HemoSphere
Advanced Monitor

Operator's manual

Edwards

Edwards Lifesciences HemoSphere Advanced Monitor Operator's Manual

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

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Made in USA

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Using This Manual

The Edwards Lifesciences HemoSphere advanced monitor operator's manual is comprised of eleven chapters, eight appendices, and an index. 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.

WARNING Read this operator's manual carefully before attempting to use the Edwards Lifesciences HemoSphere advanced monitor.

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

CAUTION Inspect all accessories and equipment for damage prior to use with the HemoSphere advanced monitor. 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 advanced monitor
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 advanced monitor and accessories
3	***Installation and Setup***: Provides information about setting up the HemoSphere advanced monitor and connections for the first time
4	***HemoSphere Advanced Monitor Quick Start***: Provides experienced clinicians and users of bedside monitors instructions for immediate monitor use
5	***Navigating the HemoSphere Advanced Monitor***: Provides information on monitoring screen views
6	***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
7	***Advanced Settings***: Provides information on advanced settings including alarm targets, graphical scales, serial port setup, and Demo Mode.
8	***Data Export and Connectivity***: Provides information on monitor connectivity for transferring patient and clinical data
9	***HemoSphere Swan-Ganz Module Monitoring***: Describes procedures for setup and operation of continuous cardiac output, intermittent cardiac output, and right ventricular end diastolic volume monitoring using the Swan-Ganz module
10	***Oximetry Monitoring***: Describes procedures for calibration and operation of oximetry (oxygen saturation) measurement
11	***Help and Troubleshooting***: Describes the Help menu and provides a list of faults, alerts, and messages, with causes and suggested actions.

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Introduction

Contents

1.1 Intended Purpose of this Manual

This manual describes the features and monitoring options of the Edwards Lifesciences HemoSphere advanced monitor. The HemoSphere advanced monitor is a modular device that displays monitored data obtained through Edwards hemodynamic technologies.

This manual has been prepared for use with the Edwards Lifesciences HemoSphere advanced monitor 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 advanced monitor with setup and operating instructions, device interfacing procedures, and limitations.

1.2 Indications For Use

1.2.1 HemoSphere Advanced Monitor with HemoSphere Swan-Ganz Module

The HemoSphere advanced monitor when used with the HemoSphere Swan-Ganz module 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. Refer to the Edwards Swan-Ganz 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.

1.2.2 HemoSphere Advanced Monitor with HemoSphere Oximetry Cable

The HemoSphere 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.

1.3 Contraindications For Use

The HemoSphere advanced monitor has no contraindications for use.

1.4 Intended Use Statement

The HemoSphere 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 advanced monitoring platform is intended for use with compatible Edwards Swan-Ganz and oximetry catheters.

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

Table 1-1 HemoSphere Swan-Ganz module available parameters list

Abbreviation	Description	Patient population
CO	continuous cardiac output	
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	adult only
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	

Table 1-1 HemoSphere Swan-Ganz module available parameters list (continued)

Abbreviation	Description	Patient population
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 advanced monitor and a connected HemoSphere oximetry cable are listed below in table 1-2.

Table 1-2 HemoSphere oximetry cable available parameters list

Abbreviation	Description	Patient population
SvO_2	mixed venous oxygen saturation	adult and pediatric
$ScvO_2$	central venous oxygen saturation	

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

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

Abbreviation	Description	Patient population
DO_2	oxygen delivery	adult and pediatric
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 advanced monitor 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 advanced monitor 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 HemoSphere Advanced Monitor Hemodynamic Technology Connections

The HemoSphere advanced monitor is equipped with three technology expansion module slots (two standard size and one large [L-Tech] size) and two cable ports. Module and cable connection points are located on the left side panel. See figure 1-1.

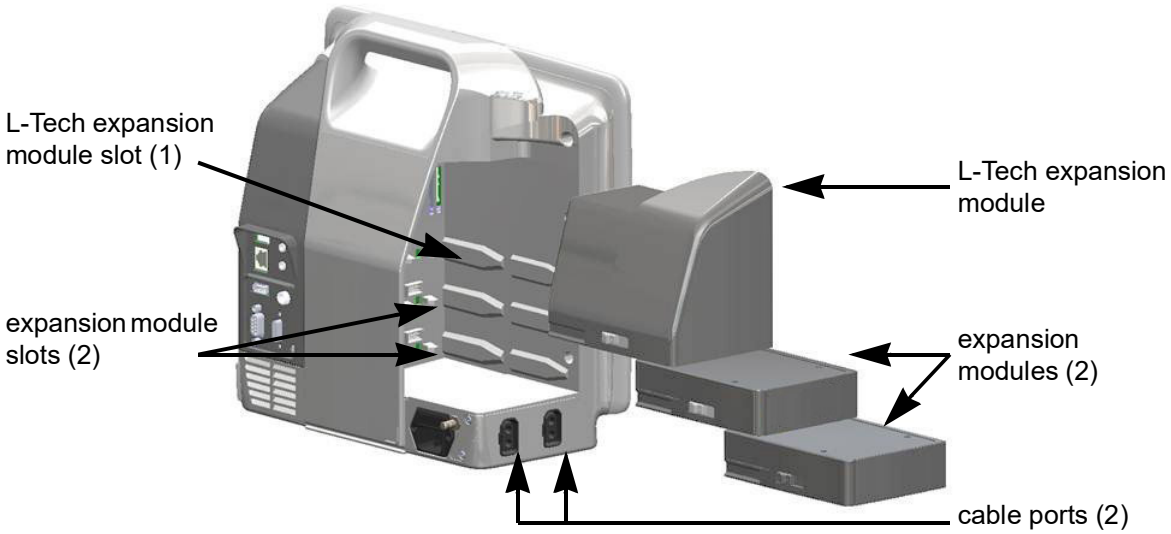
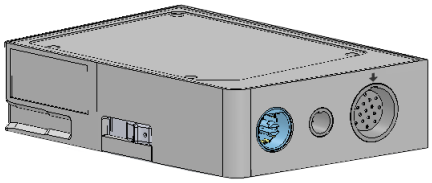


Figure 1-1 HemoSphere advanced monitor hemodynamic technology connections

Each module/cable is associated with a specific Edwards hemodynamic monitoring technology. Currently available modules include the HemoSphere Swan-Ganz module, introduced below and in detail in chapter 9, *HemoSphere Swan-Ganz Module Monitoring*. Currently available cables include the HemoSphere oximetry cable, introduced below and described in detail in chapter 10, *Oximetry Monitoring*.

1.5.1 HemoSphere Swan-Ganz Module



The HemoSphere Swan-Ganz module enables continuous cardiac output (CO) and intermittent cardiac output (iCO) monitoring with an Edwards patient CCO cable and compatible Swan-Ganz catheter. Right ventricular end diastolic volume (EDV) monitoring is available with slaved in heart rate (HR_{avg}) data from a bedside patient monitor. The HemoSphere Swan-Ganz module fits into a standard module slot. For more information, see chapter 9, *HemoSphere Swan-Ganz Module Monitoring*. Table 1-4 lists the parameters available while using the HemoSphere Swan-Ganz module.

Table 1-4 HemoSphere Swan-Ganz module 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

Table 1-4 HemoSphere Swan-Ganz module parameters description (continued)

Parameter	Description	Technology
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 thermodilution catheters
intermittent cardiac index (iCI)	intermittent cardiac output relative to body surface area (BSA)	Swan-Ganz 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
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

1.5.2 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 receptacle and can be used in combination with other hemodynamic monitoring technologies. For more information on oximetry monitoring, see chapter 10, *Oximetry Monitoring*. Table 1-5 lists the parameters available while using the HemoSphere oximetry cable.

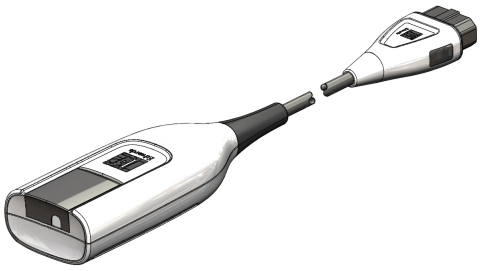


Table 1-5 HemoSphere oximetry cable parameters description

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

Table 1-5 HemoSphere oximetry cable parameters description (continued)

Parameter	Description
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)

1.5.3 Documentation and Training

Available documentation and training for the HemoSphere advanced monitor includes:

- HemoSphere Advanced Monitor Operator's Manual
- HemoSphere Advanced Monitor Quick Start Guide
- HemoSphere Swan-Ganz Module Instructions for Use
- HemoSphere Oximetry Cable Instructions for Use

Instructions for Use are included with HemoSphere Advanced Monitor components. See table B-1, "HemoSphere advanced monitor components," on page 138. For more information on how you can receive training or available documentation for the HemoSphere advanced monitor, contact your local Edwards representative or Edwards Technical Support. See appendix F, *System Care, Service and Support.*.

1.6 Manual style conventions

Table 1-6 lists the style conventions used in this manual.

Table 1-6 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 **Review** 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 30 for full list of menu icons shown on the HemoSphere advanced monitor.
Oximetry Calibration icon 	Bold text with a menu icon indicates an icon that is paired with a software term appearing on the screen as shown.

1.7 Abbreviations Found in This Manual

Table 1-7 Acronyms, Abbreviations

Abbreviation	Definition
A/D	analog/digital
BSA	body surface area
BT	blood temperature
CaO_2	arterial oxygen content
CI	cardiac index
CO	cardiac output
CCO	continuous cardiac output (used when describing certain Swan-Ganz catheters and patient CCO cable)
CVP	central venous pressure
DO_2	oxygen delivery
DO_2I	oxygen delivery index
DPT	disposable pressure transducer
EDV	end diastolic volume
EDVI	end diastolic volume index
efu	ejection fraction unit
Hct	hematocrit
HIS	hospital information systems
HGB	hemoglobin
HR	heart rate
HR_{avg}	average heart rate
iCO	intermittent cardiac output
IEC	International Electrotechnical Commission
IT	injectate temperature
LED	light emitting diode
LVSWI	left ventricular stroke work index
MAP	mean arterial pressure
MPAP	mean pulmonary artery pressure
PA	pulmonary artery
PaO_2	partial pressure of arterial oxygen
PAWP	pulmonary artery wedge pressure
POST	power-on self test
PvO_2	partial pressure of venous oxygen
RVEF	right ventricular ejection fraction
RVSWI	right ventricular stroke work index
sCI	STAT cardiac index
sCO	STAT cardiac output
$ScvO_2$	central venous oximetry
sEDV	STAT end diastolic volume
sEDVI	STAT end diastolic volume index
SpO_2	pulse oximetry saturation
SQI	signal quality indicator

Table 1-7 Acronyms, Abbreviations (continued)

Abbreviation	Definition
sRVEF	STAT right ventricular ejection fraction
ST	surface temperature
STAT	fast estimate of parameter value
SV	stroke volume
SVI	stroke volume index
SvO_2	mixed venous oxygen saturation
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
Touch	Interact with the HemoSphere advanced monitor by touching the screen.
TD	thermodilution
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

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Safety and Symbols

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 advanced monitor 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 Lifesciences HemoSphere advanced monitor.
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere advanced monitor.
- 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 advanced monitor 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 advanced monitor 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 advanced monitor in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. (chapter 3)
- Make sure the HemoSphere advanced monitor 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)
- Do not stack additional equipment or items on top of the HemoSphere advanced monitor. (chapter 3)
- The HemoSphere advanced monitor 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 may be used in the presence of electrosurgery and defibrillators. Inaccurate parameter measurements can be caused by factors such as electrocautery or electrosurgery unit interference. (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)

- Make sure the battery is fully inserted and the battery door is properly latched. Falling batteries could seriously injure patients or clinicians. (chapter 3)
- Only use Edwards approved batteries with the HemoSphere advanced monitor. 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 advanced monitor 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 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 advanced monitor 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 advanced monitor 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 6)
- Perform New Patient or clear the patient data profile whenever a new patient is connected to the HemoSphere advanced monitor. Failure to do so may result in previous patient data in the historical displays. (chapter 6)
- The analog communication ports of the HemoSphere advanced monitor share a common ground that is isolated from the catheter interface electronics. When connecting multiple devices to the HemoSphere advanced monitor, all devices should be provided with isolated power to avoid compromising the electrical isolation of any of the connected devices. (chapter 6)
- Risk and Leakage current of the final system configuration must comply with IEC 60601-1:2005/A1:2012. It is the responsibility of the user to ensure compliance. (chapter 6)
- Accessory equipment connected to the monitor must be certified according to IEC/EN 60950 for data-processing equipment or IEC 60601-1:2005/A1:2012 for electromedical equipment. All combinations of equipment must be in compliance with IEC 60601-1:2005/A1:2012 systems requirements. (chapter 6)

- When switching to a different bedside monitor, always check that the default values listed are still valid. If necessary, reconfigure the voltage range and corresponding parameter range or calibrate. (chapter 6)
- Do not turn off the audible alarms in situations in which patient safety could be compromised. (chapter 7)
- 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 7)
- Visual and audible physiological alarms are activated only if the parameter is configured on the screens as a key parameter (1-4 parameters displayed in parameter globes). 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 7)
- Make sure that Demo Mode is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data. (chapter 7)
- Do not use the HemoSphere advanced monitor as part of a Distributed Alarm System. The HemoSphere advanced monitor does not support remote alarm monitoring/management systems. Data is logged and transmitted for charting purposes only. (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 9)
- 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 135 for disclosure of the pacemaker pulse rejection capability of this instrument. (chapter 9)
- For patients requiring internal or external pacing support, the HemoSphere 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 9)
- 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 9)
- Do not wrap the main body of the oximetry cable in fabric or place directly on the patient"s skin for long periods of time (>10 min). 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 10)
- Before touching Yes 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 10)

- Only use approved HemoSphere advanced monitor 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 advanced monitor 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 advanced monitor, modules, or platform cables in any liquid solution. Do not allow any fluids to enter the instrument. (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, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity. (appendix G)
- No modification of the HemoSphere advanced monitor is allowed. (appendix G)
- Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the HemoSphere advanced monitor. Guidance on maintaining appropriate separation between communications equipment and the HemoSphere advanced monitor is provided in table G-4. (appendix G)

2.3 Cautions

The following are cautions that are used in the HemoSphere advanced monitor 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 all accessories and equipment for damage prior to use with the HemoSphere advanced monitor. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised.
- 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 advanced monitor, always disconnect the patient CCO cable and oximetry cable from the monitor before using a defibrillator. (chapter 3)
- Do not expose the HemoSphere advanced monitor to extreme temperatures. Refer to environmental specifications in appendix A. (chapter 3)
- Do not expose the HemoSphere advanced monitor to dirty or dusty environments. (chapter 3)
- Do not obstruct the HemoSphere advanced monitor ventilation openings. (chapter 3)
- Do not use the HemoSphere advanced monitor 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)
- When connecting the HemoSphere advanced monitor to external devices, refer to the external device's instruction manual for complete instructions. Verify proper operation of the system before clinical use. (chapter 6)
- Only properly trained personnel should calibrate the HemoSphere advanced monitor analog ports. (chapter 6)
- The accuracy of continuous SVR depends upon the quality and accuracy of the MAP and CVP data transmitted from the external monitors. Since MAP and CVP analog signal quality from the external monitor cannot be validated by the HemoSphere advanced monitor, actual values and the values (including all derived parameters) displayed by the HemoSphere advanced monitor may not be consistent. The accuracy of continuous SVR measurement, therefore, cannot be guaranteed. To aid in determining the quality of the analog signals, regularly compare the MAP and CVP values displayed on the external monitor to the values displayed on the physio relationship screen of the HemoSphere advanced monitor. Refer to the external input device operator's manual for detailed information regarding accuracy, calibration, and other variables which may impact the analog output signal from the external monitor. (chapter 6)
- Use a virus scan on any USB stick before inserting to prevent a virus or malware infection. (chapter 8)
- Restore Defaults replaces all settings with factory defaults. Any settings changes or customizations will be permanently lost. Do not restore defaults while monitoring a patient. (chapter 8)

- Do not force the module into the slot. Apply even pressure to slide and click the module into place. (chapter 9)
- 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 9)
- 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 9)
- 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 9)
- Make sure that the oximetry cable is securely stabilized to prevent unnecessary movement of the attached catheter. (chapter 10)
- 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 10)
- Performing an in vitro calibration after the oximetry catheter has been inserted into the patient will yield an inaccurate calibration. (chapter 10)
- The SQI signal is sometimes affected by the use of electrosurgical units. Attempt to distance electrocautery equipment and cables from the HemoSphere advanced monitor and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call your local Edwards representative for assistance. (chapter 10)
- Do not disconnect the oximetry cable while calibration or data recall are in process. (chapter 10)
- If the oximetry cable is being transferred from a HemoSphere advanced monitor to another HemoSphere advanced monitor, check that the patient height, weight, and BSA are correct prior to beginning monitoring. Re-enter patient data, if necessary. (chapter 10)
- Clean and store the instrument and accessories after each use. (appendix F)
- Do not pour or spray liquid on any portion of the HemoSphere advanced monitor, accessories, modules, 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 or modules 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 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)
- 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)

2.4 User Interface Symbols

The following are icons that appear on the HemoSphere advanced monitor screen. For more information about screen appearance and navigation, see chapter 5, *Navigating the HemoSphere Advanced Monitor*. Certain icons will only appear while monitoring with a specific hemodynamic technology module or cable, as specified.

Table 2-1 Monitor display symbols

Symbol	Description
Navigation Bar Icons	
	begin CO monitoring (HemoSphere Swan-Ganz module)
	stop CO monitoring with CO countdown timer (see *CO Countdown Timer and STAT CO* on page 101) (HemoSphere Swan-Ganz module)
	monitor screen selection
	clinical actions menu
	settings menu
	snapshot (screen capture)
	silence audible alarms
	alarms paused (silenced) with countdown timer (See *Silence Audible Alarms* on page 52)
	monitoring pause exit
Clinical Action Menu Icons	
	iCO (intermittent cardiac output) (HemoSphere Swan-Ganz module)
	oximetry calibration (HemoSphere oximetry cable)
	derived value calculator

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	event review
	patient CCO cable test (HemoSphere Swan-Ganz module)
Menu Navigation Icons	
	return to main monitoring screen
	return to previous menu
	cancel
	scroll to select item on vertical list
	vertical page scroll
	horizontal scroll
	enter
	keypad enter key
	keypad backspace key
	move cursor left by 1 character
	move cursor right by 1 character
	keypad cancel key
	item enabled

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	item not enabled
	clock/waveform - allows user to view historical data or intermittent data
Parameter Globe Icons	
	clinical/alarm indicators: green: in target range yellow: out of target range red: red alarm and/or target zone gray: no target set
	Alarms / Targets popup: parameter audible alarm indicator enabled
	Alarms / Targets popup: parameter audible alarm indicator disabled
	signal quality indicator bar See *Signal Quality Indicator* on page 116 (HemoSphere oximetry cable)
Information Bar Icons	
	HIS enabled icon on information bar See table 8-2 on page 93
	battery life indicator icons on information bar See table 5-5 on page 67

Table 2-1 Monitor display symbols (continued)

Symbol	Description
	CO countdown (HemoSphere Swan-Ganz module)
	averaged heart rate (HemoSphere Swan-Ganz module with ECG input)
	Wi-Fi signal See table 8-1 on page 92
Intervention Analysis Icons	
	intervention analysis button
	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)
	edit icon on intervention information balloon
	keyboard icon for entering notes on intervention edit screen

2.5 Symbols on Product Labels

This section provides the symbols that are on the HemoSphere advanced monitor and other available HemoSphere advanced monitoring platform accessories.

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	Provides protection against water splashing in any direction to IPX4 standard

Table 2-2 Symbols on product labels (continued)

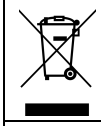
Symbol	Description
	Separate collection for electrical and electronic equipment in accordance with EC directive 2002/96/EC.
	Restriction of Hazardous Substances (RoHS) compliance - China only
	Federal Communications Commission (FCC) compliance - USA only
	This device contains a non-ionizing radiation transmitter, which can cause RF interference with other devices near this device.

Table 2-2 Symbols on product labels (continued)

Symbol	Description
eifu.edwards.com +1 888 570 4016	Consult instructions for use on eifu.edwards.com
	Instructions for use in electronic form is available by phone or website address.
C ETL US LISTED Intertek	Intertek ETL
REF	Catalogue number
SN	Serial number
EC REP	Authorized representative in the European Community
MR	Magnetic resonance unsafe
CE 0123	CE conformity marking per European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.
LOT	Lot number
PN	Part number
Pb	Lead-free
c UL us	Underwriters Laboratories product certification mark
Li-ion	Recyclable Lithium-Ion
	Do not disassemble
	Do not incinerate
Connector Identification Labels	
	Equipotential terminal stud
	USB 2.0

Table 2-2 Symbols on product labels (continued)

Symbol	Description
SS	USB 3.0
	Ethernet connection
1	Analog input 1
2	Analog input 2
	DPT pressure output
	Defibrillation proof type CF applied part or connection
ECG	ECG input from external monitor
HDMI	High-Definition Multimedia Interface output
	Connector: serial COM output (RS232)
Additional Packaging Labels	
	Keep contents dry
	Fragile. Handle with care
	This end up
	Do not use if package is damaged
20	Box made from recyclable cardboard
	Keep away from direct sunlight.

Table 2-2 Symbols on product labels (continued)

Symbol	Description
	Temperature limitations (X = lower limit, Y = upper limit)
	Humidity limitations (X = lower limit, Y = upper limit)

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 / A1:2012	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance + amendment 1 (2012)
IEC 60601-1-2: 2014	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-2-49:2011	Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
IEEE 802.11 b/g/n	Telecommunications and information exchange between systems Local and metropolitan area networks — Specific requirements Part 11: Wireless LAN Medium Access Control (MAC) and Physical Layer (PHY) Specifications

2.7 HemoSphere Advanced Monitor Essential Performance

The platform shall provide display of continuous CO and intermittent CO with a compatible Swan-Ganz catheter 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 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 133.

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. Perform a visual inspection of the packaging contents for damage. Damage may include cracks, scratches, dents or any signs that the monitor, modules or cable housing may be compromised. Report any evidence of external damage.

3.1.1 Packaging Contents

The HemoSphere advanced monitoring platform is modular and therefore packaging configurations will vary depending upon the kit ordered. The HemoSphere advanced monitoring system, which is the base kit configuration, contains the HemoSphere advanced monitor, mains power cord, power entry cover, HemoSphere battery pack, two expansion modules, one L-Tech expansion module, a quick start guide and a USB stick containing this operator's manual. See table 3-1. Additional items that may be included and shipped with other kit configurations include the HemoSphere Swan-Ganz module, patient CCO cable, and HemoSphere oximetry cable. 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 advanced monitoring components

HemoSphere advanced monitoring system (base kit)
• HemoSphere advanced monitor • HemoSphere battery pack • mains power cord • power entry cover • L-Tech expansion module • expansion module (2) • quick start guide • operator's manual (on USB stick)

3.1.2 Required Accessories for Platform Modules and Cables

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

Table 3-2 Accessories required for monitoring parameters with HemoSphere Swan-Ganz module

	Monitored and calculated parameters					
Required Accessory	CO	EDV	RVEF	SVR	iCO	SV
patient CCO cable	•	•	•	•	•	•
ECG cable		•	•			•
analog pressure input cable(s)				•		
injectate temperature probe					•	
Swan-Ganz thermodilution catheter					•	
Swan-Ganz CCO catheter or Swan-Ganz CCOmbo catheter	•			•	•	•
Swan-Ganz CCOmbo V catheter	•	•	•	•	•	•

NOTE Not all parameters can be monitored or calculated in pediatric patients. See table 1-1 on page 16 for available parameters.

Table 3-3 Accessories required for monitoring parameters with HemoSphere oximetry cable

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

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 advanced monitor, always disconnect the patient CCO cable and oximetry cable from the monitor before using a defibrillator.

3.2 HemoSphere Advanced Monitor Connection Ports

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

3.2.1 Monitor Front

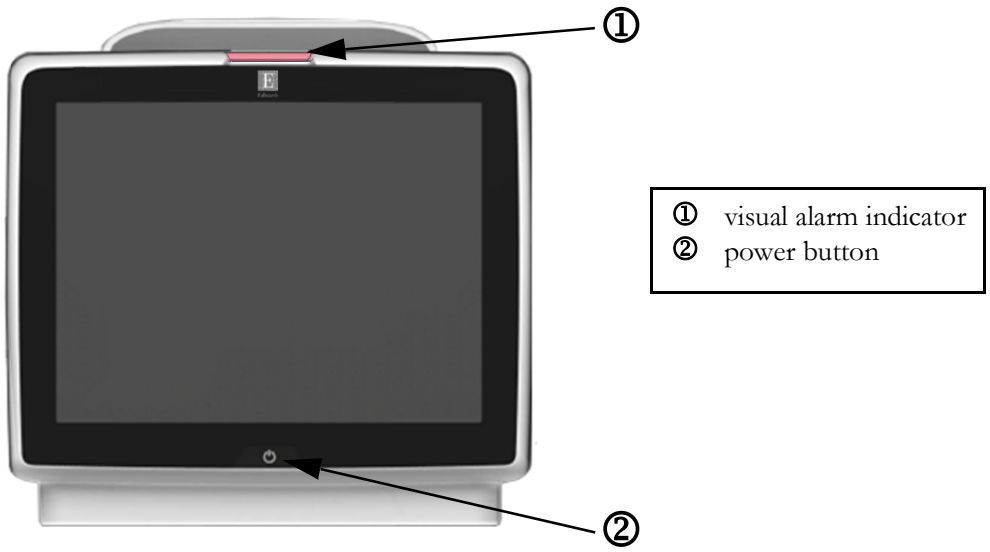
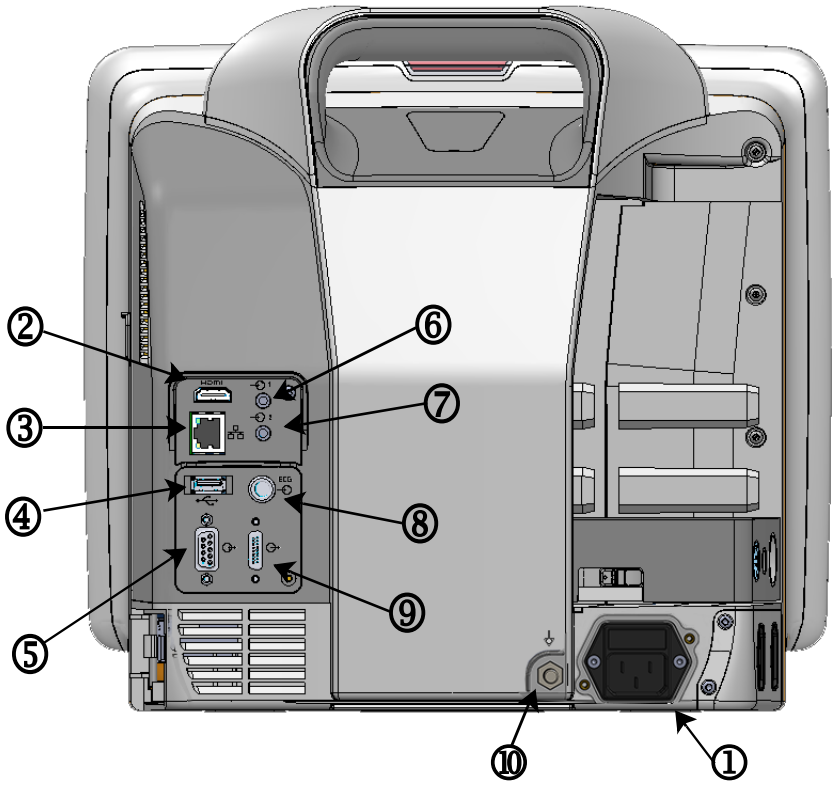


Figure 3-1 HemoSphere advanced monitor front view

3.2.2 Monitor Rear



① mains power cord connection (power entry cover removed)

② HDMI port

③ Ethernet port

④ USB port

⑤ COM1 serial port connector (RS-232)

⑥ Analog input 1

⑦ Analog input 2

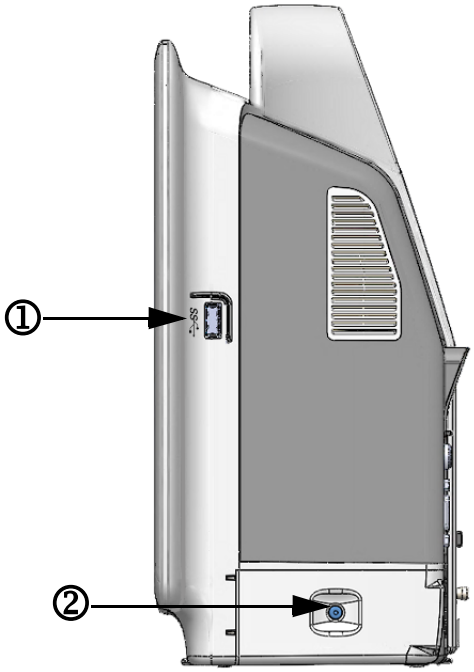
⑧ ECG input

⑨ pressure output

⑩ equipotential terminal stud

Figure 3-2 HemoSphere advanced monitor rear view (shown with HemoSphere Swan-Ganz module)

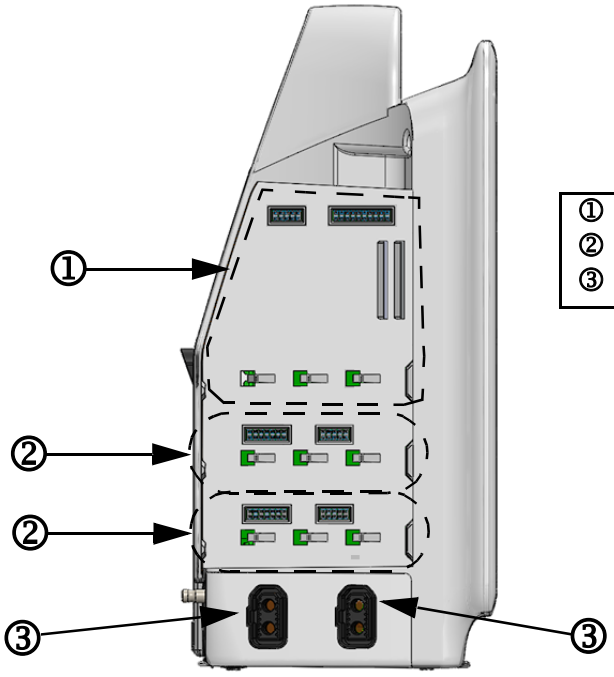
3.2.3 Monitor Right Panel



① USB port
② battery door

Figure 3-3 HemoSphere advanced monitor right panel

3.2.4 Monitor Left Panel



① L-Tech expansion module slot
② expansion module slots (2)
③ cable ports (2)

Figure 3-4 HemoSphere advanced monitor left panel (shown with no modules)

3.3 HemoSphere Advanced Monitor Installation

3.3.1 Mounting Options and Recommendations

The HemoSphere advanced monitor should be placed on a stable flat surface or securely mounted on a compatible stand, according to your institution's practices. A roll stand for the HemoSphere advanced monitor is available as an optional accessory. See *Additional Accessories Description* on page 139 more information. Contact your local Edwards representative for recommendations on additional mounting options.

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

Make sure the HemoSphere advanced monitor 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.

Do not stack additional equipment or items on top of the HemoSphere advanced monitor.

The HemoSphere advanced monitor 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 may be used in the presence of electrosurgery and defibrillators. Inaccurate parameter measurements can be caused by factors such as electrocautery or electro-surgery unit interference.

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

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

Do not expose the HemoSphere advanced monitor to dirty or dusty environments.

Do not obstruct the HemoSphere advanced monitor ventilation openings.

Do not use the HemoSphere advanced monitor 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 Installation

Open the battery door (figure 3-3) and insert the battery into the battery bay, ensuring pack is fully inserted and seated. Close the battery door and ensure that the latch is securely fastened. Follow instructions below to connect the power cord and then fully charge the battery. Do not use a new battery pack as a power source until it has been fully charged.

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 157.

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

WARNING Make sure the battery is fully inserted and the battery door is properly latched. Falling batteries could seriously injure patients or clinicians.

Only use Edwards approved batteries with the HemoSphere advanced monitor. 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 advanced monitor 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 (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.
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.
4. Reinsert the screws to fasten the cover onto the monitor.
5. Plug power cord into a hospital grade outlet.

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

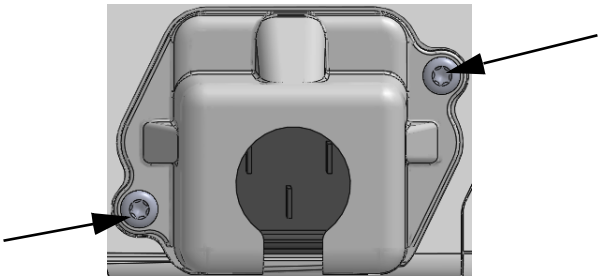


Figure 3-5 HemoSphere power entry cover - screw locations

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 advanced monitor 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 Module

The HemoSphere advanced monitor is shipped with two standard expansion modules and one L-Tech expansion module. Before inserting a new monitoring technology module, remove the expansion module by pressing the release button to unlatch and slide the blank module out.

Inspect the new module for external damage before installation. Insert the desired monitoring module into the open slot by applying even pressure to slide and click the module into place.

3.3.5 Connecting and Disconnecting a Hemodynamic Monitoring Cable

Both 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. To disconnect a cable, hold at the plug to pull it away from the monitor.

3.3.6 Connecting Cables from External Devices

The HemoSphere advanced monitor utilizes slaved-in monitored data to calculate certain hemodynamic parameters. This includes data from the pressure input data ports and ECG monitor input port. All slaved-in cable connections are located on the rear panel of the monitor (figure 3-2). See *Required Accessories for Platform Modules and Cables* on page 34 for a list of calculated parameters available with certain cable connections. For more information on configuring the analog pressure ports, see *Analog Pressure Signal Input* on page 76.

IMPORTANT NOTE **The HemoSphere advanced monitor is compatible with pressure and ECG analog slave inputs from any external patient monitor that has analog slave 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 advanced monitor's primary function of monitoring cardiac output (with the HemoSphere Swan-Ganz module) and venous oxygen saturation (with the HemoSphere oximetry cable).**

WARNING Only use HemoSphere advanced monitor 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.

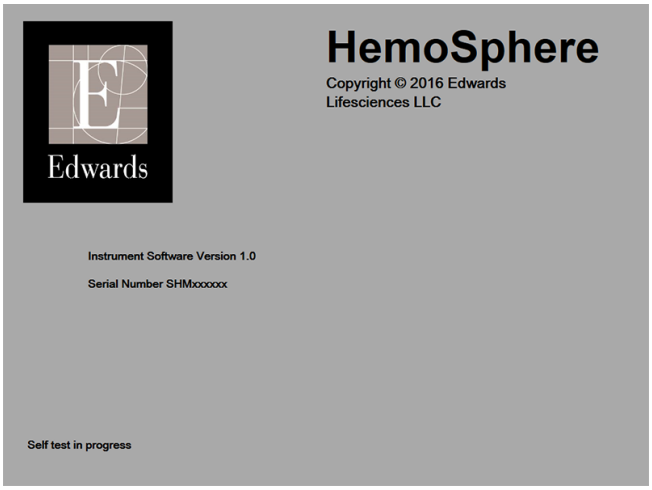


Figure 3-6 Startup screen

NOTE If the diagnostic tests detect an error condition, a system error screen will replace the startup screen. See chapter 11: *Troubleshooting* or appendix F: *System Care, Service and Support*. Otherwise, call your Edwards Lifesciences representative for assistance.

3.4.2 Select Language

Upon initial HemoSphere advanced monitor startup, language options are offered which affect the displayed language, time and date formats, and units of measurement. The language selection screen appears after the software has initialized and POST is complete. Selecting the language also sets the display units and the time and date format to the default settings for that language (see appendix D: *Monitor Settings and Defaults*).

Each of the language-related settings can be changed later in the **Date/Time** screen of the **Monitor Settings** screen and in the language option through **Monitor Settings → General**.

When the language selection screen appears, touch the desired language for use.

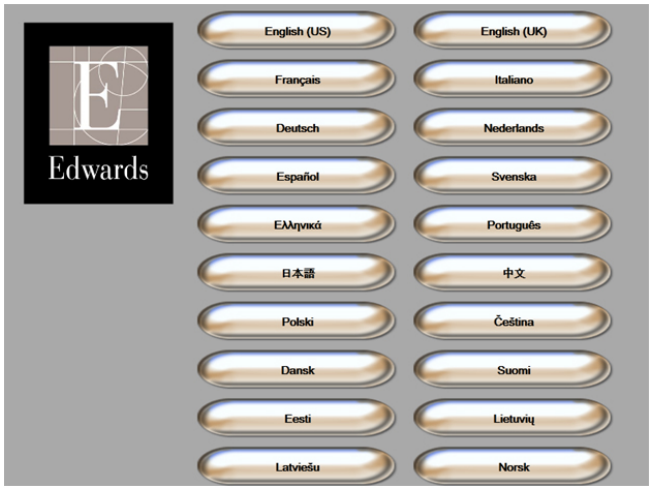


Figure 3-7 Language selection screen

NOTE Figure 3-6 and figure 3-7 are examples of startup and language selection screens.

4

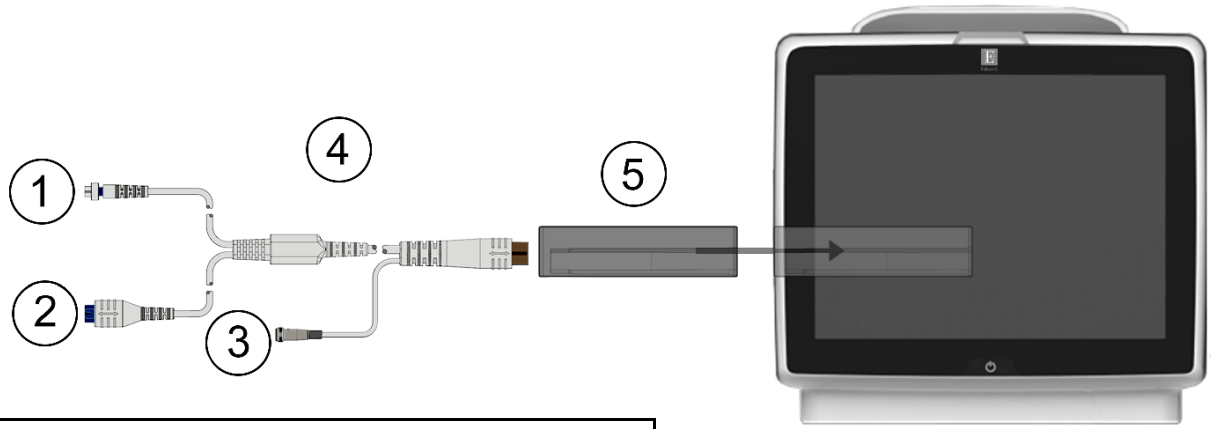
HemoSphere Advanced Monitor Quick Start

Contents

NOTE This chapter is intended for experienced clinicians. It provides brief instructions for using the HemoSphere advanced monitor. Refer to the manual chapters for more detailed information, warnings, and cautions.

4.1 HemoSphere Swan-Ganz Module Cardiac Output Monitoring

Refer to figure 4-1 for HemoSphere Swan-Ganz module monitoring connections.



① thermistor connection
② thermal filament connection
③ injectate temperature probe connection
④ patient CCO cable
⑤ HemoSphere Swan-Ganz module
⑥ HemoSphere advanced monitor

Figure 4-1 HemoSphere Swan-Ganz module monitoring connection overview

Edwards

1 Ensure that the HemoSphere advanced monitor is off and then insert the HemoSphere Swan-Ganz module into the monitor. The module will click when properly engaged.

2 Press the power button to turn on the HemoSphere advanced monitor. All functions are accessed through the touch screen.

3 Select **Continue Same Patient** button or **New Patient** button and enter new patient data.

4 Connect the patient CCO cable to the HemoSphere Swan-Ganz module.

5 Touch the monitor screen selection icon  to select the desired monitoring screen view.

6 Touch outside of a parameter globe to select the desired key parameter from the parameter popup.

7 Touch within a parameter globe to adjust **Alarms/Targets**.

8 Depending on catheter type, continue to step 9 in one of the following sections:

- section 4.1.1 for CO monitoring
- section 4.1.2 for iCO monitoring
- section 4.1.3 for EDV monitoring

4.1.1 Continuous Cardiac Output Monitoring

9 Attach the thermistor ① and thermal filament ② Swan-Ganz CCO catheter connections (figure 4-1) to the patient CCO cable.

10 Verify that the catheter is properly inserted into the patient.

11 Touch the start monitoring icon  . A countdown clock will appear on the stop monitoring icon  to indicate the time until the first CO value. After approximately 3 to 6 minutes, when sufficient data has been obtained, a CO value will appear in the parameter globe.

12 The time until the next CO measurement is displayed on the information bar. For longer time spans between calculations, select STAT CO (sCO) as a key parameter. sCO is a fast estimate of the CO value.

13 Touch the stop monitoring icon  to stop CO monitoring.

4.1.2 Intermittent Cardiac Output Monitoring

Follow steps 1-8 at the start of section 4.1 before proceeding.

9 Attach the Swan-Ganz catheter thermistor connection (①, figure 4-1) to the patient CCO cable.

10 Connect the injectate temperature probe to the injectate temperature probe connector ③ on the patient CCO cable. The injectate system type (in-line or bath) is automatically detected.

11 Touch clinical actions icon  → **iCO** icon  .

12 Select the following settings on the new set configuration screen:

- **Injectate Volume: 10 mL**, **5 mL**, or **3 mL** (bath type probe only)
- **Catheter Size: 5.5F**, **6F**, **7F**, **7.5F**, or **8F**
- **Comp Constant**: **Auto,** or keypad appears for manual entry when selected

NOTE The computation constant is automatically calculated according to injectate system type, injectate volume and catheter size. If the computation constant is manually entered, the injectate volume and catheter size selections are set to **Auto**.

- **Bolus Mode**: **Auto** or **Manual**

13 Touch the **Start Set** button.

14 If in automatic bolus mode, **Wait** appears highlighted (Wait) until the thermal baseline is achieved. If in manual bolus mode, **Ready** (Ready) will appear highlighted when the thermal baseline is achieved. Touch the **Inject** button first to start the bolus procedure.

15 When **Inject** becomes highlighted (Inject), use a rapid, smooth, continuous method to inject the bolus with the volume amount previously selected.

16 **Computing** is highlighted (Computing) and then the resultant iCO measurement is displayed.

17 Repeat steps 14-16 up to six times as desired.

18 Touch the **Review** button and if necessary, edit the bolus series.

19 Touch the **Accept** button.

4.1.3 Continuous End Diastolic Volume Monitoring

Follow steps 1-8 at the start of section 4.1 before proceeding.

9 Attach the thermistor ① and thermal filament ② Swan-Ganz volumetric catheter connections (figure 4-1) to the patient CCO cable.

10 Verify that the catheter is properly inserted into the patient.

11 Connect one end of the ECG interface cable to the rear panel of the HemoSphere advanced monitor and the other end to the bedside monitor's ECG signal output.

12 Touch the start monitoring icon  to begin CO/EDV monitoring.

13 A countdown clock will appear on the stop monitoring icon 

to indicate the time until the first CO/EDV value. After approximately 6 to 9 minutes, when sufficient data has been obtained, an EDV and/or RVEF value will appear in the configured parameter globe(s).

14 The time until the next CO measurement is displayed on the information bar. For longer time spans between calculations, select STAT parameters (sCO, sEDV, and sRVEF) as key parameters. sCO, sEDV, and sRVEF are fast estimates of CO, EDV, and RVEF.

15 Touch the stop monitoring icon 

to stop CO/EDV monitoring.

4.2 HemoSphere Oximetry Cable Monitoring

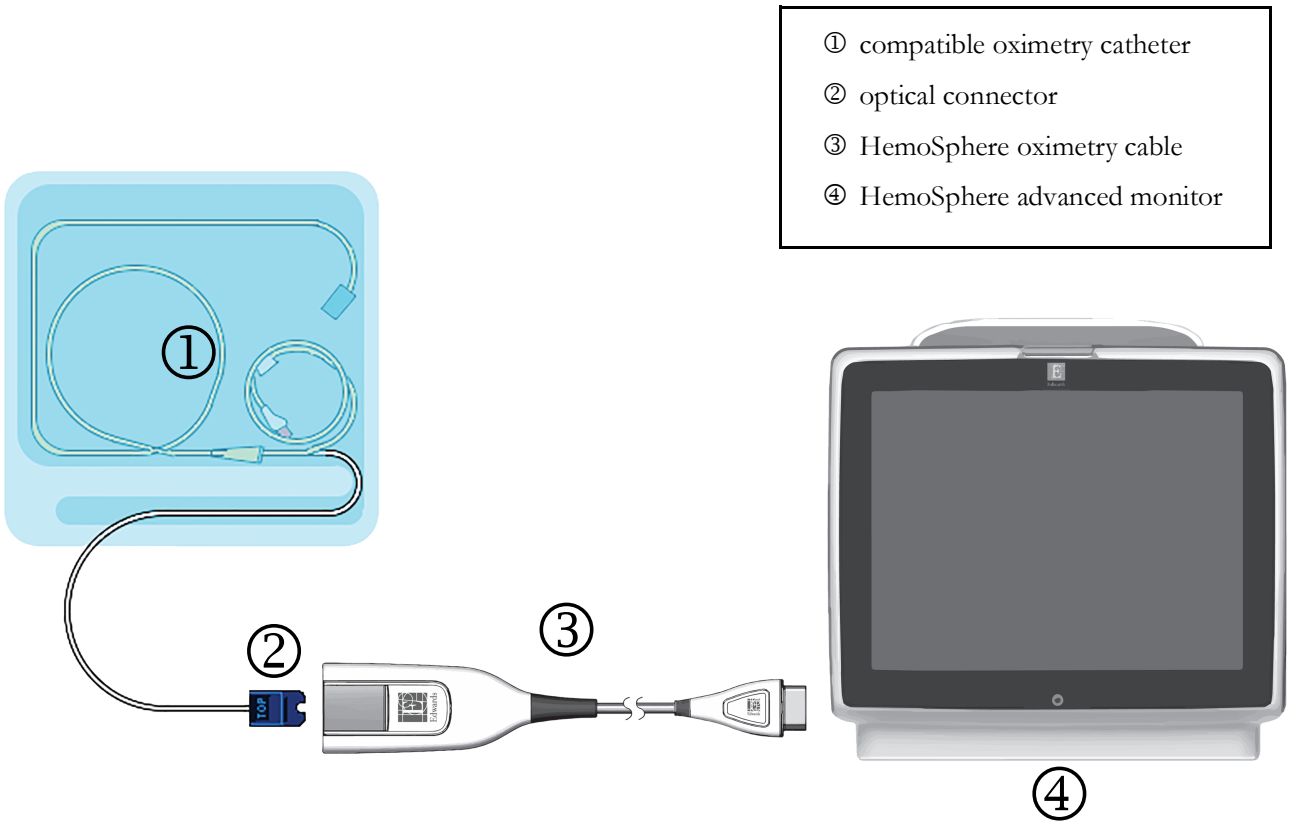


Figure 4-2 Oximetry connection overview

1. Connect the HemoSphere oximetry cable to the left side of the HemoSphere advanced monitor. See figure 4-2.
2. Press the power button to turn on the HemoSphere advanced monitor. All functions are accessed through the touch screen.
3. Select **Continue Same Patient** button or **New Patient** button and enter new patient data.
4. The HemoSphere oximetry cable must be calibrated before each monitoring session. Continue to section 4.2.1 for in vitro calibration instructions and section 4.2.2 for in vivo calibration instructions.

4.2.1 In vitro Calibration

1. Remove a section of the catheter tray lid to expose the optical connector.
2. Insert the optical connector of the catheter "TOP" side up into the oximetry cable and snap the enclosure shut.
3. Touch the clinical actions icon → **Oximetry Calibration** icon .
4. Select **Oximetry Type**: **$ScvO_2$** or **SvO_2**.
5. Touch **In vitro Calibration** button.

6 Enter either the patient's hemoglobin (**HGB)** or hematocrit (**Hct**) value. A default value may be used until the patient's HGB or Hct is available.

7 Touch **Calibrate** button.

8 When the calibration successfully completes, the following message appears:

In vitro Calibration OK, insert catheter

9 Insert the catheter as described in the catheter directions for use.

10 Touch **Start** button.

11 If **$ScvO_2$/SvO_2** are not current key parameters, touch the displayed parameter label located outside of any parameter globe to select **$ScvO_2$/SvO_2** as a key parameter from the parameter popup.

12 Touch within the **$ScvO_2$/SvO_2** parameter globe to adjust **Alarms/Targets**.

4.2.2 In vivo Calibration

1 Insert the catheter as described in the catheter directions for use.

2 Insert the optical connector of the catheter "TOP" side up into the oximetry cable and snap the enclosure shut.

3 Touch clinical actions icon → **Oximetry Calibration** icon .

4 Select **Oximetry Type**: **$ScvO_2$** or **SvO_2**.

5 Touch **In vivo Calibration** button.

If setup is unsuccessful, one of the following messages will be displayed:

Warning: Wall Artifact or Wedge Detected. Reposition catheter.

OR

Warning: Unstable Signal.

6 If a "Wall Artifact or Wedge Detected," or "Unstable Signal" message appears, attempt to troubleshoot the problem as instructed in *Chapter 10: Help and Troubleshooting* and touch **Recalibrate** button to restart the baseline setup.

OR

Touch **Continue** button to proceed to the Draw operation.

7 When baseline calibration is successful, touch **Draw** button and then draw the blood sample and send the blood sample to the lab for measured analysis by co-oximeter.

8 Enter **HGB** or **Hct** and **$ScvO_2$/SvO_2** when lab values are received.

9 Touch **Calibrate** button.

10 Touch the monitor screen selection icon to select the desired monitoring screen view.

11 Touch the displayed parameter label located outside of any parameter globe to select **$ScvO_2$/SvO_2** as a key parameter from the parameter popup window.

12 Touch within the **$ScvO_2$/SvO_2** parameter globe to adjust **Alarms/Targets**.

5

Navigating the HemoSphere Advanced Monitor

Contents

5.1 HemoSphere Advanced Monitor Screen Appearance

All monitoring functions are initiated by touching the appropriate area on the touch screen. The navigation bar, located on the left side of the screen, includes various controls for stopping and starting monitoring, scrolling and selecting screens, performing clinical actions, adjusting system settings, capturing screen shots, and silencing alarms. The main components of the HemoSphere advanced monitor screen are shown below in figure 5-1. The main window displays the current monitoring view or menu screen. For details on monitoring view types, see *Monitor Views* on page 52 . For details on other screen features, see the referenced sections in figure 5-1.

Edwards

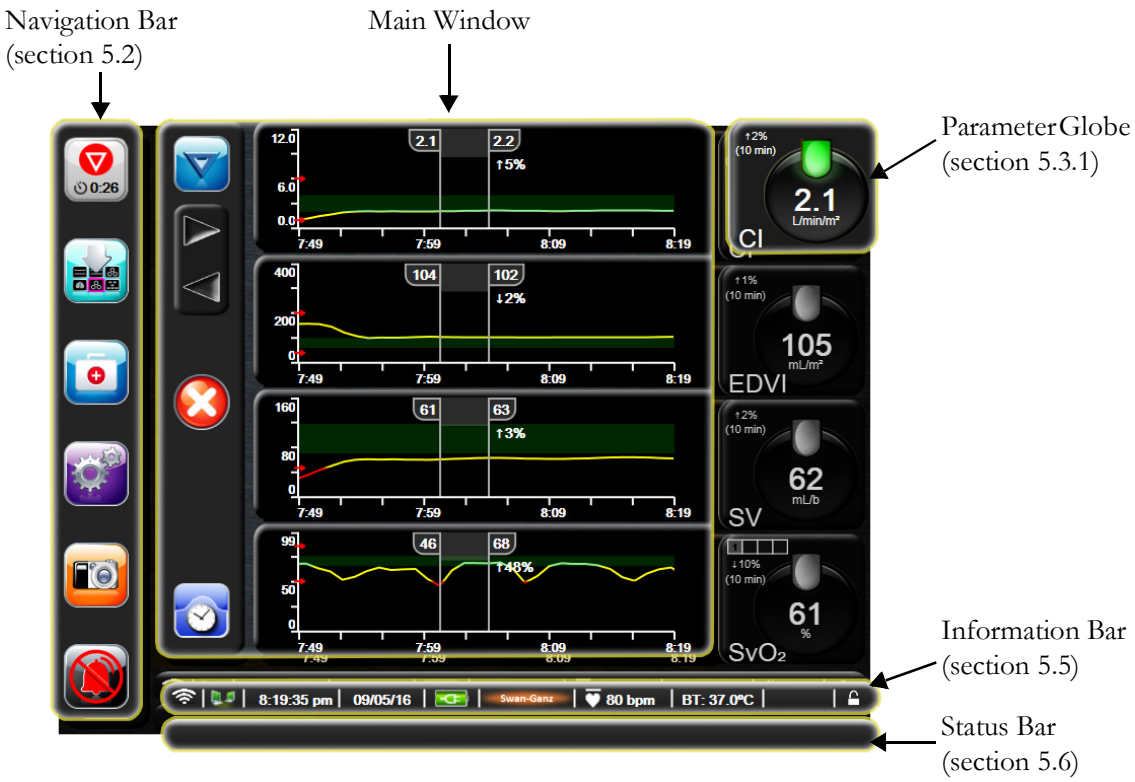


Figure 5-1 HemoSphere advanced monitor screen features

5.2 Navigation Bar

The navigation bar is present on most screens. Exceptions are the startup screen and screens indicating the HemoSphere advanced monitor has stopped monitoring.

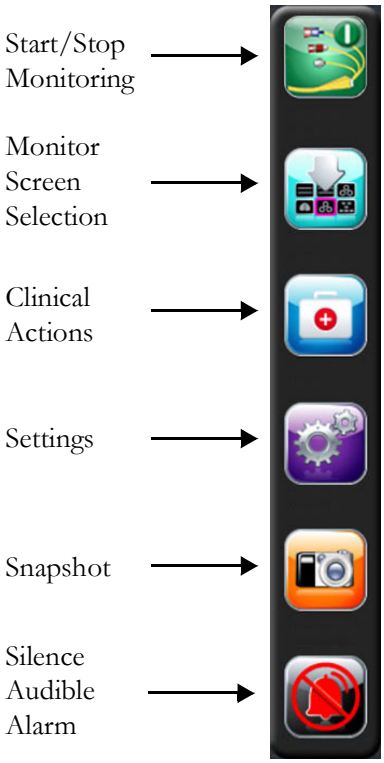


Figure 5-2 Navigation bar - HemoSphere Swan-Ganz module monitoring

Start CO Monitoring. While monitoring with the HemoSphere Swan-Ganz module, the start CO monitoring icon allows the user to initiate CO monitoring directly from the navigation bar. See *Continuous Cardiac Output* on page 99 .

Stop CO Monitoring. The stop monitoring icon indicates that CO monitoring using the HemoSphere Swan-Ganz module is underway. The user can immediately stop monitoring by touching this icon.

Monitor Screen Selection. The monitor screen selection icon allows the user to select the desired number of monitored parameters displayed and the type of monitoring view used to display them, which is highlighted in color (see figure 5-3, "Example of monitoring screen selection window," on page 53). When a monitoring view screen is selected, that monitoring mode is immediately displayed.

To return to the most recent monitoring screen displayed, touch the cancel icon  .

Clinical Actions. The clinical actions icon provides access to the following clinical actions:

- **Derived Value Calculator**
- **Event Review**

- **iCO** (HemoSphere Swan-Ganz module)
- **Patient CCO Cable Test** (HemoSphere Swan-Ganz module)
- **Oximetry Calibration** (HemoSphere oximetry cable)

A description of **Derived Value Calculator** and **Event Review** can be found in this chapter (see section 5.4.1 on page 66 and section 5.4.2 on page 66). For the remaining clinical actions, refer to the specified module or cable chapter for more information.

Settings. The settings icon provides access to configuration screens which include:

- **Patient Data**: See chapter 6: *User Interface Settings*
- **Monitor Settings**: See chapter 6: *User Interface Settings*
- **Advanced Setup**: See chapter 7: *Alarms / Targets* , chapter 7: *Adjust Scales* , and chapter 8: *Data Export and Connectivity Settings*
- **Export Data**: See chapter 8: *Data Export and Connectivity Settings*
- **Demo Mode:** See chapter 7: *Demo Mode*
- **Engineering**: See chapter 7: *Engineering*
- **Help**: See chapter 11: *On Screen Help*

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

Silence Audible Alarms. This icon silences all alarms for two minutes. New physiological alarms are silenced during the two minute period. Alarms will resume sounding after the two minutes have 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. A two minute countdown timer and "**Alarms Paused**" appear.

Monitoring Pause Exit. When the silence audible alarms button is touched for 3 consecutive seconds, a monitoring pause confirmation popup will appear asking the user to confirm suspension of monitoring operations. This function is used when the user wishes to pause monitoring. After confirmation, the silence audible alarm button on the navigation bar will switch to the monitoring pause exit button and a "**Monitoring Pause**" banner will be displayed. To return to monitoring, touch the monitoring pause exit button.

5.3 Monitor Views

There are six monitoring views: graphical trend, tabular trend, graphical/tabular trend split screen, physiology, cockpit, and physio relationship. Up to four monitored parameters can be displayed on these screens at one time.

To select a monitoring view:

1 Touch the monitor screen selection icon . The monitor screen selection menu contains icons that are based upon the look of the monitoring screens.

Figure 5-3 Example of monitoring screen selection window

2 Touch the circled number, **1**, **2**, **3**, or **4**, that represents the number of key parameters to be displayed on the monitoring screens.

3 Select and touch a monitor view button to display the key parameters in that screen format.

5.3.1 Parameter Globes

Parameter globes are located on the right side of most monitoring screens. The cockpit monitoring view is composed of larger format parameter globes which function identically as described below.

5.3.1.1 Change Parameters

1 Touch the displayed parameter label located outside the globe to change it to a different parameter.

2 A popup window will show the selected parameter highlighted in color and other parameters currently being displayed outlined in color. Available parameters appear on the screen without highlights. Figure 5-4 shows the popup window that will appear while selecting continuous parameters and monitoring with the HemoSphere Swan-Ganz module.

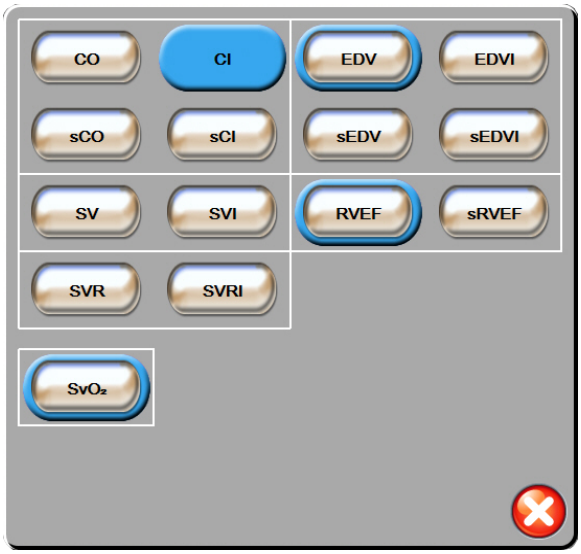


Figure 5-4 Example of key parameter selection popup window

3 Touch an available parameter to select the replacement parameter.

5.3.1.2 Change Alarm/Target

The **Alarms / Targets** popup 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. Additionally, the target settings can be adjusted with a numbered key pad or with the scroll buttons when a minor adjustment is needed. This popup screen is accessed by touching anywhere inside a monitored parameter globe or through the parameter settings screen. For more information, see *Alarms / Targets* on page 80.

NOTE There is a two minute inactivity timer associated with the popup screen.

5.3.1.3 Status Indicators

The lantern at the top of each parameter globe indicates the patient's current status. The color changes as the patient's status changes. The globes may display additional information:

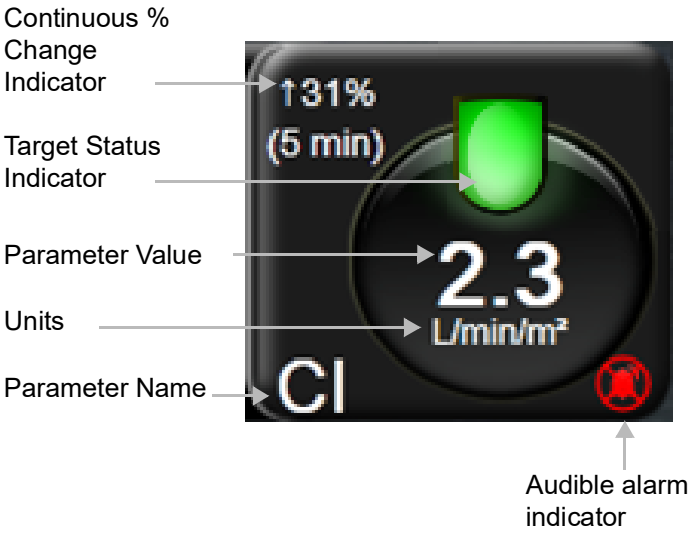
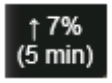


Figure 5-5 Parameter globe

Fault. When a fault condition occurs, the fault message(s) will be displayed on the status bar until the fault 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 globe displays the last value, time, and date at which the parameter was measured.

Continuous % Change Indicator. This indicator displays the percentage of change, followed by the time period over which it changed. See *Time Intervals / Averaging* on page 76 for configuration options**.**



Target Status Indicators. The colored indicator at the top of each monitoring globe indicates the patient's clinical status. For indicator colors and their clinical indications, See table 7-2, "Target status indicator colors," on page 82.

5.3.2 Graphical Trend Monitoring View

The graphical trend screen displays the current status and history of monitored parameters. The amount of history shown for monitored parameters can be configured by adjusting the time scale.

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. The colors match those of the clinical target indicator (lantern) on the key parameter globes in the graphical trend graph when targets are enabled for the parameter. The alarm limits for each parameter are displayed as colored arrows on the graph y-axis.

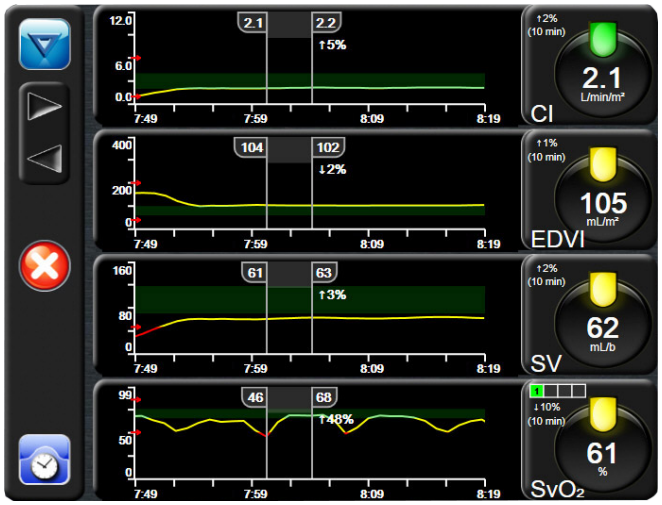


Figure 5-6 Graphical trend screen

To change the time scale of a displayed parameter, touch outside of the plot area along the x or y-axis, and a scale popup menu will appear. Touch the value side of the **Graphical Trend Time** button to select a different time period.

5.3.2.1 Graphical Trend Scroll Mode

Up to 72 hours of monitored parameter data can be viewed by scrolling back. The date appears above the parameter data during scrolling. Two dates will appear when appropriate. To start scrolling, touch the appropriate scroll mode button. Keep touching the scroll mode button to increase the scroll speed. The screen will return to live mode two minutes after the scroll button has been touched, or if the back button is touched. The scroll rate will appear below the scroll buttons.

Table 5-1 Graphical trend scroll rates

Scroll setting	Description
>>>	Scrolls at two times the current time scale
>>	Scrolls at the current time scale (one graph width)
>	Scrolls at half the current time scale (one-half graph width)

While in scroll mode the user can scroll to data older than the current time scale displays.

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

5.3.2.2 Intervention Events

While in the graphical trend screen, selecting the intervention icon provides a menu of intervention types, details and a notes section.

Figure 5-7 Graphical trend- intervention window

To enter a **New Intervention**:

1. Select the **Intervention** type from the **New Intervention** menu on left.
2. Select **Detail** from right menu tab. **Unspecified** is set as a default.
3. Select the keyboard icon to enter notes (optional).
4. Touch the enter icon .

To enter a previously used **Intervention**:

1. Select the **Intervention** from the **Recents** list tab.
2. To add, edit, or remove a note, touch the keyboard icon .
3. Touch the enter icon .

Table 5-2 Intervention events

Intervention	Indicator	Type
Intervention	(green)	Inotrope Vasodilator Vasopressor PEEP
Positional	(purple)	Passive Leg Raise Trendelenburg
Fluids	(blue)	Red Blood Cells Colloid Crystalloid
Custom	(gray)	Custom Event

After selection of the intervention type, markers indicating the intervention are visually displayed on all graphs. These markers can be selected for more information. Upon touching the marker, an information balloon will appear. See figure 5-8: "Graphical trend screen - intervention information balloon". The information balloon displays the specific intervention, date, time, and notes pertaining to the intervention. Touching the edit button allows the user to edit intervention time, date, and note. Touching the exit button closes the balloon.

NOTE The intervention information balloon has a 2 minute time out.

Intervention Editing. The time, date, and associated note for each intervention can be edited after initial entry:

1. Touch the intervention event indicator associated with the intervention to be edited.
2. Touch the edit icon located on the information balloon.
3. To change the time of the selected intervention, touch on **Time Adjust,** and enter the updated time on keypad.
4. To change the date, touch on **Date Adjust**, and enter the updated date on keypad.
5. Touch the keyboard icon to enter or edit notes.
6. Touch the enter icon .

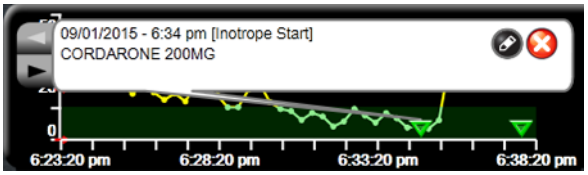


Figure 5-8 Graphical trend screen - intervention information balloon

5.3.3 Tabular Trends

The tabular trends screen displays selected key parameters and their history in a tabular format.

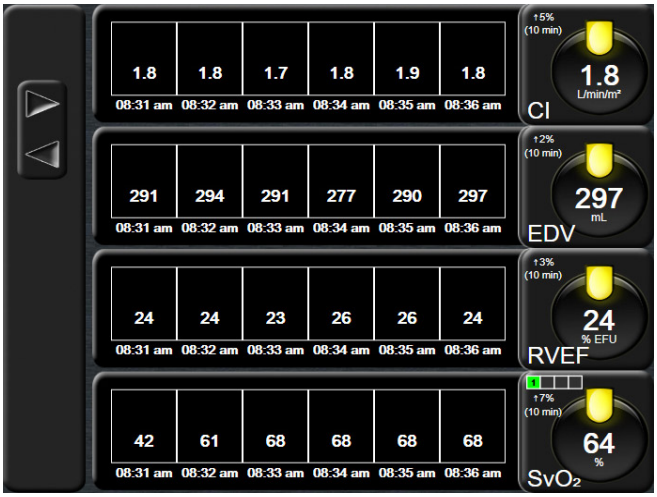


Figure 5-9 Tabular trend screen

1 To change the interval between values, touch inside the table.

2 Select a value on the **Tabular Increment** popup.

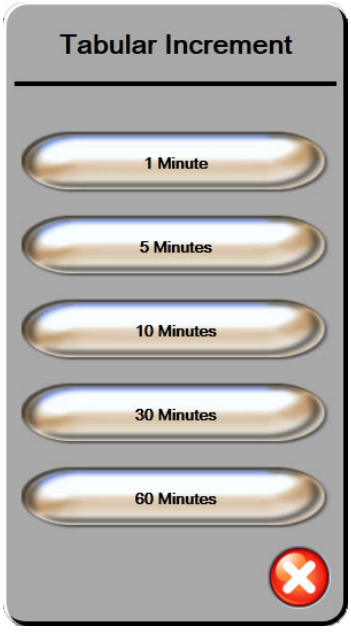


Figure 5-10 Tabular increment popup

5.3.3.1 Tabular Trend Scroll Mode

Up to 72 hours of data can be viewed by scrolling back. The scroll mode is based on the number of cells. Three scroll speeds are available: 1x, 6x, and 40x.

While the screen scrolls, the date appears above the table. If the time period overlaps two days, both dates will appear on the screen.

1 To start scrolling, touch and hold one of the gray arrows. The scroll rate will appear above the scroll icons.

Table 5-3 Tabular trend scroll rates

Setting	Time	Speed
1X	one cell	Slow
6X	six cells	Moderate
40X	forty cells	Fast

2 To exit scroll mode, stop touching the scrolling arrow or touch the return icon  .

NOTE The screen will return to live mode two minutes after the last touch of the scroll arrow icon or if the return icon is touched.

5.3.4 Graphical/Tabular Trends Split

The graphical/tabular trends split screen displays a combination of the graphical trend and tabular trend monitoring views. This display is useful for viewing the current status and history of selected monitored parameters in graphical format and other selected monitored parameters in tabular format at the same time.

If two key parameters are selected, the first key parameter is displayed in graphical trend format, and the second in tabular trend format. Key parameters can be changed by touching the parameter label located on the parameter globe. If more than two key parameters are selected, the first two parameters are displayed in graphical trend format, and the third and fourth — if a fourth is selected — are displayed in tabular trend format. The time scale for data displayed on any key parameter graphical trend view(s) is independent of the time scale displayed on the tabular trend view(s). For more information on the graphical trend view see *Graphical Trend Monitoring View* on page 55. For more on tabular trend view, see *Tabular Trends* on page 59.

5.3.5 Physiology Screen

The Physiology screen is an animation depicting the interaction between the heart, blood, and vascular system. Continuous parameter values are displayed in association with the animation.

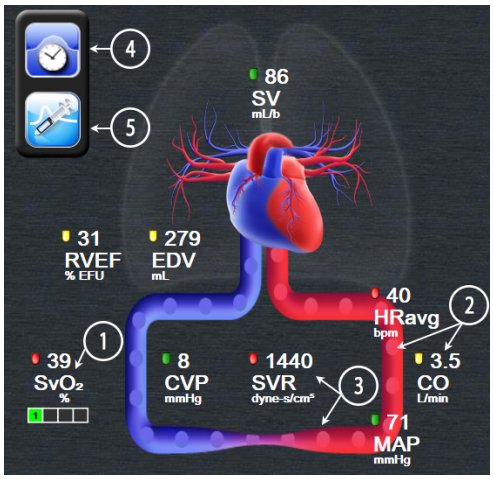


Figure 5-11 Physiology screen

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. Key features of this screen are numbered shown in figure 5-11. This example is of the continuous physiology screen during active monitoring with the HemoSphere Swan-Ganz module and slaved-in ECG, MAP, and CVP signals.

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) 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, as SVR =[(MAP-CVP)/CO]*80. 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.

NOTE The alarms/targets settings can be adjusted through the Alarms / Targets setting screen (see *Alarms / Targets Setup Screen* on page 83) or by selecting the desired parameter as a key parameter, and accessing the parameter Alarms/Targets popup window by touching inside of the parameter globe.

4. From the continuous mode, touch the clock/waveform icon at the upper left, to go to the intermittent physiology screen. This button only appears when there is historical intermittent data available. See *5.3.5.1 Historic Physiology Screen*, below.
5. Touch the syringe to go to the iCO screen to shoot bolus cardiac output.

5.3.5.1 Historic Physiology Screen

The historic physiology screen displays both intermittent bolus data and a snapshot of continuous data overlaid on a visual representation of the heart and circulatory system. The circulatory system has several variations to illustrate the patient's condition at the time of the bolus set — for example, the vessels constrict.

Up to 36 historic physiology records may be viewed via the horizontal tabs composite along the top of the screen.

5.3.6 Cockpit Screen

This monitoring screen, shown in figure 5-12, 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 globes, the value within the globe will flash when the parameter is alarming.

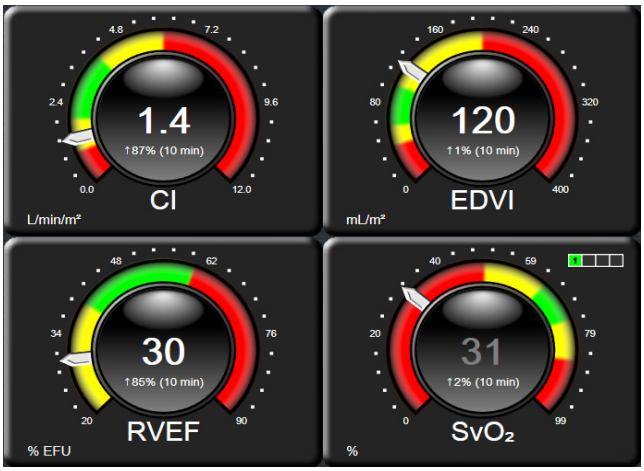


Figure 5-12 Cockpit monitoring screen

The key parameter globes shown on the cockpit screen display a more complex target and alarm indicator than the standard parameter globe. 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.

5.3.7 Physio Relationship

The physio relationship screen depicts the balance between oxygen delivery (DO_2) and oxygen consumption (VO_2). It automatically updates as parameter values change so the values are always current. The connecting lines highlight the relationship of the parameters to each other.

5.3.7.1 Continuous and Historical Modes

The physio relationship screen has two modes: continuous and historical. When in continuous mode, the intermittent and derived values are always displayed as unavailable.

Figure 5-13 Physio relationship screen

1. The vertical lines above and below the parameters appear in the same color as the parameter lantern.
2. Vertical lines that directly connect two parameters will appear in the same color as the parameter lantern below (for example, between SVRI and MAP).
3. The horizontal lines are the same color as the line above them.
4. The left bar appears after a bolus set is performed. Touch the clock/waveform icon to display historical data (see figure 5-13).
5. Touch the iCO icon to open the thermodilution new set configuration screen.

NOTE Before a thermodilution set is performed and before any values are entered (see *5.3.7.2 Parameter Boxes* below) the clock/waveform and iCO icons do not appear. Only the available continuous parameters are displayed.

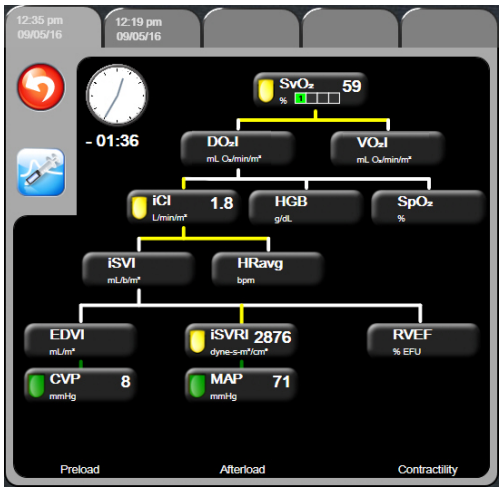


Figure 5-14 Historic physio relationship data screen

NOTE The historic physio relationship screen displays most of the parameters available on the system at a point in time. The screen displays lines connecting the parameters, highlighting the relationship of the parameters to each other. The historic physio relationship screen displays the configured (1-4) key parameters on the right hand side of the screen. There is a horizontal tab composite at the top that allows the user to navigate through the database of historic records. The record times correspond to thermodilution bolus sets and derived value calculations.

The historic physio relationship screen allows the user to enter parameters used to calculate derived parameters **DO_2** and **VO_2**, on only the most recent record. The values entered are for the time of the record and not the current time.

The historic physio relationship screen is accessed through the clock/waveform icon on the continuous physio relationship screen. Touch the return icon to return to the continuous physio relationship screen. There is no 2 minute time-out for this screen.

To calculate **DO_2** and **VO_2**, the partial pressure of arterial (PaO_2) and venous (PvO_2) oxygen is required. For the historic physio relationship screen, a PaO_2 and PvO_2 value of zero (0) is used. To calculate DO_2 and VO_2 using values other than zero (0) for PaO_2 and PvO_2, use the **Derived Value Calculator** (see section 5.4.1 on page 66).

5.3.7.2 Parameter Boxes

Each small parameter box displays:

- Parameter name
- Parameter units
- Parameter value (if available)
- Clinical target status indicator (if a value is available)

If the parameter is in a fault state, the value is blank, indicating it is or was unavailable at the time of the display.

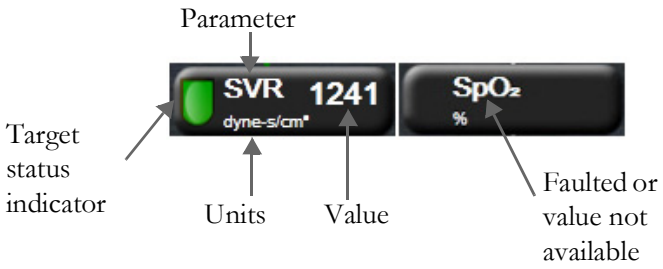


Figure 5-15 Physio relationship parameter boxes

5.3.7.3 Setting Targets and Entering Parameter Values

To change the target settings or enter a value, touch a parameter to bring up the target/enter popup. The physio relationship target/enter popup will be displayed when the following physio relationship small parameter boxes are touched:

- **HGB**
- **SpO_2**
- **SvO_2/$ScvO_2$** (when no HemoSphere oximetry cable measurement is available)
- **CVP** (when analog pressure signal input not configured)
- **MAP** (when analog pressure signal input not configured)
- **HRavg** (when ECG signal input not configured)

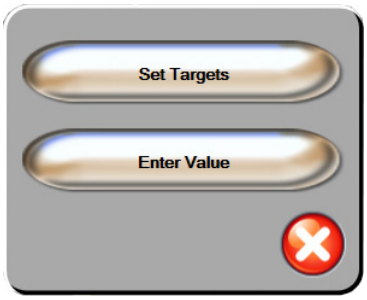


Figure 5-16 Physio relationship target/enter popup

When the value is accepted, a new time-stamped historic physio relationship record is created. It includes:

- Current continuous parameter data
- The entered value and any derived calculated values.

The historic physio relationship screen is shown with the newly created record; you can then enter the rest of the manually entered values to calculate any derived values.

5.4 Clinical Actions

Most options on the clinical actions menu are related to the current monitoring mode (e.g., while monitoring with the HemoSphere Swan-Ganz module). The following clinical actions are available across all monitoring modes.

5.4.1 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 include: DO_2, VO_2, SVR, LVSWI and RVSWI.

1. Touch the clinical actions icon → **Derived Value Calculator** icon .
2. Enter the required values and the derived calculations will automatically display.
3. Touch the home icon to return to the monitoring screen.

5.4.2 Event Review

Use **Event Review** to view parameter-related and system events that occurred during monitoring. Up to 72 hours of events are recorded in order with the most recent event at the top.

1. Touch the clinical actions icon → **Event Review** icon .
2. To scroll up or down, touch the arrow keys.
3. Touch the home icon to return to the monitoring screen.

The following events are included in the clinical event review log.

Table 5-4 Reviewed events

Event	Log time
CO Monitoring Started	When CO Monitoring is started
CO Monitoring Stopped	When the user or system stops CO monitoring
CO Cable Test Passed	When the Patient CCO Cable Test was performed and passed
Draw Blood	The Draw option is selected in the In vivo Calibration Draw Screen
HGB Update	Oximetry cable update completes following the HGB update process
iCO Bolus Performed	When an iCO bolus is performed
In vitro Calibration	When oximetry cable update completes following the In vitro calibration process
In vivo Calibration	When oximetry cable update completes following In vivo calibration process
Light Out of Range	When the Oximetry Light Range Fault occurs
Monitoring Paused	Active monitoring paused to prevent audible alarms and parameter monitoring
Monitoring Resumed	Normal monitoring resumed. Audible alarms and parameter monitoring are active

Table 5-4 Reviewed events (continued)

Event	Log time
Oximetry Disconnected	An oximetry cable disconnection is detected
Recall Oximetry Data	When recalled oximetry calibration data is accepted by the user
System Restart Recovery	When the system has resumed monitoring without being prompted following a power cycle
Time Change	The system clock is updated

5.5 Information Bar

The information bar appears on all active monitoring screens and most clinical action screens. It displays the current time, date, monitoring mode, battery status, and the lock screen symbol. While monitoring with the HemoSphere Swan-Ganz module, the CO countdown, blood temperature, and slaved in heart rate may also be displayed. When the monitor has a HIS or Wi-Fi connection, the status will be displayed. See table 8-1 on page 92 for Wi-Fi status symbols and table 8-2 on page 93 for HIS connectivity status symbols. Figure 5-17 shows an example of an information bar while monitoring with the HemoSphere Swan-Ganz module with a slaved in ECG heart rate.

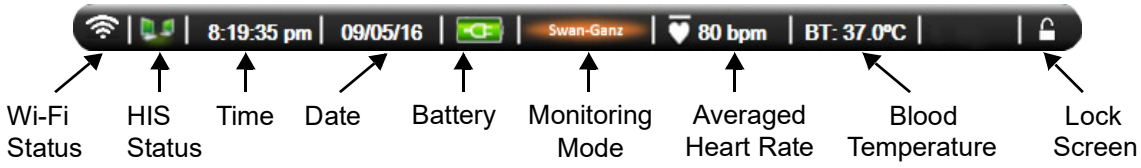


Figure 5-17 Information Bar - HemoSphere Swan-Ganz Module

NOTE Figure 5-17 is an example of an information bar with U.S. standard defaults. To see the defaults for all languages, see table D-6, "Language default settings," on page 149.

5.5.1 Battery

The HemoSphere advanced monitor allows for uninterrupted monitoring during power loss when the HemoSphere battery pack is installed. Battery life is indicated on the information bar by the symbols shown in table 5-5. For more information on battery installation, see *Battery Installation* on page 39. 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 157.

Table 5-5 Battery status

Battery symbol	Indication
	The battery has greater than 50% charge remaining.
	The battery has less than 50% charge remaining.

Table 5-5 Battery status (continued)

Battery symbol	Indication
	The battery has less than 20% charge remaining.
	The battery is charging and connected to mains power.
	The battery is fully charged and connected to mains power.
	The battery is not installed.

WARNING To prevent any interruptions to monitoring during power loss, always use the HemoSphere advanced monitor with the battery inserted.

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

5.5.2 Lock Screen

If the monitor is being cleaned or moved, lock the screen. For cleaning instructions refer to *Cleaning the Monitor and Modules* on page 153. The screen will automatically unlock once the internal timer has counted down.

1. Touch the lock screen icon.
2. Touch the time that the screen will remain locked on the **Lock Screen** popup.

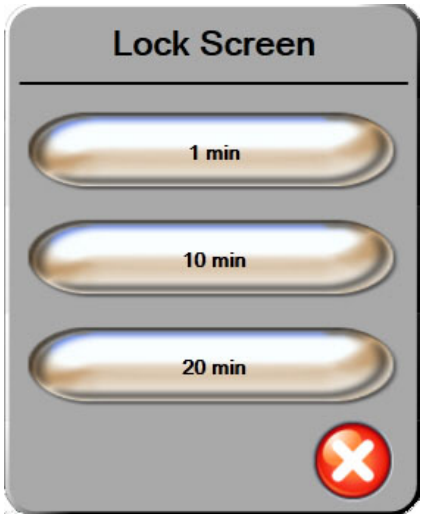


Figure 5-18 Lock screen

3. A large lock icon will appear to the right of the information and status bar.
4. To unlock the screen, touch and hold the large lock icon  .

5.6 Status Bar

The status bar appears at the bottom of all active monitoring screens. 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.

Figure 5-19 Status bar

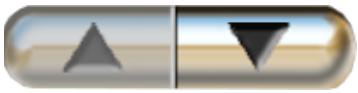
5.7 Monitor Screen Navigation

There are several standard navigational procedures on the screen.

5.7.1 Vertical Scrolling

Some screens will have more information than fits on the screen at one time. If vertical arrows appear on a review list, touch the up or down arrow to see the next set of items.

If selecting from a list, the vertical scroll arrows move up or down one item at a time.



5.7.2 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.

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.

List buttons. Some of the screens have buttons that appear to be split in two.

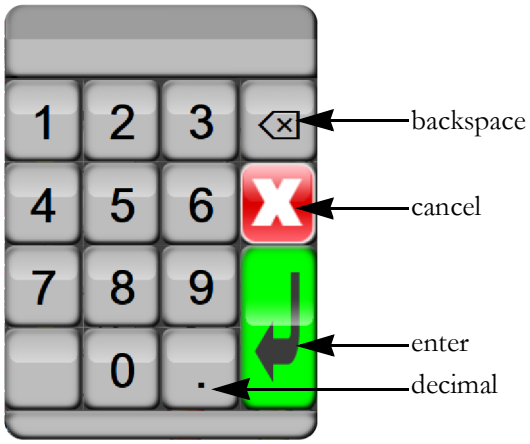
In these cases, touching anywhere on the button reveals a list of selectable items. The right side of the button displays the current selection.

Value button. Some screens have square buttons as shown below. Touch the button to display a keypad.

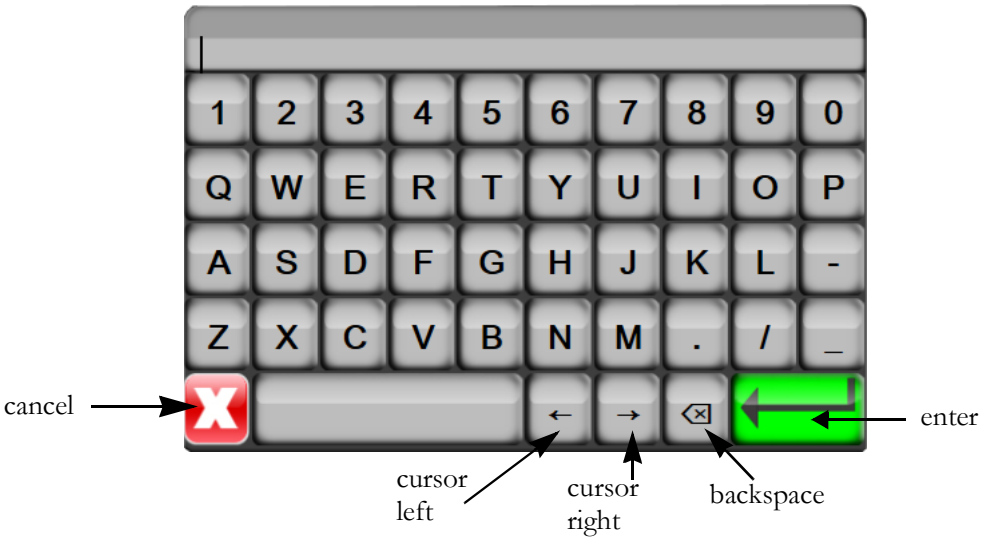
Toggle button. When an option exists between two choices, such as on/off, a toggle button appears.

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

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



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



6

User Interface Settings

Contents

6.1 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 6-1 below.

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

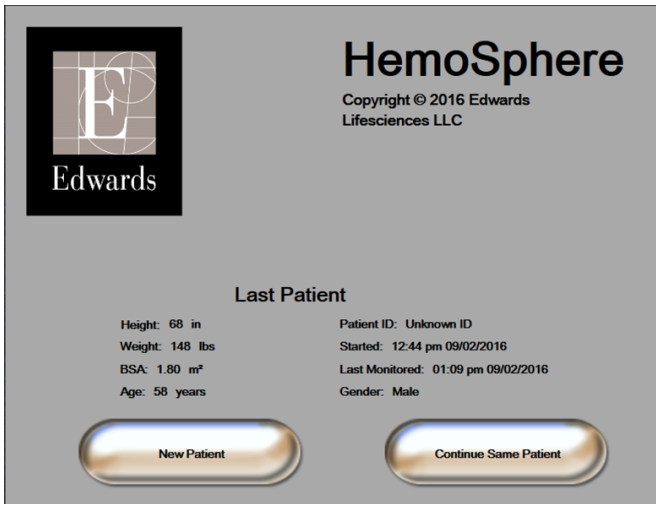


Figure 6-1 New or continuing patient screen

6.1.1 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 advanced monitor. 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 6-1). Touch **New Patient** and continue to step 6.

OR

If the monitor is already on, touch the settings icon and continue to step 2.

2 Touch **Patient Data** button.

3 Touch **New Patient** button.

4 Touch **Yes** button on the confirmation screen to start a new patient.

5 The **New Patient Data** screen appears. See figure 6-2.

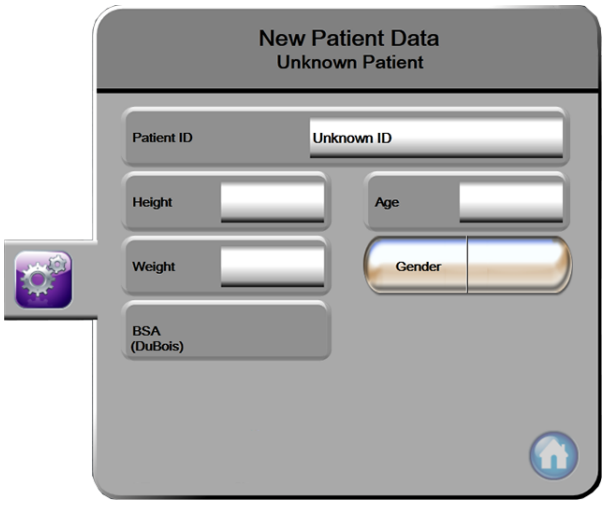


Figure 6-2 New Patient Data screen

6 Touch the enter key on the keypad/keyboard to save each patient demographic selection value and return to the patient data screen.

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

8 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.

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

10 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.

11 Touch **Gender** and select **Male** or **Female**.

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

13 Touch the home icon and refer to instructions for starting monitoring with the desired hemodynamic monitoring technology.

NOTE The home icon is disabled until all patient data is entered.

6.1.2 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 **Continue Same Patient**.

6.1.3 View Patient Data

1 Touch settings icon .

2 Touch **Patient Data** button to see patient data. The screen will also include a **New Patient** button.

3 Touch the return icon to return to the settings screen.

6.2 Monitor Settings

The **Monitor Settings** screen allows the user to change several monitor related settings.

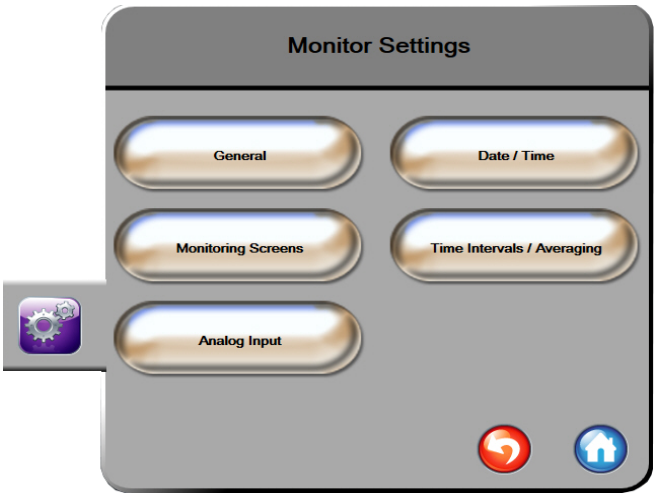


Figure 6-3 Monitor Settings

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

6.2.1 General Monitor Settings

The General Monitor Settings are those that affect every screen. These are the display language, units used, alarm volume, and snapshot sound.

The HemoSphere advanced monitor interface is available in several languages. A language selection screen appears the first time the HemoSphere advanced monitor is started. See figure 3-7, "Language selection screen," on page 42. The language screen will not appear again, but the display language can be changed at any time.

The selected language determines the default time and date format. These can also be changed independently of the language selected.

NOTE If power is lost and restored to the HemoSphere advanced monitor, 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.

6.2.1.1 Change Language

1 Touch the settings icon .

2 Touch the **Monitor Settings** button.

3 Touch **General** button.

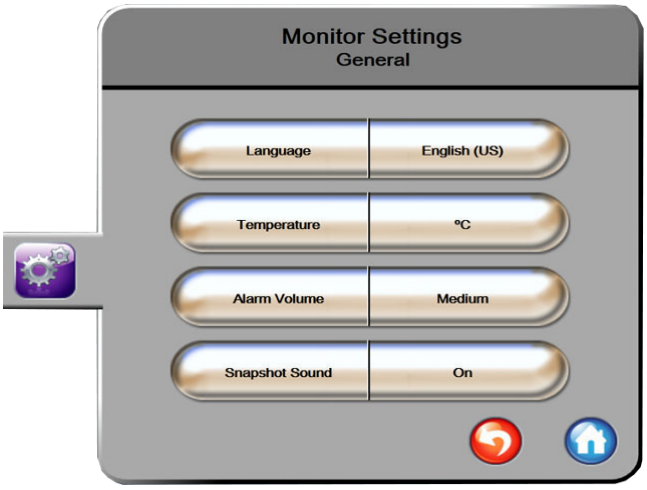


Figure 6-4 General Monitor Settings

4 Touch the value section of the **Language** button and select the desired display language.

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

NOTE See appendix D for all language default settings.

6.2.2 Change Date and Time Display

English (US) dates default to **MM/DD/YYYY**, and the time defaults to a **12 Hour** clock.

When an international language is selected, the date defaults to the format found in appendix D: *Monitor Settings and Defaults*, and the time defaults to a 24 hour clock.

1 Touch the settings icon .

2 Touch **Monitor Settings** button.

3 Touch **Date / Time** button.

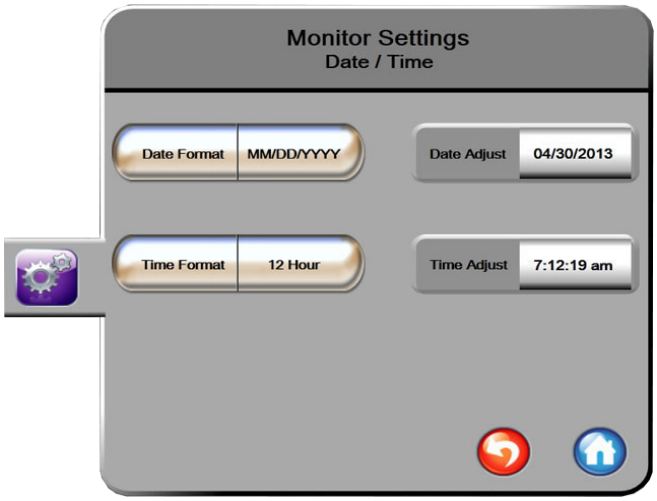


Figure 6-5 Date / Time Settings

4 Touch the value section of the **Date Format** button and touch the desired format.

5 Touch the value section of the **Time Format** button and touch the desired format.

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

6.2.2.1 Adjust Date or Time

The system time can be reset if necessary. When the time or date is changed, trended data is updated to reflect the change. Any retained data is updated to reflect the time change.

NOTE The time clock of the HemoSphere advanced monitor does not automatically adjust for daylight saving time (DST). This adjustment needs to made using the following instructions.

1 Touch the settings icon .

2 Touch **Monitor Settings** button.

3 Touch **Date / Time**.

4 To change the date, touch the value section of the **Date Adjust** button and enter the date on the keypad.

5 To change the time, touch the value section of the **Time Adjust** button and enter the time.

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

6.2.3 Monitoring Screens Settings

From the **Monitoring Screens** settings screen, the user can set physiology and physio relationship monitoring screen options.

1. Touch the settings icon  .
2. Touch the **Monitor Settings** button.
3. Touch the **Monitoring Screens** button.
4. Select the **Indexed or Non-Indexed** toggle for parameters in the physiology and physio relationship screens.

6.2.4 Time Intervals / Averaging

The **Time Intervals / Averaging** screen lets the user select the continuous % change time interval.

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

1. Touch the settings icon  .
2. Touch **Parameter Settings** button.
3. Touch **Time Intervals / Averaging** button.
4. Touch the right side of the **Continuous % Change Interval** value button and touch one of the following time interval options:

   - None
   - 5 min
   - 10 min
   - 15 min
   - 20 min
   - 30 min

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

6.2.5 Analog Pressure Signal Input

While performing CO monitoring, the HemoSphere advanced monitor can also calculate SVR by utilizing analog pressure signal inputs from a connected patient monitor.

NOTE Connecting to external input devices allows additional information to be displayed. For example, when MAP and CVP are available continuously from a bedside monitor, SVR is displayed if configured in a parameter globe. MAP and CVP are displayed on the physio relationship and physiology monitoring screens.

WARNING The analog communication ports of the HemoSphere advanced monitor share a common ground that is isolated from the catheter interface electronics. When connecting multiple devices to the HemoSphere advanced monitor, all devices should be provided with isolated power to avoid compromising the electrical isolation of any of the connected devices.

Risk and Leakage current of the final system configuration must comply with IEC 60601-1:2005/A1:2012. It is the responsibility of the user to ensure compliance.

Accessory equipment connected to the monitor must be certified according to IEC/EN 60950 for data-processing equipment or IEC 60601-1:2005/A1:2012 for electro-medical equipment. All combinations of equipment must be in compliance with IEC 60601-1:2005/A1:2012 systems requirements.

CAUTION When connecting the HemoSphere advanced monitor to external devices, refer to the external device's instruction manual for complete instructions. Verify proper operation of the system before clinical use.

Once the bedside monitor has been configured for the desired parameter output, connect the monitor via an interface cable to the selected analog input port on the HemoSphere advanced monitor.

NOTE A compatible bedside monitor must provide an analog output signal.

Please contact your local Edwards representative to obtain the correct HemoSphere advanced monitor analog input interface cable for your bedside monitor.

The following procedure describes how to configure the analog input ports of the HemoSphere advanced monitor.

1. Touch the settings icon  .
2. Touch **Monitor Settings** button.
3. Touch **Analog Input** button.
4. Select **MAP** from the **Parameter** list button for the numbered analog port where MAP is connected (**1** or **2**). The default setting values for MAP will be displayed.

NOTE If an analog signal is not detected on the selected port, "**Not Connected**" will be displayed below the **Port** list button.

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

5. Select **CVP** in the **Parameter** list button for the numbered analog port where CVP is connected. The default setting values for CVP will be displayed.

NOTE The same parameter may not be configured on more than one analog input at the same time.

6 If the default values are correct for the bedside monitor being used, touch the home icon.

If the default values are not correct for the bedside monitor being used (refer to the bedside monitor operator's manual), the user can modify the voltage range, full scale range, or perform the calibration option described in section 6.2.5.1 of this chapter.

Touch the **Full Scale Range** value button to change the displayed full scale signal value. Table 6-1 below shows the allowable input values for full scale range based on the selected parameter.

Table 6-1 Analog input parameter ranges

Parameter	Full Scale Range
MAP	0 to 510 mmHg (0 kPa to 68 kPa)
CVP	0 to 110 mmHg (0 kPa to 14.6 kPa)

NOTE A voltage reading of zero is automatically set to a minimum pressure reading of 0 mmHg (0 kPa). The **Full Scale Range** represents the full scale signal or maximum pressure reading for the selected **Voltage Range**.

Touch the **Voltage Range** list button to change the displayed voltage range. The selectable voltage ranges available for all of the parameters are:

- 0 - 1 volts
- 0 - 5 volts
- 0 - 10 volts
- Custom (see *6.2.5.1: Calibration*)

WARNING When switching to a different bedside monitor, always check that the default values listed are still valid. If necessary, reconfigure the voltage range and corresponding parameter range or calibrate.

6.2.5.1 Calibration

The calibration option is required when default values are incorrect, or the voltage range is not known. The calibration process configures the HemoSphere advanced monitor with the analog signal received from the bedside monitor.

NOTE If the default values are correct, do not calibrate.

CAUTION Only properly trained personnel should calibrate the HemoSphere advanced monitor analog ports.

1. Touch the settings icon  .
2. Touch **Monitor Settings** button.
3. Touch **Analog Input** button.
4. Select the desired port number (**1** or **2**) from the **Port** list button and corresponding parameter (**MAP** or **CVP)** from the **Parameter** list button.
5. Select **Custom** from the voltage value popup screen. The **Analog Input Custom Settings** screen will appear.
6. Simulate a full scale signal from the bedside monitor to the selected analog input port on the HemoSphere advanced monitor.
7. Set the maximum parameter value equal to the full-scale signal value.
8. Touch **Calibrate Maximum** button. The **Maximum A/D** value will appear on the **Analog Input Custom Settings** screen.

NOTE If an analog connection is not detected, the **Calibrate Maximum** and **Calibrate Minimum** buttons will be disabled and the Maximum A/D value will be displayed as **Not Connected**.

9. Repeat the process to calibrate the minimum parameter value.
10. Touch the **Accept** button to accept the displayed custom settings and return to the Analog Input Screen.
11. Repeat steps 4-10 to calibrate another port if needed, or touch the home icon  to return to the monitoring screen.

CAUTION The accuracy of continuous SVR depends upon the quality and accuracy of the MAP and CVP data transmitted from the external monitors. Since MAP and CVP analog signal quality from the external monitor cannot be validated by the HemoSphere advanced monitor, actual values and the values (including all derived parameters) displayed by the HemoSphere advanced monitor may not be consistent. The accuracy of continuous SVR measurement, therefore, cannot be guaranteed. To aid in determining the quality of the analog signals, regularly compare the MAP and CVP values displayed on the external monitor to the values displayed on the physio relationship screen of the HemoSphere advanced monitor. Refer to the external input device operator's manual for detailed information regarding accuracy, calibration, and other variables which may impact the analog output signal from the external monitor.

7

Advanced Settings

Contents

7.1 Alarms / Targets

There are two types of alarms on the HemoSphere advanced monitor:

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. Technical alarms are non-latching.

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

For physiological parameters CO/CI, sCO/sCI, SV/SVI, and $ScvO_2/SvO_2$ the upper alarm (red zone) priority is medium and the lower alarm (red zone) priority is high. For the physiological parameters SVR/SVRI, EDV/sEDV, EDVI/sEDVI, and RVEF/sRVEF the alarm priority is always medium. See *Alarm Priorities* on page 148.

Among technical alarms, faults are of medium priority, and will halt operation of the related monitoring activity. Alerts are of low priority and will not halt any monitoring activity. As faults are of higher priority than alerts, alerts will not be alarmed if there are any active faults.

All alarms have an associated text displayed on the status bar. The 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 7-1 below. For additional information, see table 11-1 on page 120.

Table 7-1 Visual alarm indicator colors

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

Edwards

The visual alarm indicator will indicate the highest active alarm priority. 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:

- HemoSphere Swan-Ganz module continuous CO and associated parameters: varies, but is typically around 57 seconds (See *CO Countdown Timer and STAT CO* on page 101).
- Oximetry: 2 seconds

All alarms are logged and stored for the given patient and can be accessed via the Data Download function (see *Data Download* on page 90). The Data Download log is cleared when initiating a new patient (see *New Patient* on page 71). The current patient can be accessed from up to 12 hours following a system power-off.

7.1.1 Silence Alarms

7.1.1.1 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 two minutes. No audio tone for any physiological alarm will be emitted during this two minutes, including new physiological alarms triggered during this time. If a technical alarm is generated during this two-minute period, the audio silence will be cleared, allowing alarm audio tones to resume. The user can also manually clear the two-minute period by pressing the alarm silence button again. Once the two-minute period has elapsed, active physiological alarms will resume audio sound.

If the physiological alarm is a medium priority, the visual alarm indicator (blinking yellow) is also disabled for two minutes. A high priority visual alarm indicator (blinking red) cannot be disabled. For information on physiological alarm priorities, see *Alarm Priorities* on page 148.

NOTE Physiological parameters can be configured to have no alarms. See sections 7.1.5 and7.1.7.

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

7.1.1.2 Technical Alarms

During an active technical alarm, the user can silence the alarm and clear the visual alarm indicator (medium and low priority) by touching the silence audible alarms icon  . The visual alarm indicator and audio tone will remain inactive unless another technical or physiological alarm condition triggers, or the original technical alarm resolves and re-triggers.

7.1.2 Set Alarm Volume

The alarm volume ranges from low to high with a default of medium. It applies to physiological alarms, technical faults, and alerts. Alarm volume can be changed at any time.

1 Touch the settings icon .

2 Touch **Monitor Settings** button.

3 Touch **General** button.

4 Touch the right side of the **Alarm Volume** list button to select the desired volume.

5 Touch the home icon to return to the monitoring screen

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.

7.1.3 Set Targets

Targets are visual indicators (lanterns) set by the clinician to indicate if the patient is in the ideal target zone (green), warning target zone (yellow), or alarm zone (red). 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 a audible alarm.

Parameters that can "Alarm" are indicated by a bell icon in the **Alarms / Targets** settings screen. High/low alarms by default also become the ranges for the red caution zone for that parameter. Parameters which DO NOT have the ability to set a high/low alarm will not have a bell icon in the **Alarms/Targets** settings screen for that parameter but can still have target ranges set.

Table 7-2 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.

Table 7-2 Target status indicator colors

Color	Indication
Red 	Red alarm and/or target zones can be considered “Alarm” parameters indicated by a bell icon in the **Alarms /Targets** 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 have a bell icon in the **Alarms /Target**s 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.

7.1.4 Alarms / Targets Setup Screen

The **Alarms / Targets** Setup Screen allows the clinician to view and set up alarms and targets for each key parameter. From the **Alarms/Targets** screen, located within the **Advanced Setup** settings menu, the user can adjust targets and enable/disable audible alarms. Any features accessed through the **Advanced Setup** settings menu are passcode protected and should only be altered by experienced clinicians. The settings for each key parameter are displayed in a parameter box. The currently configured key parameters are the first set of key parameters displayed. The remaining key parameters are displayed in a defined order. The parameters also indicate what the target ranges are based on: Custom Default, Edwards Default, and Modified.

Table 7-3 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.
Modified	Parameter target range was changed for this patient.

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

To modify **Alarms / Targets**:

1. Touch the settings icon  .
2. Touch **Advanced Setup** button and enter the required password.
3. Touch **Parameter Settings** button → **Alarms / Targets** button.

4 Touch anywhere in a parameter box to display the **Alarms / Targets** popup for the parameter.

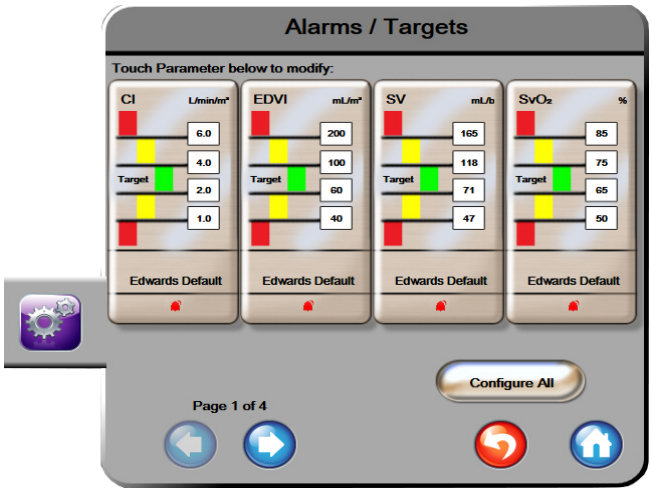


Figure 7-1 Alarms / Targets configuration

NOTE There is a 2 minute inactivity timer associated with this screen.

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

7.1.5 Configure All Targets

Targets can easily be configured or changed all at the same time. From the Configure All screen, the user can:

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

1 Touch the settings icon  .

2 Touch **Advanced Setup** button and enter the required password.

3 Touch **Parameter Settings** button → **Alarms / Targets** button.

4 Touch the **Configure All** button.

5 To enable or disable all audible alarms for all parameters, touch the **Disable All** or **Enable All** buttons within the **Audible Alarm** box.

6 To enable or disable all targets for parameters that support target ranges, touch the **Target On/Off** toggle button.

7 To restore all settings to your custom defaults, touch **Restore All to Custom Defaults**. The message, "**This action will restore ALL Alarms and Targets to the Custom Defaults.**" appears.

8 Touch **Continue** button on the confirmation popup to confirm the restore.

9 To restore all settings to the Edwards defaults, touch **Restore All to Edwards Defaults.** The message, "**This action will restore ALL Alarms and Targets to the Edwards' Defaults**." appears.

10 Touch **Continue** button on the confirmation popup to confirm the restore.

7.1.6 Set Custom Defaults

When custom defaults are set up, they can be enabled or disabled at any time through the Configure All or individual Alarms/Targets Settings screen.

1 Touch the settings icon .

2 Touch **Advanced Setup** button and enter the required password.

3 Touch **Parameter Settings** button → **Alarms / Targets** button.

4 Touch the **Configure All** button.

5 Touch the **Set Custom Defaults** button.

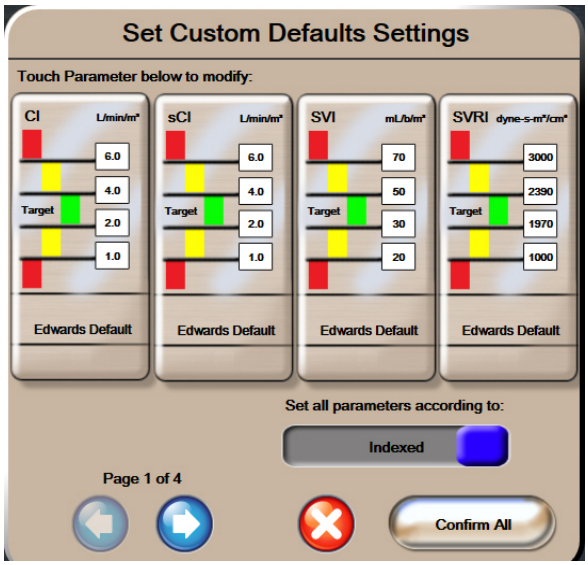


Figure 7-2 Set custom default Alarms / Targets

6 The defaults can be displayed as **Indexed** or **Non-Indexed**. Choose the desired format on the **Set all parameters according to:** toggle button.

7 Touch the parameter of interest.

8 Touch the value button for each target setting and enter the desired value. The corresponding indexed or non-indexed value for that parameter will be set automatically.

9 Continue steps 7 and 8 for each parameter. Touch the right or left arrow at the bottom of the screen to display the next or previous set of parameters.

10 When all desired parameters have been modified, touch **Confirm All**.

7.1.7 Configure Targets and Alarms for One Parameter

The **Alarms/Targets** popup lets the user set up alarm and target values for the selected parameter. The user can also enable or disable the audible alarm. 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 globe to open the alarms/targets popup for that parameter. The alarms/targets popup is also available on the physio relationship screen by touching a parameter box.
2. To disable the audible alarm for the parameter, touch the **Audible Alarm** icon at the top right of the popup.

NOTE Parameters that DO NOT have the ability to set a high/low alarm will not have an **Audible Alarm** icon on the **Alarms / Targets** popup.

3. To disable visual targets for the parameter, touch the **Target** enabled icon at the top left of the popup. The target indicator for that parameter will appear gray.
4. Use the arrows to adjust the zone settings or touch the value button to open a numeric keypad.

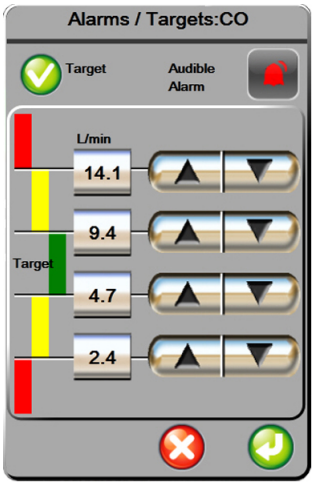


Figure 7-3 Set individual parameter alarms and targets

5. When the values are correct, touch the enter icon.
6. To cancel, touch the cancel icon.

WARNING Visual and audible physiological alarms are activated only if the parameter is configured on the screens as a key parameter (1-4 parameters displayed in parameter globes). If a parameter is not selected and displayed as a key parameter, the audible and visual physiological alarms are not triggered for that parameter.

7.2 Adjust Scales

The graphical trend data fills the graph from left to right with the most recent data at the right. The parameter scale is on the vertical axis with the time scale on the horizontal.

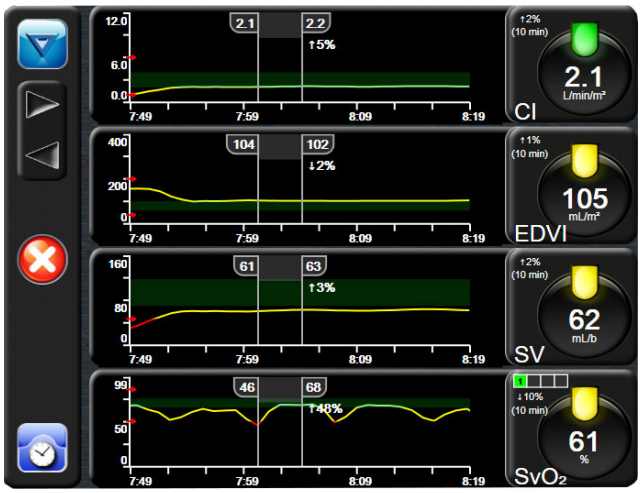


Figure 7-4 Graphical trend screen

The scales setup screen allows the user to set up both the parameter and time scales. The key parameters are at the top of the list. Use the horizontal scroll buttons to see additional parameters.

1. Touch the settings icon .
2. Touch **Advanced Setup** button and enter the required password.
3. Touch **Parameter Settings** button → **Adjust Scales** button.

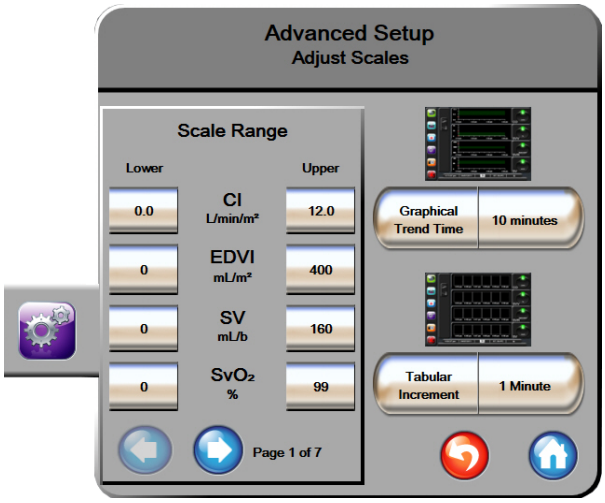


Figure 7-5 Adjust scales

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

4 For each parameter, touch the **Lower** button to enter the minimum value to appear the vertical axis. Touch the **Upper** button to enter the maximum value. Use the horizontal scroll icons to view additional parameters.

5 Touch the right side of the **Graphical Trend Time** value button to set the total amount of time displayed on the graph. The options are:

- 3 minutes
- 5 minutes
- 10 minutes
- 15 minutes
- 30 minutes
- 1 hour
- 2 hours (default)
- 4 hours
- 6 hours
- 12 hours
- 18 hours
- 24 hours
- 48 hours

6 Touch the right side of the **Tabular Increment** value icons to set the amount of time to each tabbed value. The options are:

- 1 minute (default)
- 5 minutes
- 10 minutes
- 30 minutes
- 60 minutes

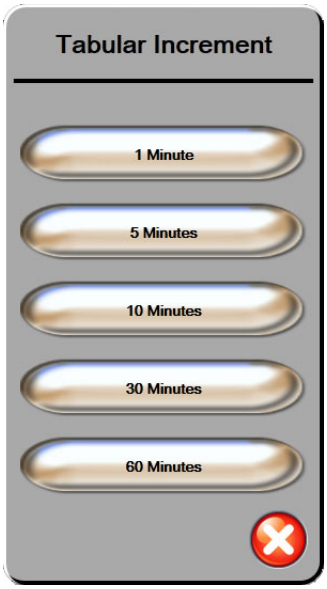


Figure 7-6 Tabular increment popup

7 To advance to the next set of parameters, touch the arrow at the bottom left.

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

7.3 Serial Port Setup

Use the **Serial Port Setup** screen to configure the serial port for digital data transfer. The screen displays until the return icon is touched

1. Touch the settings icon  .
2. Touch **Advanced Setup** button and enter the required password.
3. Touch **Serial Port Setup** button.
4. Touch the list button of any serial port setup parameter to change the default value shown.
5. Touch the return icon  when configuration of serial port settings is complete.

NOTE A RS232 9 pin serial port is available for real time communication to support patient monitoring systems through the IFMout protocol.

7.4 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 advanced monitoring platform user interface retains the same functionality as a fully operational platform. Simulated patient demographics must be entered to demonstrate Swan-Ganz technology 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  .
2. Touch the **Demo Mode** button.

NOTE When the HemoSphere advanced monitoring platform runs in **Demo Mode**, all audible alarms are disabled

3. Touch **Yes** on the **Demo Mode** confirmation screen.
4. See chapter 9: *HemoSphere Swan-Ganz Module Monitoring* for details on monitoring with the HemoSphere Swan-Ganz module.
5. The HemoSphere advanced monitoring platform must be restarted prior to monitoring a patient.

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

7.5 Engineering

The engineering menu can only be operated by a system engineer and is password protected. If an error is encountered, start by referring to chapter 11: *Troubleshooting* .

8

Data Export and Connectivity Settings

Contents

8.1 Export Data

The **Export Data** screen lists a number of data export features of the HemoSphere advanced monitor. This screen is password protected. From this screen clinicians can export diagnostic reports, delete monitoring sessions, or export monitoring data reports. For more on exporting monitoring data reports, see below.

8.1.1 Data Download

The **Data Download** screen allows the user to export monitored patient data to a USB device in Windows Excel XML 2003 format.

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

1. Touch the settings icon  .
2. Touch the **Export Data** button.
3. Enter password when prompted in **Export Data Password** popup window.
4. Make sure an approved Edwards USB device has been inserted.

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

5. Touch the **Data Download** button.

Monitoring Data. To generate a spreadsheet of monitored patient data:

1 Touch the value side of the Interval button and select the 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
2 Touch the **Start Download** button.

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

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

All monitored patient data may be cleared by the user. Touch the **Clear All** button and confirm to clear.

8.2 Clear Data and Settings

The **Clear Data and Settings** screen allows the user to restore the factory defaults. For more information on factory defaults, see below.

8.2.1 Restore Factory Defaults

When the defaults are restored, the HemoSphere advanced monitor stops all functions and restores the system to a factory default state.

CAUTION Restore Defaults replaces all settings with factory defaults. Any settings changes or customizations will be permanently lost. Do not restore defaults while monitoring a patient.

1 Touch the settings icon  .
2 Touch the **Advanced Setup** button.
3 Enter **Advanced Setup Password**. See service manual for clinician passcode.
4 Touch **Clear Data and Settings** button.
5 Touch **Restore Factory Defaults** button.
6 A confirmation screen appears. Touch **Yes** to continue.
7 Turn the monitor power off and then follow the start-up process.

8.3 Wireless Settings

The HemoSphere advanced monitor can connect to available wireless networks.

1 Touch the settings icon  .
2 Touch the **Advanced Setup** button and enter password. See service manual for clinician passcode.

3 Touch the **Wireless** button.

4 Select the desired wireless network from the list of available connections and enter the password if required.

NOTE Do not connect to an unrecognized or unsecured network. See *Cyber Security* on page 95.

Wi-Fi connection status is indicated on the information bar by the symbols shown in table 8-1.

Table 8-1 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

8.4 HIS Connectivity

The HemoSphere advanced monitor has the ability to interface with the Hospital Information Systems (HIS) to send and receive patient demographics and physiological data. The HemoSphere advanced monitor supports Health Level 7 (HL7) messaging standard and implements Integrating Healthcare Enterprise (IHE) profiles. HL7's version 2.6 messaging standard is the most commonly used means for electronic data exchange in the clinical domain. Use a compatible interface to access this feature. The HemoSphere advanced monitor HL7 communication protocol, also referred to as HIS Connectivity, facilitates the following types of data exchanges between the HemoSphere advanced monitor and external applications and devices:

- Sending of physiological data from the HemoSphere advanced monitor to the HIS and/or medical devices
- Sending of physiological alarms and device faults from the HemoSphere advanced monitor to the HIS

- HemoSphere advanced monitor retrieval of patient data from the HIS.

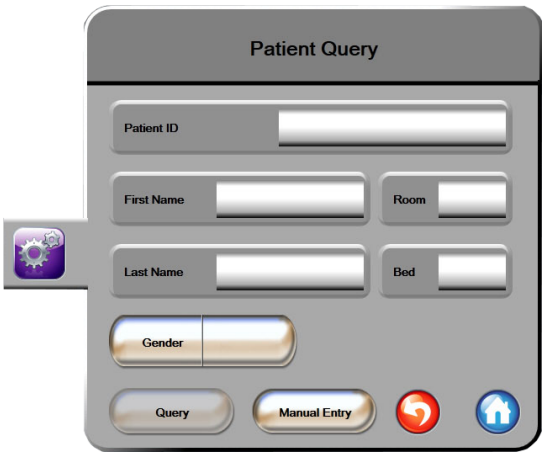


Figure 8-1 HIS- Patient query screen

HIS connectivity status is indicated on the information bar by the symbols shown in Table 8-2.

Table 8-2 HIS connectivity status

HIS symbol	Indication
	Connection to all configured HIS actors are good.
	Unable to establish communication with configured HIS actors.
	Patient ID is set to “Unknown” in all outbound HIS messages.
	Intermittent errors are occurring in communications with configured HIS actors.
	Persistent errors are occurring in communications with configured HIS actors.

8.4.1 Patient Demographic Data

The HemoSphere advanced monitor, with HIS Connectivity enabled, can retrieve patient demographics data from enterprise application. Once the HIS Connectivity feature is enabled, touch the **Query** button. The **Patient Query** screen allows the user to search for a patient based on name, patient ID or room and bed information. The **Patient Query** screen can be used to retrieve patient demographics data when starting a new patient or to associate the patient physiological data being monitored on the HemoSphere advanced monitor with a patient record retrieved from HIS.

Once a patient is selected form the query results, patient demographics data is displayed in the **New Patient Data** screen.

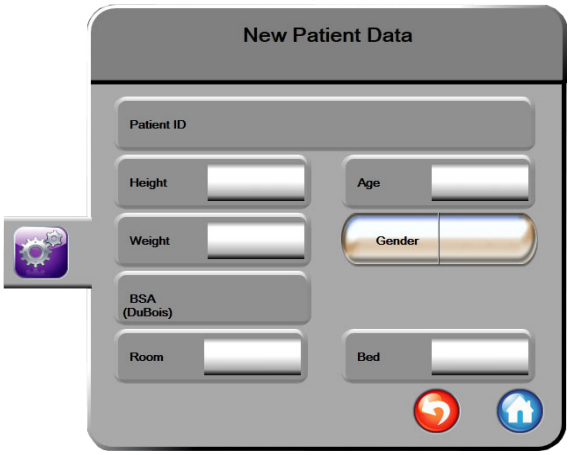


Figure 8-2 HIS- New patient data screen

The user can enter or edit patient height, weight, age, gender, room and bed information on this screen. The selected or updated patient data can be saved by touching the home icon . Once patient data is saved, the HemoSphere advanced monitor generates unique identifiers for the selected patient and sends out this information in outbound messages with physiological data to the enterprise applications.

8.4.2 Patient Physiological Data

The HemoSphere advanced monitor can send monitored and calculated physiological parameters in outbound messages. Outbound messages can be sent to one or more configured enterprise applications. Continuously monitored and calculated parameters with the HemoSphere advanced monitor can be sent to the enterprise application.

8.4.3 Physiological Alarms and Device Faults

The HemoSphere advanced monitor can send physiological alarms and device faults to configure HIS. Alarms and faults can be sent to one or more configured HIS. Statuses of individual alarms including change in states are sent out to the enterprise application.

For more information on how to receive access to HIS Connectivity, contact your local Edwards representative or Edwards Technical Support.

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

8.5 Cyber Security

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

- **Physical Access**: Limit use of the HemoSphere advanced monitor to authorized users.
- **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 advanced monitor interface outside of its intended purpose could pose cyber security risks. No HemoSphere advanced monitor connections are meant to control the operations of another device. All available interfaces are shown in *HemoSphere Advanced Monitor Connection Ports* on page 35 and specifications for these interfaces are listed in table A-5, "HemoSphere advanced monitor technical specifications," on page 135.

8.5.1 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.

9

HemoSphere Swan-Ganz Module Monitoring

Contents

9.1 Connecting the HemoSphere Swan-Ganz Module

The HemoSphere Swan-Ganz module is compatible with all approved Edwards Swan-Ganz pulmonary artery catheters. The HemoSphere Swan-Ganz module acquires and processes 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 Swan-Ganz module connections. See figure 9-1.

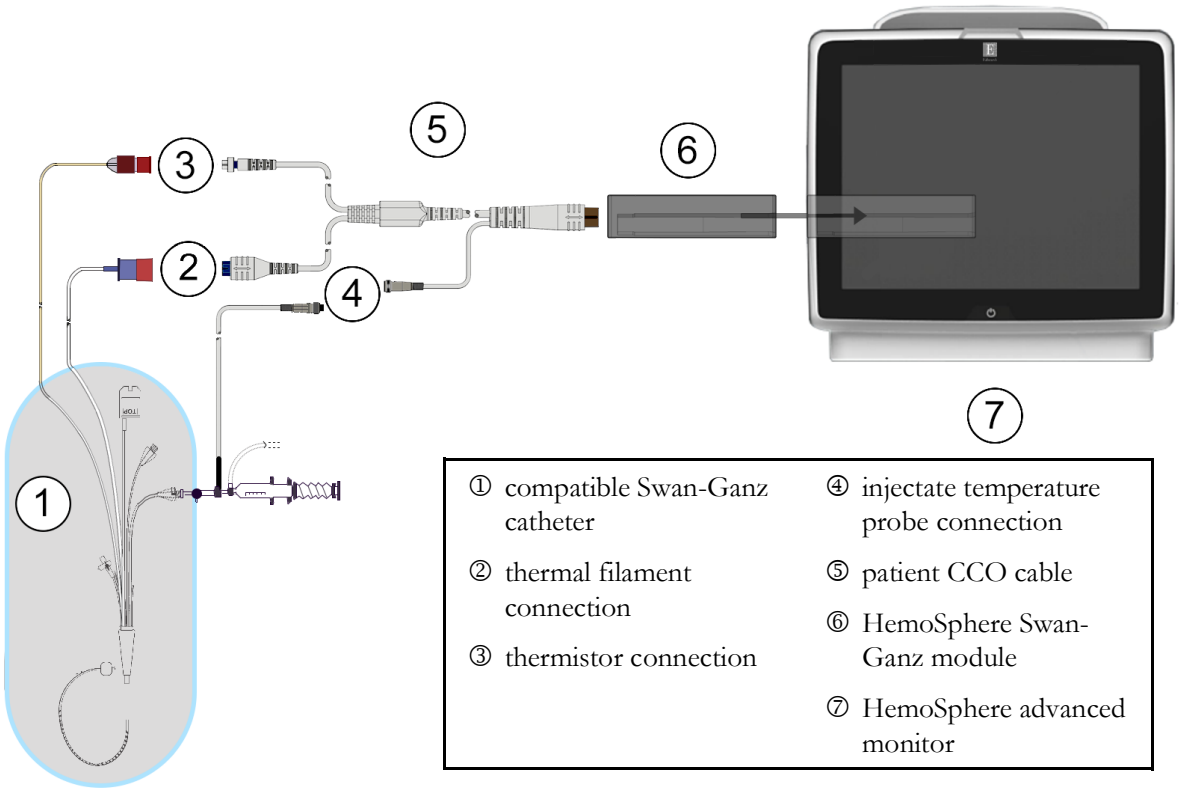


Figure 9-1 HemoSphere Swan-Ganz module connection overview

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.

The patient CCO cable and any attached compatible catheter is an APPLIED PART.

1. Ensure that the HemoSphere advanced monitor is off before inserting the HemoSphere Swan-Ganz module.
2. Insert the HemoSphere Swan-Ganz module into the HemoSphere advanced monitor. The module will click when properly engaged.

CAUTION Do not force the module into the slot. Apply even pressure to slide and click the module into place.

3. Press the power button to turn on the HemoSphere advanced monitor and follow steps for entering patient data. See *Patient Data* on page 71. Connect the patient CCO cable to the HemoSphere Swan-Ganz module.

4 Connect the compatible Swan-Ganz catheter to the patient CCO cable. See table 9-1 below for available parameters and required connections.

Table 9-1 Available HemoSphere Swan-Ganz module parameters and required connections

Parameter	Required connection	See
CO	thermistor and thermal filament connection	*Continuous Cardiac Output* on page 99
iCO	thermistor and injectate (bath or in-line) probe	*Intermittent Cardiac Output* on page 102
EDV/RVEF (SV)	thermistor and thermal filament connection *HR slaved-in by HemoSphere advanced monitor	*EDV/RVEF Monitoring* on page 108
SVR	thermistor and thermal filament connection *MAP and CVP slaved-in by HemoSphere advanced monitor	*SVR* on page 111

5 Follow the necessary directions for monitoring. See *Continuous Cardiac Output* on page 99, *Intermittent Cardiac Output* on page 102 or *EDV/RVEF Monitoring* on page 108.

9.1.1 Patient CCO Cable Test

To test the integrity of the Edwards patient CCO cable, perform a cable integrity test. It is recommended to test the integrity of the cable as part of a troubleshooting process. This does not test the injectate temperature probe connection of the cable.

To access the patient CCO cable test window, touch the clinical actions icon → **Patient CCO Cable Test** icon . Refer to figure 9-2 for numbered connections.

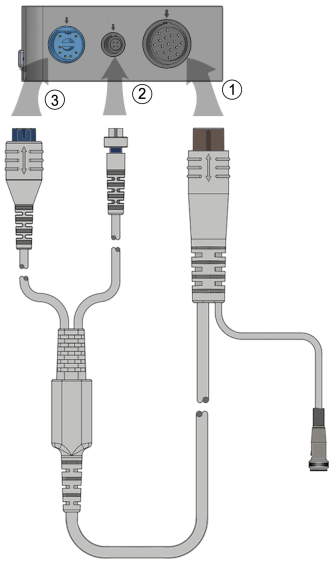


Figure 9-2 Patient CCO cable test connections

1 Attach the patient CCO cable to the inserted HemoSphere Swan-Ganz module ①.

2 Attach the patient CCO cable thermal filament connector ③ and thermistor connector ② to their mating test ports on the HemoSphere Swan-Ganz module.

3 Touch the **Start** button to begin the cable test. A progress bar will appear.

4 Replace the patient CCO cable if it fails the cable test.

5 Touch the enter icon when the cable has passed. Disconnect the patient cable thermal filament connector and thermistor connector from the HemoSphere Swan-Ganz module.

9.2 Continuous Cardiac Output

The HemoSphere advanced monitor 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 advanced monitor continuously measures and displays the cardiac output in liters per minute without operator calibration or intervention.

9.2.1 Connecting the Patient Cables

1 Connect the patient CCO cable to the inserted HemoSphere Swan-Ganz module as previously described in section 9.1.

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 9-3 on page 100.

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

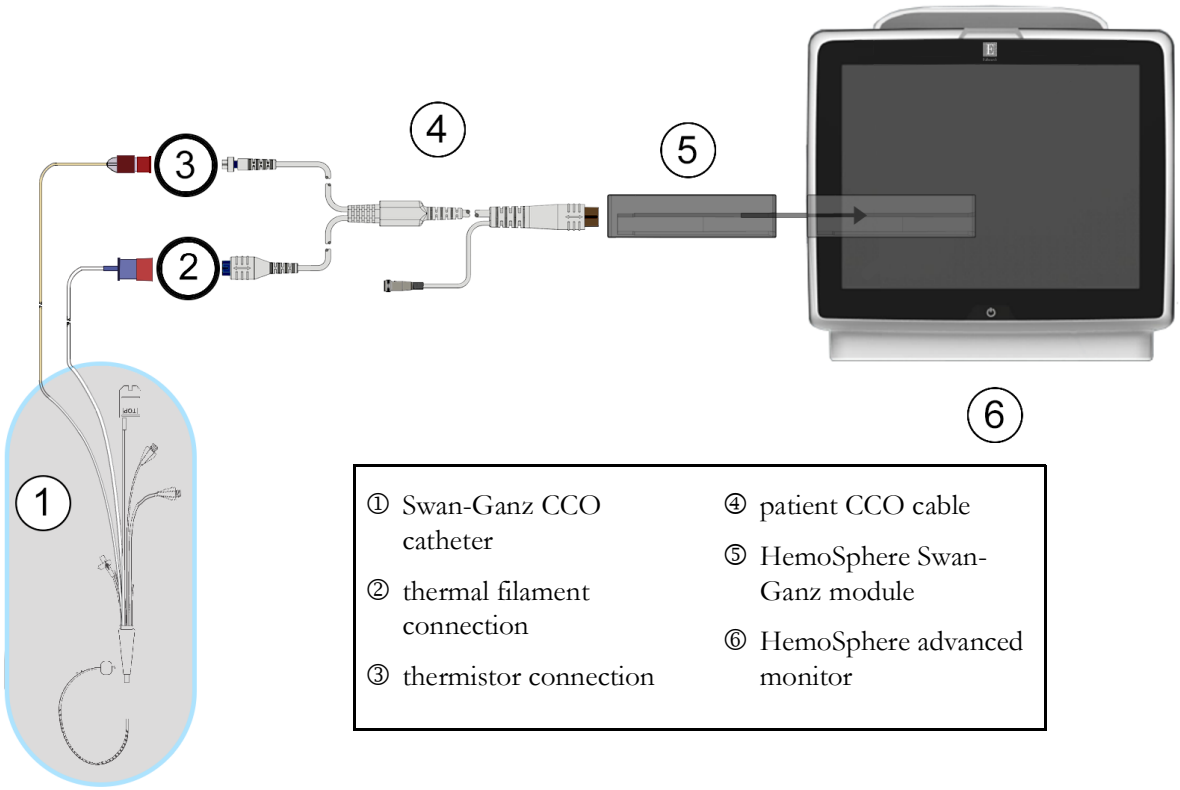


Figure 9-3 CO connection overview

9.2.2 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  to begin CO monitoring. The CO countdown timer will appear on the stop monitoring icon. After approximately 3 to 6 minutes, when sufficient data has been obtained, a CO value will appear in the parameter globe. 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.

9.2.3 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 9-2 shows the alert/fault messages that appear on the screen at different time points while the signal stabilizes. Refer to table 11-6, "HemoSphere Swan-Ganz module CO faults/alerts," on page 124 for more information on CO faults and alerts.

Table 9-2 Unstable thermal signal time lapse for CO alert and fault messages

Condition	Alert CO		Fault CO
	Signal Adapting — Continuing	Unstable Blood Temp. — Continuing	Thermal Signal Loss
Monitoring Commencing: minutes from commencement without CO measurement	6	15	30
Monitoring in Progress: minutes from last CO update	na	6	20

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  .

9.2.4 CO Countdown Timer and STAT CO

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. 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 *Graphical/Tabular Trends Split* on page 60.

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

9.3 Intermittent Cardiac Output

The HemoSphere Swan-Ganz module 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).

9.3.1 Connecting Patient Cables

1. Connect the patient CCO cable to the inserted HemoSphere Swan-Ganz module as previously described in section 9.1.
2. Attach the catheter end of the patient CCO cable to the thermistor connector on the Swan-Ganz iCO catheter as shown by ② in figure 9-4.

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

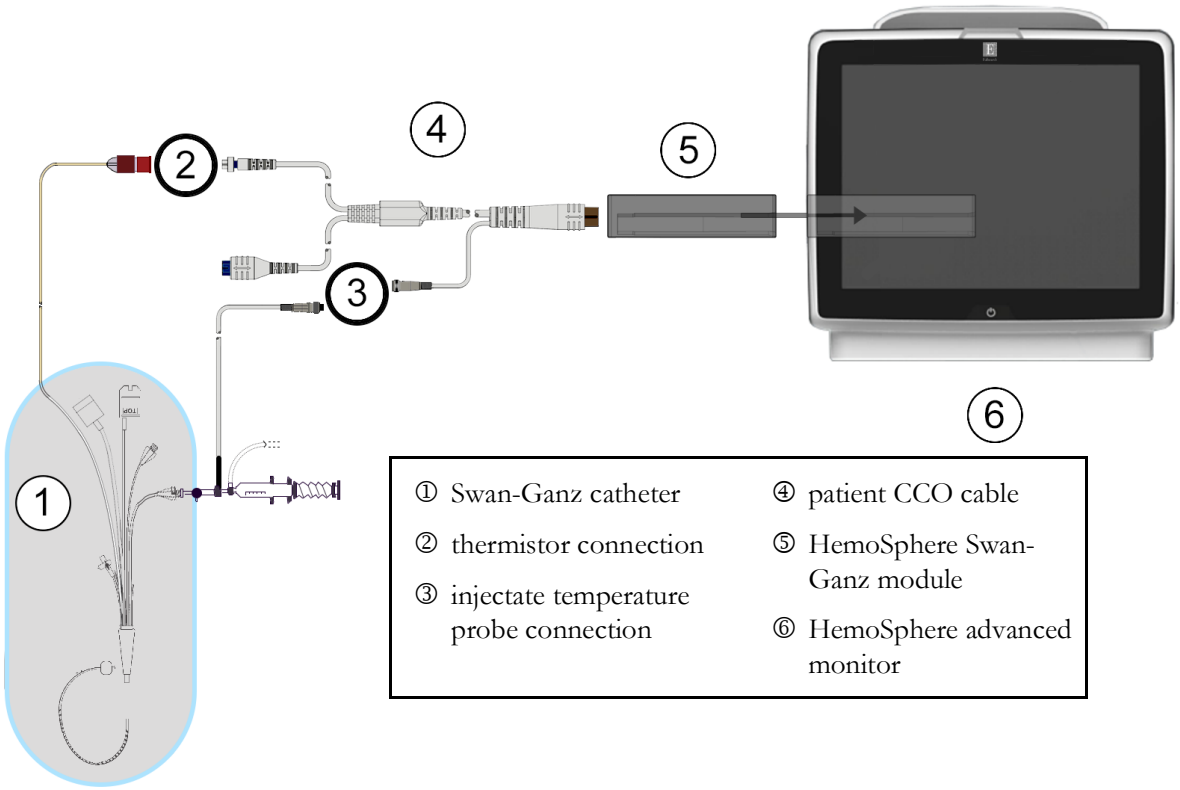


Figure 9-4 iCO connection overview

9.3.1.1 Probe Selection

An injectate temperature probe senses injectate temperature. The selected probe is connected to the patient CCO cable (figure 9-4). 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 9-4.

9.3.2 Configuration Settings

The HemoSphere advanced monitor provides the operator with the choice of entering a specific computation constant, or configuring the HemoSphere Swan-Ganz module 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 clinical actions icon → **iCO** icon .

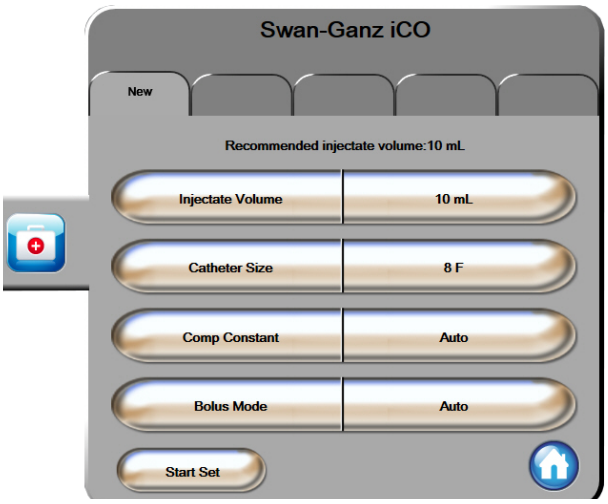


Figure 9-5 iCO new set configuration screen

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 Swan-Ganz module 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 "**Connect injectate probe for iCO monitoring**" is displayed.

9.3.2.1 Select Injectate Volume

Select a value from the **Injectate Volume** list button. 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.

9.3.2.2 Select Catheter Size

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

- **5.5F**
- **6F**
- **7F**

- **7.5F**
- **8F**

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

9.3.2.3 Select Computation Constant

To manually enter a computation 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**.

9.3.2.4 Select Mode

Select **Auto** or **Manual** from the **Mode** list button. The default mode is **Auto**. In the **Auto** mode, the HemoSphere advanced monitor automatically highlights an **Inject** message upon achieving a baseline blood temperature. The **Manual** mode operation is similar to the **Automatic** 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.

9.3.3 Instructions for Bolus Measurement Modes

The HemoSphere Swan-Ganz module factory default setting for bolus measurement is **Auto** mode. In this mode, the HemoSphere advanced monitor 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 screen.

1 Touch the **Start Set** button at the bottom of the iCO new set configuration screen 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.

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** highlighted (Wait).

3 When the thermal baseline is established **Inject** becomes highlighted on the screen (Inject), signifying when to begin the bolus injection series.

OR

If in manual mode, **Ready** (Ready) will appear highlighted on the screen when the thermal baseline is established. Touch the **Inject** button when ready to inject and then **Inject** becomes highlighted 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 highlighted (Computing) and the resultant iCO measurement is displayed.

5 When the thermal washout curve is complete the HemoSphere advanced monitor 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.

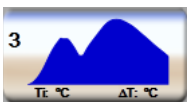
While in **Manual** bolus mode, the operator has a maximum of 30 seconds in which to make a bolus injection after touching the **Inject** button. If no injection is detected within the time interval, the **Inject** button is enabled again and the Inject message disappears.

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** button.

7 Remove any of the six injections in the set by touching on it on the review screen.

Touch  → 

A red "X" appears over the waveform removing it from the averaged CO/CI value. Waveforms that are irregular or questionable will have an icon next to the waveform data set. If desired, touch the cancel icon to delete the 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 return icon to resume the series and add additional bolus injections (up to six) for averaging.

9.3.4 Thermodilution Summary Screen

After the set has been accepted, the set summary will be displayed as a time stamped tab on the thermodilution summary screen. This screen can be accessed anytime by touching the historical thermodilution icon from certain monitoring screens or by touching the clinical actions icon → **iCO** icon .

The following actions are available to the operator on the thermodilution summary screen:

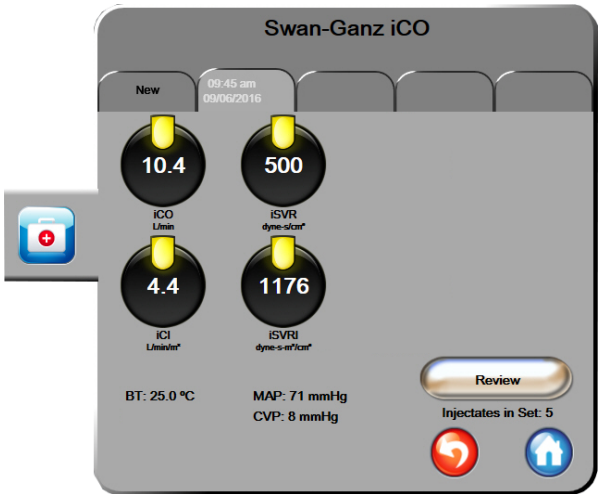


Figure 9-6 Thermodilution summary screen

New Set. Touch the return icon or the **New** tab to perform another thermodilution set. The previous CO/CI average value and associated washout curves will be saved as a tab in the thermodilution summary screen.

Review. Review the thermal washout curves from the bolus set. Touch any tab to review the thermal washout curves from other bolus sets.

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

9.4 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. During EDV monitoring, the HemoSphere advanced monitor continuously displays EDV and right ventricular ejection fraction (RVEF) measurements. EDV and RVEF are time-averaged values that can be numerically displayed in parameter globes, 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.

9.4.1 Connecting Patient Cables

1. Connect the patient CCO cable to the inserted HemoSphere Swan-Ganz module as previously described in section 9.1.
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 9-7.
3. Verify that the catheter is properly inserted into the patient.

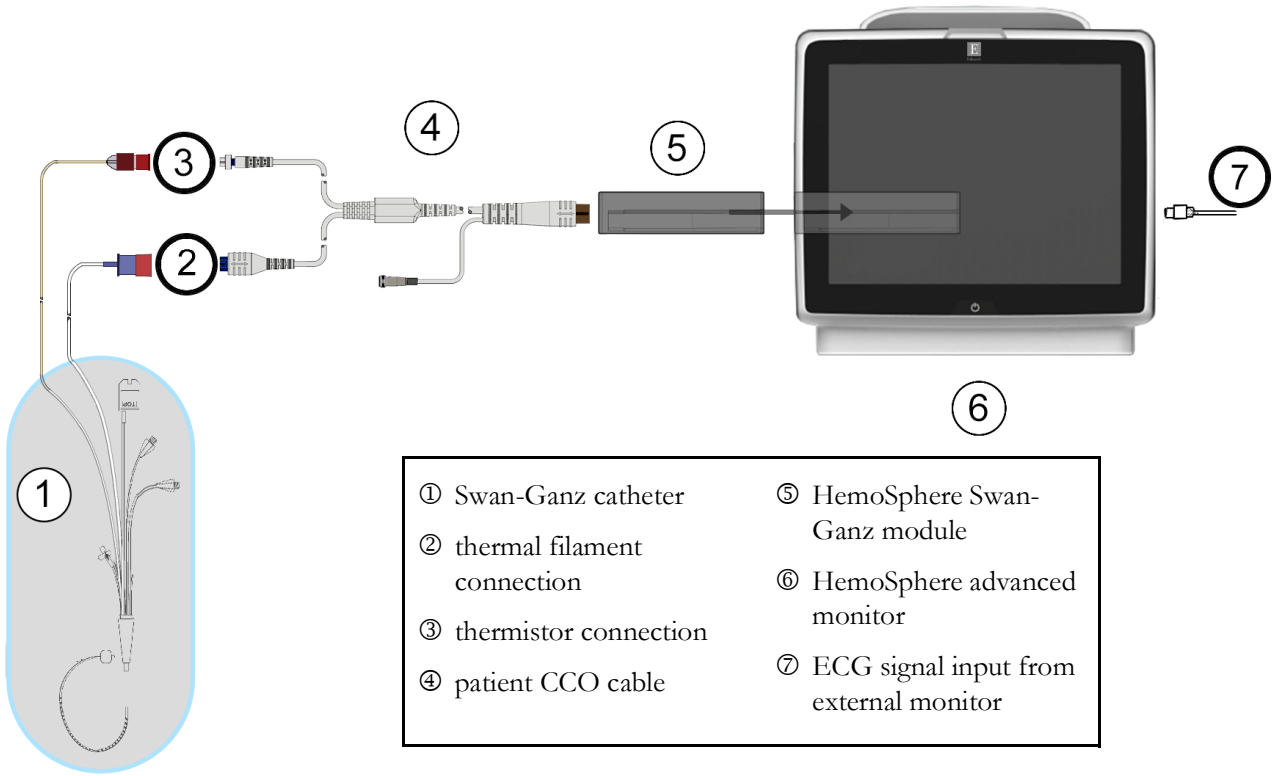


Figure 9-7 EDV/RVEF connection overview

9.4.2 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 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 advanced monitor for EDV and RVEF measurements. For compatible ECG interface cables, contact your local Edwards representative.

IMPORTANT NOTE **The HemoSphere advanced monitor is compatible with an ECG analog slave input from any external patient monitor that has an analog slave 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 advanced monitor's primary function of monitoring cardiac output (with the HemoSphere Swan-Ganz module) 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 135 for disclosure of the pacemaker pulse rejection capability of this instrument.

For patients requiring internal or external pacing support, the HemoSphere 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.

9.4.3 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 6 to 9 minutes, when sufficient data has been obtained, an EDV and/or RVEF value will appear in the configured parameter globes. 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: EDV – Signal Adapting — Continuing

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.

9.4.4 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: EDV – Signal Adapting — Continuing

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: EDV – Heart Rate Signal Loss

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 slave 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 11-7, "HemoSphere Swan-Ganz module EDV and SV faults/alerts," on page 125 and table 11-10, "HemoSphere Swan-Ganz module general troubleshooting," on page 129.

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

, the parameter globe 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.

9.4.5 STAT EDV and RVEF

A hemodynamically unstable thermal signal may delay the HemoSphere advanced monitor 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. EDV, EDVI, and RVEF values can be graphically trended over time alongside numerical values of sEDV, sEDVI, and sRVEF using the graphical/tabular trends split screen monitoring view. Up to two parameters can be viewed in tabular format on this screen. See *Graphical/Tabular Trends Split* on page 60.

9.5 SVR

While performing CO monitoring, the HemoSphere advanced monitor can also calculate SVR by utilizing MAP and CVP analog pressure signal inputs from a connected patient monitor. See *Analog Pressure Signal Input* on page 76.

10

Oximetry Monitoring

Contents

10.1 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. The HemoSphere oximetry cable must be calibrated before monitoring.

1. Connect the HemoSphere oximetry cable to the HemoSphere advanced monitor. The following message will appear:

   Oximetry Initializing, Please Wait

2. If the HemoSphere advanced monitor is not on, turn on the power switch and follow steps for entering patient data. See *Patient Data* on page 71.
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.

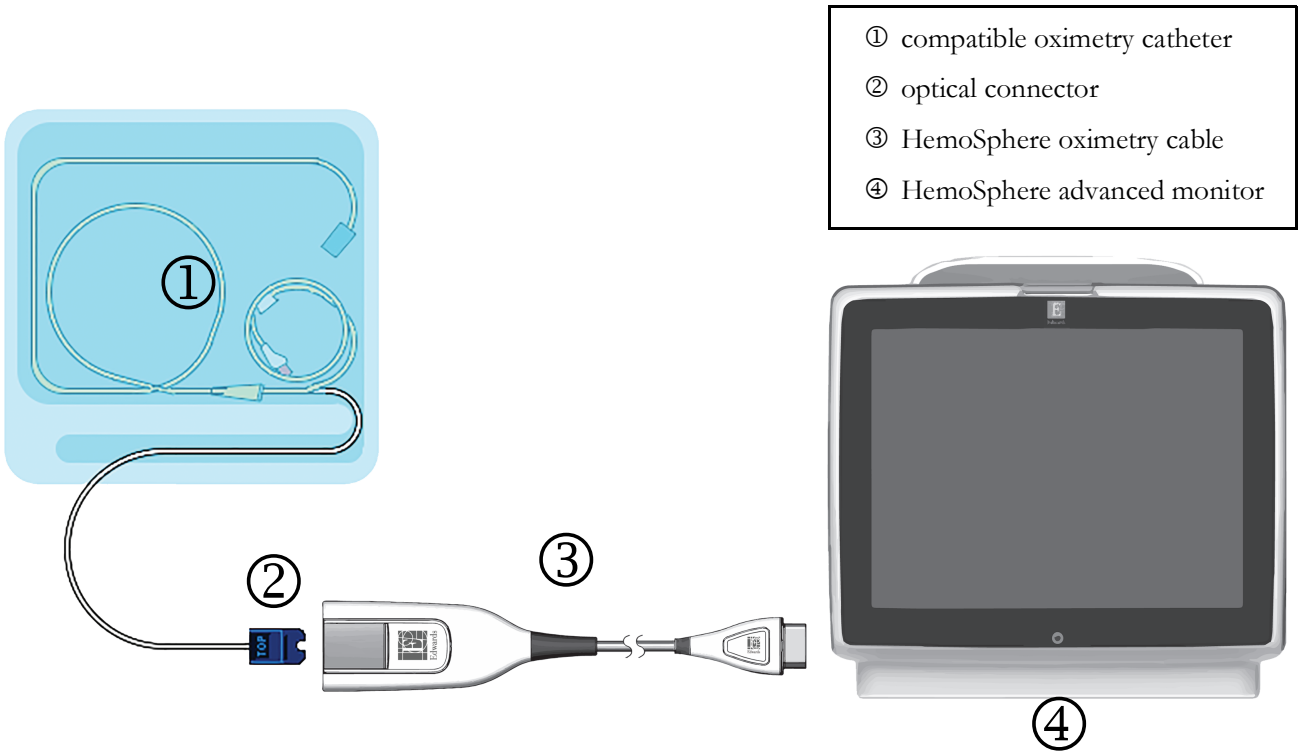


Figure 10-1 Oximetry connection overview

NOTE Appearance of catheter shown in figure 10-1 is for example only. Actual appearance may vary depending on catheter model.

The HemoSphere oximetry cable and any attached compatible catheter is an APPLIED PART.

CAUTION Make sure that the oximetry cable is securely stabilized to prevent unnecessary movement of the attached catheter.

Do not wrap the main body of the oximetry cable in fabric or place directly on the patient's skin for long periods of time (>10 min). 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.

10.2 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.

CAUTION 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 clinical actions icon → **Oximetry Calibration** icon .

2 At the top of the **Oximetry Calibration** screen, select **Oximetry Type**: **$ScvO_2$** or **SvO_2**.

3 Touch **In vitro Calibration** button.

4 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 10-1 for acceptable ranges.

Table 10-1 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

5 Touch **Calibrate** button to start the calibration process.

6 When the calibration successfully completes, the following message appears:
In vitro Calibration OK, insert catheter

7 Insert the catheter as described in the catheter instructions for use.

8 Touch **Start** button.

10.2.1 In Vitro Calibration Error

If the HemoSphere advanced monitor 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 Calibration menu.

10.3 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 116.

1 Touch clinical actions icon → **Oximetry Calibration** icon .

2 At the top of the **Oximetry Calibration** screen, select **Oximetry Type**: **$ScvO_2$** or **SvO_2**.

3 Touch **In vivo Calibration** button.

If setup is unsuccessful, one of the following messages will be displayed:

Warning: Wall Artifact or Wedge Detected. Reposition catheter.

OR

Warning: Unstable Signal.

4 If a "Wall Artifact or Wedge Detected," or "Unstable Signal" message appears, attempt to troubleshoot the problem as instructed in table 11-12, "Oximetry warnings," on page 131 and touch **Recalibrate** button to restart the baseline setup.

OR

Touch **Continue** button to proceed to the draw operation.

5 When baseline calibration is successful, touch **Draw** button and then draw the blood sample.

6 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.

7 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 10-2 for acceptable ranges.

Table 10-2 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.

8 Enter the lab oximetry value (**$ScvO_2$** or **SvO_2**).

9 Touch **Calibrate** button.

10.4 Signal Quality Indicator

Signal quality indicator (SQI) is a reflection of the signal quality based on the catheter condition and position within the vessel. The SQI bar boxes fill based on the level of oximetry signal quality with the level number displayed in the left bar box. 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 10-3.

Table 10-3 Signal quality indicator levels

Level	Color	Description
1 - Normal	Green	All aspects of the signal are optimal
2 - Intermediate	Green	Indicates a moderately compromised signal
3 - Poor	Yellow	Indicates poor signal quality
4 - Unacceptable	Red	Indicates a severe problem with one or more aspects of signal quality

Signal quality may be compromised by the following:

- 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 1 or 2. When SQI is 3 or 4, see *Oximetry Error Messages* on page 130 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 advanced monitor and plug the power cords into separate AC circuits if possible. If signal quality problems persist, call your local Edwards representative for assistance.

10.5 Recall Oximetry Data

Recall Oximetry Data can be used to recall data from the oximetry cable after a patient has been transported away from the HemoSphere advanced monitor. 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 advanced monitor, 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 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 advanced monitor, make sure that previous patient data is cleared.

3 Once the patient has been transferred, reconnect the oximetry cable to the HemoSphere advanced monitor and turn it on.

4 Touch clinical actions icon → **Oximetry Calibration** icon .

5 Touch **Recall Oximetry Data** button.

6 If the oximetry cable data is less than 24 hours old, touch **Yes** button to start oximetry monitoring using the recalled calibration information.

OR

Touch **No** button and perform an in vivo calibration.

WARNING Before touching **Yes** 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 settings icon .

8 Touch **Patient Data** button.

CAUTION If the oximetry cable is being transferred from a HemoSphere advanced monitor to another HemoSphere advanced monitor, 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 advanced monitors current. If the date and/or time of the HemoSphere advanced monitor being transported "from" differs from the HemoSphere advanced monitor 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.

10.6 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 clinical actions icon → **Oximetry Calibration** icon .

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 icon  .

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.

10.7 HemoSphere Oximetry Cable Reset

Use HemoSphere oximetry cable reset when the SQI level is continuously high. An oximetry cable reset may stabilize the signal quality. It should be performed only after attempting other actions to resolve the high SQI as defined in Troubleshooting.

NOTE The HemoSphere advanced monitor will not permit an oximetry cable reset before performing a calibration or recalling calibration from the oximetry cable.

1 Touch clinical actions icon  → **Oximetry Calibration** icon  .

2 Touch **Oximetry Cable Reset** button.

3 A progress bar will appear. Do not disconnect the oximetry cable.

10.8 New 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 clinical actions icon  → **Oximetry Calibration** icon  .

2 Touch **New Catheter** button.

3 Touch **Yes** button.

11

Troubleshooting

Contents

11.1 On Screen Help

The main help screen allows the user navigate to specific help for HemoSphere 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 settings icon  .
2. Touch the **Help** button to access the main help screen.
3. Touch the category help button corresponding to the technology for which help is needed: **Monitor**, **Swan-Ganz Module**, or **Oximetry**.
4. Touch the type of help needed based on the message type: **Faults**, **Alerts**, **Warnings**, or **Troubleshooting.**
5. A new screen appears with a list of the selected messages.
6. Touch a message or troubleshooting item from the list and touch **Select** to access information for that message or troubleshooting item. To view the full list, use the arrow buttons to move the selection highlight up or down the list. The next screen displays the message along with possible causes and suggested actions.

11.2 Monitor Status Lights

The HemoSphere advanced monitor has a visual alarm indicator to alert the user to alarm conditions. See *Alarm Priorities* on page 148 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.

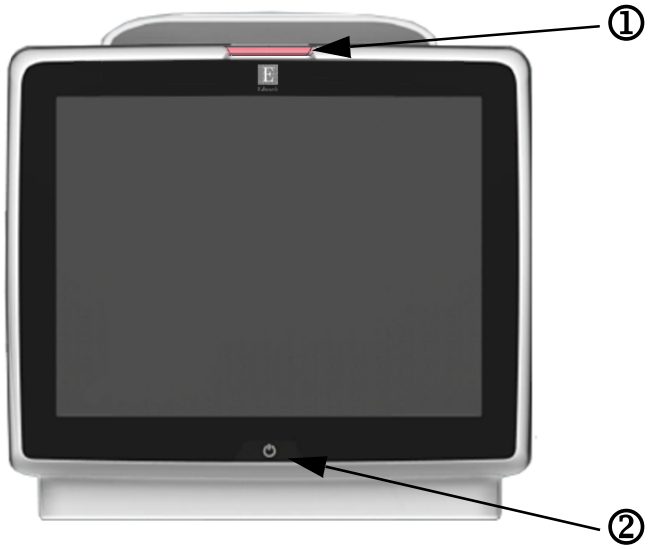


Figure 11-1 HemoSphere advanced monitor LED indicators

① visual alarm indicator ② monitor power status

Table 11-1 HemoSphere advanced monitor 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 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 11-2 HemoSphere advanced monitor 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
Monitor power OFF	No light	Solid OFF	None

11.3 HemoSphere Advanced Monitor Error Messages

11.3.1 System Faults/Alerts

Table 11-3 System faults/alerts

Message	Possible causes	Suggested actions
Fault: Module Slot 1 – Hardware Failure	Module 1 is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins Try switching to module slot 2 If problem persists, contact Edwards Technical Support
Fault: Module Slot 2 – Hardware Failure	Module 2 is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins Try switching to module slot 1 If problem persists, contact Edwards Technical Support
Fault: Cable Port 1 – Hardware Failure	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 cable port 2 If problem persists, contact Edwards Technical Support
Fault: Cable Port 2 – Hardware Failure	Cable is not inserted properly Connection points on cable or port are damaged	Re-insert the cable Check for bent or broken pins Try switching to cable port 1 If problem persists, contact Edwards Technical Support
Fault: Module Slot 1 – Software Failure	There is a software error with the module inserted in module slot 1	Contact Edwards Technical Support
Fault: Module Slot 2 – Software Failure	There is a software error with the module inserted in module slot 2	Contact Edwards Technical Support
Fault: Cable Port 1 – Software Failure	There is a software error with the cable inserted in cable port 1	Contact Edwards Technical Support
Fault: Cable Port 2 – Software Failure	There is a software error with the cable inserted in cable port 2	Contact Edwards Technical Support
Fault: Module Slot 1 – Communication Error	Module 1 is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins Try switching to module slot 2 If problem persists, contact Edwards Technical Support
Fault: Module Slot 2 – Communication Error	Module 2 is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins Try switching to module slot 1 If problem persists, contact Edwards Technical Support
Fault: Cable Port 1 – Communication Error	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 cable port 2 If problem persists, contact Edwards Technical Support
Fault: Cable Port 2 – Communication Error	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 cable port 1 If problem persists, contact Edwards Technical Support
Fault: Monitor – Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Module Slot 1 - Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support

Table 11-3 System faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: Module Slot 2 - Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Cable Port 1 - Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Cable Port 2 - Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: Second Swan-Ganz Module Detected	Multiple Swan-Ganz module connections detected	Disconnect one of the Swan-Ganz modules
Fault: Swan-Ganz Module Disconnected	HemoSphere Swan-Ganz module removed during monitoring HemoSphere Swan-Ganz module not detected Connection points on slot or module are damaged	Confirm that module is properly inserted Remove and re-insert the module Check module for bent or broken pins Try switching to other module slot If problem persists, contact Edwards Technical Support
Fault: Second Oximetry Cable Detected	Multiple oximetry cable connections detected	Disconnect one of the oximetry cables
Fault: Oximetry Cable Disconnected	Oximetry cable connection at HemoSphere advanced monitor not detected Bent or missing oximetry cable connector pins	Verify secure oximetry cable /catheter connection Check oximetry cable connector for bent/missing pins
Fault: Internal System Failure	Internal system malfunction	Power cycle the system 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 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
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: Low Battery	The battery has less than 20% charge remaining or will be depleted within 8 minutes	Connect the HemoSphere 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 battery is properly seated in the battery bay Remove and re-insert the battery pack Change HemoSphere battery pack If problem persists, contact Edwards Technical Support
Alert: Wireless Module Failure	There was an internal hardware failure in the wireless module	Disable and re-enable wireless connection.
Alert: HIS Connectivity Loss	There was a loss in HL7 communication Poor Ethernet connection Poor Wi-Fi connection	Check Ethernet connection Check Wi-Fi connection If problem persists, contact Edwards Technical Support

11.3.2 System Warnings

Table 11-4 HemoSphere advanced monitor warnings

Message	Possible causes	Suggested actions
Battery Needs Conditioning	Gas gauge is not synched to actual battery capacity status	To ensure uninterrupted measurement, make certain the HemoSphere advanced monitor is connected to 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 fully charged state for at least two hours • Disconnect the monitor from electrical outlet and continue to run the system on battery power • The HemoSphere advanced monitor will power down automatically when the battery is fully depleted • Allow the battery to rest in fully depleted state for five hours or more • Connect monitor to an electrical outlet to fully charge battery If the condition battery message persists, replace battery pack
Service Battery	Internal battery fault occurred	Power cycle the system If condition persists, replace the battery pack
Alarm Volume Setting Might be Inaudible	The alarm volume is set to Low	Set the alarm volume to greater than Low to ensure that alarms are adequately monitored

11.3.3 Numeric Keypad Errors

Table 11-5 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 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.
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.

11.4 HemoSphere Swan-Ganz Module Error Messages

11.4.1 CO Faults/Alerts

Table 11-6 HemoSphere Swan-Ganz module CO faults/alerts

Message	Possible causes	Suggested actions
Fault: CO – Blood Temp Out of Range (<31 °C or >41 °C)	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: CO – Cardiac Output < 1.0 L/min	Measured CO < 1.0 L/min	Follow hospital protocol to increase CO Resume CO monitoring
Fault: CO – Catheter Memory, Use Bolus Mode	Poor catheter thermal filament connection Patient CCO cable malfunction Catheter CO error Patient CCO cable is connected to cable test ports	Verify secure thermal filament connection. Check catheter/ patient CCO cable thermal filament connections for bent/missing pins Perform patient CCO cable test Change patient CCO cable Use Bolus CO mode Replace catheter for CO measurement
Fault: CO – Catheter Verification, Use Bolus Mode	Patient CCO cable malfunction Catheter CO error Catheter connected is not an Edwards CCO catheter	Perform patient CCO cable test Change patient CCO cable Use Bolus CO mode Verify catheter is an Edwards CCO catheter
Fault: CO – Check Catheter and Cable Connections	Catheter thermal filament and thermistor connections not detected Patient CCO cable malfunction	Verify patient CCO cable and catheter connections Disconnect thermistor and thermal filament connections and check for bent/missing pins Perform patient CCO cable test Change patient CCO cable
Fault: CO – Check Thermal Filament Connection	Catheter thermal filament connection not 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 Perform patient CCO cable test Change patient CCO cable Verify catheter is an Edwards CCO catheter Use Bolus CO mode
Fault: CO – Check Thermal Filament Position	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

Table 11-6 HemoSphere Swan-Ganz module CO faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: CO – Check Thermistor Connection	Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C Patient CCO cable malfunction	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 Perform patient CCO cable test Change patient CCO cable
Fault: CO – Signal Processor, Use Bolus Mode	Data processing error	Resume CO monitoring Power monitor off and on to restore system Use Bolus CO mode
Fault: 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 Module	Electrocautery interference Internal system malfunction	Disconnect patient CCO cable during electrocautery use Remove and reinsert module to reset If problem persists, contact Edwards Technical Support
Alert: CO – Signal Adapting - Continuing	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 Minimizing patient discomfort may reduce temperature variations Temporarily turn off sequential compression device per hospital procedure
Alert: CO – Unstable Blood Temp. - Continuing	Large pulmonary artery blood temperature variations detected Sequential compression device interference	Wait for CO measurement to be updated Minimizing patient discomfort may reduce temperature variations Temporarily turn off sequential compression device per hospital procedure

11.4.2 EDV and SV Faults/Alerts

Table 11-7 HemoSphere Swan-Ganz module EDV and SV faults/alerts

Message	Possible causes	Suggested actions
Alert: EDV – Heart Rate Signal Loss	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 average heart rate is within range Select appropriate lead configuration to maximize heart rate triggers Verify cable connection between the HemoSphere advanced monitor and bedside monitor is secure Change ECG interface cable

Table 11-7 HemoSphere Swan-Ganz module EDV and SV faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: EDV – Exceeding HR Threshold Limit	Patient's time-averaged heart rate out of range (HR_{avg} <30 or >200 bpm)	Wait until average heart rate is within range Select appropriate lead configuration to maximize heart rate triggers Verify cable connection between the HemoSphere advanced monitor and bedside monitor is secure Change ECG interface cable
Alert: EDV – Signal Adapting - Continuing	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: SV – Heart Rate Signal Loss	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 average heart rate is within range Select appropriate lead configuration to maximize heart rate triggers Verify cable connection between HemoSphere advanced monitor and bedside monitor is secure Change ECG interface cable

11.4.3 iCO Faults/Alerts

Table 11-8 HemoSphere Swan-Ganz module iCO faults/alerts

Message	Possible causes	Suggested actions
Fault: iCO – Check Injectate Probe Connection	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: iCO – Check Thermistor Connection	Catheter thermistor connection not detected Monitored blood temperature is <15 °C or >45 °C Patient CCO cable malfunction	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 Change patient CCO cable
Fault: 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
Fault: iCO – Injectate Temperature Out of Range, Check Probe	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: iCO – Blood Temperature 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 bolus injections when blood temperature is within range
Alert: iCO – Unstable Baseline	Large pulmonary artery blood temperature variations detected	Allow more time for blood temperature baseline to stabilize Use Manual mode
Alert: 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: 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 large thermal signal
Alert: 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 large thermal signal

Table 11-8 HemoSphere Swan-Ganz module iCO faults/alerts (continued)

Message	Possible causes	Suggested actions
Alert: 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

11.4.4 SVR Faults/Alerts

Table 11-9 HemoSphere Swan-Ganz module SVR faults/alerts

Message	Possible causes	Suggested actions
Alert: SVR – Slaved-In Pressures Signal Loss	HemoSphere advanced monitor analog input port not configured to accept MAP and CVP Analog input interface cable connections not detected Inaccurate input signal External monitor malfunction	Verify correct voltage range and low/high voltage values on the HemoSphere advanced monitor for external monitor Verify cable connection between the monitoring platform and bedside monitor is secure Verify correct height/weight entries and units of measure for patient's BSA Check for signal at external monitor's analog output device Change external device module, if used
Alert: SVR – Configure Analog Inputs for SVR Monitoring	HemoSphere advanced monitor analog input ports not configured to accept MAP and CVP signals	Use the analog input settings screen to configure analog input ports 1 and 2 for external monitor MAP and CVP signal output

11.4.5 General Troubleshooting

Table 11-10 HemoSphere Swan-Ganz module general troubleshooting

Message	Possible causes	Suggested actions
Connect HemoSphere Swan-Ganz module for CO monitoring	Connection to the HemoSphere Swan-Ganz module has not been detected	Insert the HemoSphere Swan-Ganz module into slot 1 or slot 2 of the monitor Remove and re-insert module
Connect patient CCO cable for CO monitoring	Connection between the HemoSphere Swan-Ganz module and patient CCO cable has not been detected	Verify connection between patient CCO cable and the inserted HemoSphere Swan-Ganz module Disconnect patient CCO cable and check for bent/missing pins Change patient CCO cable
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 Perform patient CCO cable test Change patient CCO cable
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 Perform patient CCO cable test Change patient CCO cable Verify catheter is an Edwards CCO catheter
Connect injectate probe for iCO monitoring	Connection between patient CCO cable and 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
Connect analog inputs for SVR monitoring	Analog input interface cable connections not detected	Verify cable connection between the monitoring platform and bedside monitor is secure Check for signal at external monitor’s analog output device
Configure analog inputs for SVR monitoring	HemoSphere advanced monitor analog input ports not configured to accept MAP and CVP signals	Use the analog input settings screen to configure analog input ports 1 and 2 for external monitor MAP and CVP signal output
Connect ECG Input for EDV or SV monitoring	ECG interface cable connection not detected	Verify cable connection between the HemoSphere advanced monitor and bedside monitor is secure Change 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

Table 11-10 HemoSphere Swan-Ganz module general troubleshooting (continued)

Message	Possible causes	Suggested actions
HemoSphere 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 advanced monitor uses up to 3 minutes of HR data to calculate HRavg	Stop CO monitoring and verify heart rate is the same for the HemoSphere advanced monitor and external monitor Select appropriate lead configuration to maximize heart rate triggers and minimize atrial spike sensing Verify signal output from external monitoring device Wait for patient's HR to stabilize Change ECG interface cable
HemoSphere Advanced Monitor Display of MAP and CVP ≠ External Monitor	HemoSphere advanced monitoring platform configured incorrectly Inaccurate input signal External monitor malfunction	Verify correct voltage range and low/high voltage values on monitoring platform for external monitor Confirm correct units of measure for analog input port voltage values (mmHg or kPa) Verify correct height/weight entries and units of measure for patient's BSA Check for signal at external monitor's analog output device Change analog input interface cable

11.5 Oximetry Error Messages

11.5.1 Oximetry Faults/Alerts

Table 11-11 Oximetry faults/alerts

Message	Possible causes	Suggested actions
Fault: Oximetry – Light Range	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
Fault: Oximetry – Red/IR Transmit	Debris or film obstructing oximetry cable / catheter connector lens Oximetry cable malfunction	Clean oximetry cable / catheter connectors with 70% isopropyl alcohol and swab, let air dry and recalibrate Power monitor off and on to restore platform Change oximetry cable and recalibrate
Fault: 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: 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
Fault: Oximetry – Signal Processing Malfunction	Oximetry cable malfunction	Power monitor off and on to restore platform Change oximetry cable and recalibrate If problem persists, contact Edwards Technical Support
Fault: Oximetry Cable Memory	Oximetry cable memory malfunction	Disconnect and then reconnect the oximetry cable Change oximetry cable and recalibrate

Table 11-11 Oximetry faults/alerts (continued)

Message	Possible causes	Suggested actions
Fault: Oximetry Cable Temperature	Oximetry cable malfunction	Power monitor off and on to restore platform 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 the cable body feels warm, allow it to cool before operating again If problem persists, contact Edwards Technical Support
Fault: Oximetry Cable Malfunction	Internal system malfunction	Power monitor off and on to restore platform If problem persists, contact Edwards Technical Support
Alert: Oximetry – SQI = 4	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	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

11.5.2 Oximetry Warnings

Table 11-12Oximetry warnings

Message	Possible causes	Suggested actions
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
Warning: Unstable Signal	Changing $ScvO_2$/SvO_2, HGB/Hct, or unusual hemodynamic values	Stabilize patient per hospital protocol and perform in vivo calibration
Warning: 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.

11.5.3 Oximetry General Troubleshooting

Table 11-13 Oximetry general troubleshooting

Message	Possible causes	Suggested actions
Oximetry Cable Not Calibrated — Select Oximetry to Calibrate	Oximetry cable has not been calibrated (in vivo or in vitro) Recall oximetry data function has not been performed Oximetry cable malfunction	Run in-vitro calibration Run in-vivo calibration Recall calibration values
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
Connect oximetry cable for oximetry monitoring	Oximetry cable connection at HemoSphere monitoring platform not detected Bent or missing oximetry cable connector pins	Verify secure oximetry cable connection Check oximetry cable connector for bent/missing pins

Appendix A

Specifications

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-1represents 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 HemoSphere advanced monitor essential performance – non-transient electromagnetic phenomena

Module or 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 15 seconds.

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Table A-1 HemoSphere advanced monitor essential performance – non-transient electromagnetic phenomena (continued)

Module or cable	Parameter	Essential Performance
HemoSphere Swan-Ganz module	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.
	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 oximetry cable	oxygen saturation (mixed venous SvO_2 or central venous $ScvO_2$)	Measurement of oxygen saturation within specified accuracy (±2 % oxygen saturation). Alarm if oxygen saturation outside of alarm ranges.

Table A-2 identifies the minimum performance for transient electromagnetic phenomena, such as electrical fast transients and surges, according to IEC 60601-1-2.

Table A-2 HemoSphere advanced monitor essential performance – transient electromagnetic phenomena

Parameter	Essential Performance
All	After the transient electromagnetic phenomena, the system shall return to an operational state within 10 seconds. If 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.

A.2 HemoSphere Advanced Monitor Specifications

Table A-3 HemoSphere advanced monitor physical and mechanical specifications

HemoSphere advanced monitor		
Weight	10 lbs (4.5 kg)	
Dimensions	Height	11.7 in (297 mm)
	Width	12.4 in (315 mm)
	Depth	5.56 in (141 mm)
Footprint	Width	10.6 in (269 mm)
	Depth	4.8 in (122 mm)
Display	Active Area	12.1 in (307 mm)
	Resolution	1024 x 768 LCD
Operating system	Windows 7 embedded	
Speaker count	1	

Table A-4 HemoSphere advanced monitor environmental specifications

Environmental specification		Value
Temperature	Operational	10 to 32.5 °C
	Non-operational*	-18 to 45 °C
Relative humidity	Operational	20 to 90% non-condensing
	Non-operational	90% non-condensing at 45 °C
Altitude	Operational	0 to 10,000 feet (3048 m)
	Non-operational	0 to 20,000 feet (6096 m)

*NOTE Battery capacity starts to degrade with extended exposure above 35 °C.

Table A-5 HemoSphere advanced monitor technical specifications

Input/Output	
Touch screen	Projective capacitive touch
RS-232 serial port (1)	Edwards proprietary protocol; Maximum data rate = 57.6 kilo baud
USB ports (2)	one USB 2.0 (rear) and one USB 3.0 (side)
RJ-45 Ethernet port	One
HDMI port	One
Analog inputs (2)	Input voltage range: 0 to 10V; Selectable full-scale: 0 to 1V, 0 to 5V, 0 to 10V; >100 kΩ input impedance; 1/8 in. stereo jack; Bandwidth: 0 to 5.2 Hz; Resolution: 12 bits ±1 LSB of full scale
DPT pressure output (1)	DPT pressure out
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.

Table A-5 HemoSphere advanced monitor technical specifications (continued)

Input/Output (continued)	
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	connection to Wi-Fi networks that are compliant to 802.11b/g/n, minimum

A.3 HemoSphere Battery Pack Specifications

Table A-6 HemoSphere battery pack physical specifications

HemoSphere battery pack		
Weight	1.1 lb (0.5kg)	
Dimensions	Height	1.38 in (35 mm)
	Width	3.15 in (80 mm)
	Depth	5.0 in (126 mm)

Table A-7 HemoSphere battery pack environmental specifications

Environmental specification		Value
Temperature	Operational	10 to 37 °C
	Recommended storage	21 °C
	Maximum long term storage	35 °C
Relative humidity	Operational	5 to 95% non-condensing at 40 °C

Table A-8 HemoSphere battery pack technical specifications

Specification	Value
Output voltage (nominal)	12.8 V
Maximum discharge current	5 A
Cells	4 x $LiFePO_4$ (lithium iron phosphate)

A.4 HemoSphere Swan-Ganz Module Specifications

Table A-9 HemoSphere Swan-Ganz module physical specifications

HemoSphere Swan-Ganz module		
Weight	1.0 lbs (0.45 kg)	
Dimensions	Height	1.36 in (3.45 cm)
	Width	3.53 in (8.96 cm)
	Depth	5.36 in (13.6 cm)

Table A-10 HemoSphere Swan-Ganz module 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)
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
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] 10 to 90% change under conditions of stable blood temperature

A.5 HemoSphere Oximetry Cable Specifications

Table A-11 HemoSphere oximetry cable specifications

HemoSphere oximetry cable		
Weight	1.0 lbs (0.45 kg)	
Dimensions	Length	9.6 ft (2.9 m)

Table A-12 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.

Appendix B

Accessories

Contents

B.1 Accessories List

WARNING Only use approved HemoSphere advanced monitor 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 advanced monitor components

Description	Model number
HemoSphere advanced monitor	
HemoSphere advanced monitor	HEM1
HemoSphere battery pack	HEMBAT10
HemoSphere expansion module	HEMEXPM10
HemoSphere L-tech expansion Module	HEMLTECHM10
HemoSphere advanced monitor roll stand	HEMRLSTD1000
HemoSphere advanced monitoring system (base kit)	HEMKITBASE2
HemoSphere advanced monitor with HemoSphere Swan-Ganz module	HEMKITSG2
HemoSphere advanced monitor with HemoSphere oximetry cable	HEMKITOX2
HemoSphere advanced monitoring platform	HEMKITSGOX2

Table B-1 HemoSphere advanced monitor components

Description	Model number
HemoSphere Swan-Ganz monitoring	
HemoSphere Swan-Ganz module	HEMSGM10
Patient CCO cable	70CC2
Edwards Swan-Ganz catheters	*
In-line temperature probe (CO-SET+ closed injectate delivery system)	93522
Bath temperature injectate probe	9850A
HemoSphere oximetry monitoring	
HemoSphere oximetry cable	HEMOXSC100
HemoSphere oximetry cradle	HEMOXCR1000
Edwards oximetry Catheter	*
HemoSphere advanced monitor cables	
Pressure slave cable	**
ECG monitor slave cables	**

Edwards

Table B-1 HemoSphere advanced monitor components

Description	Model number
Additional HemoSphere Accessories	
HemoSphere advanced monitor operator's manual	***
HemoSphere advanced monitor service manual	***
HemoSphere advanced monitor quick start guide *contains HemoSphere advanced monitor operator's manual*	HEMQG1000

* Please contact your Edwards representative for model and ordering information.

** Edwards Lifesciences slave 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.

*** Please contact your Edwards representative for the most current version.

B.2 Additional Accessories Description

B.2.1 Roll Stand

The HemoSphere advanced monitor roll stand is intended for use with the HemoSphere advanced monitor. 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.

Appendix C

Equations for Calculated Patient Parameters

This section describes the equations used to calculate continuous and intermittent patient parameters displayed on the HemoSphere advanced monitor.

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 the $ScvO_2$.

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 $CaO_2 = (0.0138 \times HGB \times SpO_2) + (0.0031 \times PaO2)$ (mL/dL) $CaO_2 = [0.0138 \times (HGB_{SI} \times 1.611) \times SpO_2] + [0.0031 \times (PaO_{2SI} \times 7.5)]$ (mL/dL) where: HGB – Total Hemoglobin, g/dL HGB_{SI} – Total Hemoglobin, mmol/L SpO_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 is assumed to be 0	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
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
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

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
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	%
PVR	Pulmonary Vascular Resistance PVR = {(MPAP - PAWP) x 80} /CO $PVR = \{(MPAP_{SI} - PAWP_{SI}) \times 60\} / CO$ 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	$dyne\text{-}s/cm^5$ kPa-s/L
PVRI	Pulmonary Vascular Resistance Index PVRI = {(MPAP – PAWP) x 80} /CI $PVRI = \{(MPAP_{SI} – PAWP_{SI}) \times 60\} / CI$ 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 CO – Cardiac Index, $L/min/m^2$	$dyne\text{-}s\text{-}m^2/cm^5$ $kPa\text{-}s\text{-}m^2/L$

Table C-1 Cardiac and oxygenation profile equations (continued)

Parameter	Description and formula	Units
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
SV	Stroke Volume SV = (CO/PR) x 1000 where: CO – Cardiac Output, L/min PR – Pulse rate, beats/min	mL/beat
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 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 $(kPa\text{-}s\text{-}m^2/L)_{SI}$
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 Index 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 Oxygen Consumption Index VO_2 e/ 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	880 lbs / 400.0 kg	lbs or kg
BSA	0.08	5.02	m^2
ID	0 digits	12 digits	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
CO/iCO/sCO	L/min	0.0	12.0	1.0
CI/iCI/sCI	$L/min/m^2$	0.0	12.0	1.0
SV	mL/b	0	160	20
SVI	$mL/b/m^2$	0	80	20
$ScvO_2/SvO_2$	%	0	99	10
SVR/iSVR	$dyne\text{-}s/cm^5$	500	1500	100
SVRI/iSVRI	$dyne\text{-}s\text{-}m^2/cm^5$	500	3000	200
EDV/sEDV	mL	0	800	20
EDVI/sEDVI	mL/m^2	0	400	20
RVEF/sRVEF	%	0	100	10

NOTE The HemoSphere advanced monitor 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	Range
CO	L/min	1.0 to 20.0
iCO	L/min	0.0 to 20.0
sCO	L/min	1.0 to 20.0
CI	L/min/m^2	0.0 to 20.0
iCI	L/min/m^2	0.0 to 20.0
sCI	L/min/m^2	0.0 to 20.0
SV	mL/b	0 to 300
SVI	mL/b/m^2	0 to 200
SVR	dyne-s/cm^5	0 to 5000
SVRI	dyne-s-m^2/cm^5	0 to 9950
iSVR	dyne-s/cm^5	0 to 5000
iSVRI	dyne-s-m^2/cm^5	0 to 9950
Oximetry ($ScvO_2$/SvO_2)	%	0 to 99
EDV	mL	0 to 800
sEDV	mL	0 to 800
EDVI	mL/m^2	0 to 400
sEDVI	mL/m^2	0 to 400
RVEF	%	0 to 100
sRVEF	%	0 to 100
CVP	mmHg	0 to 50
MAP	mmHg	0 to 300
HRavg	bpm	0 to 220

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	$L/min/m^2$	1.0	2.0	4.0	6.0
SVI	$mL/b/m^2$	20	30	50	70
SVRI/iSVRI	$dyne\text{-}s\text{-}m^2/cm^5$	1000	1970	2390	3000
$ScvO_2/SvO_2$	%	50	65	75	85
EDVI/sEDVI	mL/m^2	40	60	100	200
RVEF/sRVEF	%	20	40	60	60
DO_2I	mL $O_2/min/m^2$	300	500	600	800
VO_2I/VO_2Ie	mL $O_2/min/m^2$	80	120	160	250
CVP	mmHg	2	2	8	10
MAP	mmHg	60	70	100	120
HRavg	bpm	60	70	90	100
HGB	g/dL	7.0	11.0	17.0	19.0
	mmol/L	4.3	6.8	10.6	11.8
SpO_2	%	90	94	100	100

NOTE Non-indexed ranges are based on indexed ranges and entered BSA values.

D.5 Alarm Priorities

Table D-5 Parameter alarm red zone priorities

Parameter	Lower alarm (red zone) priority	Upper alarm (red zone) priority
CO/CI/sCO/sCI	High	Medium
SV/SVI	High	Medium
SVR/SVRI	Medium	Medium
$ScvO_2/SvO_2$	High	Medium
EDV/EDVI/sEDV/sEDVI	Medium	Medium
RVEF/sRVEF	Medium	Medium

NOTE 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 message and visual indicator will be replaced by the higher priority alarm message(s) and associated visual indicator.

Most technical faults are medium priority. Alerts and other system messages are low priority.

D.6 Language Default Settings*

Table D-6 Language default settings

Language	Default display units				Time format	Date format	CO trend averaging time
	PaO_2	HGB	Height	Weight			
English (US)	mmHg	g/dL	in	lbs	12 hour	MM/DD/YYYY	20 seconds
English (UK)	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Français	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Deutsch	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Italiano	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Español	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Svenska	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Nederlands	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Ελληνικά	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Português	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
日本語	mmHg	g/dL	cm	kg	24 hour	MM/DD/YYYY	20 seconds
中文	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Čeština	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Polski	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Suomi	kPa	mmol/l	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Norsk	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Dansk	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Eesti	mmHg	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Lietuvių	mmHg	g/dl	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Latviešu	kPa	mmol/L	cm	kg	24 hour	DD.MM.YYYY	20 seconds
Note: Temperature defaults to Celsius for all languages.							

NOTE Languages listed above are for reference only and may not be available for selection.

Appendix E

Computation Constants

E.1 Computation Constant Values

In iCO mode, the HemoSphere Swan-Ganz module 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 Swan-Ganz module 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 advanced monitor does not require routine service or preventive maintenance to maintain its optimum performance level. It 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 advanced monitor 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.

F.2 Cleaning the Monitor and Modules

WARNING **Shock or fire hazard!** Do not immerse the HemoSphere advanced monitor, modules, or platform cables in any liquid solution. Do not allow any fluids to enter the instrument.

The HemoSphere advanced monitor and modules can be cleaned using a lint-free cloth dampened with cleaning agents that are based on the following chemical content:

- 70% isopropyl
- 2% glutaraldehyde
- one-tenth bleach solution
- quaternary ammonium solution.

Do not use any other cleaning agents. Unless otherwise stated, these cleaning agents are approved for all HemoSphere advanced monitoring accessories, cables and modules.

CAUTION Do not pour or spray liquid on any portion of the HemoSphere advanced monitor, accessories, modules, 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 or modules
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 monitor approved cleaning agents.

CAUTION Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing.

1. 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.

F.3.1 Cleaning the HemoSphere Oximetry 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. Use sterile alcohol preps containing 70% isopropyl alcohol solution to clean the oximetry cable housing and the connecting 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 Patient CCO 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. Wipe the cable with a damp, soft cloth using 10% bleach and 90% water solution as needed.
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.4 Service and Support

See chapter 11: *Troubleshooting* for diagnosis and remedies. If this information does not solve the problem, contact Edwards Lifesciences.

Edwards provides HemoSphere advanced monitor 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 advanced monitor'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

China: Edwards (Shanghai) Medical Products Co., Ltd.
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Phone 41.22.787.4300

India: Edwards Lifesciences (India) Pvt. Ltd.
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Phone 81.3.6894.0500

Australia: Edwards Lifesciences Pty Ltd
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North Ryde
NSW 2113
PO Box 137, North Ryde BC
NSW 1670
Australia
Phone +61(2)8899 6300

Brazil: Edwards Lifesciences Comércio de Produtos Médico-Cirúrgicos Ltda.
Rua Verbo Divino, 1547 - 1º andar -
Chácara Santo Antônio
São Paulo - SP - Brasil
CEP 04719-002
Phone 55.11.5567.5337

F.6 Monitor Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the HemoSphere advanced monitor 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 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.

F.7.1 Battery Maintenance

F.7.1.1 Battery Conditioning

The battery pack may require periodic conditioning. This feature should only be performed by trained hospital staff or technicians. Refer to the HemoSphere advanced monitor service manual for conditioning instructions.

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.7.1.2 Battery Storage

The battery pack can remain stored in the HemoSphere advanced monitor. Refer to "HemoSphere Advanced Monitor Specifications" on page 134 for environmental specifications for storage.

NOTE Long term storage at high temperatures may decrease life of battery pack.

F.8 Testing of Alarm Signals

Each time the HemoSphere advanced monitor 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 advanced monitor 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 advanced monitor. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the HemoSphere advanced monitor 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 advanced monitor 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 60601-1-2:2007 and IEC 60601-2-49:2011-02*

IEC/EN 60601-1-2:2014-02 and IEC 60601-2-49:2011-02

The HemoSphere advanced monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the HemoSphere advanced monitor should assure that it is used in such an environment.

Table G-1 List of accessories, cables and sensors necessary for compliance

Description	Length	
HemoSphere oximetry cable	9.6 ft 2.9 m	
mains power cable	USA 10 ft 3.1 m	EU 8.2 ft 2.5 m
Patient CCO cable	8 ft 2.44 m	

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, sensors, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity.

No modification of the HemoSphere advanced monitor is allowed.

Portable and mobile RF communication equipment can potentially affect all electronic medical equipment, including the HemoSphere advanced monitor.
Guidance on maintaining appropriate separation between communications equipment and the HemoSphere advanced monitor is provided in table G-4.

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.

Table G-2 Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HemoSphere advanced monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere advanced monitor should assure that it is used in such an environment.		
Emissions	**Compliance**	**Description**
RF emissions CISPR 11	Group 1	The HemoSphere advanced monitor 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 advanced monitor 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-3 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 advanced monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere advanced monitor 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
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-4 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HemoSphere advanced monitor

The HemoSphere advanced monitor 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 advanced monitor 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 5.0 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-5 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere advanced monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere advanced monitor 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment.
	±1 kV for 1 kV for input/output lines > 3 meters	±1 kV for 1 kV for input/output lines > 3 meters	
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	<5% U_T (>95% dip in U_T) for 0.5 cycle	<5% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the HemoSphere advanced monitor user requires continued operation during power mains interruptions, it is recommended that the HemoSphere advanced monitor be powered by an uninterruptible power supply or battery.
	40%U_T (60% dip in U_T) for 5 cycles	40% U_T	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T	
	<5% U_T (>95% dip in U_T) for 5 sec	<5% 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.
NOTE: U_T is the AC mains voltage prior to application of the test level.			

Table G-6 Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere advanced monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere advanced monitor 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 advanced monitor, 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 advanced monitor is used exceeds the applicable RF compliance level above, the HemoSphere advanced monitor 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 advanced monitor.

[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 advanced monitor contains wireless communication technology that provides enterprise-class Wi-Fi connectivity. HemoSphere advanced monitor wireless technology supports IEEE 802.11a/b/g/n with a fully integrated security supplicant providing 802.11i/WPA2 Enterprise authentication, data encryption.

Technical details of the wireless technology implemented in the HemoSphere advanced monitor are provided in the following table.

Table G-7 HemoSphere advanced monitor wireless information

Feature	Description
Wi-Fi standards	IEEE 802.11a, 802.11b, 802.11g, 802.11n
Wi-Fi media	Direct Sequence-Spread Spectrum (DSSS) Complementary Code Keying (CCK) Orthogonal Frequency Divisional Multiplexing (OFDM)
Wi-Fi Media Access Protocol	Carrier sense multiple access with collision avoidance (CSMA/CA)
Wi-Fi Data Rates Supported	802.11a (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b (DSSS, CCK): 1, 2, 5.5, 11 Mbps 802.11g (OFDM): 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11n (OFDM, HT20, MCS 0-7): 6.5,13,19.5, 26, 39,52, 58.5, 72.2 Mbps 7.2,14.4, 21.7, 28.9,43.3, 57.8, 65 Mbps
Modulation	BPSK at 1, 6, 6.5, 7.2 and 9 Mbps QPSK at 2, 12, 13, 14.4,18, 19.5 and 21.7 Mbps CCK at 5.5 and 11 Mbps 16-QAM at 24, 26, 28.9, 36, 39 and 43.3 Mbps 64-QAM at 48, 52, 54, 57.8, 58.5, 65, and 72.2 Mbps
802.11n Spatial Streams	1X1 SISO (Single Input, Single Output)
Regulatory Domain Support	FCC (Americas, Parts of Asia, and Middle East) ETSI (Europe, Middle East, Africa, and Parts of Asia) MIC (Japan) (formerly TELEC) KC (Korea) (formerly KCC)
2.4 GHz Frequency Bands	ETSI: 2.4 GHz to 2.483 GHz MIC: 2.4 GHz to 2.495 GHz FCC: 2.4 GHz to 2.483 GHz KC: 2.4 GHz to 2.483 GHz
2.4 GHz Operating Channels	ETSI: 13 (3 non-overlapping) MIC: 14 (4 non-overlapping) FCC: 11 (3 non-overlapping) KC: 13 (3 non-overlapping)
5 GHz Frequency Bands	ETSI: 5.15 GHz to 5.35 GHz 5.47 GHz to 5.725 GHz MIC: 5.15 GHz to 5.35 GHz 5.47 GHz to 5.725 GHz FCC: 5.15 GHz to 5.35 GHz 5.47 GHz to 5.725 GHz 5.725 GHz to 5.825 GHz KC: 5.15 GHz to 5.25 GHz 5.725 GHz to 5.825 GHz
5 GHz Operating Channels	ETSI: 19 non-overlapping MIC: 19 non-overlapping FCC: 24 non-overlapping KC: 19 non-overlapping

Table G-7 HemoSphere advanced monitor wireless information (continued)

Feature	Description
Maximum Transmit Power Note: *Maximum transmits power varies according to individual country regulations. All values nominal, ±2 dBm. At 2.4 GHz, a single spatial stream and 20 MHz channel bandwidth is supported.*	**802.11a** 6 Mbps 15 dBm (31.623 mW) 54 Mbps 12 dBm (19.953 mW) **802.11b** 1 Mbps 16 dBm (39.81 mW) 11 Mbps 16 dBm (39.81mW) **802.11g** 6 Mbps 16 dBm (39.81 mW) 54 Mbps 12 dBm (25.12 mW) **802.11n (2.4 GHz)** 6.5 Mbps (MCS0) 16 dBm (39.81 mW) 65 Mbps (MCS7) 12 dBm (15.85 mW) **802.11n (5 GHz HT20)** 6.5 Mbps (MCS0) 15 dBm (31.62mW) 65 Mbps (MCS7) 12 dBm (15.85mW)
Typical Receiver Sensitivity Note: *All values nominal, +/-3 dBm. Variant by channels.*	**802.11a** 6 Mbps -90 dBm 54 Mbps -73 dBm (PER <= 10%) **802.11b** 1 Mbps -89 dBm 11 Mbps -82 dBm (PER <= 8%) **802.11g** 6 Mbps -85 dBm 54 Mbps -68 dBm (PER <= 10%) **802.11n (2.4 GHz)** MCS0 Mbps -86 dBm MCS7 Mbps -65 dBm **802.11n (5 GHz HT20)** MCS0 Mbps -90 dBm MCS7 Mbps -70 dBm
Security	**Standards** Wireless Equivalent Privacy (WEP) Wi-Fi Protected Access (WPA) IEEE 802.11i (WPA2) **Encryption** Wireless Equivalent Privacy (WEP, RC4 Algorithm) Temporal Key Integrity Protocol (TKIP, RC4 Algorithm) Advanced Encryption Standard (AES, Rijndael Algorithm) **Encryption Key Provisioning** Static (40-bit and 128-bit lengths) Pre-Shared (PSK) Dynamic **802.1X Extensible Authentication Protocol Types** EAP-FAST, EAP-TLS, EAP-TTLS PEAP-GTC, PEAP-MSCHAPv2, PEAP-TLS LEAP **FIPS 140-2 Mode** Operation restricted to WPA2-AES with EAP-TLS, and WPA2-PSK/AES **Note:** If no encryption key has been established (such as during authentication), 802.1x/EAPOL authentication packets are transmitted and received unencrypted; all other transmit and receive data packets are discarded.

Table G-7 HemoSphere advanced monitor wireless information (continued)

Feature	Description
Compliance	ETSI Regulatory Domain EN 300 328 — EN 55022:2006 Class B EN 300 328 v1.8.1 (BT 2.1) — EN 55024:1998 +A1:2001, A2:2003 EN 301 489-1 — EN 61000-3-2:2006 EN 301 489-17 — EN 61000-3-3:1995 +A1:2001, A2:2005 EN 301 893 — EU 2002/95/EC (RoHS) EN 60950-1 **FCC Regulatory Domain (Certification ID:** SQG-WB45NBT) FCC 15.247 DTS – 802.11b/g (Wi-Fi): 2.4 GHz & 5.8 GHz FCC 15.407 UNII – 802.11a (Wi-Fi): 2.4 GHz & 5.4 GHz FCC Part 15 Class B UL 60950 **Industry Canada (Certification ID:** 3147A-WB45NBT) RSS-210 – 802.11a/b/g/n (Wi-Fi) – 2.4 GHz, 5.8 GHz, 5.2 GHz, and 5.4 GHz ICES-003, Class B **MIC (Japan) (Certification ID:** 201-140137 **)** STD-T71 Article 2 Item 19, Category WW (2.4GHz Channels 1-13) Article 2 Item 19-2, Category GZ (2.4GHz Channel 14) Article 2 Item 19-3 Category XW (5150-5250 W52 & 5250-5350 W53) **KC (Korea) (Certification ID:** MSIP-CRM-LAI-WB45NBT)
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	PCB Dipole
Antenna Dimensions	36 mm x 12 mm x 0.1 mm

G.3.1 Quality of Service for Wireless Technology

The HemoSphere advanced monitor wireless technology enables transmission of physiologic data, alarms, and device notifications to supported Hospital Information Systems (HIS) for electronic charting and archival purposes only. Wirelessly transmitted data is not intended for remote alarm management or real-time, remote data visualization systems. Quality of service (QoS) is specified in terms of total data loss for a normal connection where the HemoSphere advanced monitor is operating at medium wireless signal strength or higher (table 8-1), with good HIS connection (table 8-2). HemoSphere advanced monitor wireless data transmission has been validated to have less than 5% total data loss under these conditions. HemoSphere advanced 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 advanced monitor supports data transmission using Health Level 7 (HL7) messaging standard. All data transmitted is expected to be acknowledged by the receiving system. Data is resent if not sent successfully. The HemoSphere advanced monitor automatically tries to re-establish any HIS connections that are interrupted. If pre-existing HIS connection(s) cannot be reestablished, the HemoSphere advanced monitor alerts the user with an audible alert and message (**Alert: HIS Connectivity Loss**, see table 11-3).

G.3.2 Wireless Security Measures

The wireless signals are secured using industry standard wireless security protocols (table G-7). 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 advanced monitoring platform 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 advanced monitor wireless technology, ensure a minimum distance between portable and mobile RF communications equipment (transmitters) and the HemoSphere advanced monitor are maintained. Refer to table G-4 for additional details on separation distances.

G.3.4 Federal Communication Commission (FCC) Interference Statements

IMPORTANT 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 B 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.

FCC 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.

IMPORTANT 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.

This device is intended only for OEM integrators under the following conditions:

- The antenna must be installed such that 20 cm is maintained between the antenna and users, and
- The transmitter module may not be co-located with any other transmitter or antenna,
- For all products marketed in the United States, the OEM must limit the operation channels from CH1 to CH11 for 2.4 GHz band by the supplied firmware programming tool. The OEM shall not supply any tool or information to the end-user regarding Regulatory Domain change.

As long as the three conditions above are met, further transmitter testing is not required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this module installed.

IMPORTANT NOTE	In the event that these conditions cannot be met (for example, certain laptop configurations or co-location with another transmitter), then the FCC authorization is no longer considered valid and the FCC ID cannot be used on the final product. In these circumstances, the OEM integrator is responsible for re-evaluating the end product (including the transmitter) and obtaining a separate FCC authorization.

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 licence-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.

G.3.6 European Union R&TTE Statements

This device complies with the essential requirements of the R&TTE Directive 1999/5/EC. The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the R&TTE Directive 1999/5/EC:

- **EN60950-1:2001 A11:2004**
  Safety of Information Technology Equipment
- **EN 300 328 V1.8.1: (2006-10)**
  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 301 489-1 V1.6.1: (2005-09)**
  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 V1.2.1 (2002-08)**
  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 V1.5.1 (2008-12)**
  Electromagnetic compatibility and Radio spectrum Matters (ERM); Broadband Radio Access Networks (BRAN); Specific conditions for 5 GHz high performance RLAN equipment
- **EU 2002/95/EC (RoHS)**
  Declaration of Compliance – EU Directive 2003/95/EC; 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 1999/5/EC.

Appendix H

Glossary

Alarms
Audible and visual indicators that notify operator that a measured patient parameter is outside the alarm limits.

Alarm Limits
Maximum and minimum values for monitored patient parameters.

Baseline Blood Temperature
Blood temperature that serves as the basis for cardiac output measurements.

Blood Temperature (BT)
Temperature of the blood in the pulmonary artery when the catheter is properly positioned.

Body Surface Area (BSA)
The calculated surface area of a human body.

Bolus (iCO) Mode
Functional state of the HemoSphere Swan-Ganz module in which cardiac output is measured by the bolus thermodilution method.

Bolus Injection
A known volume of iced or room temperature fluid, which is injected into a port on the pulmonary artery catheter and serves as the indicator for measuring cardiac output.

Button
A screen image with text that, when touched, initiates an action or provides access to a menu.

Cardiac Index (CI)
Cardiac output adjusted for body size.

Cardiac Output (CO)
Volume of blood ejected per minute from the heart into the systemic circulation measured in liters per minute.

Central Venous Oxygen Saturation ($ScvO_2$)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the superior vena cava (SVC). Displayed as $ScvO_2$.

Central Venous Pressure (CVP)
The average pressure in the superior vena cava (right atrium) as measured by an external monitor. Indicates venous return to the right side of the heart.

Computation Constant
A constant used in the cardiac output equation that accounts for density of blood and injectate, injectate volume, and indicator loss in the catheter

Default Settings
Initial operating conditions assumed by the system.

End-Diastolic Volume (EDV)
The volume of blood in the right ventricle at the end of diastole.

End-Diastolic Volume Index (EDVI)
Right heart end diastolic volume adjusted for body size.

Estimated Oxygen Consumption (VO_2e)
An expression of the estimated rate at which oxygen is used by tissues, usually given in mL/min of oxygen consumed in 1 hour by 1 milligram dry weight of tissue. Calculated with $ScvO_2$.

Heart Rate (HR)
Number of ventricular contractions per minute. HR data slaved in from an external monitor is averaged over time and displayed as HRavg.

Hematocrit (Hct)
Percentage of blood volume that contain red blood cells.

Hemoglobin (HGB)
Oxygen carrying component of red blood cells. Volume of red blood cells measured in grams per deciliter.

Icon
A screen image that represents a specific screen, platform status, or menu item. When enabled and touched, icons initiate an action or provide access to a menu.

Injectate
Fluid used for iCO (bolus thermodilution cardiac output) measurement.

Intermittent Cardiac Index (iCI)
Intermittent cardiac output adjusted according to body size.

Intermittent Cardiac Output (iCO)
Intermittent measurement of blood ejected per minute from the heart into the systemic circulation measured through thermodilution.

Mean Arterial Pressure (MAP)
Average systemic arterial blood pressure as measured by an external monitor.

Mixed Venous Oxygen Saturation (SvO_2)
Percentage of hemoglobin saturated with oxygen in the venous blood as measured in the pulmonary artery. Displayed as SvO_2.

Oxygen Consumption (VO_2)
An expression of the rate at which oxygen is used by tissues, usually given in mL/min of oxygen consumed in 1 hour by 1 milligram dry weight of tissue. Calculated with SvO_2.

Oxygen Delivery (DO_2)
Amount of oxygen in milliliters per minute (mL/min) delivered to the tissues.

Oxygen Delivery Index (DO_2I)
Amount of oxygen in milliliters per minute ($mL/min/m^2$) delivered to the tissues, adjusted for body size.

Oximetry (Oxygen Saturation, $ScvO_2/SvO_2$)
Percentage of hemoglobin saturated with oxygen in the blood.

Patient CCO Cable Test
Test to verify the integrity of the patient CCO cable.

Right Ventricular Ejection Fraction (RVEF)
Percentage of blood volume ejected from the right ventricle during systole.

Signal Quality Indicator (SQI)
The oximetry signal quality based on the catheter condition and positioning in the vessel.

Slave Cable
Cable that transfers data to the HemoSphere advanced monitor from another monitor.

STAT Value
A fast estimate of CO/CI, EDV/EDVI, and RVEF values.

Stroke Volume (SV)
Amount of blood ejected from the ventricles with each contraction.

Stroke Volume Index (SVI)
Stroke volume adjusted for body size.

Systemic Vascular Resistance (SVR)
A derived measure of impedance to blood flow from left ventricle (afterload).

Systemic Vascular Resistance Index (SVRI)
Systemic vascular resistance adjusted for body size.

Thermal Filament
Area on the CCO thermodilution catheter that transfers small amounts of energy into the blood to serve as indicator for trending cardiac output continuously.

Thermistor
Temperature sensor near the tip of the pulmonary artery catheter.

Thermodilution (TD)
A variant of the indicator dilution technique using temperature change as the indicator.

USB
Universal Serial Bus.

Washout Curve
Indicator dilution curve produced by a bolus injection. Cardiac output is inversely related to the area under this curve.

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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 devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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