flash at a higher frequency for a high priority physiological alarm as compared to a medium physiological alarm. If medium and high priority alarms are sounding at the same time, the physiological high priority alarm tone will be heard. If a low priority alarm is active and a medium or higher priority alarms is generated, the low priority alarm visual indicator will be replaced by the higher priority alarm visual indicator.

Most technical faults are medium priority. Alerts and other system messages are low priority.

Appendix E

Computation Constants

E.1 Computation Constant Values

In iCO mode, the HemoSphere Alta Swan-Ganz patient cable computes cardiac output employing either a bath probe setup or an in-line temperature probe using the computation constants listed in the following tables. The HemoSphere Alta Swan-Ganz patient cable automatically senses the type of injectate temperature probe being used, and the corresponding injectate temperature, catheter size, and injectate volume define the computation constant to be used.

NOTE The computation constants given below are nominal and generally applicable to the specified catheter sizes. For computation constants specific to the catheter being used, refer to the catheter directions for use.

Model-specific computation constants are entered manually in the setup menu for the iCO mode.

Table E-1 Computation constants for bath temperature probe

Injectate temperature range* (°C)	Injectate volume (mL)	Catheter size (French)				
		8	7.5	7	6	5.5
Room temp. 22.5–27 °C	10 5 3	0.612 0.301 0.177	0.594 0.283 0.159	0.595 0.287 0.165	0.607 0.304 0.180	0.616 0.304 0.180
Room temp. 18–22.5 °C	10 5 3	0.588 0.283 0.158	0.582 0.277 0.156	0.578 0.274 0.154	0.597 0.297 0.174	0.606 0.298 0.175
Cold (iced) 5–18 °C	10 5 3	0.563 0.267 0.148	0.575 0.267 0.150	0.562 0.262 0.144	0.573 0.278 0.159	0.581 0.281 0.161
Cold (iced) 0–5 °C	10 5 3	0.564 0.262 0.139	0.564 0.257 0.143	0.542 0.247 0.132	0.547 0.259 0.144	0.555 0.264 0.148

* To optimize cardiac measurement, it is recommended that the temperature of the injectate correspond to one of the temperature ranges listed in the catheter's directions for use.

Table E-2 Computation constants for in-line temperature probe

Injectate temperature range* (°C)	Injectate volume (mL)	Catheter size (French)				
		8	7.5	7	6	5.5
Room temp. 22.5–27 °C	10 5	0.601 0.294	0.599 0.301	0.616 0.311	0.616 0.307	0.624 0.310
Room temp. 18–22.5 °C	10 5	0.593 0.288	0.593 0.297	0.603 0.295	0.602 0.298	0.612 0.304
Cold (iced) 5–18 °C	10 5	0.578 0.272	0.578 0.286	0.570 0.257	0.568 0.276	0.581 0.288
Cold (iced) 0–5 °C	10 5	0.562 0.267	0.563 0.276	0.537 0.217	0.533 0.253	0.549 0.272

* To optimize cardiac measurement, it is recommended that the temperature of the injectate correspond to one of the temperature ranges listed in the catheter's directions for use.

Appendix F

System Care, Service and Support

Contents

F.1 General Maintenance

The HemoSphere Alta advanced monitoring platform contains no user-serviceable parts, and should be repaired only by qualified service representatives. This appendix provides instructions for cleaning the monitor and monitor accessories and contains information on how to contact your local Edwards representative for support and information on repair and/or replacement.

WARNING The HemoSphere Alta advanced monitoring platform contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.

CAUTION Clean and store the instrument and accessories after each use.

CAUTION Follow all cleaning instructions carefully to ensure that the monitor and platform cables are thoroughly cleaned. After cleaning, inspect the HemoSphere Alta advanced monitor and all accessories for any residue or foreign material. If residue is still visible after cleaning, please repeat the cleaning instructions. Follow any additional cleaning instructions provided by the manufacture of listed approved cleaning agents.

The HemoSphere Alta advanced monitoring platform and monitor cables are electrostatic discharge (ESD) sensitive. Do not attempt to open cable housing or use if the housing has been damaged.

F.2 Cleaning the Monitor and Cables

WARNING **Shock or fire hazard!** Do not immerse the HemoSphere Alta advanced monitoring platform or monitor cables in any liquid solution. Do not allow any fluids to enter the instrument.

The HemoSphere Alta advanced monitoring platform and cables can be cleaned using common hospital cleaning products such as the following products or their equivalent unless otherwise stated below:

- Clorox Healthcare bleach germicidal wipes
- PDI sani-cloth germicidal disposable wipes
- PDI super sani-cloth germicidal disposable wipe (purple cap)
- Metrex CaviWipes1 wipes
- Clorox Healthcare Hydrogen Peroxide cleaner disinfectant wipe

The HemoSphere Alta advanced monitoring platform and cables can also be cleaned using a lint-free cloth dampened with the following cleaning agents:

- 10% bleach solution
- 70% isopropyl alcohol
- Metrex CaviCide1 or Quaternary ammonium solution
- hydrogen peroxide solution (3%)

Do not use any other cleaning agents. Unless otherwise stated, these cleaning agents are approved for all HemoSphere Alta advanced monitoring platforming accessories, and cables.

CAUTION Do not pour or spray liquid on any portion of the HemoSphere Alta advanced monitoring platform, accessories or cables.

Do not use any disinfecting solution other than the types specified.

DO NOT:

Allow any liquid to come in contact with the power connector

Allow any liquid to penetrate connectors or openings in the monitor case

If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the monitor. Disconnect power immediately and call your Biomedical Department or local Edwards representative.

F.3 Cleaning the Platform Cables

Platform cables can be cleaned using the cleaning agents listed above in section F.2 and the following methods.

CAUTION Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

1. Use an approved disposable cleaning wipe or moisten a lint-free cloth with disinfectant and wipe the surfaces.
2. Follow the disinfectant wipe with rinsing wipes using cotton gauze moistened with sterile water. Use sufficient rinsing wipes to remove all residual disinfectant.
3. Dry the surface with a clean dry cloth.

Store platform cables in a cool, dry place in original packaging to prevent damage. Additional instructions specific to certain cables are listed in the following sub-sections.

CAUTION Do not use any other cleaning agents, spray, or pour cleaning solution directly on platform cables.
Do not steam, radiate, or EO sterilize platform cables.
Do not immerse platform cables.

F.3.1 Cleaning the HemoSphere Oximetry Cable

Use the cleaning agents listed above in section F.2, except for hydrogen peroxide based cleaners, to clean the oximetry cable housing and the connecting cable.The fiber-optic interface of the oximetry cable must be kept clean. The optical fibers within the oximetry catheter fiber optic connector mate with the optical fibers in the oximetry cable. Moisten a lint-free cotton-tipped applicator with sterile alcohol and apply gentle pressure to clean the optical fibers recessed within the front of the oximetry cable housing.

CAUTION Do not steam, radiate, or EO sterilize the HemoSphere oximetry cable.
Do not immerse the HemoSphere oximetry cable.

F.3.2 Cleaning the HemoSphere Alta Patient Cable and Connector

The patient CCO cable contains electrical and mechanical components and is therefore subject to normal use wear and tear. Visually inspect the cable insulation jacket, strain relief and connectors before each use. If any of the following conditions are present, discontinue use of the cable.

- Broken insulation
- Frays
- Connector pins are recessed or bent
- Connector is chipped and/or cracked

1. The patient CCO cable is not protected against fluid ingress. Use a soft cloth dampened with the cleaning agents listed in section F.2 to clean the CCO cable.
2. Air dry the connector.

CAUTION If any electrolytic solution, for example Ringer's lactate solution, is introduced into the cable connectors while they are connected to the monitor, and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.

Do not immerse any cable connectors in detergent, isopropyl alcohol or glutaraldehyde.

Do not use a hot air gun to dry cable connectors.

3 Please contact Technical Support or your local Edwards representative for further assistance.

F.3.3 Cleaning the HemoSphere Pressure Cable

The HemoSphere pressure cable can be cleaned using the cleaning agents listed in section F.2, except for hydrogen peroxide based cleaners, and methods specified for platform cables at the start of this section (section F.3). Disconnect the pressure cable from the monitor to air dry the transducer connector. To blow dry the transducer connector, use clean, dry wall air, canned air, or CO_2 aerosol for at least two minutes. If left to dry under room conditions, allow the connector to dry for two days before using.

CAUTION If any electrolytic solution, for example Ringer's lactate solution, is introduced into the cable connectors while they are connected to the monitor, and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.

Do not immerse any cable connectors in detergent, isopropyl alcohol or glutaraldehyde.

Do not use a hot air gun to dry cable connectors.

Device contains electronics. Handle with care.

F.3.4 Cleaning the ForeSight Oximeter Cable

The following cleaning agents are recommended to clean the ForeSight oximeter cable:

- Aspeti-Wipe
- 3M Quat #25
- Metrex CaviCide
- Phenolic germicidal detergent solution (per manufacturer's recommendations)
- Quaternary ammonium germicidal detergent solution (per manufacturer's recommendations)

See the product directions for use and labeling for detailed information on active ingredients and any disinfecting claims.

The ForeSight oximeter cable is designed to be cleaned using wipes or towelettes designed for that purpose. When all surfaces have been cleaned, wipe the entire surface of the module using a soft cloth dampened with fresh water to remove any trace residue.

The sensor cables may be cleaned using wipes or towelettes designed for that purpose. They may be cleaned by wiping from the ForeSight oximeter cable housing end towards the sensor connections.

WARNING Do not, under any circumstances, perform any cleaning or maintenance of the ForeSight oximeter cable while the module is being used to monitor a patient. The monitor must be turned off and the HemoSphere Alta advanced monitoring platform power cord disconnected, or the cable must be disconnected from the monitor and the sensors removed from the patient.

Before starting cleaning or maintenance of any sort, check the ForeSight oximeter cable, cable connections, sensors, and other accessories for damage. Check the cables for bent or broken prongs, cracks, or fraying. If any damage is noted, the cable must not be used until it has been inspected and serviced or replaced. Contact Edwards Technical Support.

There is a risk of serious injury or death if this procedure is not followed.

F.3.5 Cleaning the Heart Reference Sensor and Pressure Controller

The heart reference sensor (HRS) and pressure controller can be cleaned using the following disinfectants:

- 70% isopropyl alcohol solution
- 10% sodium hypochlorite water solution

1 Moisten a clean cloth with disinfectant and wipe the surfaces.

2 Dry the surface with a clean, dry cloth.

CAUTION Do not disinfect the heart reference sensor or pressure controller by autoclave or gas sterilization.

Do not immerse the pressure controller, heart reference sensor, or any cable connectors in fluid.

Clean and store the heart reference sensor after each use.

F.3.5.1 Removing the Pressure Controller Band

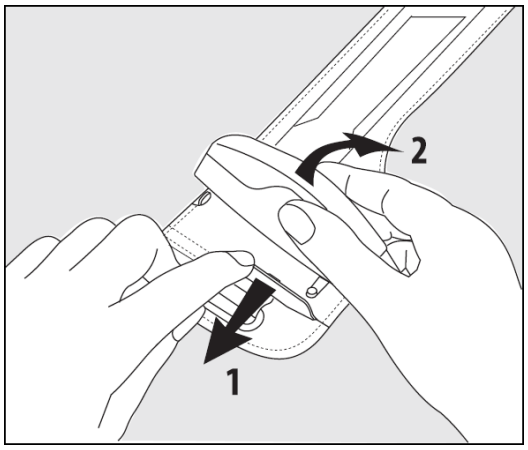


Figure F-1 Removing pressure controller from band

To remove the pressure controller from the pressure controller band, pull the sleeve slightly outwards (see step 1 in figure F-1) and tilt the pressure controller to remove it from the sleeve (see step 2 in figure F-1). The pressure controller band is intended for limited reuse. The operator shall assess whether reuse is appropriate. When reused, follow the platform cleaning instruction listed in *Cleaning the Monitor and Cables* on page 381. Replace if damaged.

F.4 Service and Support

See chapter 14, *Troubleshooting* for diagnosis and remedies. If this information does not solve the problem, contact Edwards Lifesciences.

Edwards provides HemoSphere Alta advanced monitoring platform operations support:

- Within the United States and Canada, call 1.800.822.9837.
- Outside the United States and Canada, contact your local Edwards Lifesciences representative.
- E-mail operational support questions to tech_support@edwards.com.

Have the following information before you call:

- The HemoSphere Alta advanced monitoring platform's serial number, located on the rear panel;
- The text of any error message and detailed information as to the nature of the problem.

F.5 Edwards Lifesciences Regional Headquarters

USA:
Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
949.250.2500
800.424.3278
www.edwards.com

Switzerland:
Edwards Lifesciences S.A.
Route de l'Etraz 70
1260 Nyon, Switzerland
Phone 41.22.787.4300

Japan:
Edwards Lifesciences LLC
Shinjuku Front Tower
21-1, Kita-Shinjuku, Shinjuku-ku
Tokyo 169-0074 Japan
Phone 81.3.6895.0301

Brazil:
Edwards Lifesciences
Avenida das Nações Unidas,
14.401 - Parque da Cidade
Torre Sucupira - 17º. Andar - cj. 171
Chácara Santo Antônio – São Paulo/SP
CEP 04794-000
Brazil
Phone 55.11.5567.5200

China:
Edwards (Shanghai) Medical
Products Co., Ltd.
Unit 2602-2608, 2 Grand Gateway,
3 Hong Qiao Road, Xu Hui District
Shanghai, 200030
China
Phone 86.21.5389.1888

India:
Edwards Lifesciences (India) Pvt. Ltd.
Techniplex II, 7th floor,
Unit no 1 & 2, off. S.V.Road
Goregaon west-Mumbai
400062
India
Phone +91.022.66935701 04

Australia:
Edwards Lifesciences Pty Ltd
Unit 2 40 Talavera Road
North Ryde
NSW 2113
PO Box 137, North Ryde BC
NSW 1670
Australia
Phone +61(2)8899 6300

F.6 Monitor Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the HemoSphere Alta advanced monitoring platform and/or cables are disinfected and decontaminated appropriately in accordance with your country's laws for equipment containing electrical and electronic parts prior to disposal.

For single use parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

F.6.1 Battery Recycling

Replace the HemoSphere battery pack when it no longer holds a charge. After removal, follow your local recycling guidelines.

CAUTION Recycle or dispose of the lithium-ion battery in accordance to all federal, state, and local laws.

F.7 Preventive Maintenance

Periodically examine the HemoSphere Alta advanced monitor exterior for general physical condition. Make sure the housing is not cracked, broken or dented, and that everything is present. Make sure there is no sign of spilled liquids or signs of abuse.

Routinely inspect cords and cables for fraying and cracks, and make sure there are no exposed conductors. In addition, check that the enclosure door at catheter connection point of the oximetry cable moves freely and latches properly. Do not pull on any platform cables when unplugging them from the HemoSphere Alta advanced monitoring platform.

The HemoSphere Alta monitoring platform (HemoSphere Alta Smart Recovery monitor [ALTASR1], HemoSphere Alta All-on-One monitor[ALTAALL1] and HemoSphere Alta Cardiac monitor [ALTACR1]) should be sent to a qualified Edwards Service Center for preventive maintenance every two years.

F.7.1 Battery Maintenance

To check the battery health, review the Battery Information by touching the settings icon → **System Status** button. Under the **Battery Information** heading, the **Full Charge Capacity (mAh)** should be 60% of **Design Charge Capacity (mAh),** or approximately 4140 mAh. For battery ordering information, contact your local Edwards representative. To access the battery remove the 2 captive screws (see figure 3-3 on page 71). To facilitate removal of the screws, hold the battery door closed while unscrewing. Similarly, hold the door closed while re-installing the battery door and tightening the screws.

WARNING **Explosion Hazard!** Do not open battery, dispose of in fire, store at high temperature or short circuit. It may ignite, explode, leak or get hot, causing serious personal injury or death.

F.7.1.1 Battery Storage

The battery pack can remain stored in the HemoSphere Alta advanced monitoring platform. Refer to *HemoSphere Alta Advanced Monitoring Platform Characteristics and Specifications* on page 352 for environmental specifications for storage.

NOTE Long term storage at high temperatures may decrease life of battery pack.

F.7.2 HRS Preventive Maintenance

The finger component of the heart reference sensor (HRS) may be damaged if subjected to moderate to significant surface impact. Although the likelihood of damage is small, the resulting displayed values would be biased by the difference in height from the heart to the finger cuff. Even though this damage cannot be seen by looking at the heart reference sensor, it is possible to confirm whether the damage has occurred by following the below procedure prior to each use:

1. Connect the heart reference sensor to the pressure controller connected to the HemoSphere Alta advanced monitoring platform and go to the zeroing screen.
2. As instructed in *Apply the Heart Reference Sensor* on page 178, bring the two ends of the heart reference sensor level with each other.
3. Observe the value shown on the zeroing screen.
4. Raise one end of the heart reference sensor 6 inches (15 cm) above the other end.
5. Observe that the value shown has changed by at least 5 mmHg.
6. Reverse the ends such that the other end is now 6 inches (15 cm) above the first end.
7. Observe the value shown changed in the opposite direction by at least 5 mmHg from the original value.

If the value does not change as described, then the heart reference sensor may have been damaged. Contact your local Technical Support office as indicated on the inside cover or *Service and Support* on page 384. A replacement unit shall be provided. If the value does change, the heart reference sensor is functioning normally and can be used for hemodynamic monitoring.

F.8 Testing of Alarm Signals

Each time the HemoSphere Alta advanced monitoring platform is powered on, a self test is automatically performed. As a part of the self test, an alarm tone will sound. This indicates that the audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, periodically adjust alarm limits and check that the appropriate alarm behavior is observed.

F.9 Warranty

Edwards Lifesciences (Edwards) warrants that the HemoSphere Alta advanced monitoring platform is fit for the purposes and indications described in the labeling for a period of one (1) year from the date of purchase when used in accordance with the directions for use. Unless equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty of merchantability or fitness for a particular purpose. This warranty does not include cables, batteries, probes, or oximetry cables used with the HemoSphere Alta advanced monitoring platform. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the HemoSphere Alta advanced monitoring platform at Edwards' option.

Edwards shall not be liable for proximate, incidental, or consequential damages. Edwards shall not be obligated under this warranty to repair or replace a damaged or malfunctioning HemoSphere Alta advanced monitoring platform if such damage or malfunction is caused by the customer's use of catheters other than those manufactured by Edwards.

Appendix G

Guidance and Manufacturer's Declaration

Contents

G.1 Electromagnetic Compatibility

Reference: *IEC/EN 60601-1-2 Edition 4.1 2020-09 and IEC80601-2-49 2018*

The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified in this appendix. The customer or the user of the HemoSphere Alta advanced monitoring platform should assure that it is used in such an environment. When connected to the HemoSphere Alta advanced monitoring platform, all accessory cables listed in table B-1 on page 363 comply with the EMC standards listed above.

G.2 Instructions for Use

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following information and tables.

WARNING Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

No modification of the HemoSphere Alta advanced monitoring platform is allowed.

Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic ant-theft systems and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Alta advanced monitoring platform.
Guidance on maintaining appropriate separation between communications equipment and the

HemoSphere Alta advanced monitoring platform is provided in table G-3. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere monitoring platform.

CAUTION The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer for help.

NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment..

Table G-1 Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Alta advanced monitoring platform should assure that it is used in such an environment.		
Emissions	**Compliance**	**Description**
RF emissions CISPR 11	Group 1	The HemoSphere Alta advanced monitoring platform uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The HemoSphere Alta advanced monitoring platform is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table G-2 Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	**MHz**			**W**	**Meters**	**(V/m)**
The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Alta advanced monitoring platform should ensure that it is used in such an environment.						
385	380 - 390	TETRA 400	Pulse modulation ² 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ³ ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation ² 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ² 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ² 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ² 217 Hz	2	0.3	28

Table G-2 Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment (continued)

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Alta advanced monitoring platform should ensure that it is used in such an environment.						
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation ² 217 Hz	0.2	0.3	9
Note: *If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.*						
[1]For some services, only the uplink frequencies are included.						
[2]The carrier shall be modulated using a 50 % duty cycle square wave signal.						
[3]As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Table G-3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HemoSphere Alta advanced monitoring platform

The HemoSphere Alta advanced monitoring platform is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. To help prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the HemoSphere Alta advanced monitoring platform as recommended below, according to the maximum output power of the communications equipment.

Transmitter Frequency	150 kHz to 80 MHz	80 to 800 MHz	800 to 2500 MHz	2.5 to 6.5 GHz
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Transmitter Power (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.24	0.24
0.1	0.37	0.37	0.74	0.74
1	1.2	1.2	2.3	2.3
10	3.7	3.8	7.4	7.4
100	12	12	23	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table G-4 Wireless coexistence Radiated Anechoic Chamber (RAC) results – Normal Mode (2.4, 5 and 6 GHz WiFi) for HemoSphere Alta advanced monitor (EUT) with unintended signal present

Test Frequency	Unintended Signal Tx to Unintended Signal Rx Distance	HemoSphere Alta Monitor (EUT) to Router (Support) Distance	EUT KPI	PER % (Unintended Signal Tx & Unintended Signal Rx)
2.4 GHz[1]	10 m	10 m	HemoSphere Alta Monitor (EUT) connection with Companion Device (support) maintained. No inaccurate transmission/reception of data experienced.	0.22 %
	1 cm*	10 m		0.24 %
5 GHz[2]	10 m	10 m		0.08 %
	1 cm*	10 m		0.16 %
6 GHz[3]	10 m	10 m		0.14 %
	1 cm*	10 m		0.18 %

[1]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -39.90 dBm.

[2]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -38.89 dBm.

[3]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -55.85 dBm.

**1 cm between EUT and unintended signal Tx source (Rohde and Schwarz CMW 270) and unintended signal Rx source (Tablet).*

Table G-5 Wireless coexistence Radiated Anechoic Chamber (RAC) results – Normal Mode (2.4, 5 and 6 GHz WiFi) for companion device (router) with unintended signal present

Test Frequency	Unintended Signal Tx to Unintended Signal Rx Distance	HemoSphere Alta Monitor (EUT) to Router (Support) Distance	EUT KPI	PER % (Unintended Signal Tx & Unintended Signal Rx)
2.4 GHz[1]	10 m	10 m	HemoSphere Alta Monitor (EUT) connection with Companion Device (support) maintained. No inaccurate transmission/reception of data experienced.	0.50 %
	1 cm*	10 m		0.74 %
5 GHz[2]	10 m	10 m		0.24 %
	1 cm*	10 m		0.54 %
6 GHz[3]	10 m	10 m		0.18 %
	1 cm*	10 m		0.88 %

[1]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -40.84 dBm.

[2]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -30.02 dBm.

[3]Received Signal Strength (RSS) of the HemoSphere Alta Monitor (EUT) at the receiver: -41.58 dBm.

**1 cm between Companion Device and unintended signal Tx source (Rohde and Schwarz CMW 270) and unintended signal Rx source (Tablet).*

Table G-6 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Alta advanced monitoring platform should assure that it is used in such an environment.			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air	±15 kV	
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines > 3 meters	±2 kV for power supply lines ±1 kV for input/ output lines > 3 meters	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	
	±2 kV line(s) to earth	±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply AC input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°,and 315°)	0% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the HemoSphere Alta advanced monitoring platform user requires continued operation during power mains interruptions, it is recommended that the HemoSphere Alta advanced monitoring platform be powered by an uninterruptible power supply or battery.
	0% U_T (100% dip in U_T) for 1 cycle (single phase at 0°)	0% U_T	
	70% U_T (30% dip in U_T) for 25/30 cycles (single phase at 0°)	70% U_T	
	Interrupt: 0% U_T (100% drop in U_T) for 250/300 cycles	0% U_T	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A(rms)/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Field IEC 61000-4-39	134.2 kHz with modulation at 2.1 kHz at 65 A/m 13.56 Mhz with modulation at 50 kHZ at 7.5 A/m	65 A/m 7.5 A/m	Proximity Magnetic Field should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the AC mains voltage prior to application of the test level.			

Table G-7 Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Alta advanced monitoring platform is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Alta advanced monitoring platform should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the HemoSphere Alta advanced monitoring platform, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = [1.2] x $\sqrt{P}$; 150 kHz to 80 MHz d = [1.2] x $\sqrt{P}$; 80 MHz to 800 MHz d = [2.3] x $\sqrt{P}$; 800 MHz to 2500 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment with the following symbol: 
Conducted RF IEC 61000-4-6	6 Vrms (ISM band) 150 kHz to 80 MHz	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 to 2700 MHz	3 V/m	

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HemoSphere Alta advanced monitoring platform is used exceeds the applicable RF compliance level above, the HemoSphere Alta advanced monitoring platform should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HemoSphere Alta advanced monitoring platform.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

G.3 Wireless Technology Information

The HemoSphere Alta monitor contains wireless communication technology that provides enterprise-class Wi-Fi 6E connectivity. HemoSphere Alta monitor wireless technology supports IEEE 802.11a/b/d/e/g/h/i/k/n/r/u/v/w/ac/ax with a fully integrated security supplicant providing 802.11i/WPA2 Enterprise authentication and data encryption. It supports dual stream Wi-Fi in the 2.4GHz, 5GHz and 6Ghz bands as well as Bluetooth 5.2.

Technical details of the wireless technology implemented in the HemoSphere Alta monitor are provided in the following table.

Table G-8 HemoSphere Alta monitor wireless information

Feature	Description
Wi-Fi CERTIFIED*	Wi-Fi 6E (802.11ax) Wi-Fi 4,5,6 (legacy)
IEEE WLAN standards	IEEE 802.11a, b, d, e, g, h, i, k, n, r, u, v, w, ax
Type of modulation	DSSS, OFDM/OFDMA, GFSK, pi/4-DQPSK, 8-DPSK
Supported Radios	802.11b/g/n/ax — 2.4GHz (2400.0 – 2483.5 MHz) 802.11a/n/ac/ax — 5.2GHz (5150.0 – 5350.0 MHz) 5.6GHz (5470.0 – 5725.0 MHz) 5.8GHz (5725.0 – 5895.0 MHz) 6 GHz (5.925 – 7.125 GHz)
Security methods	WPA3 personal and enterprise including WPA2 transition mode
Wi-Fi Media Access Protocol	Carrier sense multiple access with collision avoidance (CSMA/CA)
Authentication Protocols	802.1X EAP-TLS EAP-TTLS/MSCHAPv2 PEAPv9-MSCHAPv2 (EAP-SIM, EAP-AKA)
Encryption	128-bit AES-CCMP, 256-bit AES-GCMP
Bluetooth Operation Details	**Bluetooth Basic Rate +EDR** Transmit frequency: 2402 MHz to 2480 MHz Receive frequency: 2402 MHz to 2480 MHz Modulation: GFSK, $\Pi/4$ DQPSK, 8DPSK Transmit power: 13.2 dBm, e.i.r.p. **Bluetooth Low Energy (BLE)** Transmit frequency: 2402 MHz to 2480 MHz Receive frequency: 2402 MHz to 2480 MHz Modulation: GFSK Transmit power: 9.9 dBm, e.i.r.p.

Table G-8 HemoSphere Alta monitor wireless information (continued)

Feature	Description	
Wi-Fi Operation Details	**IEEE 802.11b/g/n/ax WLAN**	
	Transmit frequency	2412 MHz to 2472 MHz (20 MHz) 2422 MHz to 2462 MHz (40 MHz)
	Receive frequency	2412 MHz to 2472 MHz (20 MHz) 2422 MHz to 2462 MHz (40 MHz)
	Modulation	DSSS (DBPSK, DQPSK, CCK), OFDM/OFDMA (BPSK, QPSK, 16QAM, 64QAM, 1024QQAM)
	Transmit power	20 dBm, e.i.r.p.
	IEEE 802.11a/n/ac/ax WLAN	
	Transmit frequency	5180 MHz to 5320 MHz (20 MHz) 5190 MHz to 5310 MHz (40 MHz) 5210 MHz to 5290 MHz (80 MHz) 5250 MHz (160 MHz)
	Receive frequency	5180 MHz to 5320 MHz (20 MHz) 5190 MHz to 5310 MHz (40 MHz) 5210 MHz to 5290 MHz (80 MHz) 5250 MHz (160 MHz)
	Modulation	OFDM/OFDMA (BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM)
	Transmit power	22.9 dBm e.i.r.p.
	IEEE 802.11a/n/ac/ax WLAN	
	Transmit frequency	5500 MHz to 5700 MHz (20 MHz) 5510 MHz to 5670 MHz (40 MHz) 5530 MHz to 5610 MHz (80 MHz) 5570 MHz (160 MHz)
	Receive frequency	5500 MHz to 5700 MHz (20 MHz) 5510 MHz to 5670 MHz (40 MHz) 5530 MHz to 5610 MHz (80 MHz) 5570 MHz (160 MHz)
	Modulation	OFDM/OFDMA (BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM)
	Transmit power	22.9 dBm e.i.r.p.
	IEEE 802.11a/n/ac/ax WLAN	
	Transmit frequency	5745 MHz to 5825 MHz (20 MHz) 5755 MHz to 5795 MHz (40 MHz) 5775 MHz (80 MHz)
	Receive frequency	5745 MHz to 5825 MHz (20 MHz) 5755 MHz to 5795 MHz (40 MHz) 5775 MHz (80 MHz)
	Modulation	OFDM/OFDMA (BPSK, QPSK, 16QAM, 64QAM, 256QAM, 1024QAM)
	Transmit power	13.95 dBm e.i.r.p.

Table G-8 HemoSphere Alta monitor wireless information (continued)

Feature	Description
Wi-Fi Operation Details (continued)	**IEEE 802.11ax WLAN** Transmit frequency: 5995 MHz to 6415 MHz (20 MHz); 5965 MHz to 6405 MHz (40 MHz); 5985 MHz to 6385 MHz (80 MHz); 6025 MHz to 6345 MHz (160 MHz) Receive frequency: 5995 MHz to 6415 MHz (20 MHz); 5965 MHz to 6405 MHz (40 MHz); 5985 MHz to 6385 MHz (80 MHz); 6025 MHz to 6345 MHz (160 MHz) Modulation: OFDMA (1024QAM) Transmit power: 22.8 dBm e.i.r.p.
Security	**Standards** WPA3 personal and enterprise including WPA2 transition mode **Encryption** 128-bit AES-CCMP, 256-bit AES-GCMP **Authentication Protocols** 802.1X EAP-TLS EAP-TTLS/MSCHAPv2 PEAPv0-MSCHAPv2 (EAP-SIM, EAP-AKA, EAP-AKA')
Compliance	ETSI Regulatory Domain EN 300 328; EN 60950-1 EN 300 328 v1.8.1 (BT 2.1); EN 55022:2006 Class B EN 301 489-1; EN 55024:1998 +A1:2001, A2:2003 EN 301 489-17; EN 61000-3-2:2006 EN 301 893; EN 61000-3-3:1995 +A1:2001, A2:2005 EN 301 489-3; EU 2002/95/EC (RoHS) **FCC Regulatory Domain (Certification ID:** PD9AX210D2**)** **Industry Canada (Certification IC ID:** 1000M-AX210D2**)** **MIC (Japan) (Certification ID:**  **)** RF: 003-200255 TEL: D200217003 **KC (Korea) (Certification ID:** R-C-INT-AX210D2W**)** **NCC (Taiwan) (Certification ID:** CCAH20Y10090T9**)** **acma (Australia)** **ANATEL (Brazil) (Certification ID:** 04022-21-04423**)** **China (CMIIT ID:** 2020AJ15108(M)**)**

Table G-8 HemoSphere Alta monitor wireless information (continued)

Feature	Description
Certifications	Wi-Fi Alliance 802.11a, 802.11b, 802.11g, 802.11n WPA Enterprise WPA2 Enterprise Cisco Compatible Extensions (Version 4) FIPS 140-2 Level 1 Linux 3.8 running on 45 Series Wi-Fi Module with ARM926 (ARMv5TEJ) - OpenSSL FIPS Object Module v2.0 (validation certificate #1747)
Antenna Type	PIFA

G.3.1 Quality of Service for Wireless and Wired Technology

Quality of service (QoS) is specified in terms of total data loss for a normal connection where the HemoSphere Alta monitor is operating at medium wireless signal strength or higher (table 7-1 on page 133) with good network connection. HemoSphere Alta monitor wireless data transmission has been validated to have less than 5% total data loss under these conditions. HemoSphere Alta monitor wireless technology has an effective range of 150 feet, line of sight and 75 feet, non-line of sight. The effective range might be affected due to the presence of other wireless emitters.

The HemoSphere Alta monitor supports data transmission via a wired or wireless connection. All data transmitted is expected to be acknowledged by the receiving system. Data is resent if not sent successfully. The HemoSphere Alta monitor automatically tries to re-establish any connections that are interrupted. If a pre-existing connection cannot be reestablished, the HemoSphere Alta monitor alerts the user with an audible alert and message (for example: Alert: HemoSphere Remote App Connectivity – System Error [see table 14-8 on page 322]).

CAUTION The wireless Quality of Service (QoS) may be influenced by the presence of other devices that create radio frequency interference (RFI). Such RFI devices may include electrocautery equipment, cellular telephones, wireless PC and tablets, pagers, RFID, MRI, or other electrically powered devices. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

G.3.2 Wireless Security Measures

The wireless signals are secured using industry standard wireless security protocols (table G-8). Wireless security standards WEP and WPA have been shown to be vulnerable to intrusions and are not recommended. Edwards recommends securing wireless data transmission by enabling IEEE 802.11i (WPA2) security and FIPS mode. Edwards also recommends implementing network security measures like virtual LANs with firewalls to further secure HemoSphere Alta monitor data in transit to the HIS.

G.3.3 Troubleshooting Wireless Coexistence Issues

The instrument has been tested and complies with the limits of IEC 60601-1-2. If you experience communication issues with HemoSphere Alta monitor wireless technology, ensure a minimum distance between portable and mobile RF communications equipment (transmitters) and the HemoSphere Alta monitor are maintained. Refer to table G-3 for additional details on separation distances.

G.3.4 Federal Communication Commission (FCC) Interference Statements

NOTE To comply with FCC RF exposure compliance requirements, the antenna used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

1. Reorient or relocate the receiving antenna.
2. Increase the separation between the equipment and receiver.
3. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
4. Consult the dealer or an experienced radio/TV technician for help.

CAUTION Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device is restricted to *indoor* use when operated in the 5.15 to 5.25 GHz frequency range.

FCC requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems.

This device does not permit operations on channels 116-128 (5580 – 5640 MHz) for 11na and 120-128 (5600-5640 MHz) for 11a which overlap the 5600 -5650 MHz band.

NOTE FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.

G.3.5 Industry Canada Statements

RF Radiation Hazard Warning

To ensure compliance with FCC and Industry Canada RF exposure requirements, this device must be installed in a location where the antennas of the device will have a minimum distance of at least 20 cm from all persons. Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Maximum Antenna Gain – If the integrator configures the device such that the antenna is detectable from the host product.

This radio transmitter (IC ID: 3147A-WB45NBT) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

"To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication"

"This device has been designed to operate with an antenna having a maximum gain of [4] dBi. Antenna having a higher gain is strictly prohibited per regulations of Industry Canada. The required antenna impedance is 50 ohms."

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

CAUTION	Industry Canada requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems.

G.3.6 European Union Radio Equipment Directive (RED) Statements

This device complies with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED). The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED):

- **EN 62368-1:2014/A11:2017**
  Safety requirements for audio/video, information, and technology equipment
- **EN 300 328 V2.2.2: (2019-07)**
  Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
- **EN 62311:2008 | EN 50665:2017 | EN 50385:2017**
  RF exposure
- **EN 301 489-1 V2.2.0 (2017-03)**
  Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- **EN 301 489-17 V3.2.0 (2017-03)**
  Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
- **EN 301 893 V2.1.1 (2017-05)**
  Electromagnetic compatibility and Radio spectrum Matters (ERM); Broadband Radio Access Networks (BRAN); Specific conditions for 5 GHz high performance RLAN equipment
- **EU 2015/863 (RoHS 3)**
  Declaration of Compliance – EU Directive 2015/863; Reduction of Hazardous Substances (RoHS)

This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

Hereby, Edwards Lifesciences, declares that this monitor is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (RED).

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

Edwards Lifesciences • One Edwards Way, Irvine CA 92614 USA • edwards.com

Edwards