HemoSphere Vita Monitor

Operator's manual

Edwards

Edwards HemoSphere Vita Monitor Operator's Manual

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

Edwards Technical Support

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CAUTION

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

Manufactured by	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
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HemoSphere Vita monitor with initial release

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Using This Manual

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

The Edwards HemoSphere Vita monitor operator's manual is comprised of twelve chapters and seven appendices. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

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

WARNING

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

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

CAUTION

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

WARNING

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

Chapter	Description
1	***Introduction***: Provides an overview of the HemoSphere Vita 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 Vita monitor and accessories
3	***Installation and Setup***: Provides information about setting up the HemoSphere Vita monitor and connections for the first time
4	***HemoSphere Vita Monitor Quick Start***: Provides experienced clinicians and users of bedside monitors instructions for immediate monitor use
5	***Navigating the HemoSphere Vita 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 Settings***: Provides information on monitor connectivity for transferring patient and clinical data

Chapter	Description
9	***HemoSphere Non-Invasive VitaWave Module Monitoring***: Describes the methodology behind VitaWave technology and gives instructions for setup and application of patient monitoring equipment as well as how to measure non-invasive blood pressure
10	***Tissue Oximetry Monitoring***: Describes procedures for setup and operation of FORE-SIGHT tissue oximetry monitoring
11	***Advanced Features***: Describes the advanced monitoring features that are currently available for upgrade with the HemoSphere Vita monitoring platform
12	***Help and Troubleshooting***: Describes the Help menu and provides a list of faults, alerts, and messages, with causes and suggested actions

Appendix	Description
A	***Specifications***
B	***Accessories***
C	***Equations for Calculated Patient Parameters***
D	***Monitor Settings and Defaults***
E	***Monitor Care, Service and Support***
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1

Introduction

Contents

1.1 Intended Purpose of this Manual

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

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

Note

The following components may have alternative labeling conventions:

ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).

ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

Not all finger cuffs are supplied with a sizing aid. Refer to the product IFU for detailed instructions on proper finger cuff sizing, if applicable.

1.2 Indications For Use

1.2.1 HemoSphere Vita Monitor with HemoSphere Vita Technology Module and ForeSight Oximeter Cable

The non-invasive ForeSight oximeter cable is intended for use as an adjunct monitor of absolute regional hemoglobin oxygen saturation of blood under the sensors in individuals at risk for reduced-flow or no-flow ischemic states. The ForeSight oximeter cable is also intended to monitor relative changes of oxygenated hemoglobin, deoxygenated hemoglobin, and their summation, total hemoglobin, of blood under the sensors. The ForeSight

oximeter cable is intended to allow for the display of StO_2 and relative change in total hemoglobin on the HemoSphere Vita monitor.

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

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

1.2.2 HemoSphere Vita Monitor with HemoSphere VitaWave Module

The HemoSphere Vita monitor when used with the HemoSphere VitaWave module, pressure controller and a compatible Edwards finger cuff are indicated for patients over 18 years of age in which the balance between cardiac function, fluid status and vascular resistance needs continuous assessment. It may be used for monitoring hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol in a hospital environment. In addition, the non-invasive system is indicated for use in patients with co-morbidities for which hemodynamic optimization is desired and invasive measurements are difficult. The HemoSphere Vita monitor and compatible Edwards finger cuffs non-invasively measures blood pressure and associated hemodynamic parameters. Refer to the VitaWave finger cuff indications for use statements for information on target patient population specific to the finger cuff 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

1.3.1 HemoSphere Vita Monitor with ForeSight Oximeter Cable

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

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

1.3.2 HemoSphere Vita Monitor with HemoSphere VitaWave Module

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

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

1.4 Intended Use Statement

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

The HemoSphere Vita monitoring platform is intended for use with compatible Edwards ForeSight/ForeSight Jr sensors and VitaWave finger cuffs.

Tissue oxygen saturation, StO_2, can be monitored with the HemoSphere Vita monitor, a connected HemoSphere Vita technology module, and the ForeSight oximeter cable as listed below in Table 1-1 on page 18.

Table 1-1: HemoSphere Vita technology module with ForeSight oximeter cable available parameters list

Abbreviation	Definition	Sub-system technology used	Patient population	Hospital environment
StO_2	tissue oxygen saturation	ForeSight oximeter cable and HemoSphere Vita technology module	adult and pediatric	operating room, intensive care unit, emergency room
ΔctHb	relative change in total hemoglobin			

A comprehensive list of parameters available while monitoring with the HemoSphere Vita monitor and a connected HemoSphere VitaWave module are listed below in Table 1-2 on page 18.

Table 1-2: HemoSphere VitaWave module available parameters list

Abbreviation	Definition	Sub-system technology used	Patient population	Hospital environment
DIA_{ART}	arterial diastolic blood pressure	HemoSphere VitaWave module	adult only	operating room and intensive care unit
MAP	mean arterial blood pressure			
PR	pulse rate			
SYS_{ART}	arterial systolic blood pressure			
For more information, see Waveform Reconstruction and Hemodynamic Analysis (VitaWave Algorithm) on page 99.				

WARNING

Improper use of the HemoSphere Vita 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 Vita 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.

1.5 Expected Clinical Benefit

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

1.6 HemoSphere Vita Monitor Hemodynamic Technology Connections

The HemoSphere Vita monitor is equipped with three technology expansion module slots (two standard size and one large [L-Tech] size). Module and cable connection points are located on the left side panel. See Figure 1-1 on page 19.

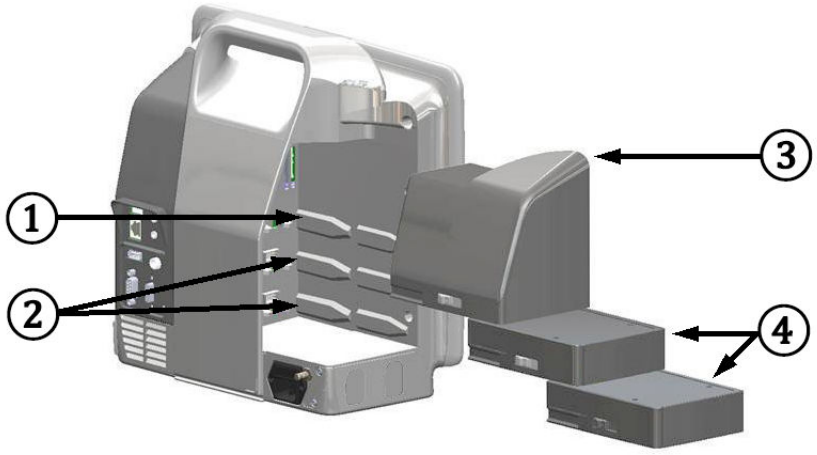


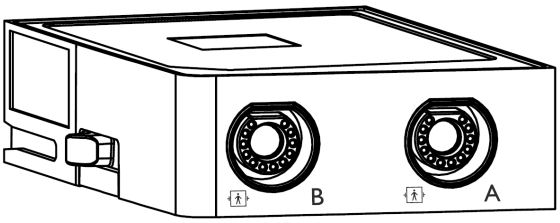
Figure 1-1: HemoSphere Vita monitor hemodynamic technology connections

1. L-Tech expansion module slot (1)
2. expansion module slots (2)
3. L-Tech expansion module
4. expansion modules (2)

Each module/cable is associated with a specific Edwards hemodynamic monitoring technology. Currently available module includes the HemoSphere Vita technology module introduced below and described in detail in chapter 10, HemoSphere Tissue Oximetry Monitoring on page 118. The large technology (L-Tech) module includes the HemoSphere VitaWave module and is introduced below and described in detail in chapter 9, HemoSphere VitaWave Module Non-Invasive Monitoring on page 98.

1.6.1 HemoSphere Vita Technology Module

The HemoSphere technology module fits into a standard module slot. This module connects with the ForeSight oximeter cable for tissue oximetry (StO_2).



1.6.1.1 HemoSphere Vita Technology Module and ForeSight Oximeter Cable

The HemoSphere Vita technology module enables tissue oximetry (StO_2) monitoring with a ForeSight oximeter cable and compatible tissue oximetry sensors. For more information on tissue oximetry monitoring, see chapter 10, HemoSphere Tissue Oximetry Monitoring on page 118. Table 1-3 on page 20 lists the parameters available while using the HemoSphere Vita technology module and ForeSight oximeter cable.

Note

The following components may have alternative labeling conventions:

ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).

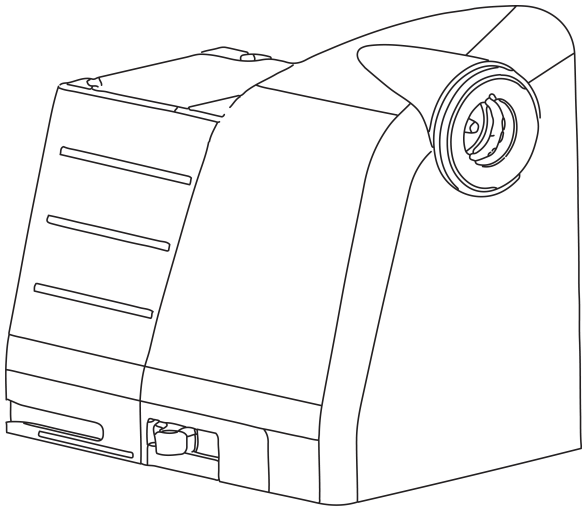
ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

Table 1-3: HemoSphere Vita technology module with ForeSight oximeter cable parameters description

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

1.6.2 HemoSphere VitaWave Module

The HemoSphere VitaWave module with a connected compatible pressure controller and finger cuff(s) enables non-invasive measurement of a patient's arterial pressure waveform and associated hemodynamic parameters. The HemoSphere VitaWave module fits into the large technology (L-Tech) slot. For more information, see chapter 9, HemoSphere VitaWave Module Non-Invasive Monitoring on page 98.



Note

HemoSphere VitaWave module has been validated for compatibility with Edwards ClearSight and Acumen IQ finger cuffs.

Table 1-4: HemoSphere VitaWave module key parameters description

Parameter	Description	Technology
diastolic blood pressure (DIA_{ART})	diastolic blood pressure	VitaWave cuff*
mean arterial pressure (MAP)	averaged systemic blood pressure over one cardiac cycle	VitaWave cuff*
pulse rate (PR)	number of arterial blood pressure pulses per minute	VitaWave cuff*
systolic pressure (SYS_{ART})	systolic blood pressure	VitaWave cuff*
**HemoSphere VitaWave Module is compatible with ClearSight cuff and Acumen IQ cuff*		

1.6.3 Documentation and Training

Available documentation and training for the HemoSphere Vita monitor includes:

- HemoSphere Vita Monitor Operator's Manual
- HemoSphere Vita Monitor Quick Start Guide
- HemoSphere Pressure-Out Cable Instructions for Use
- Edwards Heart Reference Sensor Instructions for Use
- HemoSphere Battery Instructions for Use
- HemoSphere Roll Stand Instructions for Use

Instructions for Use are included with HemoSphere Vita Monitor components. See Table B-1 on page 170. For more information on how you can receive training or available documentation for the HemoSphere Vita monitor, contact your local Edwards representative or Edwards Technical Support. See appendix E, System Care, Service and Support on page 178.

1.7 Manual Style Conventions

Table 1-5 on page 21 lists the style conventions used in this manual.

Table 1-5: 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 32 for full list of menu icons shown on the HemoSphere Vita monitor.

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

1.8 Abbreviations Found in This Manual

Table 1-6: Acronyms, Abbreviations

Abbreviation	Definition
A/D	analog/digital
ART	systemic arterial blood pressure
BMI	body mass index
BSA	body surface area
ΔctHb	relative change in total hemoglobin
DIA_{ART}	systemic arterial diastolic blood pressure
DPT	disposable pressure transducer
HEMPC	pressure controller
HGB	hemoglobin
HR	heart rate
HR_{avg}	average heart rate
IA	Intervention Analysis
IEC	International Electrotechnical Commission
LED	light emitting diode
MAP	mean arterial pressure
NIBP	non-invasive blood pressure
OR	operating room
PC2	pressure controller
POST	power-on self test
PR	pulse rate
SaO_2	oxygen saturation
SQI	signal quality indicator
ST	surface temperature
StO_2	tissue oxygen saturation
SYS_{ART}	systemic arterial systolic blood pressure
Touch	Interact with the HemoSphere Vita monitor by touching the screen.

Abbreviation	Definition
USB	Universal Serial Bus

2

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 Vita 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 HemoSphere Vita monitor.
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Vita 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 Vita 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 Vita 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)
- **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 Vita monitor in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide. (chapter 3)
- This product contains metallic components. Do NOT use in a Magnetic Resonance (MR) environment. (chapter 3)
- Make sure the HemoSphere Vita 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)
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. (chapter 3)
- The HemoSphere Vita 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 is rated for use with high-frequency surgical equipment. Inaccurate parameter measurements can be caused by interference from high-frequency surgical equipment. To reduce hazards that can arise from the use of high-frequency surgical equipment, only use undamaged patient cables and accessories connected as specified in this operator's manual. (chapter 3)
- This system is rated for use with defibrillators. To ensure proper defibrillator-proof operation, only use undamaged patient cables and accessories connected as specified in this operators manual. (chapter 3)
- All IEC/EN 60950 equipment, including printers, to be positioned no closer than 1.5 meters to the patient's bed. (chapter 3)
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 in) to any part of the HemoSphere Vita monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance this equipment could result. (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 Vita 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 Vita 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 Vita 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 Vita 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 Vita 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 Vita monitor. Failure to do so may result in previous patient data in the historical displays. (chapter 6)
- Do not use alarm settings/presets that differ from the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating theater. Conflicting alarms can affect patient safety. (chapter 7)
- 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 tiles). If a parameter is not selected and displayed as a key parameter, the audible and visual physiological alarms are not triggered for that parameter. (chapter 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)
- VitaWave technology use not recommended for patients age < 18 years of age. (chapter 9)
- Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component. (chapter 9)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere VitaWave module (applied part connection) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 9)
- Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance. (chapter 9)
- Do not sterilize any components of the HemoSphere Vita non-invasive system. The HemoSphere Vita non-invasive system is provided non sterile. (chapter 9)
- Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (chapter 9)
- Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (chapter 9)
- Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks. (chapter 9)
- The HemoSphere Vita non-invasive system monitoring components are not defibrillation proof. Disconnect the system before defibrillating. (chapter 9)
- Only use compatible Edwards finger cuffs, heart reference sensor and other HemoSphere Vita non-invasive system accessories, cables and or components that have been supplied and labeled by Edwards. Using

other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy. (chapter 9)

- Always remove HemoSphere Vita non-invasive system sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient. (chapter 9)
- Do not overtighten the pressure controller band or finger cuff(s). (chapter 9)
- Do not apply pressure controller band on injured skin as this can cause further injury. (chapter 9)
- Improper finger cuff placement or sizing can lead to inaccurate monitoring. (chapter 9)
- Do not use the HemoSphere Vita non-invasive system as a heart rate monitor. (chapter 9)
- If using the instrument during full body irradiation, keep all HemoSphere Vita non-invasive system monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected. (chapter 9)
- Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements. (chapter 9)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere Vita technology module (applied part connection, defibrillation proof) is connected to a compatible monitoring platform. Connecting external equipment or configuring the system in a way not described in these instructions will not meet this standard. Failure to use the device as instructed may increase the risk of electrical shock to the patient/operator. (chapter 10)
- Inspect all of the ForeSight oximeter cable connections for damage prior to installation. If any damage is noted, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical support. There is a risk that damaged parts could reduce the performance of the cable or present a safety hazard. (chapter 10)
- To remove any chance of contamination between patients, the ForeSight oximeter cable and cable connections should be cleaned after each case. (chapter 10)
- To reduce the risk of contamination and cross infection, if the ForeSight oximeter cable or cable connections are grossly contaminated, with blood or other bodily fluids, it should be disinfected. If the ForeSight oximeter cable or cable connections cannot be disinfected, it should be serviced, replaced or discarded. Contact Edwards Technical support. (chapter 10)
- To reduce the risk of damaging internal elements of the cable assemblies — within the ForeSight oximeter cable housing — avoid excessive pulling, bending or other types of stress on the cable connections. (chapter 10)
- Do not modify, service or alter the product in any way. Servicing, alteration or modification may affect patient/operator safety and/or product performance. (chapter 10)
- Sensors are not sterile and therefore should not be applied on abraded, cracked, or lacerated skin. Exercise caution when applying sensors to a site with delicate skin. Applying sensors, tape or pressure to such a site may reduce circulation and/or cause skin deterioration. (chapter 10)
- Do not place sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis, pneumoencephalus, or edema. (chapter 10)
- If electrocautery procedures will be performed, sensors and electrocautery electrodes should be placed as far apart as possible to prevent unwanted skin burns; a distance of at least 15 cm (6 in) is recommended. (chapter 10)
- Use only Edwards supplied accessories with the ForeSight oximeter cable. Edwards accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the ForeSight oximeter cable. Connecting a non-Edwards sensor will cause an appropriate alert on that channel and no StO_2 values will be recorded. (chapter 10)
- Sensors are designed for single-patient use, and are not to be reprocessed – re-used sensors present a risk of cross-contamination or infection. (chapter 10)
- Use a new sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies. (chapter 10)

- If a sensor seems damaged in any way, it must not be used. (chapter 10)
- Always read the sensor packaging. (chapter 10)
- Exercise extreme care when applying sensors. Sensor circuits are conductive and must not come into contact with other grounded, conductive parts other than EEG or entropy monitors. Such contact would bridge the patient's isolation and cancel the protection provided by the sensor. (chapter 10)
- Failure to apply sensors properly may cause incorrect measurements. Misapplied sensors or sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation. (chapter 10)
- Do not position a sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the sensor or the patient lying on a sensor) transfers weight from the sensor to the skin, which can injure skin and reduce sensor performance. (chapter 10)
- The sensor site must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site. (chapter 10)
- Do not connect more than one patient to the ForeSight oximeter cable. This may compromise the patient's isolation and cancel the protection provided by the sensor. (chapter 10)
- The ForeSight oximeter cable has been designed to promote patient safety. All cable parts are "Type BF Defibrillation Proof" and are protected against the effects of the defibrillator discharge and may remain attached to the patient. Cable readings may be inaccurate during defibrillator use and up to twenty (20) seconds thereafter. (chapter 10)
- No separate actions are required when using this equipment with a defibrillator, but only Edwards-supplied sensors must be used for proper protection against the effects of a cardiac defibrillator. (chapter 10)
- Do not come into contact with patients during defibrillation, or serious injury or death could result. (chapter 10)
- If the accuracy of any value displayed on the monitor is questionable, determine the patient's vital signs by alternative means. The functions of the alarm system for patient monitoring must be verified at regular intervals and whenever the integrity of the product is in doubt. (chapter 10)
- Testing of the ForeSight oximeter cable operation should be done at least once every 6 months, as described in HemoSphere Vita service manual. Failure to comply may lead to injury. If the cable fails to respond, it must not be used until it has been inspected and serviced or replaced. See technical support contact information on inside cover. (chapter 10)
- Only use approved HemoSphere Vita 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 Vita monitor contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages. (appendix E)
- **Shock or fire hazard!** Do not immerse the HemoSphere Vita monitor, modules, or platform cables in any liquid solution. Do not allow any fluids to enter the instrument. (appendix E)
- Do not, under any circumstances, perform any cleaning or maintenance of the ForeSight oximeter cable, while the cable is being used to monitor a patient. The cable must be turned off and the HemoSphere Vita monitor power cord disconnected, or the cable must be disconnected from the monitor and the sensors removed from the patient. (appendix E)
- Before starting cleaning or maintenance of any sort, check the ForeSight oximeter cable, cable connections, ForeSight sensors, and other accessories for damage. Check the cables for bent or broken prongs, cracks, or fraying. If any damage is noted, the cable must not be used until it has been inspected and serviced or replaced. Contact Edwards Technical Support. (appendix E)
- There is a risk of serious injury or death if this procedure is not followed. (appendix E)
- **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 E)
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. (appendix F)

- No modification of the HemoSphere Vita monitor is allowed. (appendix F)
- Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic ant-theft systems and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Vita monitor. Guidance on maintaining appropriate separation between communications equipment and the HemoSphere Vita monitor is provided in Table F-3 on page 187. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere monitoring platform. (appendix F)

2.3 Cautions

The following are cautions that are used in the HemoSphere Vita 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 the HemoSphere Vita monitor and all accessories and equipment used with the monitor for damage prior to use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised.
- 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)
- Do not expose the HemoSphere Vita monitor to extreme temperatures. Refer to environmental specifications in appendix A. (chapter 3)
- Do not expose the HemoSphere Vita monitor to dirty or dusty environments. (chapter 3)
- Do not obstruct the HemoSphere Vita monitor ventilation openings. (chapter 3)
- Do not use the HemoSphere Vita 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)
- Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis. (chapter 4)
- Use a virus scan on any USB stick before inserting to prevent a virus or malware infection. (chapter 8)
- The HemoSphere VitaWave module displays and analyzes a reconstructed radial arterial waveform. Clinicians should consider this waveform reconstruction, especially if they are experienced with viewing a brachial arterial pressure waveform. (chapter 9)
- Do not force the module into the slot. Apply even pressure to slide and click the module into place. (chapter 9)
- The effectiveness of HemoSphere Vita non-invasive system has not been evaluated in patients under 18 years of age. (chapter 9)
- 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 9)
- Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis. (chapter 9)
- The HemoSphere Vita non-invasive system is not intended for use as an apnea monitor. (chapter 9)
- In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud’s disease, blood pressure measurement can become impossible. (chapter 9)
- Inaccurate non-invasive measurements can be caused by factors such as:

    - Improperly calibrated and/or leveled HRS
    - Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:

        * Intra-aortic balloon pumps

  - Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure.
  - Poor blood circulation to the fingers.
  - A bent or flattened finger cuff.
  - Excessive patient movement of fingers or hands.
  - Artifacts and poor signal quality.
  - Incorrect placement of finger cuff, position of finger cuff, or finger cuff too loose.
  - Electrocautery or electrosurgical unit interference.

  (chapter 9)
- Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation. (chapter 9)
- The effectiveness of Edwards compatible finger cuffs has not been established in pre-eclamptic patients. (chapter 9)
- The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against an ECG heart rate. (chapter 9)
- The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis. (chapter 9)
- Monitoring without an HRS may lead to measurement inaccuracies. Ensure patient remains still with accurately measured finger to heart height difference. (chapter 9)
- Do not place the patient in a non-supine position while monitoring without an HRS. This may lead to an inaccurate vertical offset entry for the HRS and measurement inaccuracies. (chapter 9)
- Do not perform a BP calibration during monitoring periods when blood pressure appears unstable. This may result in inaccurate blood pressure measurements. (chapter 9)
- Avoid placing the ForeSight oximeter cable where the status LED cannot be easily seen. (chapter 10)
- Applying too much pressure may break the retaining tab, which may present a risk of the cable falling on the patient, bystander, or operator. (chapter 10)
- Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the cable in any position that might present a risk that the cable may fall on the patient, bystander or operator. (chapter 10)
- Avoid placing the ForeSight oximeter cable under sheets or blanket that could restrict air flow around the cable that may increase the cable's case temperature and present an injury. (chapter 10)
- Do not force the module into the slot. Apply even pressure to slide and click the module into place. (chapter 10)
- Sensors should not be placed on high density hair areas. (chapter 10)
- The sensor must be able to rest flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the sensor and the skin will affect the validity of the data collected and may result in an alarm message. (chapter 10)
- When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection. (chapter 10)
- Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the ForeSight oximeter cable in any position that might present a risk that the module may fall on the patient, bystander or operator. (chapter 10)
- Once patient monitoring has started, do not replace the sensor or disconnect the sensor for more than 10 minutes to avoid restarting the initial StO_2 calculation. (chapter 10)
- Measurements may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment, and measurements may be inaccurate during use of such equipment. (chapter 10)
- Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate or erroneous measurements, as may intravascular dyes or any substance containing dyes that change usual blood pigmentation. Other factors that may affect measurement accuracy include: myoglobin, hemoglobinopathies,

anemia, pooled blood under the skin, interference from foreign objects in the Sensor path, Bilirubinemia, externally applied coloring (tattoos), high levels of HGB or Hct and birthmarks. (chapter 10)

- When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection. (chapter 10)
- When compared to earlier software versions, a ForeSight oximeter cable with a software version of V3.0.7 or later and used with pediatric sensors (small and medium) is more responsive in the display StO_2 values. Specifically, in the range below 60%, StO_2 measurements could be reported lower than in earlier software versions. Clinicians should consider the faster response and potentially modified StO_2 values when using V3.0.7 software, especially if they are experienced with earlier software versions of the ForeSight oximeter cable. (chapter 10)
- If any of the ForeSight oximeter cable LEDs fail to turn on, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical Support. There is a risk that damaged parts could reduce the performance of the cable. (chapter 12)
- Do not pinch any heart reference sensor tubes or wires under the pressure controller cover during application. Be careful the only wire between the back mounting notch is the pressure controller cable. (appendix B)
- Do not lift PCCVR from any other point than the front tab. (appendix B)
- Clean and store the instrument and accessories after each use. (appendix E)
- The HemoSphere Vita monitor modules and platform cables are electrostatic discharge (ESD) sensitive. Do not attempt to open cable or module housing or use if the housing has been damaged. (appendix E)
- Do not pour or spray liquid on any portion of the HemoSphere Vita monitor, accessories, modules, or cables. (appendix E)
- Do not use any disinfecting solution other than the types specified. (appendix E)
- 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 E)
- Conduct periodic inspections of all cables for defects. Do not coil cables tightly when storing. (appendix E)
- Do not use any other cleaning agents, spray, or pour cleaning solution directly on platform cables. (appendix E)
- Do not steam, radiate, or EO sterilize platform cables. Do not immerse platform cables. (appendix E)
- Do not disinfect the heart reference sensor or pressure controller by autoclave or gas sterilization. (appendix E)
- Do not immerse any cable connectors in fluid. (appendix E)
- Clean and store the heart reference sensor after each use. (appendix E)
- Recycle or dispose of the lithium-ion battery in accordance to all federal, state, and local laws. (appendix E)
- 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 F)

2.4 User Interface Symbols

The following are icons that appear on the HemoSphere Vita monitor screen. For more information about screen appearance and navigation, see chapter 5, Navigating the HemoSphere Vita Monitor on page 56. 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	
	Start non-invasive monitoring (HemoSphere VitaWave module)
	Stop non-invasive monitoring (HemoSphere VitaWave module)
	Resume non-invasive monitoring after cuff pressure release (HemoSphere VitaWave module)
	Zero & Waveform
	Settings menu
	Home (return to main monitoring screen)
	Display pressure waveform
	Hide pressure waveform
	Silence audible alarms
	Alarms paused (silenced) with countdown timer (see **Silence Audible Alarms** in Navigation Bar on page 57)
	Resume monitoring with elapsed time from monitoring pause
	Patient Data (demographics have been entered)
	Patient Data (demographics have been skipped)

Clinical Tools Menu Icons	
	Event Review
	Zero & Waveform
	BP Calibration (VitaWave BP) (HemoSphere VitaWave module)
	HRS Calibration
	ctHb Tools
	Patient Data

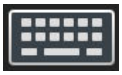
Menu Navigation Icons	
	Return to main monitoring screen
	Return to previous menu
	Cancel
	Scroll to select item on vertical list
	Vertical page scroll
	Horizontal scroll
	Enter
	Keypad enter key
	Keypad backspace key
	Move cursor left by 1 character
	Move cursor right by 1 character

Menu Navigation Icons	
	Keypad cancel key
	Item enabled
	Item not enabled
	Clock/waveform - allows user to view historical data or intermittent data

Parameter Tile Icons	
	Alarms/Targets menu: parameter audible alarm indicator enabled
	Alarms/Targets menu: parameter audible alarm indicator disabled
	Signal quality indicator bar See SQI on page 110 (HemoSphere VitaWave module)
	ΔctHb value (StO_2 only) (advanced feature)

Information Bar Icons	
	Snapshot (screen capture)
	Battery life indicator icons on information bar See Table 5-5 on page 72
	Screen Brightness
	Alarm Volume
	Lock Screen
	Help menu shortcut
	Event Review

Information Bar Icons	
	Time until cuff pressure release mode (HemoSphere VitaWave module, see Calibrate the Heart Reference Sensor on page 112)
	Time until conclusion of cuff pressure release mode (HemoSphere VitaWave module, see Calibrate the Heart Reference Sensor on page 112)

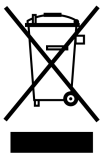
Intervention Analysis Icons	
	Intervention analysis button
	Intervention analysis type indicator for custom event (gray)
	Intervention analysis type indicator for positional challenge (purple)
	Intervention analysis type indicator for a fluid challenge (blue)
	Intervention analysis type indicator for intervention (green)
	Intervention analysis type indicator for oximetry (red)
	Intervention analysis type indicator for event (yellow)
	Edit icon on intervention information balloon
	Keyboard icon for entering notes on intervention edit screen

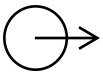
2.5 Symbols on Product Labels

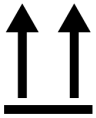
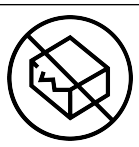
This section provides the symbols that are on the HemoSphere Vita monitor and other available HemoSphere Vita monitoring platform accessories.

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

Symbol	Description
	Separate collection for electrical and electronic equipment in accordance with EC directive 2012/19/EU.
	Federal Communications Commission (FCC) compliance - USA only
	This device contains a non-ionizing radiation transmitter, which can cause RF interference with other devices near this device.
	Follow instructions for use on the website
	Intertek ETL
	Model number
	Serial number
	Authorized representative in the European Community
	MR unsafe
	Conformité Européenne (CE Mark) of TÜV SÜD Product Service GmbH (notified body)
	Batch code
	Quantity
	Medical device
	Unique device identifier
	Importer

Connector Identification Labels	
	Equipotential terminal stud
	USB 3.0
	Pressure (DPT) output
	Defibrillation proof type BF applied part or connection
	Type BF applied part or connection
	Continuous non-invasive arterial blood pressure
	Remove the pressure controller cover from this end
	Do not remove pressure controller cover from this end

Additional Packaging Labels	
	Keep dry
	Fragile, handle with care
	This end up
	Do not use if package is damaged and consult instructions for use

Additional Packaging Labels	
	Box made from recyclable cardboard
	Follow instructions for use
	Store in a cool, dry place
	Use-by date
	Environment-friendly use period (EFUP) - China only

Note

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

2.6 Applicable Standards

Table 2-3: Applicable standards

Standard	Title
IEC 60601-1:2005 / 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 60601-2-34: 2011	Medical electrical equipment — Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment
IEC 60601-2-49:2011/ IEC 80601-2-49:2018	Medical electrical equipment — Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment/monitors
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 Vita Monitor Essential Performance

The platform shall provide non-invasive measurement of arterial blood pressure with a compatible Edwards finger cuff according to the specifications provided in appendix A. The platform shall provide display of StO_2 with a compatible oximetry module and sensor according to the specifications provided in appendix A. The platform shall provide alarm, alert, indicator, and/or system status when unable to provide accurate measurement of the applicable hemodynamic parameter. For more information, see Essential Performance Characteristics on page 162.

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

3

Installation and Setup

Contents

3.1 Unpacking

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

3.1.1 Packaging Contents

The HemoSphere Vita monitoring platform is modular and therefore packaging configurations will vary depending upon the kit ordered. The HemoSphere Vita monitoring system, which is the base kit configuration, contains the HemoSphere Vita 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 on page 40. 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 on page 170, for a full list of available accessories.

Table 3-1: HemoSphere Vita monitoring components

HemoSphere Vita monitoring system (base kit)
• HemoSphere Vita 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: Finger cuff options for monitoring parameters with HemoSphere VitaWave module

	Monitored and calculated parameters	
Finger cuff options (one required)	**PR**	**SYS/ DIA/ MAP**
VitaWave finger cuff	•	•
ClearSight/Acumen IQ finger cuff	•	•

Table 3-3: Accessories required for monitoring parameters with HemoSphere Vita technology module

Required accessory	Tissue oximetry (StO_2)
ForeSight oximeter cable	•
ForeSight/ForeSight Jr sensor	•

WARNING

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

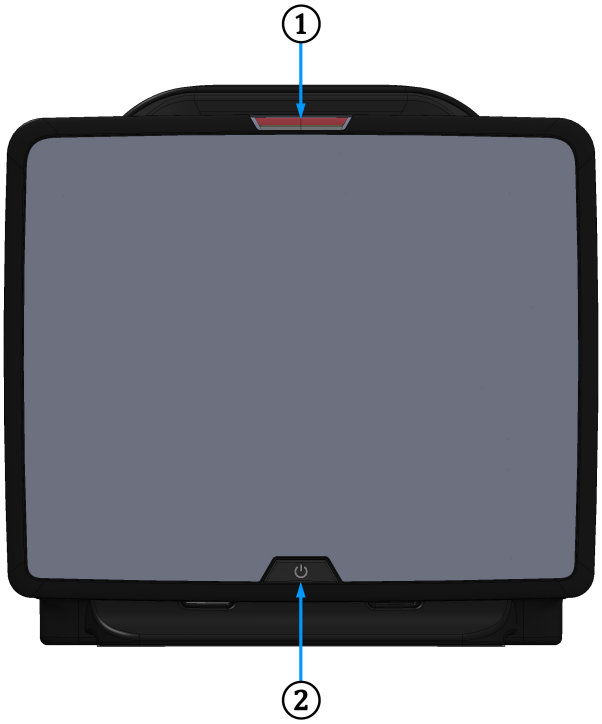
CAUTION

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

3.2 HemoSphere Vita 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 Vita monitor.

3.2.1 Monitor Front

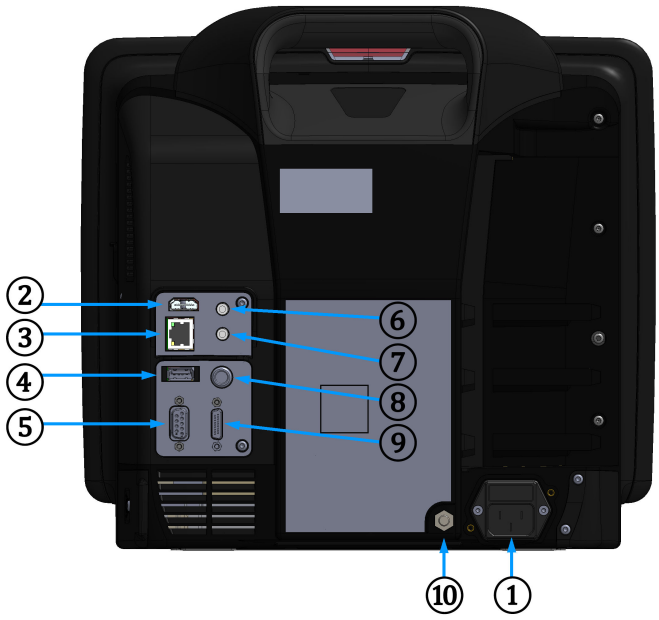


1. visual alarm indicator

2. power button

Figure 3-1: HemoSphere Vita monitor front view

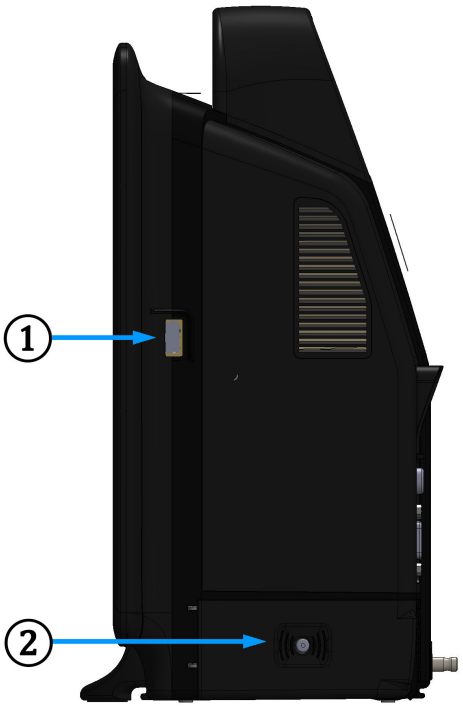
3.2.2 Monitor Rear



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 Vita monitor rear view

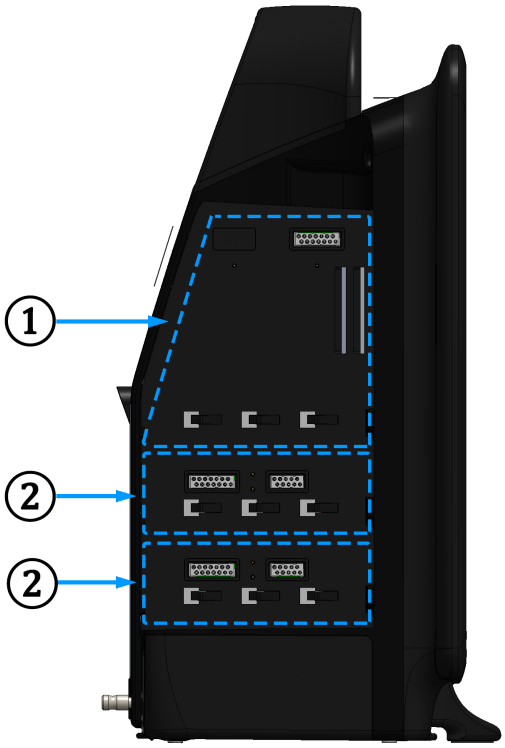
3.2.3 Monitor Right Panel



1. USB port **2.** battery door

Figure 3-3: HemoSphere Vita monitor right panel

3.2.4 Monitor Left Panel



1. L-Tech expansion module slot

2. expansion module slots (2)

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

3.3 HemoSphere Vita Monitor Installation

3.3.1 Mounting Options and Recommendations

The HemoSphere Vita monitor should be placed on a stable flat surface or securely mounted on a compatible stand, according to your institution's practices. The operator should be positioned in front of the monitor and at close proximity during use. The device is intended to be used by only one user at a time. A roll stand for the HemoSphere Vita monitor is available as an optional accessory. See Additional Accessories Description on page 171 for more information. Contact your local Edwards representative for recommendations on additional mounting options.

WARNING

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

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

Make sure the HemoSphere Vita 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.

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

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

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

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

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

CAUTION

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

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

Do not obstruct the HemoSphere Vita monitor ventilation openings.

Do not use the HemoSphere Vita 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 on page 44) 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 183.

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 Vita 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 Vita 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 on page 48) 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 Vita monitoring platform without an installed power cord entry cover. Failure to do so may result in fluid ingress.

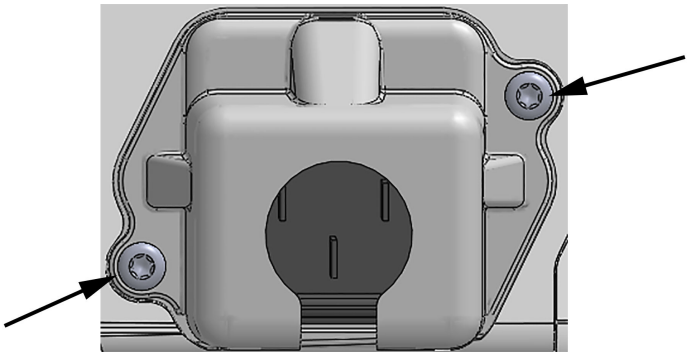


Figure 3-5: HemoSphere Vita monitor power entry cover - screw locations

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 on page 43) 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 Vita 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 Vita 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.

WARNING

Only use HemoSphere Vita 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.

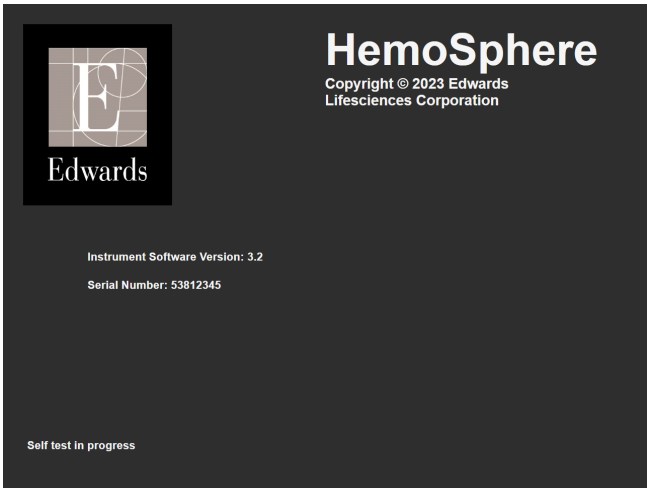


Figure 3-6: Startup screen

Note

If the diagnostic tests detect an error condition, a system error screen will replace the startup screen. See chapter 12: Troubleshooting on page 141 or appendix E: System Care, Service and Support on page 178. Otherwise, call your Edwards Lifesciences representative for assistance.

3.4.2 Select Language

Upon initial HemoSphere Vita 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 on page 174).

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

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

Figure 3-7: Language selection screen

Note

Figure 3-6 on page 49 and Figure 3-7 on page 50 are examples of startup and language selection screens.

3.4.3 Select Device ID

Upon initial HemoSphere Vita monitor startup, the user can select a **Device ID** or name for the monitor on the **New Patient Data** screen. See New Patient on page 78. The **Device ID** defaults to the monitor serial number but can be changed to any 20 character name. The **Device ID** is displayed at the center of the information bar. See Information Bar on page 71.

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

3.5 Power Off and Power Save Mode

To power the monitor off, touch the power button. See (2) in Figure 3-1 on page 42. The following options will be displayed:

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

4

HemoSphere Vita Monitor Quick Start

Contents

Note

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

4.1 HemoSphere Tissue Oximetry Monitoring

The HemoSphere Vita technology module is compatible with the ForeSight oximeter cable and ForeSight/ForeSight Jr sensors. The HemoSphere Vita technology module fits into a standard module slot.

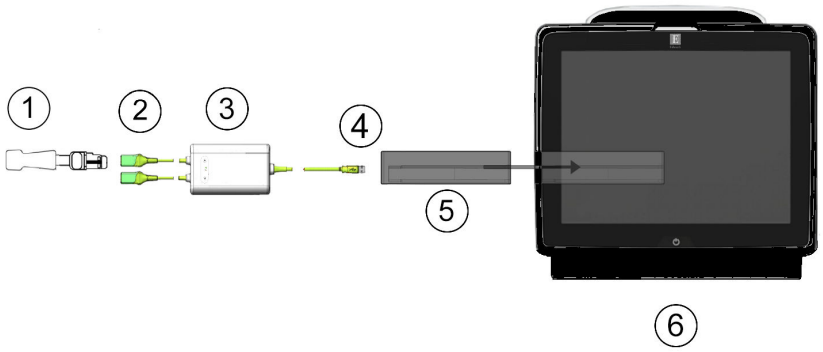
Note

The following components may have alternative labeling conventions:

ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).

ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

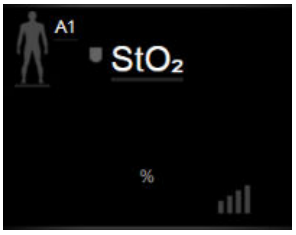
4.1.1 Connecting the HemoSphere Vita Technology Module

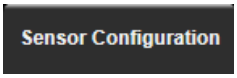
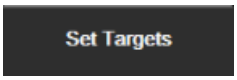


1. ForeSight/ForeSight Jr sensor
2. ForeSight/ForeSight Jr sensor connections (2)
3. ForeSight oximeter cable housing
4. Cable to module connections (2)
5. HemoSphere Vita technology module
6. HemoSphere Vita monitor

Figure 4-1: Tissue oximetry monitoring connection overview

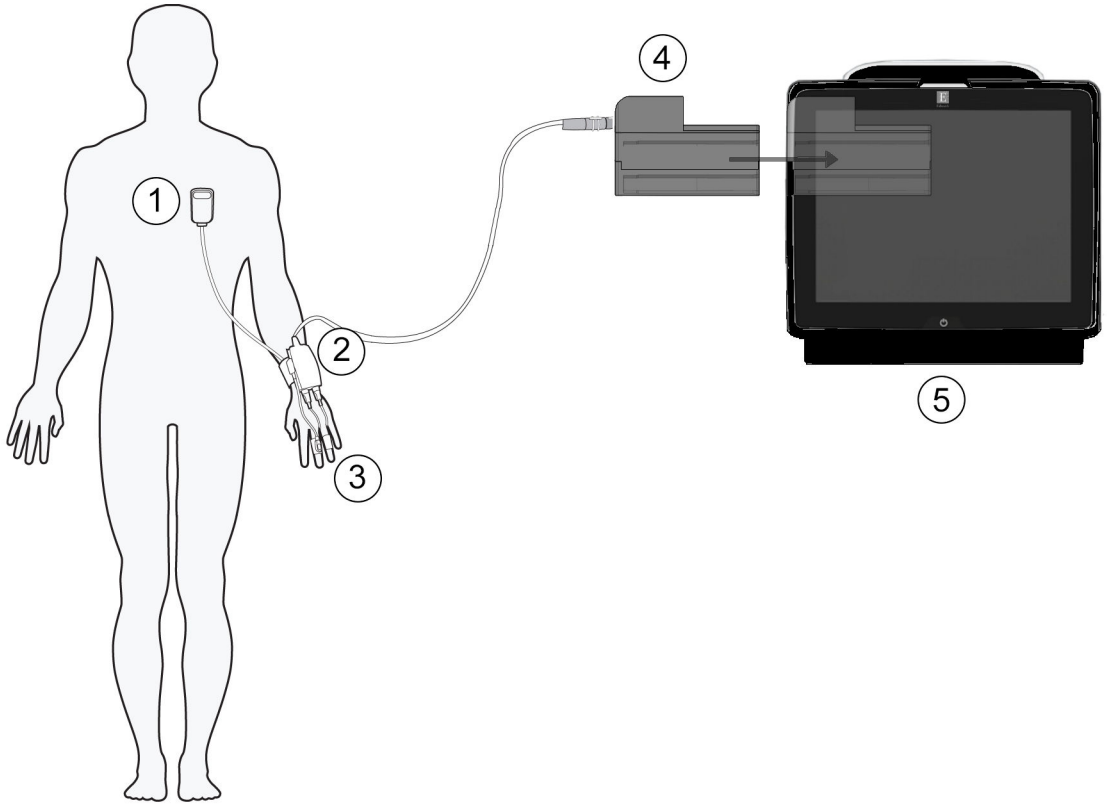
1. Insert the HemoSphere Vita technology module into the monitor. The module will click when properly engaged.
2. Press the power button to turn on the HemoSphere Vita monitor. All functions are accessed through the touch screen.
3. Select **Continue Same Patient** button or **New Patient** button and enter new patient data.
4. Ensure proper orientation, then plug the ForeSight oximeter cable into the technology module. Up to two ForeSight oximeter cables can be connected to each technology module.
5. Connect the compatible ForeSight/ForeSight Jr sensor(s) to the ForeSight oximeter cable. Up to two sensors can be connected to each ForeSight oximeter cable. See Attaching Sensors to the Patient on page 128 and refer to the ForeSight and ForeSight Jr sensor instructions for use for proper application directions.
6. Monitoring begins automatically once the ForeSight sensor(s) are connected to the ForeSight oximeter cable.
7. If **StO_2** is not a current key parameter, touch the displayed parameter label located inside of any parameter tile to select **StO_2 <Ch>** as a key parameter from the **Select Parameter** tab of the tile configuration menu, where **<Ch>** is the sensor channel. The channel options are **A1** and **A2** for ForeSight oximeter cable A and **B1** and **B2** for ForeSight oximeter cable B.
8. The channel will appear in the upper left corner of the parameter tile. Touch the patient figure  on the parameter tile to access the **Sensor Configuration** tab of the tile configuration menu.



9. Select the Patient monitoring mode: adult  or pediatric  .
10. Select the anatomical location of the sensor. See Table 10-1 on page 126 for a list of available sensor locations.
11. Touch the home icon  to return to the monitoring window.
12. Touch anywhere in the **StO_2** parameter tile → **Sensor Configuration** tab  to adjust **Skin Check Reminder** or **Averaging** for that sensor.
13. Touch anywhere in the **StO_2** parameter tile → **Set Targets** tab  to adjust **Alarms/Targets** for **StO_2**.

4.2 HemoSphere VitaWave Module Monitoring

4.2.1 Connecting the HemoSphere Vita Non-Invasive System



1. heart reference sensor
2. pressure controller
3. finger cuff(s)
4. HemoSphere VitaWave module
5. HemoSphere Vita monitor

Figure 4-2: HemoSphere Vita non-invasive system connection overview

1. Insert the HemoSphere VitaWave module into the large technology (L-Tech) slot of monitor. The module will click when properly engaged.
2. Press the power button to turn on the HemoSphere Vita 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 pressure controller to the HemoSphere VitaWave module.
5. Wrap the pressure controller band around the patient's wrist and attach the compatible pressure controller to the band. Either wrist can be used however the non-dominant arm is preferred.
6. Select the proper size finger cuff by using the finger cuff sizing aid.
7. Place the finger cuff on the patient's finger. Refer to the product IFU for detailed instructions on proper finger cuff placement and actual device illustrations.

Note

Cuff sizing may not be applicable to all cuffs.

HemoSphere VitaWave module has been validated for compatibility with Edwards ClearSight and Acumen IQ finger cuffs.

8. Connect finger cuff to pressure controller.

Note

After 8 hours of accumulated monitoring on the same finger, the HemoSphere non-invasive system will stop monitoring and display a warning to place the cuff on another finger if continued monitoring is desired.

9. Connect heart reference sensor to the pressure controller.
10. Apply the heart end of the HRS to the patient at phlebostatic axis level by using an HRS clip.

CAUTION

Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.

11. Attach the other end of the HRS to the finger cuff.
12. Touch the start monitoring icon 

on the navigation bar or on setup help screen to begin monitoring.
13. Touch the stop monitoring icon 

on the navigation bar to end monitoring at any time.
14. Touch the settings icon  → **Select Screens** tab 

to select the desired monitoring screen view.
15. Touch inside of a parameter tile to select the desired key parameter from the parameter tile configuration menu.
16. Touch within a parameter tile to adjust **Alarms/Targets**.

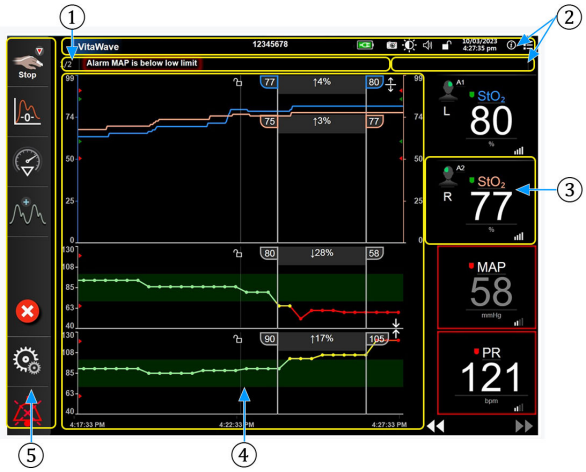
5

Navigating the HemoSphere Vita Monitor

Contents

5.1 HemoSphere Vita 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 Vita monitor screen are shown below in Figure 5-1 on page 57. The main window displays the current monitoring view or menu screen. For details on monitoring view types, see Monitor Views on page 60. For details on other screen features, see the referenced sections in Figure 5-1 on page 57.



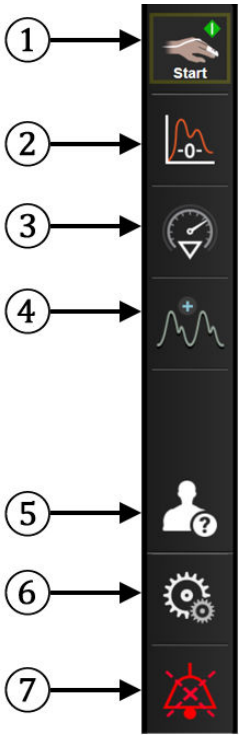
1. Status Bar (section 5.6)
2. Information Bars (section 5.5)
3. Parameter Tile (section 5.3.2)
4. Main Window/Monitor Views (section 5.3)
5. Navigation Bar (section 5.2)

Figure 5-1: HemoSphere Vita 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 Vita monitor has stopped monitoring. All available icons are described in detail below.

1. Start Monitoring[1]
2. Zero & Waveform
3. Intervention Analysis[2]
4. Blood Pressure Waveform Display
5. Patient Data
6. Settings
7. Silence Audible Alarm



Additional Icons

Start/Stop Monitoring[1]

Resume Monitoring with Pause Elapsed Time

Hide Blood Pressure Waveform

Home

Pause Monitoring

Silence Audible Alarms Permanently

[1]*non-invasive VitaWave monitoring,* [2]*graphical trend screens*

Figure 5-2: Navigation bar and icons

Start Non-Invasive Monitoring. While monitoring with the HemoSphere VitaWave module, the start monitoring icon allows the user to initiate non-invasive blood pressure directly from the navigation bar. See Connecting the HemoSphere Vita Non-Invasive System on page 100.

Stop Non-Invasive Monitoring. The stop non-invasive monitoring icon indicates that non-invasive blood pressure and hemodynamic parameter monitoring using the HemoSphere VitaWave module is underway.

Zero & Waveform. This icon allows the user to access the **Zero & Waveform** screen directly from the navigation bar. See Connecting the HemoSphere Vita Non-Invasive System on page 100.

Intervention Analysis. This icon allows the user to access the Intervention Analysis menu. From here clinical interventions can be logged. See Intervention Events on page 64.

Display Blood Pressure Waveform. This icon allows the user to display the blood pressure waveform during non-invasive monitoring. See Live Blood Pressure Waveform Display on page 67.

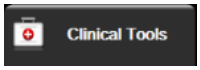
Hide Blood Pressure Waveform. This icon allows the user to hide the blood pressure waveform.

Patient Data (Demographics Entered). This icon appears on the Navigation bar once patient demographics have been entered.

Patient Data (Demographics Skipped). This icon appears on the Navigation bar when patient demographics have been skipped. Touch this icon at any point to enter patient demographics.

Home. This icon returns the user to the main monitoring screen.

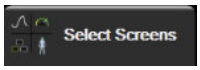
Settings. The settings icon provides access to four configuration screens which include:



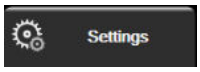
Clinical Tools. The clinical actions screen provides access to the following clinical tools:

- **Zero & Waveform**
- **Event Review**
- **Patient Data** (see Patient Data on page 77)
- **ctHb Tools** (ForeSight oximeter cable - see Relative Change in Total Hemoglobin – ΔctHb on page 138)
- **BP Calibration** (HemoSphere VitaWave module)
- **HRS Calibration** (HemoSphere VitaWave module - see Calibrate the Heart Reference Sensor on page 112)

A description of **Event Review** can be found in this chapter (see Clinical Tools on page 69). For the remaining clinical actions, refer to the specified module or cable chapter for more information.



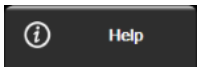
Select Screens. The select screens tab allows the user to select the desired number of monitored parameters displayed and the type of monitoring view used to display them, which is highlighted in color (see Figure 5-3 on page 60). When a monitoring view screen is selected, that monitoring mode is immediately displayed.



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

- **General Settings**: See chapter 6: User Interface Settings on page 76
- **Advanced Setup**: See chapter 7: Alarms/Targets on page 84, chapter 7: Adjust Scales on page 90, and chapter 8: Data Export and Connectivity Settings on page 94
- **Export Data**: See chapter 8: Data Export and Connectivity Settings on page 94
- **Demo Mode**: See chapter 7: Demo Mode on page 92
- **VitaWave**: See chapter 11: VitaWave Settings and Cuff Options on page 111

Advanced Setup and **Export Data** are password protected menu options. See Password Protection on page 76.



Help. See chapter 12: On Screen Help on page 141

Silence Audible Alarms. This icon silences all audio and visual indicator alarms for up to five minutes. The alarm pause interval options are 1, 2, 3, 4 and 5 minutes. New physiological alarms are silenced during the pause period. Alarms will resume sounding after the pause period has elapsed. Faults are silenced until the fault is cleared and re-occurs. If a new fault occurs, the alarm sound will resume.

Audible Alarms Silenced. Indicates that alarms are temporarily silenced. A countdown timer and "**Alarms Paused**" appear. An alarm paused indicator  will appear on any parameter tile that is currently alarming. Touch the silence audible alarms icon continuously for five seconds to show additional alarm silencing options (below).

Silence All Alarms Permanently. Touch this icon on the alarm expansion menu to silence all alarms indefinitely. Selecting this alarm silence option requires a Super User password. See Password Protection on page 76.

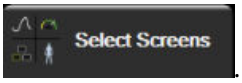
Non-Pulsatile Mode. Touch this icon to pause monitoring and enter **Non-Pulsatile Mode**. A confirmation banner will appear to confirm suspension of monitoring operations. Exception: tissue oximetry monitoring and associated alarms will remain active during **Non-Pulsatile Mode**. See Table D-3 on page 175 for active parameters.

Resume Monitoring. After Non-Pulsatile mode confirmation, a resume monitoring icon and elapsed time will appear on the navigation bar. A "**Non-Pulsatile Mode**" banner will be displayed. To return to monitoring, touch the resume monitoring icon.

5.3 Monitor Views

There are two classic monitoring views: graphical trend and tabular trend. Up to four key parameters can be viewed on both monitoring views. The position of any key parameter on the screen can be moved by holding down the parameter tile or parameter gauge then dragging and dropping it to the new desired position.

5.3.1 Change Monitor Views

1. Touch the settings icon  → **Select Screens** tab 

. 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 parameter tiles on monitoring screens.
3. Select and touch a monitor view button to display the key parameters in that screen format.

5.3.2 Parameter Tiles

Parameter tiles are located on the right side of most monitoring screens.

5.3.2.1 Change Parameters

1. Touch the displayed parameter label located inside the parameter tile to change it to a different parameter.
2. The tile configuration menu 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 on page 61 shows the parameter selection tab of the tile configuration menu that will appear while selecting continuous parameters and monitoring with the HemoSphere VitaWave module. The appearance of this window while monitoring with other HemoSphere modules or cables varies from what is shown in Figure 5-4 on page 61.

Parameters are organized into categories. Categories, listed below, are grouped together on the parameter selection configuration menu. See Figure 5-4 on page 61.

PRESSURE. These blood pressure parameters include SYS_{ART}, DIA_{ART}, MAP and PR.

OXIMETRY. Oximetry parameters include tissue oximetry (StO_2).

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

3. Touch an available parameter to select the replacement parameter.
4. To change the order of any key parameter, touch and hold the parameter tile until the tile appears with a blue outline. Drag and drop the parameter tile to the new desired location to update the order of key parameters.

5.3.2.2 Change Alarm/Target

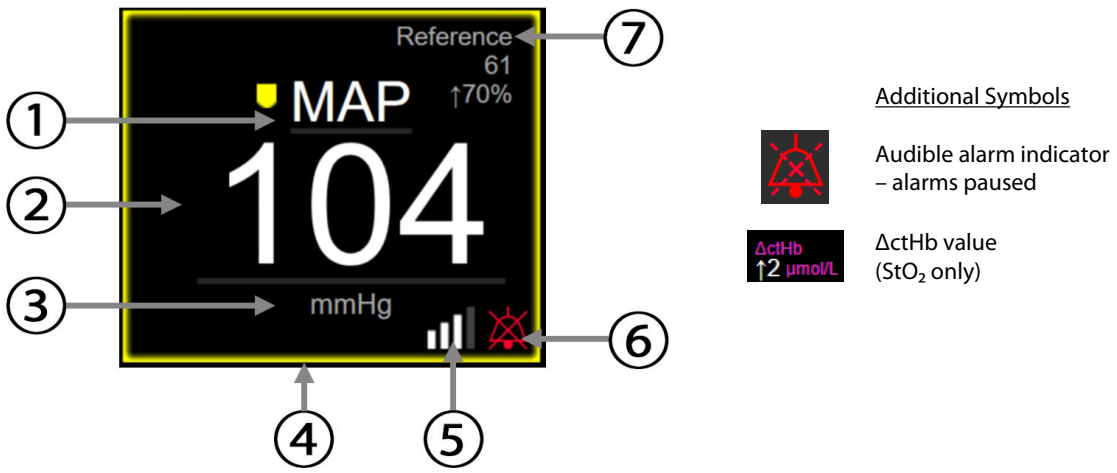
The **Alarms/Targets** screen lets the user view and set up alarm and target values for the selected parameter or enable/disable the audible alarm and target settings. Additionally, the target settings can be adjusted with a numbered key pad or with the scroll buttons when a minor adjustment is needed. This screen is accessed by touching the parameter value on a parameter tile or through the parameter settings screen. For more information, see Alarms/Targets on page 84.

Note

There is a two minute inactivity timer associated with this menu screen.

5.3.2.3 Status Indicators

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



1. parameter name
2. parameter value
3. units
4. target status indicator (outline)
5. SQI bar (StO_2 and non-invasive monitoring)
6. audible alarm indicator – alarms off
7. continuous change interval

Figure 5-5: Parameter tile

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

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

Continuous Change Interval. This indicator displays the percentage of change or absolute value of change, followed by the time period over which it changed. See Time Intervals / Averaging on page 82 for configuration options.

SQI Bar. The SQI bar  is a reflection of the signal quality during oximetry or non-invasive monitoring. Signal quality is based on the near-infrared light tissue perfusion index for tissue oximetry, see Table 10-5 on page 138. For non-invasive finger cuff monitoring, SQI is based on the quality of the pressure waveform signal from the plethysmograph sensor of the finger cuff. For non-invasive SQI levels, see Table 9-2 on page 111.

Target Status Indicators. The colored indicator outlining each monitoring tile indicates the patient's clinical status. For indicator colors and their clinical indications, see Table 7-2 on page 86.

5.3.3 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. Color plotting can be disabled through general settings. The colors match those of the clinical target indicator (parameter tile outline) on the key parameter tiles in the graphical trend graph when targets are enabled for the parameter. The alarm limits for each parameter are displayed as colored arrows on the graph y-axis.

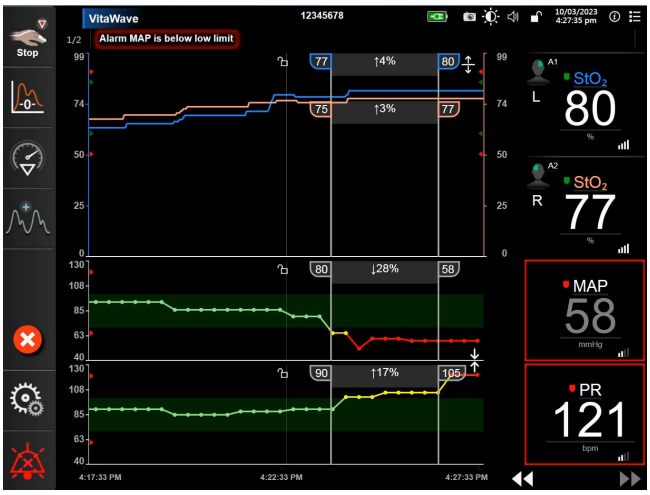


Figure 5-6: Graphical trend screen

To change the time scale of the displayed parameters, 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. To move the order of a trend plot, hold the plot down and drag and drop it to a new location. To combine plots, drop the parameter plot onto another graphical trend plot, or touch the combine icon  located between plots. The y-axis values for the second parameter will appear on the right side of the plot. To return to separate graphical trend plots, touch the expand icon  .

5.3.3.1 Graphical Trend Scroll Mode

Up to 72 hours of monitored parameter data can be viewed by scrolling back. To start scrolling, swipe to the right/left or touch the appropriate scroll mode button as shown above. 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 cancel icon  is touched. The scroll rate will appear between 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.

5.3.3.2 Intervention Events

While in the graphical trend screen or other monitoring views that display graphical trend plots such as the main monitoring view, selecting the intervention icon  provides a menu of intervention types, details and a notes section.

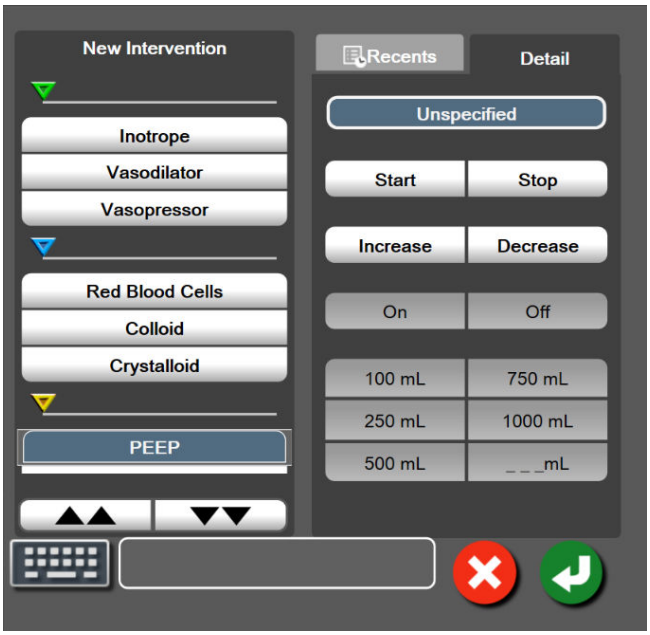
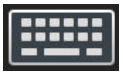


Figure 5-7: Graphical trend- intervention window

To enter a New Intervention:

1. Select the **Intervention** type from the **New Intervention** menu on left. Use the vertical scroll arrows to view all available **Intervention** types.
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:

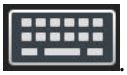
1. Select the **Intervention** from the **Recents** list tab.
2. To add, edit, or remove a note, touch the keyboard icon  .
3. Touch the enter icon  .

Table 5-2: Intervention events

Intervention	Indicator	Type
Intervention	 (green)	Inotrope Vasodilator Vasopressor
Positional	 (purple)	Passive Leg Raise Trendelenburg
Fluids	 (blue)	Red Blood Cells Colloid Crystalloid
Event	 (yellow)	PEEP Induction Cannulation CPB Cross Clamp Cardioplegia Pump Flow Circulatory Arrest Warming Cooling Selective Cerebral Perfusion
Custom	 (gray)	Custom Event BP Calibration*
**System generated markers*		

Note

Interventions initiated through the clinical tools menu, such as BP Calibration, are system generated and cannot be entered through the intervention analysis menu.

After selection of the intervention type, markers indicating the intervention are visually displayed on all graphs. These markers can be selected for more information. Upon touching the marker, an information balloon will appear. See Figure 5-8 on page 66. 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.

   Note

   The date or time of system generated intervention markers cannot be edited.

5. Touch the keyboard icon to enter or edit notes.
6. Touch the enter icon .

Figure 5-8: Graphical trend screen - intervention information balloon

5.3.3.3 Live Blood Pressure Waveform Display

To display the real-time blood pressure waveform, touch the display pressure waveform icon  . The display waveform icon appears on the navigation bar while monitoring with the graphical trend or main monitoring screens. A live pressure waveform graph panel will be displayed above the first monitored parameter graph. A numeric reading of the beat to beat systolic, diastolic and mean arterial pressure will be displayed above the first monitored parameter tile. To change the sweep speed (x-axis scale) of the graph, touch the scale area and a popup menu will appear to allow input of a new sweep speed. If multiple monitoring technologies are connected, touch the parameter name on the waveform parameter tile to switch between monitored pressure waveforms.

To stop display of live blood pressure waveform, touch the hide pressure waveform icon  .

Note

If there are 4 key parameters being displayed when the display pressure waveform button is touched, display of the 4th key parameter is temporarily removed and the blood pressure waveform graph is placed at the top of the remaining 3 Key Parameter trend graphs.

5.3.4 Tabular Trends

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

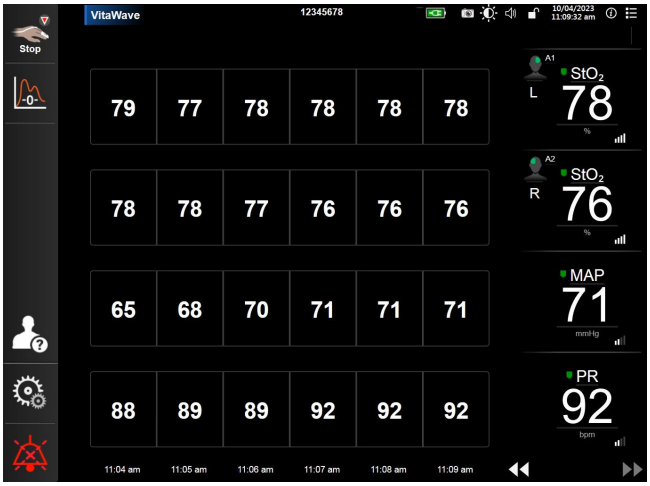


Figure 5-9: Tabular trend screen

1. To change the interval between values, touch inside the table.
2. Select a value on the **Tabular Increment** popup.

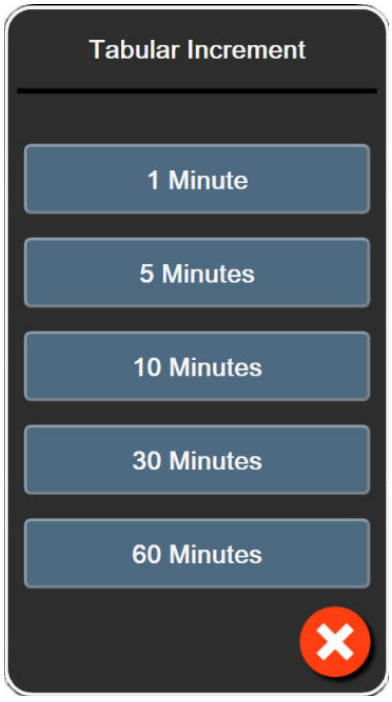


Figure 5-10: Tabular increment popup

5.3.4.1 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 double arrows below the parameter tiles. The scroll rate will appear between the scroll icons.

Table 5-3: Tabular trend scroll rates

Setting	Time	Speed
>	one cell	Slow
>>	six cells	Moderate
>>>	forty cells	Fast

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

Note

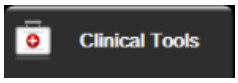
The screen will return to live mode two minutes after the last touch of the scroll arrow icon or if the cancel icon is touched.

5.4 Clinical Tools

The following clinical actions are available on the HemoSphere Vita monitor.

5.4.1 Event Review

Use **Event Review** to view parameter-related and system events that occurred during monitoring. This includes the start and end time of any faults, alerts, physiological alarms, or system messages. Up to 72 hours of events and alarm messages are recorded in order with the most recent event at the top.

1. Touch the settings icon  → **Clinical Tools** tab 

→ **Event Review** icon  .

   OR

   touch the **Event Review** shortcut on the information bar  .

2. To view system logged events (see Table 5-4 on page 69) select the **Events** tab. To view system generated messages, touch the **Alarms** tab. To scroll up or down on either screen, touch the arrow keys.
3. Touch the home icon  to return to the monitoring screen.

The following events are included in the **Events** tab of the event review log.

Table 5-4: Reviewed events

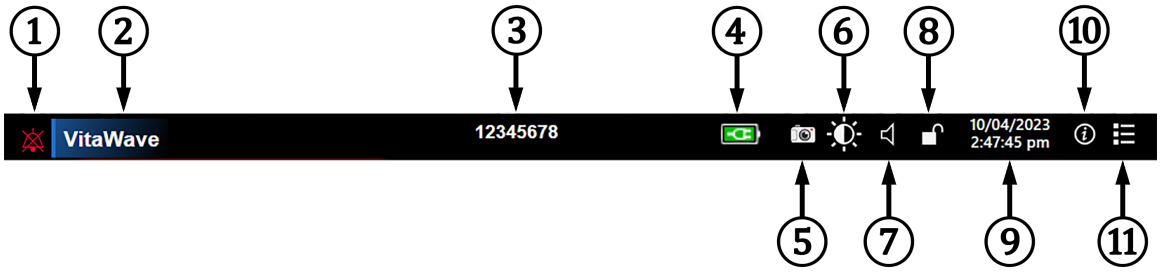
Event	When time logged
BP Calibration Cleared	The existing BP Calibration is cleared
BP Calibration Failed REFERENCE: SYS {0}, DIA {1}	Blood pressure calibration has failed where {0} is the user-entered reference value for SYS and {1} is the user-entered value for DIA
BP Calibration Successful REFERENCE: SYS {0}, DIA {1}	Blood pressure calibration is successfully completed where {0} is the user-entered reference value for SYS and {1} is the user-entered value for DIA
BSA Change	The BSA value changes from the previous BSA value (including when BSA goes to/from blank)
VitaWave Monitoring Started	The user begins non-invasive system monitoring
VitaWave Monitoring Started (No HRS; Finger {0} {1} above heart)	The user begins non-invasive system monitoring without an HRS and the verified height offset of the monitored finger is the specified distance above the heart, where {0} is the value and {1} is the unit of measurement (CM or IN)
VitaWave Monitoring Started (No HRS; Finger {0} {1} below heart)	The user begins non-invasive system monitoring without an HRS and the verified height offset of the monitored finger is the specified distance below the heart, where {0} is the value and {1} is the unit of measurement (CM or IN)

Event	When time logged
VitaWave Monitoring Started (No HRS; Finger at heart level)	The user begins non-invasive system monitoring without an HRS and the verified height offset between the monitored finger and heart is zero
VitaWave Monitoring Stopped	The user or system stops non-invasive system monitoring
VitaWave Monitoring Resumed	When monitoring resumes after a cuff pressure release
Continuous monitoring has reached the 72 hour limit.	Non-invasive system monitoring has stopped due to 72 hour limit
Cuff 1 Monitoring	Cuff 1 monitoring begins
Cuff 2 Monitoring	Cuff 2 monitoring begins
Cuff Pressure Released	A cuff pressure release has occurred
Cuff Pressure Release Acknowledged	The **Acknowledge** button is touched on **Pressure Release** notification popup
[IA#N] <sub-type> <detail> <note>	An intervention analysis is performed where #N is the enumeration of interventions for this patient <sub-type> is the intervention sub-type selected (for general Intervention: Inotrope, Vasodilator, or Vasopressor; for Fluid analysis: Red Blood Cells, Colloid, or Crystalloid; for Position Challenge: Passive Leg Raise or Trendelenburg; for Event: PEEP, Induction, Cannulation, CPB, Cross Clamp, Cardioplegia, Pump Flow, Circulatory Arrest, Warming, Cooling, Selective Cerebral Perfusion) <detail> is the selected detail <note> is note added by user
[IA#N] ΔctHb Reset Initiated	The **Reset ΔctHb** button is touched on the **ctHb Tools** screen
[IA#N] Custom <detail> <note>	A Custom intervention analysis is performed where #N is the enumeration of interventions for this patient <detail> is the selected detail <note> is note added by user
[IA#N Updated] Note: <updated note>	The note associated with the Nth intervention was edited but the time and date were not edited. Logged when the Accept button on Edit Intervention popup is enabled and touched. N is the enumeration of the original intervention.
[IA#N Updated] Time: <Updated date> - <Updated Time>	The date or time associated with the Nth intervention was edited but the note was not edited. Logged when the Accept button on Edit Intervention popup is enabled and touched. N is the enumeration of the original intervention.
[IA#N Updated] Time: <Updated date> - <Updated Time>; Note: <updated note>	The (time OR date) AND note associated with the Nth intervention were edited. Logged when the Accept button on Edit Intervention popup is enabled and touched. N is the enumeration of the original intervention.
Monitoring Stopped as Single Cuff Use Has Exceeded 8 Hours	Monitoring for 8 continuous hours on a single cuff has occurred
Positioning Mode: <mode>	The user has started non-invasive system monitoring and the positioning mode is selected as <**Patient Sedated and Stationary**> or <**Variable Patient Positioning**>
Postpone Pressure Release	Monitoring is extended to delay a finger cuff pressure release

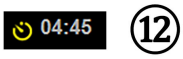
Event	When time logged
Switched Cuff - Restarting	Monitoring is switched from one cuff to the other during non-invasive double cuff monitoring
System Restart Recovery	When the system has resumed monitoring without being prompted following a power cycle
Time Change	The system clock is updated
Vertical Offset Updated: Finger <position>	The finger to height offset is updated by the user during **Patient Sedated and Stationary** positioning mode where <position> is the verified height offset between the monitored finger and heart.

5.5 Information Bar

The information bar appears on all active monitoring screens and most clinical tools screens. It displays the Device ID, current time, date, battery status, screen brightness menu shortcut, alarm volume menu shortcut, help screen shortcut, event review shortcut, and the lock screen symbol. See Figure 5-11 on page 71 for an example of an information bar while monitoring with the HemoSphere VitaWave module.



Additional Icons



1. alarms silenced
2. sensor technology
3. Device ID
4. battery status
5. snapshot
6. screen brightness
7. alarm volume
8. lock screen
9. date/time
10. help menu
11. event review
12. cuff release countdown[1]

[1] *non-invasive HemoSphere VitaWave module monitoring*

Figure 5-11: Information bar

Note

Figure 5-11 on page 71 is an example of an information bar with selected language standard defaults. To see the defaults for all languages, see Table D-6 on page 176.

5.5.1 Battery

The HemoSphere Vita 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 on page 72. For more information on battery installation, see Battery Installation on page 46. 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 183.

Table 5-5: Battery status

Battery symbol	Indication
	The battery has greater than 50% charge remaining.
	The battery has less than 50% charge remaining.
	The battery has less than 20% charge remaining.
	The battery is charging and connected to mains power.
	The battery is 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 Vita 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 Screen Brightness

To adjust the screen brightness, touch the shortcut located on the information bar  .

5.5.3 Alarm Volume

To adjust the alarm volume, touch the shortcut located on the information bar  .

5.5.4 Screen Capture

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 Vita monitor is required to save the image. Touch the snapshot icon located on the information bar  .

5.5.5 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 178. 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.

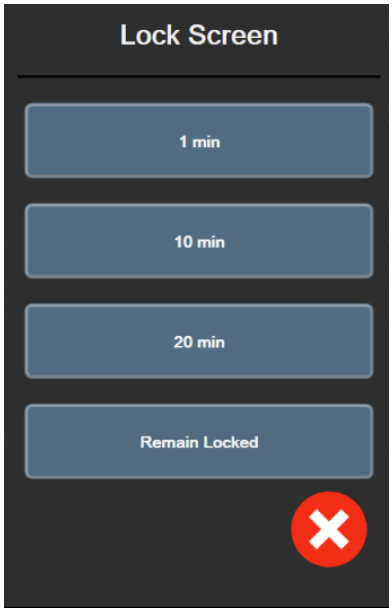


Figure 5-12: Lock screen popup

3. A red lock icon will appear on the information bar.
4. To unlock the screen, touch the red lock icon  and touch **Unlock Screen** on the **Lock Screen** menu.

5.6 Status Bar

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

Figure 5-13: 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.

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

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

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

List buttons. Some of the screens have buttons that appear next to menu text.

In these cases, touching anywhere on the button reveals a list of selectable items associated with the menu text. The button displays the current selection.

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

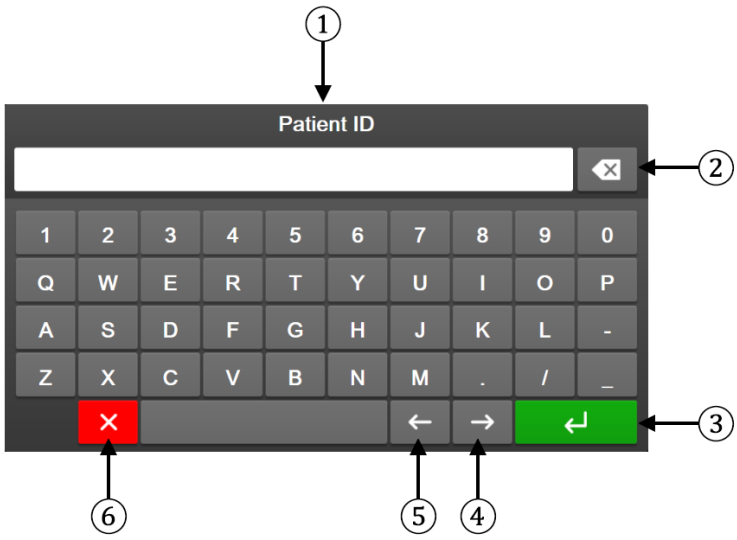
Toggle button. When an option exists between two choices, such as on/off, a toggle button appears.

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

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

1. data type
2. units
3. backspace
4. enter
5. cancel

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



1. data type
2. backspace
3. enter
4. cursor right
5. cursor left
6. cancel

6

User Interface Settings

Contents

6.1 Password Protection

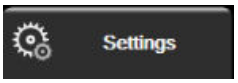
The HemoSphere Vita monitor has three levels of password protection.

Table 6-1: HemoSphere Vita monitor password levels

Level	Digits required	User description
Super User	four	Clinicians
Secure User	eight	Hospital authorized personnel
Edwards User	rolling password	internal Edwards use only

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

Two settings menu options are password protected: **Advanced Setup** and **Export Data**.

To access the **Advanced Setup** features described below in table 6-2, touch settings icon  → **Settings** tab 

→ **Advanced Setup** button.

Table 6-2: Advanced setup menu navigation and password protection

Advanced setup menu selection	Sub-menu selection	Super User	Secure User	Edwards User
Parameter Settings	Alarms/Targets	•	•	•
	Adjust Scales	•	•	•
System Reset	Restore Factory Defaults	no access	•	•
	Data Wipe	no access	•	•
	Decommission Monitor	no access	no access	•
Connectivity	Serial Port Setup	no access	•	•

Advanced setup menu selection	Sub-menu selection	Super User	Secure User	Edwards User
Service	Manage Features	no access	•	•
	System Status	no access	•	•
	Software Update	no access	•	•
Change Passwords		no access	•	•
Engineering	Alarm Settings	no access	•	•
	Tissue Oximetry	no access	•	•

To access the **Export Data** features described below in table 6-3, touch settings icon → **Settings** tab → **Export Data** button.

Table 6-3: Export data menu navigation and password protection

Export data menu selection	Super User	Secure User	Edwards User
Diagnostics Export	•	•	•
Data Download	•	•	•
Manage Clinical Data	no access	•(if enabled)	•
Export Service Data	•	•	•

6.1.1 Changing passwords

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

1. Touch settings icon → **Settings** tab → **Advanced Setup** button.
2. Enter the **Secure User** password.
3. Touch **Change Passwords** button.
4. Enter the new **Super User** and/or **Secure User** password digits in both value boxes until the green check mark appears. A check mark confirms that the minimum digit requirement has been met and both entries of the desired password are identical.
5. Touch the **Confirm** button.

6.2 Patient Data

After the system is turned on, the user has the option to either continue monitoring the last patient or to start monitoring a new patient. See Figure 6-1 on page 78.

Note

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

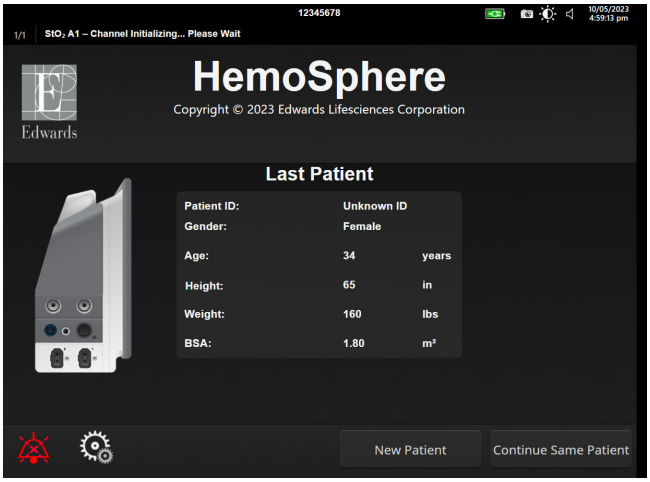


Figure 6-1: New or continuing patient screen

6.2.1 New Patient

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

WARNING

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

The user has the option of entering a new patient, with or without specific demographics, upon initial startup of the system or while the system is running.

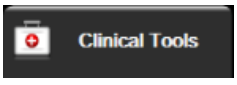
WARNING

Perform **New Patient** or clear the patient data profile whenever a new patient is connected to the HemoSphere Vita 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 on page 78). Touch **New Patient** and continue to step 6.

   OR

   Touch **Skip** to start monitoring without inputting the patient's demographics and continue to step 15.

   If the monitor is already on, touch the settings icon → **Clinical Tools** tab 

and continue to step 2.

Note

If the user skips entering patient demographics, only the following limited parameters can be monitored: StO_2, ΔctHb, SYS_{ART}, DIA_{ART}, MAP, and PR.

2. Touch **Patient Data** icon  .
3. Touch **End Session** 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 on page 79.

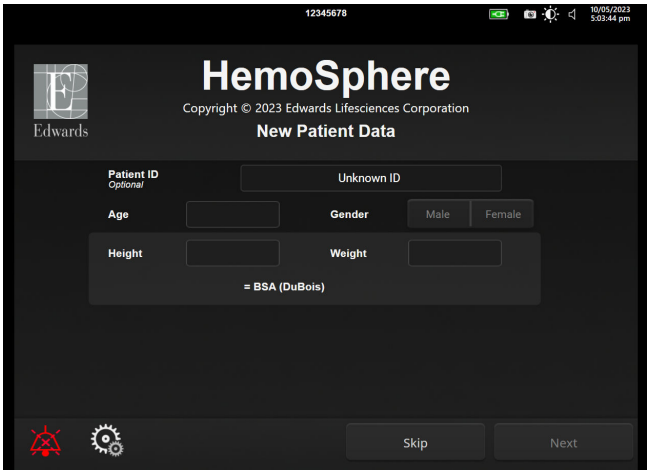


Figure 6-2: New Patient Data screen

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. If desired, enter the **Room** and **Bed** for the patient. Entering this information is optional.
14. Touch the **Next** button.

Note

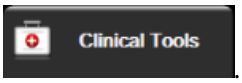
The **Next** button is disabled until all patient data is entered.

15. Refer to instructions for starting monitoring with the desired hemodynamic monitoring technology.

6.2.2 Continue Monitoring Patient

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

6.2.3 View Patient Data

1. Touch settings icon → **Clinical Tools** tab 

2. Touch **Patient Data** icon to see patient data. The screen will also include an **End Session** button.
3. Touch the return icon to return to the settings screen. The patient demographic popup screen will appear. If returning to the same patient, review the patient demographics and press **Yes** if they are correct.

6.3 General Monitor Settings

The General Monitor Settings are those that affect every screen. These are the display language, units used, alarm volume, snapshot sound, date/time settings, screen brightness, Device ID, and monitoring screen display settings.

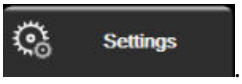
The HemoSphere Vita monitor interface is available in several languages. A language selection screen appears the first time the HemoSphere Vita monitor is started. See Figure 3-7 on page 50. The language screen will not appear again, but the display language can be changed at any time.

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 Vita 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.

6.3.1 Change Language

1. Touch the settings icon → **Settings** tab 

2. Touch the **General** button.

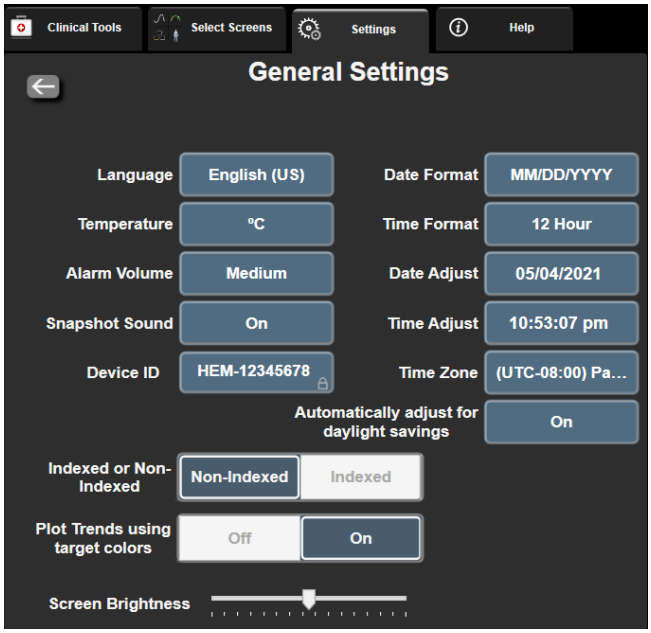


Figure 6-3: General Monitor Settings

3. Touch the value section of the **Language** button and select the desired display language.
4. Touch the home icon to return to the monitoring screen.

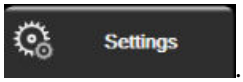
Note

See appendix D Language Default Settings on page 176 for all language default settings.

6.3.2 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 on page 174, and the time defaults to a 24 hour clock.

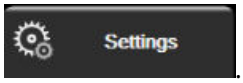
1. Touch the settings icon → **Settings** tab 

.
2. Touch **General** button.
3. Touch the value section of the **Date Format** button and touch the desired format.
4. Touch the value section of the **Time Format** button and touch the desired format.
5. Touch the value section of the **Time Zone** button to select the desired time zone.
6. The monitor time setting can adjust for daylight savings. Select **On** next to "**Automatically adjust for daylight savings**" to enable this adjustment.

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

6.3.2.1 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.

1. Touch the settings icon  → **Settings** tab  .
2. Touch **General** button.
3. To change the date, touch the value section of the **Date Adjust** button and enter the date on the keypad.
4. To change the time, touch the value section of the **Time Adjust** button and enter the time.

Note

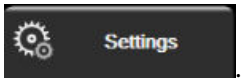
The time and date can also be adjusted by touching the date/time directly on the information bar.

---

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

6.3.3 Monitoring Screens Settings

From the **General Settings** screen, the user can also set physiology and physio relationship monitoring screen and graphical trend monitoring screen options.

1. Touch the settings icon  → **Settings** tab  .
2. Touch the **General** button.
3. Next to **Plot Trends using target colors** select **On** or **Off** to display target colors on graphical trend monitoring screens.

6.3.4 Time Intervals / Averaging

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

Note

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

---

1. Touch within a parameter tile to access the parameter configuration menu.
2. Touch the **Intervals / Averaging** tab.

6.3.4.1 Display Parameter Value Change

The change in value or percent change in value of a key parameter over a selected time interval can be displayed on a parameter tile.

1. Touch the **Change Display** menu button to select the format for which the change interval is displayed: **% Changed** or **Value Difference**.
2. Touch the **Change Interval** value button and select one of the following time interval options:

   - None
   - Reference
   - 1 min
   - 3 min
   - 5 min
   - 10 min
   - 15 min
   - 20 min
   - 30 min

   If **Reference** is selected, the change interval will be calculated from the start of monitoring. The **Reference Value** can be adjusted on the **Intervals / Averaging** tab of the tile configuration menu.

7

Advanced Settings

Contents

7.1 Alarms/Targets

There are two types of alarms on the HemoSphere Vita monitor intelligent alarm system:

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

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

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

All alarms have an associated text displayed on the status bar. The intelligent alarm system will actively cycle through every active alarm text on the status bar. In addition, alarms will generate the visual alarm indicator shown in Table 7-1 on page 84. For additional information, see Table 12-1 on page 142.

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

The visual alarm indicator will indicate the highest active alarm priority. Alarm messages displayed on the status bar are outlined in the alarm priority color indicated in Table 7-1 on page 84. The audible tone associated with the highest priority active alarm will be played. Where the priority levels are the same, physiological alarms take priority over faults and alerts. All technical alarms are generated once detected by the system; there is no inherent delay in alarms from the point of detection. For physiological alarms, the delay is the amount of time it takes to calculate the next physiological parameter after the parameter is out of range continuously for five or more seconds:

- HemoSphere VitaWave module hemodynamic parameters: 20 seconds
- HemoSphere VitaWave module arterial blood pressure parameters (SYS/DIA/MAP) while arterial waveform is displayed: 5 heartbeats
- Oximetry: 2 seconds

Note

Arterial blood pressure (ART) related physiological and technical alarms will only sound after ART is zeroed and mean arterial pressure (MAP) has 10 continuous readings above 10 mmHg.

All alarms are logged and stored for the given patient and can be accessed via the Data Download function (see Data Download on page 94). The Data Download log is cleared when initiating a new patient (see New Patient on page 78). The current patient can be accessed from up to 12 hours following a system power-off.

WARNING

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

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

For information on physiological alarm priorities, see Alarm Priorities on page 176.

Note

Physiological parameters can be configured to have no alarms. See Configure All Targets on page 88 and Configure Targets and Alarms for One Parameter on page 88.

WARNING

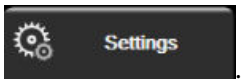
Do not turn off the audible alarms in situations in which patient safety could be compromised.

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 → **Settings** tab 

.
2. Touch **General** button.
3. Touch the right side of the **Alarm Volume** list button to select the desired volume.
4. 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 set by the clinician to indicate if the patient is in the ideal target zone (green), warning target zone (yellow), or alarm zone (red). Target colors are displayed as a shaded outline around parameter tiles (see Figure 5-5 on page 62). The use of target zone ranges can be enabled or disabled by the clinician. Alarms (high/low) differ from target zones in that the alarm parameter value flashes and has an audible alarm.

Parameters that can "Alarm" are 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.
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/Targets** 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 password 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.

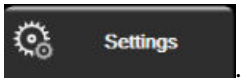
Table 7-3: Target defaults

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 → **Settings** tab 

.
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** menu for the parameter.

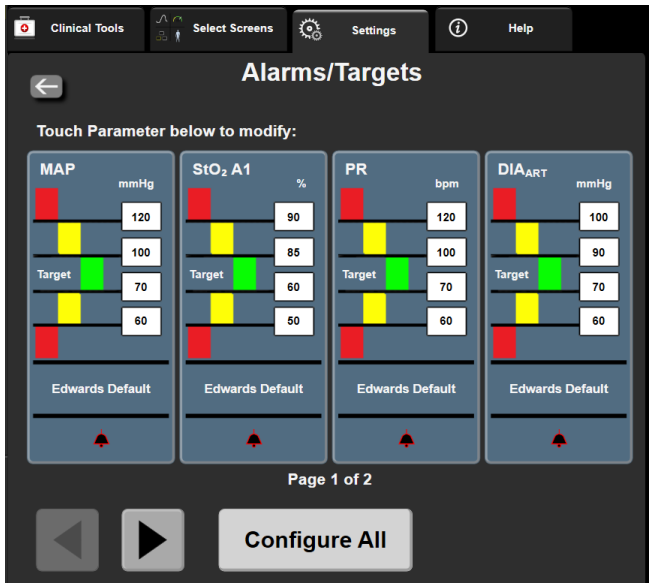


Figure 7-1: Alarms/Targets configuration

Note

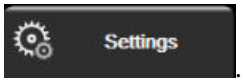
There is a 2 minute inactivity timer associated with this screen.

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

7.1.5 Configure All Targets

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

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

1. Touch the settings icon  → **Settings** tab 

.
2. Touch **Advanced Setup** button and enter the required **Secure User** password.
3. Touch **Parameter Settings** button → **Alarms/Targets** button.
4. Touch the **Configure All** button.
    - To enable or disable all audible physiological alarms for all parameters, touch the **Disabled**/**Enabled** toggle button for **Targets** within the **Audible Alarm** box.
    - To enable or disable all audible technical alarms for all parameters, touch the **Disabled**/**Enabled** toggle button for **All Alarms** within the **Audible Alarm** box.
    - To restore all settings to the custom defaults, touch **Restore All to Custom Defaults**. The message, **"This action will restore ALL Alarms and Targets to the Custom Defaults."** appears. Touch **Continue** button on the confirmation popup to confirm the restore.
    - 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. Touch **Continue** button on the confirmation popup to confirm the restore.

7.1.6 Configure Targets and Alarms for One Parameter

The **Alarms/Targets** menu lets the user set up alarm and target values for the selected parameter. The user can also enable or disable the audible and LED visual 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 tile to open the alarms/targets menu for that parameter.
2. To disable the audible and LED visual alarm for the parameter, touch the **Audible Alarm** icon  at the top right of the menu.

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** menu.

3. To disable visual targets for the parameter, touch the **Target** enabled icon at the top left of the menu. 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.

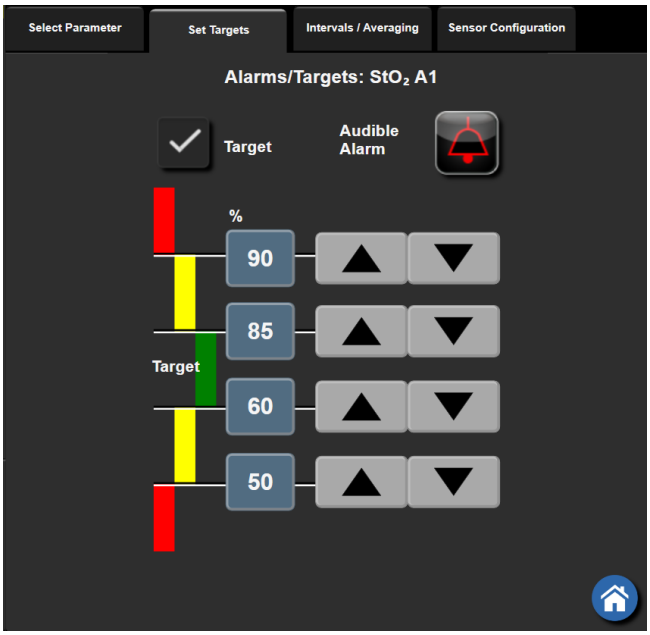


Figure 7-2: Set individual parameter alarms and targets

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 tiles). If a parameter is not selected and displayed as a key parameter, the audible and visual physiological alarms are not triggered for that parameter.

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.

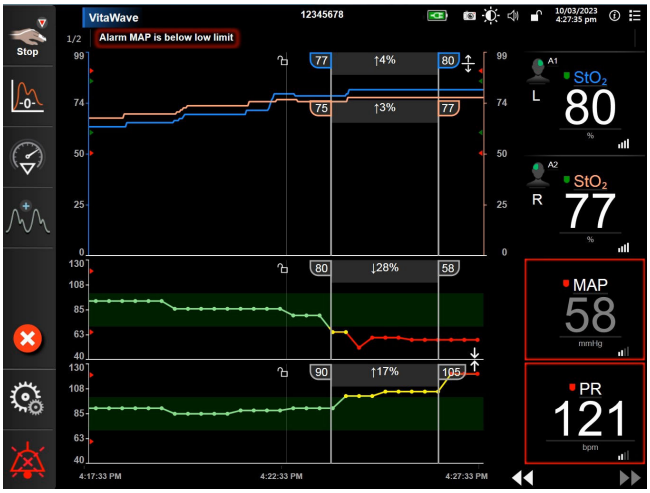
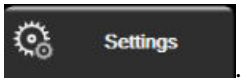


Figure 7-3: Graphical trend screen

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 → **Settings** tab 

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

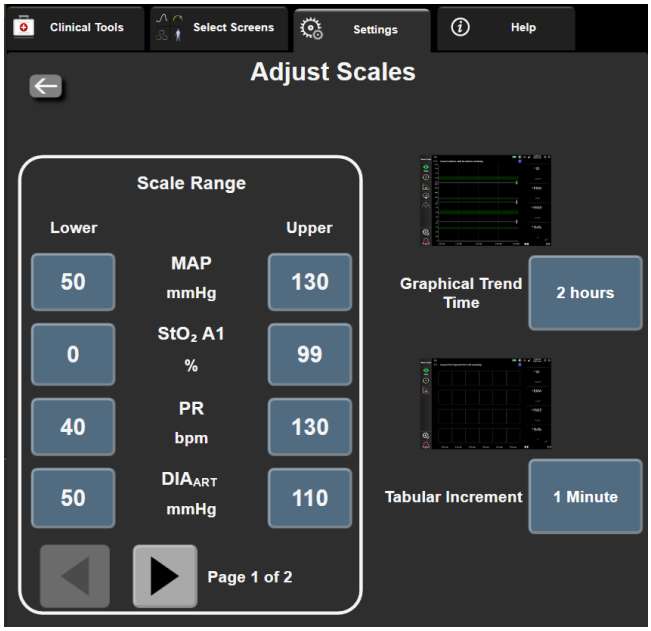


Figure 7-4: Adjust scales

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 icon to set the amount of time to each tabbed value. The options are:

   - 1 Minute (default)
   - 5 Minutes
   - 10 Minutes
   - 30 Minutes
   - 60 Minutes

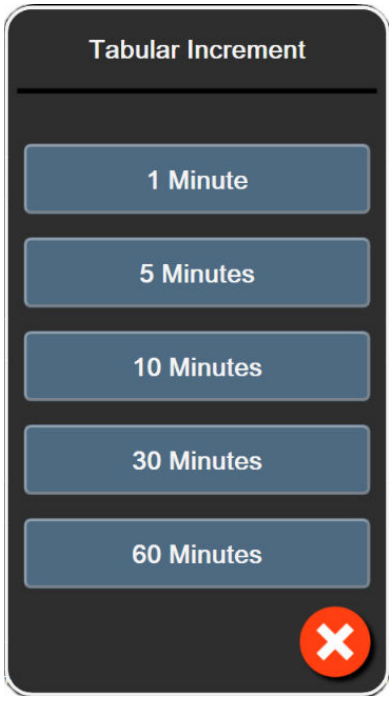


Figure 7-5: Tabular increment popup

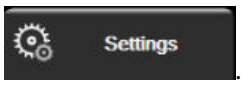
7. To advance to the next set of parameters, touch the arrow at the bottom left.
8. Touch the home icon to return to the monitoring screen.

7.3 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 Vita monitoring platform user interface retains the same functionality as a fully operational platform. Simulated patient demographics must be entered to demonstrate the selected monitoring mode functions. The user can touch the controls as if a patient was being monitored.

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

1. Touch the settings icon → **Settings** tab 

.
2. Touch the **Demo Mode** button.

Note

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

3. See HemoSphere VitaWave Module Non-Invasive Monitoring on page 98 for details on monitoring with the HemoSphere VitaWave module and **Non-Invasive** monitoring mode.
4. Touch **Yes** on the **Demo Mode** confirmation screen.
5. The HemoSphere Vita 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.

8

Data Export and Connectivity Settings

Contents

8.1 Export Data

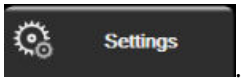
The **Export Data** screen lists a number of data export features of the HemoSphere Vita monitor. This screen is password protected. From this screen clinicians can export diagnostic reports, delete monitoring sessions, or export monitoring data reports. For more on exporting monitoring data reports,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

.
2. Touch the **Export Data** button.
3. Enter password when prompted in **Export Data Password** popup window. All passwords are set during system initialization. Contact your hospital administrator or IT department for password.
4. Ensure a USB device has been inserted.

   Note

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

   CAUTION

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

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

8.1.1.1 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

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

8.1.1.2 Case Report

To generate a report of key parameters:

1. Touch the **Case Report** button.
2. Select desired parameters from the case report popup menu. A maximum of three parameters can be selected.
3. Check **De-identify** to exclude patient demographic data  .
4. Touch the enter icon to export PDF  .

Note

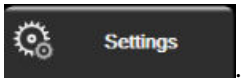
Do not disconnect the USB device until the **"Download complete. Remove the USB drive."** message appears.

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.

8.1.2 Diagnostic Export

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

1. Touch the settings icon  → **Settings** tab 

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

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

8.2 Cybersecurity

This chapter outlines ways in which patient data can be transferred to and from the HemoSphere Vita monitor. It is important to note that any facility using the HemoSphere Vita 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 policies for managing this information. Steps that can be taken to safeguard this information and the general security of the HemoSphere Vita monitor include:

- **Physical Access**: Limit use of the HemoSphere Vita monitor to authorized users. The HemoSphere Vita monitor has password protection for certain configuration screens. Passwords should be protected. See Password Protection on page 76 for more information.
- **Active Use**: Users of the monitor should take measures to limit patient data storage. Patient data should be removed from the monitor after a patient is discharged and patient monitoring has ended.
- **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 Vita monitor interface outside of its intended purpose could pose cyber security risks. No HemoSphere Vita monitor connections are meant to control the operations of another device. All available interfaces are shown in HemoSphere Vita Monitor Connection Ports on page 41 and specifications for these interfaces are listed in Table A-5 on page 164.

8.2.1 Cybersecurity Updates

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

8.2.2 Vulnerability Management

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

8.2.3 Cybersecurity Incident Response

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

8.2.4 HIPAA

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

9

HemoSphere VitaWave Module Non-Invasive Monitoring

Contents

9.1 HemoSphere Vita Non-Invasive System Methodology

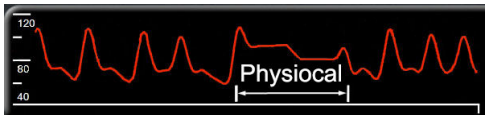
The HemoSphere Vita non-invasive system is composed of the HemoSphere Vita monitor with VitaWave module and connected pressure controller, heart reference sensor, and compatible Edwards finger cuff(s). See system connections in Figure 9-1 on page 101. Accurate measurement of the patient's blood pressure and key hemodynamic parameters is based on the Volume Clamp method, Physiocal method and VitaWave algorithm.

9.1.1 Volume Clamp Method

The VitaWave and Acumen IQ finger cuffs use the Volume Clamp method developed by Czech physiologist J.Peñáz (Penaz J 1973)[1]. The finger cuff is equipped with a plethysmograph sensor, which is a combination of a light source and light receiver, to continuously monitor changes in finger arterial blood volume. An inflatable bladder within the cuff rapidly adjusts to this change in volume to equilibrate the pressure of the cuff with the pressure inside of the artery. The artery is therefore clamped at its "un-stretched" volume and the pressure of the cuff is equal to that of the finger arterial pressure at all times.

9.1.2 Physiocal Method

The Physiocal method, developed by K.H. Wesseling (K.H. Wesseling et al. 1995)[2], is short for physiological calibration.



Physiocal adjusts for changes in the "un-stretched" volume during a normal measurement period. Cuff pressure is kept constant for one or more heart beats and blood pressure measurement is momentarily interrupted to observe the physiological properties of the finger artery. Early in the measurement period, these interruptions occur regularly. If the properties of the artery are sufficiently constant over time, the interval between Physiocal

adjustments will be increased up to 70 heart beats, with higher intervals representing increased measurement stability.

9.1.3 Waveform Reconstruction and Hemodynamic Analysis (VitaWave Algorithm)

The arterial blood pressure waveform is known to change between the arm and finger arteries due to physiological reasons. The VitaWave algorithm uses advanced processing methods to reconstruct the finger pressure waveform into a radial arterial pressure waveform. Waveform reconstruction yields beat-to-beat values of systolic (SYS), diastolic (DIA) and mean (radial) arterial (MAP) non-invasive pressures. Waveform hemodynamic analysis yields values for pulse rate (PR) using an advanced pulse contour method.

CAUTION

The HemoSphere VitaWave module displays and analyzes a reconstructed radial arterial waveform. Clinicians should consider this waveform reconstruction, especially if they are experienced with viewing a brachial arterial pressure waveform.

All non-invasive parameters selected as a key parameter (see Table 1-2 on page 18) are averaged and have an update rate of 20 seconds.

9.1.4 Heart Reference Sensor

The heart reference sensor (HRS) takes into account differences in pressure between the finger and heart. The hydrostatic pressure changes due to difference in height between the finger and heart are compensated by the HRS. One end of the HRS is placed on the finger at the cuff level, and the other end is placed at heart level.

9.1.5 Discoloration, Numbness, or Tingling of the Fingertip

The Volume Clamp methodology places a continual pressure on the finger which never fully occludes the arteries, but inhibits venous return and causes some venous congestion in the fingertip distal to the cuff. As a result, the patient's fingertip may often experience discoloration (blue or red coloring) after a few minutes of monitoring. After longer periods of monitoring (approximately 30 minutes - 2 hours), some patients may experience some tactile sensations (tingling or numbness) in the fingertip. Immediately after removing the cuff, the middle phalanx often shows a slightly decreased volume and may show some reactive hyperemia or swelling. All of these phenomena generally subside within a few minutes of relieving the cuff pressure. Keeping the fingers and hand warm during the measurement improves the arterialization of the fingertip, which can improve coloration and reduce the rate of occurrence of tactile numbing.

9.1.6 Single Cuff Monitoring

A single compatible Edwards finger cuff can be used for accumulated monitoring of the same patient for up to 8 hours on a single finger. During single cuff monitoring, the HemoSphere Vita non-invasive system will automatically release the pressure in the cuff at regular user selected intervals (30 minutes, 2 hours, and 4 hours). See Calibrate the Heart Reference Sensor on page 112.

Note

After 8 hours of accumulated monitoring on the same finger, the HemoSphere Vita non-invasive system will stop monitoring and display a warning to place the cuff on another finger if continued monitoring is desired.

9.1.7 Double Cuff Monitoring

For monitoring periods lasting longer than 8 hours, the HemoSphere Vita non-invasive system enables two compatible Edwards finger cuffs to be connected simultaneously on separate fingers. In this configuration, the system switches active monitoring between the two cuffs at a user selected interval — 15, 30, or 60 minutes — to allow for minimally interrupted continuous monitoring. During cuff switching, there may be up to a minute pause in monitoring. See VitaWave Settings and Cuff Options on page 111.

Note

The HemoSphere Vita non-invasive system does not continuously monitor a single finger for more than 60 minutes when two cuffs are used. The double cuff monitoring feature allows for minimum interruptions to monitoring for durations of up to 72 hours. Continuous monitoring cannot be extended beyond 60 minutes on a single finger during double cuff monitoring.

When using the double cuff configuration, ensure that each finger is sized separately. It is not uncommon for patients to have two different sized fingers requiring two different sized compatible Edwards finger cuffs. Failure to select the correct finger cuff can result in measurement inaccuracy.

Cuff sizing may not be applicable to all cuffs.

Upon starting a measurement, the finger cuff will expire after 72 hours for a single patient.

9.1.8 Methodology References

1. Penaz J (1973), "Photoelectric measurement of blood pressure, volume and flow in the finger" *Digest of the 10th Int Conf Med Biol Engng, Dresden*, p. 104.
2. Wesseling KH, et al. (1995), "Physiocal, calibration finger vascular physiology for Finapres" *Homeostasis* 36 (2-3), pp. 67-82.

9.2 Connecting the HemoSphere Vita Non-Invasive System

The HemoSphere VitaWave module is compatible with all approved Edwards finger cuffs. See Figure 9-1 on page 101 for an overview of the HemoSphere non-invasive system connections.

1. Align and insert the HemoSphere VitaWave module into an large technology (L-Tech) module slot on the left panel of the HemoSphere Vita monitor. The module will click in place when properly engaged.

   CAUTION

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

2. Press the power button to turn on the HemoSphere Vita monitor and follow steps for entering patient data. See Patient Data on page 77.

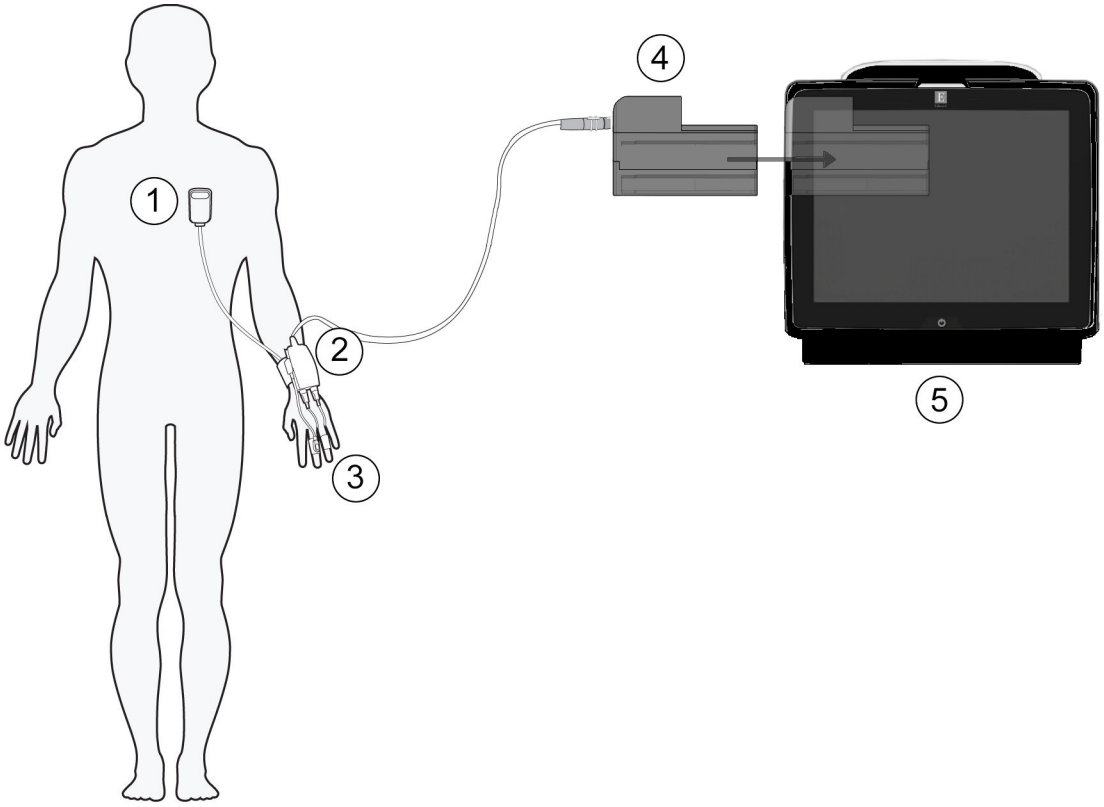
   WARNING

   VitaWave technology use not recommended for patients age < 18 years of age.

3. Follow instructions below on how to apply the pressure controller, select finger cuff size and apply the finger cuff(s) to the patient.

Note

Cuff sizing may not be applicable to all cuffs.



1. heart reference sensor*
2. pressure controller*
3. finger cuff(s)*
4. HemoSphere VitaWave module
5. HemoSphere Vita monitor

Figure 9-1: HemoSphere Vita non-invasive system connection overview

Note

Components indicated by * in Figure 9-1 on page 101 legend are APPLIED PARTS as defined in IEC 60601-1 that in normal use necessarily come into physical contact with the patient for the HemoSphere Vita non-invasive system to perform its function.

WARNING

Components that are not indicated as APPLIED PARTS should not be placed in a location where the patient may come into contact with the component.

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

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

Do not sterilize any components of the HemoSphere Vita non-invasive system. The HemoSphere Vita non-invasive system is provided non sterile.

Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.

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

Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks.

The HemoSphere Vita non-invasive system monitoring components are not defibrillation proof. Disconnect the system before defibrillating.

Only use compatible Edwards finger cuffs, heart reference sensor and other HemoSphere Vita non-invasive system accessories, cables and or components that have been supplied and labeled by Edwards. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

Always remove HemoSphere Vita non-invasive system sensors and components from the patient and completely disconnect the patient from the instrument before bathing the patient.

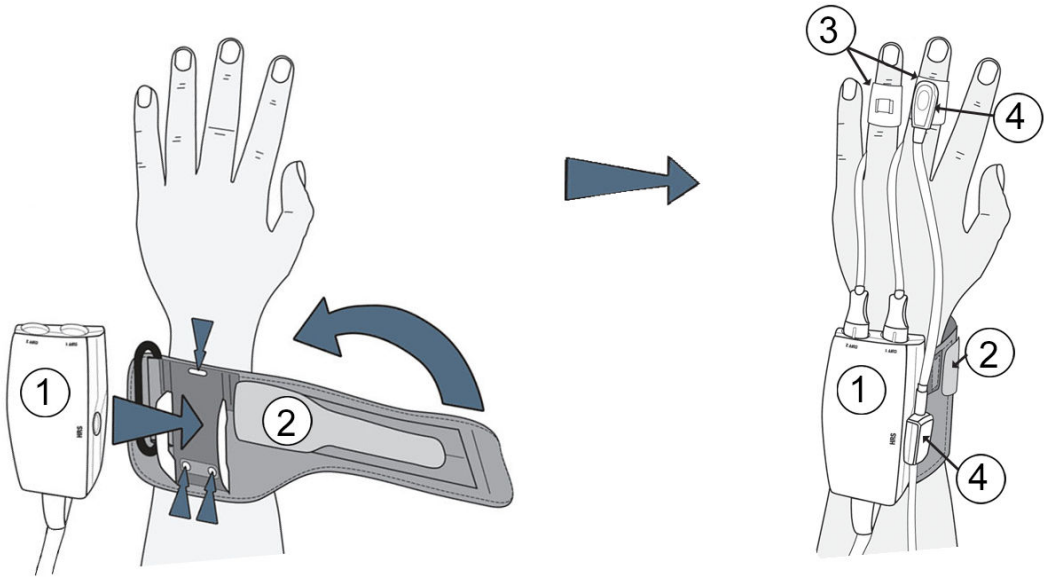
CAUTION

The effectiveness of HemoSphere Vita non-invasive system has not been evaluated in patients under 18 years of age.

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

9.2.1 Apply the Pressure Controller

The pressure controller is worn on the patient's wrist and connects to the HemoSphere VitaWave module, HRS and finger cuff(s). See Figure 9-2 on page 103.



1. pressure controller

2. pressure controller band

3. finger cuff(s)

4. heart reference sensor

Figure 9-2: Pressure controller application

1. Wrap the pressure controller band around the patient's wrist. The non dominant hand is preferred for monitoring in awake patients. (Figure 9-2 on page 103, left)
2. Snap the pressure controller into the plastic sleeve of the band, making sure that the cuff connectors are facing towards the fingers.
3. Attach the pressure controller cable to the HemoSphere VitaWave module. (Figure 9-1 on page 101)
4. Remove the plastic connector caps in order to connect the finger cuff (s) and heart reference sensor.

Note

It is recommended that the cuff connector caps be kept and used to protect the pressure controller against the ingress of water and dirt when only a single cuff is used.

WARNING

Do not overtighten the pressure controller band or finger cuff(s).

Do not apply pressure controller band on injured skin as this can cause further injury.

9.2.2 Select Finger Cuff Size

Not all finger cuffs are supplied with a sizing aid. Refer to the product IFU for detailed instructions on proper finger cuff sizing, if applicable.

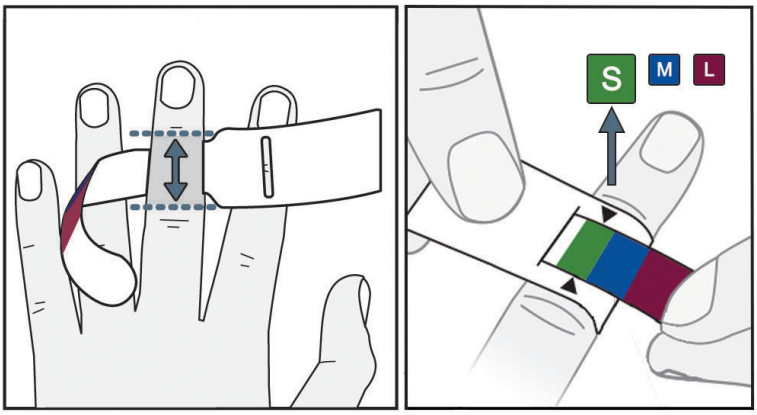


Figure 9-3: Cuff size selection

1. Size the finger(s) that will be used for monitoring by using the finger cuff sizing aid. Best results are obtained from the middle, ring or index finger. The cuff is not intended to be placed on the thumb or previously fractured fingers.
2. Wrap the sizing aid around the middle phalanx of the finger by pulling the color coded smaller end through the slot to create a snug fit.
3. The black arrows indicate suitable cuff size. Match the indicated color with the correct finger cuff size.

WARNING

Improper finger cuff placement or sizing can lead to inaccurate monitoring.

9.2.3 Apply Finger Cuff(s)

Refer to the product IFU for detailed instructions on proper compatible Edwards finger cuff placement and actual device illustrations.

Single Patient Use. The VitaWave and Acumen IQ finger cuffs are designed for single patient use. Upon starting a measurement, the finger cuff will expire after 72 hours for a single patient.

Double Cuff Monitoring. The HemoSphere Vita non-invasive system allows two compatible Edwards finger cuffs to be connected simultaneously to alternate the measurement between two fingers. This feature allows for minimum interruptions to monitoring for durations of up to 72 hours and is required for measurements that take longer than 8 hours. This feature can also be used to increase patient comfort.

9.2.4 Apply the Heart Reference Sensor

The Heart Reference Sensor (HRS) should always be used in conscious patients, freely moving patients or those patients that will be frequently re-positioned during the case. Follow the on-screen prompts or the steps below to connect the HRS.

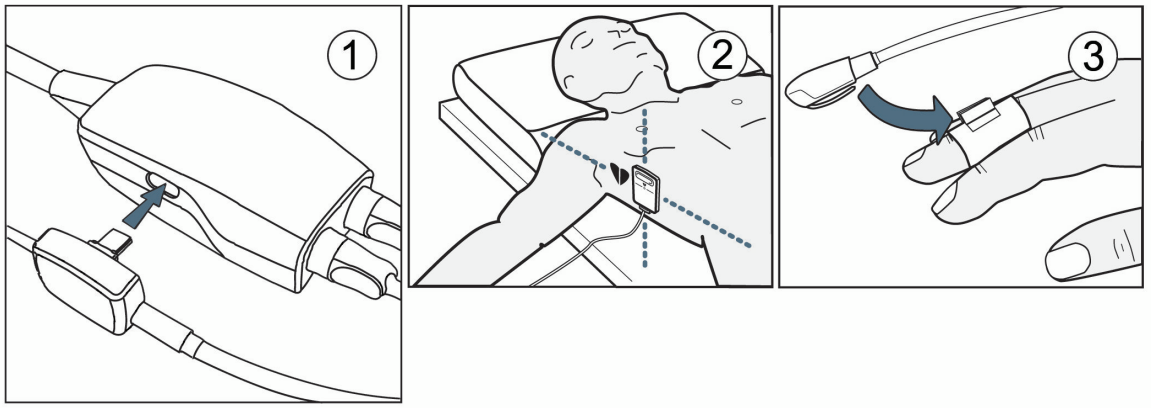


Figure 9-4: Heart reference sensor application

CAUTION

Make sure that the HRS is correctly applied so that it can be leveled to the phlebostatic axis.

1. Connect the HRS to the pressure controller. See (1) in Figure 9-4 on page 105.
2. Place the pressure controller cover on the pressure controller. (optional - see Pressure Controller Cover on page 171)
3. Apply the heart end of the HRS to the patient at phlebostatic axis level by using an HRS clip. See (2) in Figure 9-4 on page 105.

   Note

   If the patient is rotated or moved, the phlebostatic axis will rotate or move with the patient. If necessary, be sure to reapply the heart end of the HRS to ensure that it is still at the same vertical level as the heart in the patient's new position.

4. Attach the other end of the HRS to the finger cuff. See (3) in Figure 9-4 on page 105.
5. Touch the start monitoring icon 

on the navigation bar or on setup help screen to begin monitoring.
6. Touch the stop monitoring icon 

on the navigation bar to end monitoring at any time.
7. If VitaWave non-invasive blood pressure measurements vary from a reference measurement, assess the integrity of the HRS by performing an HRS calibration. An HRS calibration must be performed as part of the troubleshooting process. See Calibrate the Heart Reference Sensor on page 112.

9.2.5 Accuracy of VitaWave Blood Pressure Measurements

Precaution. Correlation of blood pressure measurements to the reference arterial line may be affected during initial system startup and following a system restart.

Table 9-1 on page 106 provides a summary of repeated measurements from the same patient to provide accuracy of VitaWave non-invasive blood pressure outputs.

Table 9-1: 95% Confidence interval (CI) results for repeated blood pressure measurements from the same patient (Bootstrap Re-sampling)

Parameter	Bias [95% CI]	Precision [95% CI]
SYS (mmHg)	-2.74 [-4.95, -0.72]	6.15 [4.25, 7.82]
MAP (mmHg)	-1.29 [-2.33, -0.22]	3.14 [2.15, 4.14]
DIA (mmHg)	-1.07 [-2.26, 0.21]	3.71 [2.43, 5.29]

9.2.6 General Troubleshooting of HemoSphere Vita Non-Invasive System Monitoring

Listed below are common issues that may occur during normal monitoring and some troubleshooting steps.

- If VitaWave non-invasive system blood pressure measurements vary from a reference measurement, assess the integrity of the HRS by performing an HRS calibration. An HRS calibration must be performed as part of the troubleshooting process. See Calibrate the Heart Reference Sensor on page 112.
- If waveform does not appear within minutes after monitoring is initiated, check the status bar for any faults or alerts that may indicate there is a problem. Touch the question icon for more information on a displayed message or see Table 12-8 on page 150.
- During measurement, the tip of the finger being monitored by the cuff may show some coloring. This is normal and will disappear within a few minutes of cuff removal.
- During measurement, a conscious patient may notice slight pulsations in the finger to which the cuff is applied. These pulsations will stop momentarily during Physiocals. The patient should be made aware that these irregularities are normal and not caused by the patient's heart.
- If the patient is responsive, instruct the patient to keep the hand relaxed and not tense the muscles or overstretch the hand.
- Make sure that the blood flow to the hand is not (partially) obstructed, e.g. because the wrist is pressing on a hard surface.
- Some situations, such as cold hands, may make it difficult to start monitoring. If the patient has cold hands, try to warm the hand.

WARNING

Do not use the HemoSphere Vita non-invasive system as a heart rate monitor.

If using the instrument during full body irradiation, keep all HemoSphere Vita non-invasive system monitoring components out of the irradiation field. If a monitoring component is exposed to the irradiation, the readings may be affected.

Strong magnetic fields may cause malfunction of the instrument and burn wounds to the patient. Do not use the instrument during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The device may affect the MR image, and the MRI unit may affect the accuracy of the measurements.

CAUTION

The HemoSphere Vita non-invasive system is not intended for use as an apnea monitor.

In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible.

Inaccurate non-invasive measurements can be caused by factors such as:

- Improperly calibrated and/or leveled HRS
- Excessive variations in blood pressure. Some conditions that cause BP variations include, but are not limited to:

  * Intra-aortic balloon pumps
- Any clinical situation where the arterial pressure is deemed inaccurate or not representative of aortic pressure.
- Poor blood circulation to the fingers.
- A bent or flattened finger cuff.
- Excessive patient movement of fingers or hands.
- Artifacts and poor signal quality.
- Incorrect placement of finger cuff, position of finger cuff, or finger cuff too loose.
- Electrocautery or electrosurgical unit interference.

Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation.

The effectiveness of Edwards compatible finger cuffs has not been established in pre-eclamptic patients.

The pulsations from intra-aortic balloon support can be additive to the pulse rate on the instrument pulse rate display. Verify patient's pulse rate against an ECG heart rate.

The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis.

9.3 Optional HRS

Optional HRS is a feature that must be enabled. If this feature is enabled, steps vary from how described previously in Heart Reference Sensor on page 99. The HemoSphere non-invasive system finger cuff algorithm must account for differences in pressure due to the change in vertical level of the monitored finger relative to the heart. This can be performed in one of two ways on the **Patient Positioning Mode Selection** window (see Figure 9-5 on page 108):

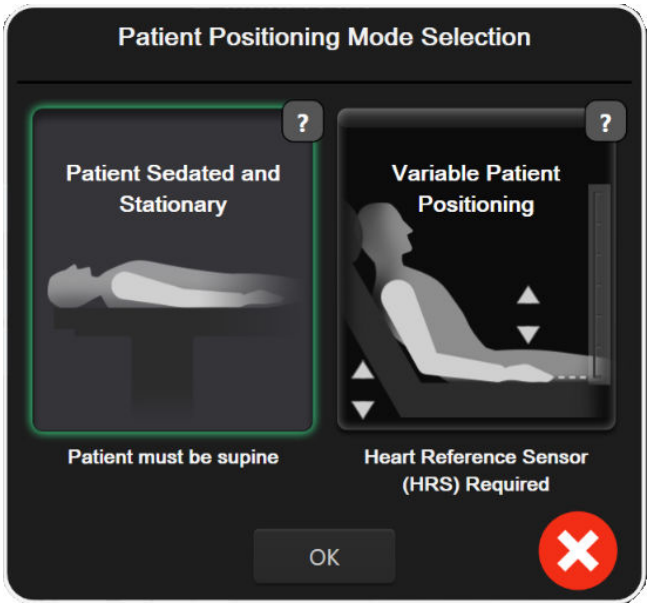
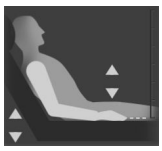


Figure 9-5: Patient Positioning Mode Selection – Optional HRS

Manually enter height differences. Use this method to account for height differences only in stationary and sedated patients. After entering patient data, touch on the **Patient Sedated and Stationary** icon and proceed with steps outlined below in Patient Sedated and Stationary on page 108.



Use Heart Reference Sensor (HRS). The HRS must be used in patients where the vertical level of the finger relative to the heart may change at any time during monitoring. After entering patient data, touch the **Variable Patient Positioning** button and proceed with steps outlined in the Heart Reference Sensor on page 99.

9.3.1 Patient Sedated and Stationary

This mode could be chosen for those patients under general anesthesia with limited or no re-positioning needs anticipated. The HRS can be used during this mode, but is not required.

1. Touch **Patient Sedated and Stationary** button to highlight and select this mode.
2. Touch **OK**.

CAUTION

Monitoring without an HRS may lead to measurement inaccuracies. Ensure patient remains still with accurately measured finger to heart height difference.

Do not place the patient in a non-supine position while monitoring without an HRS. This may lead to an inaccurate vertical offset entry for the HRS and measurement inaccuracies.

Note

If an HRS is connected, a popup screen with the message "**Alert: HRS Detected**" is displayed. To start monitoring with the HRS, touch **Yes** and proceed to step 2 under Apply the Heart Reference Sensor on page 105. To monitor without an HRS, disconnect the HRS and touch **No** and proceed with the steps below.

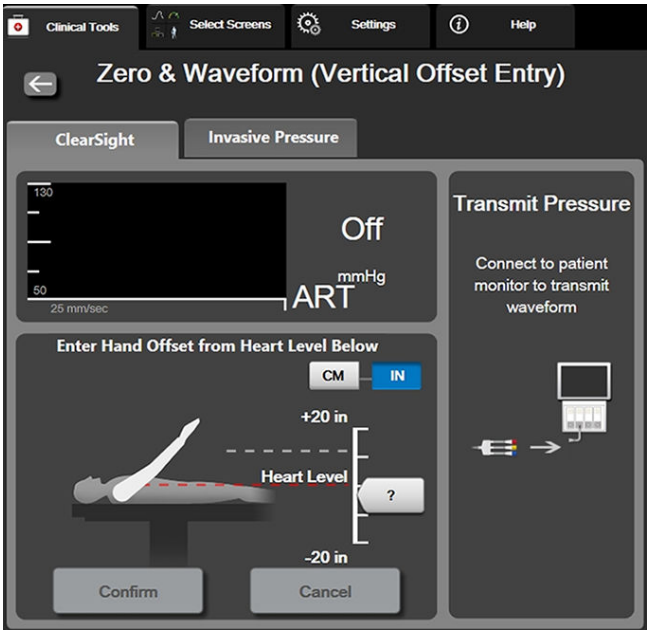


Figure 9-6: Zero & Waveform screen – Vertical Offset Entry

3. The **Zero & Waveform** screen in this mode (shown in Figure 9-6 on page 109) will depict a vertical scale bar to represent the offset of the hand relative to the heart; the heart level is set at zero. A positive offset signifies a patient position where the hand is above the heart. Select the units of the scale bar: **CM** or **IN**.
4. Use the slider to move the vertical level of the hand and set the offset between the hand and heart.
5. Touch the next arrow  .
6. A confirmation screen will appear. If the displayed offset is correct for the current patient position, touch **Start Monitoring** to begin monitoring. If the displayed offset value is incorrect, touch **Cancel** and adjust the offset value as needed.
7. Touch the stop monitoring icon 

on the navigation bar to end monitoring at any time.

Two alerts will cycle through on the information bar with the texts "**Alert: No HRS Connected – Verify Patient Positioning**" and "**Alert Current Offset: Finger <position>**" where <position> is the verified height offset between the monitored finger and heart. The offset value must be updated each time a patient is re-positioned in this mode. In addition, if monitoring is stopped for more than one minute, the vertical offset must be verified again upon restarting monitoring.

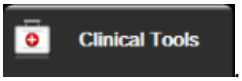
9.3.2 Update Offset Value During Monitoring

To update the finger to heart vertical offset value:

1. Touch the Zero & Waveform icon  located on the navigation bar or through the Clinical Tools menu.
2. Touch the **Update Offset** button on the **Zero & Waveform (Vertical Offset Entry)** screen.
3. Use the slider to move the vertical level of the hand to set the offset value to match the new patient position.
4. Touch the next arrow  .
5. A confirmation screen will appear. If the displayed offset is correct for the current patient position, touch **Confirm Offset** to begin monitoring. If the displayed offset value is incorrect, touch **Cancel** and adjust the offset value as needed.

9.3.3 Change Patient Positioning Mode

To change the patient position mode between **Patient Sedated and Stationary** and **Variable Patient Positioning**:

1. Touch settings icon  → **Clinical Tools** tab  .
2. Touch **Patient Data** icon  .
3. Touch the **Positioning Mode** list button to access the **Patient Positioning Mode Selection** screen.
4. Touch and highlight the desired patient positioning mode: **Patient Sedated and Stationary** or **Variable Patient Positioning**.
5. Touch the OK button and follow steps outlined in Patient Sedated and Stationary on page 108 for **Patient Sedated and Stationary** or Heart Reference Sensor on page 99 for **Variable Patient Positioning**.

Note

While monitoring with an HRS and switching to **Variable Patient Positioning** from **Patient Sedated and Stationary**, monitoring will stop. Touch the start monitoring icon  to restart monitoring after touching the enter icon.

9.4 SQI

A signal quality indicator (SQI) is present on all non-invasive parameter tiles during HemoSphere Vita non-invasive system monitoring. SQI level is calculated with each parameter update every 20 seconds. See Table 9-2 on page 111 below for a description of arterial waveform SQI levels. SQI levels of one and two are typically associated with alert conditions. An SQI level of zero is shown when monitoring is initializing (starting or resuming). A zero SQI value can also be associated with a fault condition. See Table 12-8 on page 150 for a list of finger cuff faults and alerts.

Table 9-2: Arterial waveform SQI levels

Appearance	Level	Indication
	4	Normal
	3	Intermediate (moderately compromised)
	2	Poor (possible alert status causing limited signal)
	1	Unacceptable (possible alert status causing extremely limited or no signal; see Table 12-8 on page 150 for a list of finger cuff alerts)
	0	Pressure waveform unavailable (see Table 12-8 on page 150 for a list of finger cuff faults)

9.5 Physiocal Display

Physiocal is an automatic calibration of the arterial waveform which occurs at regular intervals during noninvasive monitoring. Physiocal can be observed on the live pressure waveform display as a stepwise increase in pressure upon startup and as brief interruptions throughout monitoring. The interval between Physiocals is displayed on the arterial waveform graph in parenthesis next to the Physiocal interval icon (see Table 9-3 on page 111). To accurately account for changes in the finger artery characteristics throughout monitoring, Physiocal is performed at regular intervals resulting in momentary interruptions to the arterial waveform.

Table 9-3: Physiocal Interval Status

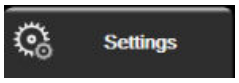
Appearance	Physiocal beats interval	Indication
	≥30	Normal measurement stability
	<30	Frequent Physiocal interruptions; variable physiological artery properties and decreased measurement stability
	--	Physiocal being performed or status not available

9.6 VitaWave Settings and Cuff Options

The VitaWave settings screen allows the user to select the time interval between cuff pressure release and the switching time interval for double cuff monitoring. Sensor status and information for connected finger cuff(s) and HRS are displayed and HRS calibration is also performed from this screen.

Note

Allow for at least 10 minutes of monitoring before reviewing sensor status information.

1. Touch settings icon  → **Settings** tab 

→ **VitaWave** button.
2. Touch the **Options** tab to view monitoring settings. All selection options on this settings screen are not available during active monitoring or during cuff pressure release mode.

Single Cuff. For single cuff monitoring, select a cuff pressure release time interval from the available option list. At the end of the cuff pressure time release interval, the pressure will be released from the cuff for a duration indicated by the countdown timer on the information bar. See Cuff Pressure Release Mode on page 113.

Double Cuff. For double cuff monitoring, select a switching time interval from the available option list.

Optional HRS. The optional heart reference sensor (HRS) feature can be **enabled** or **disabled** from this toggle button. This menu option is an advanced feature and must be enabled. If the **Optional HRS** feature is enabled, the user has the option of manually entering a vertical offset value between the hand and heart instead of using an HRS. See Optional HRS on page 107.

3. Touch the **Sensor Status** tab to view connected finger cuff(s) and HRS status and information.
4. Touch the **HRS Calibration** tab to calibrate the HRS.

9.6.1 Calibrate the Heart Reference Sensor

The Heart Reference Sensor (HRS) should be calibrated to ensure optimal performance.

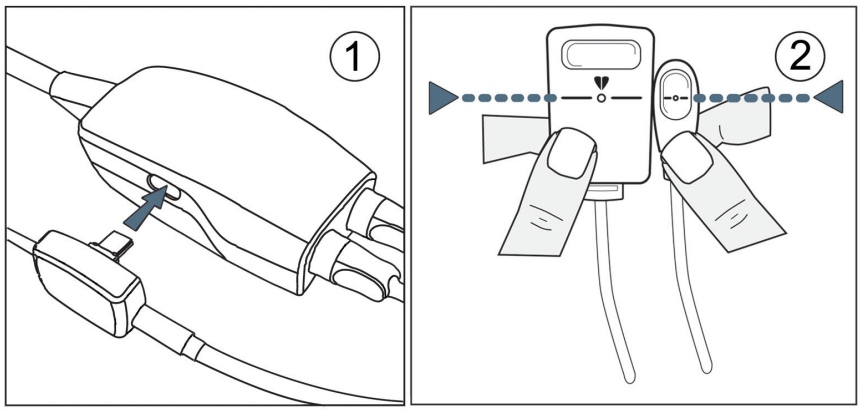
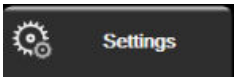
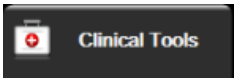


Figure 9-7: Heart reference sensor calibration

1. Navigate to the **HRS Calibration** screen by touching the settings icon → **Settings** tab 

→ **VitaWave** button → **HRS Calibration** tab.

   OR

   Touching the settings icon → **Clinical Tools** tab 

→ **HRS Calibration** icon  .

2. Connect the HRS to the pressure controller. See (1) in Figure 9-7 on page 112.
3. Vertically align both ends of the HRS and touch the **Calibrate** button. See (2) in Figure 9-7 on page 112.
4. Wait for the indication that the HRS has been calibrated.

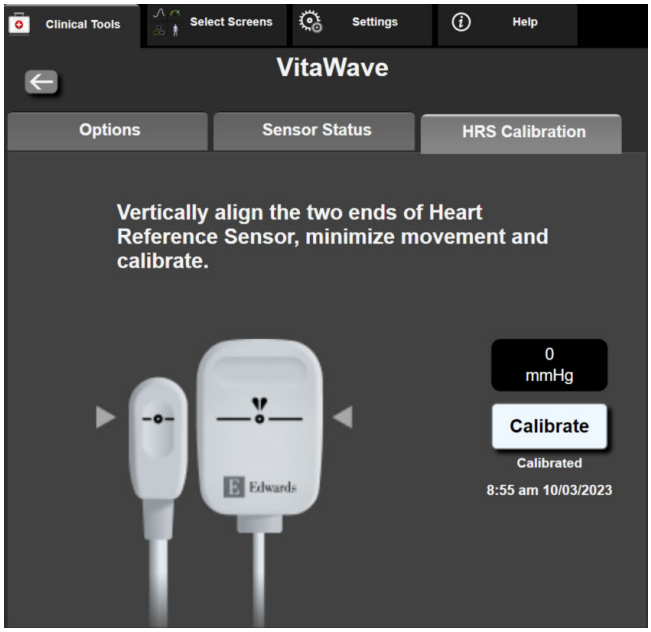


Figure 9-8: HRS calibration screen

9.6.2 Cuff Pressure Release Mode

During single cuff monitoring, the HemoSphere Vita non-invasive system will automatically release pressure from the finger cuff at regular intervals.

When ≤5 minutes remain until **Cuff Pressure Release Mode**, a white countdown timer icon will appear on the information bar along with the time remaining until pressure release. A notification popup will indicate that the countdown clock has been initiated. The user has the option to extend the countdown time until cuff pressure release by touching **Postpone** on the notification popup. Continuous monitoring will not be extended beyond the 8 hour cumulative monitoring limit on a single finger. Refer to Single Cuff Monitoring on page 99 and Double Cuff Monitoring on page 100.

At the end of the cuff pressure time release interval, pressure will be released from the cuff and monitoring will be temporarily suspended. A notification will appear on the screen to indicate that finger cuff pressure has been released. The cuff pressure release icon will appear yellow and the timer will indicate time until monitoring is automatically resumed.

During **Cuff Pressure Release Mode**, a countdown clock appears on the navigation bar. A **Pressure Release Active** popup menu will appear on the screen. This menu can also be accessed by touching the navigation or information bar countdown clocks. Menu options on this popup include: **Postpone Release** and **Stop Monitoring**.

Note

Cuff pressure release intervals can only be changed when monitoring is stopped. Avoid frequent changes to cuff release intervals during a patient monitoring session.

9.7 Blood Pressure Calibration

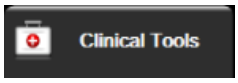
The **BP Calibration** screen allows the user to calibrate VitaWave finger cuff monitored blood pressure values with reference blood pressure monitored values. Both brachial oscillometric cuff or radial arterial line reference values can be used.

Note

BP Calibration is not available during double cuff monitoring.

CAUTION

Do not perform a BP calibration during monitoring periods when blood pressure appears unstable. This may result in inaccurate blood pressure measurements.

1. Touch the settings icon  → **Clinical Tools** tab 

→ **BP Calibration** icon  .
2. Touch **Add Measurement** to enter the reference BP values.

Note

Once the **Add Measurement** button is touched, the current VitaWave BP values are displayed and the user has five minutes to enter reference BP values. If more than five minutes are needed, the **Add Measurement** button can be touched again to reset the five minute timer.

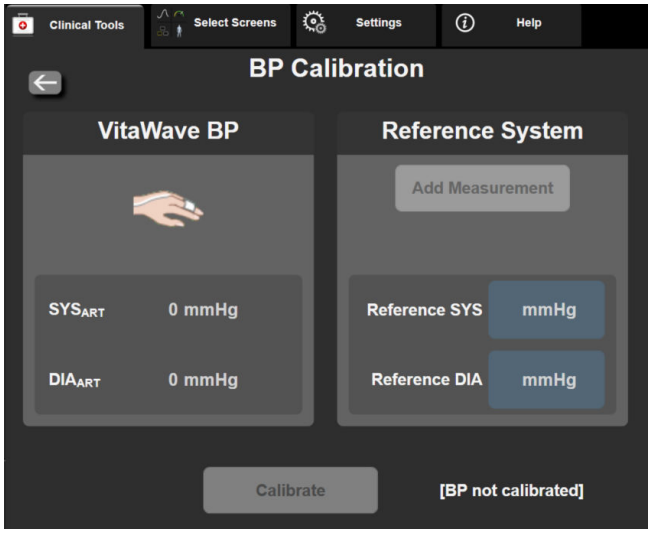


Figure 9-9: BP Calibration Screen

3. Enter a **Reference SYS** and **Reference DIA** value.
4. Touch **Calibrate** to complete the calibration process. The abbreviation of calibration (**CAL**) will appear above the parameter name on the BP tile to indicate that VitaWave BP has been calibrated.
5. To clear the last entered BP reference values, touch **Clear BP Calibration**.

Note

The current **BP Calibration** will be cleared if monitoring is paused for more than 10 minutes.

If monitoring without an HRS, BP Calibration will be disabled for one minute after updating the HRS vertical offset entry.

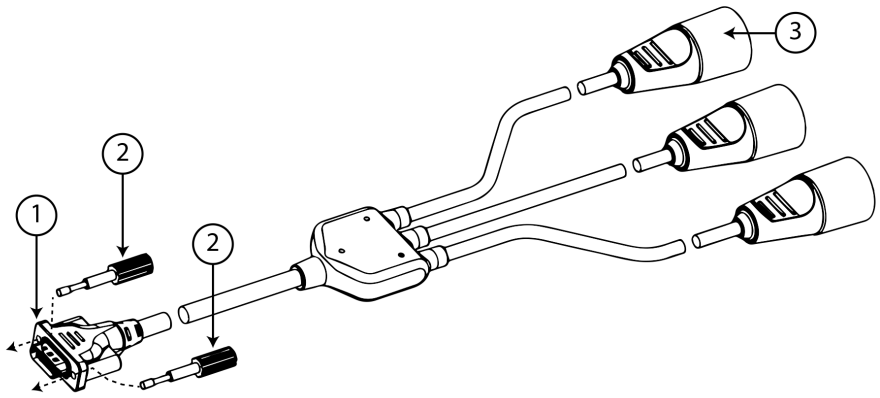
Table 9-4 on page 115 provides bias and precision performance data for each parameter of the VitaWave system, comparing BP calibrated with radial line monitored patients and BP Calibration with brachial oscillometric cuff monitored patients.

Table 9-4: BP Calibration performance data

Parameter (units)	Calibration reference	Bias	Precision
SYS (mmHg)	Radial	2.2 [1.3, 3.1]	2.8 [2.0, 3.5]
DIA (mmHg)	Radial	1.1 [0.4, 1.8]	2.1 [1.6, 2.6]
MAP (mmHg)	Radial	1.3 [0.4, 2.3]	2.8 [2.1, 3.6]
PR (bpm) RMSE	Radial	0.59 [0.23, 0.91]	N/A

9.8 Output Signal to Patient Monitor

The **Zero & Waveform** screen provides the user with the option to send the arterial waveform signal to a bedside patient monitor. The HemoSphere pressure-out cable is a reusable accessory that enables the user to output arterial pressure monitored by the HemoSphere Vita monitor to a compatible patient monitor for standard pressure monitoring. Device performance, including functional characteristics, have been verified in a comprehensive series of testing to support the safety and performance of the device for its intended use when used in accordance with the established Instructions For Use.



1. monitor connection

2. jack screws

3. arterial pressure plug (red)

Figure 9-10: HemoSphere pressure-out cable

1. Touch the Zero & Waveform icon  located on the navigation bar or through the Clinical Tools menu.
2. Plug the 18-pin connector of the HemoSphere pressure-out cable (see (1) in Figure 9-10 on page 116) into the rear panel of the monitor at the pressure-out port denoted by the analog out symbol  . See (9) in Figure 3-2 on page 43.
3. Use the two jack screws to properly secure the pressure-out cable plug in place. See (2) in Figure 9-10 on page 116.
4. Connect the arterial pressure (AP, red, (3)) pressure signal plug into a compatible patient monitor. Ensure that the selected connector is fully engaged. Refer to the patient monitor instructions for use.
5. Zero patient monitor and confirm 0 mmHg is displayed. See (2) in Figure 9-11 on page 117. Refer to the patient monitor instructions for use.
6. Toggle to the **Transmit Waveform** icon  to begin pressure signal output to the patient monitor. See (3) in Figure 9-11 on page 117.
7. A "**Sending Waveform Started:**" message with the timestamp is displayed when the live waveform is being transmitted to the connected patient monitor. See (3) in Figure 9-11 on page 117.

Note

Normal interruptions to arterial waveform monitoring, such as during Physiocal, cuff switching, or cuff pressure release mode, can trigger an alert on the patient monitor.

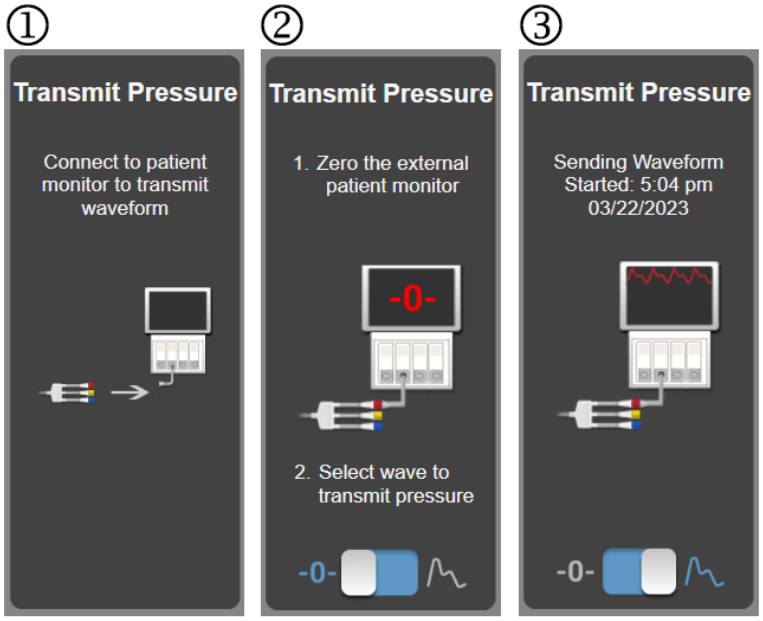


Figure 9-11: Transmit arterial pressure waveform to patient monitor

10

HemoSphere Tissue Oximetry Monitoring

Contents

10.1 HemoSphere Tissue Oximetry Monitoring

The HemoSphere Vita technology module is an interface module intended to be used with the ForeSight oximeter cable to display continuous monitoring of blood oxygen saturation in the tissue (StO_2). The ForeSight oximeter cable is a non-invasive device that measures absolute tissue oxygen saturation. It operates on the principle that blood contains hemoglobin in two primary forms – oxygenated hemoglobin (HbO_2) and de-oxygenated hemoglobin (Hb) – which absorb near-infrared light in different, measurable ways.

Tissue oxygen saturation (StO_2) levels are determined by the ratio of oxygenated hemoglobin to total hemoglobin at the microvascular level (arterioles, venules, and capillaries) in the region to which the sensor is applied:

$$\%StO_2 = \frac{\text{Oxygenated Hemoglobin}}{\text{Total Hemoglobin}} = \frac{HbO_2}{HbO_2 + Hb} \times 100$$

The ForeSight oximeter cable incorporates Edwards technology to project harmless near-infrared light (in five precise wavelengths) through the overlying tissue (e.g. scalp and skull) and into the underlying tissue (e.g. brain) via a disposable sensor on the patient's skin. Reflected light is captured by detectors positioned on the sensor for optimal signal collection. After analyzing the reflected light, the cable provides the tissue oxygen saturation level to the HemoSphere Vita technology module and HemoSphere Vita monitor as an absolute number and provides a graphical representation of historical values.

A pulse oximeter only reflects arterial blood oxygen saturation (SpO_2) and requires pulsations to operate; whereas the ForeSight oximeter cable measures even in pulseless conditions and displays the balance of oxygen supply and demand in a target tissue (StO_2), e.g., brain, abdomen, limb muscle. Thus, HemoSphere Vita monitor StO_2 values indicate overall tissue oxygenation state, which provides direct feedback for guiding care interventions.

Note

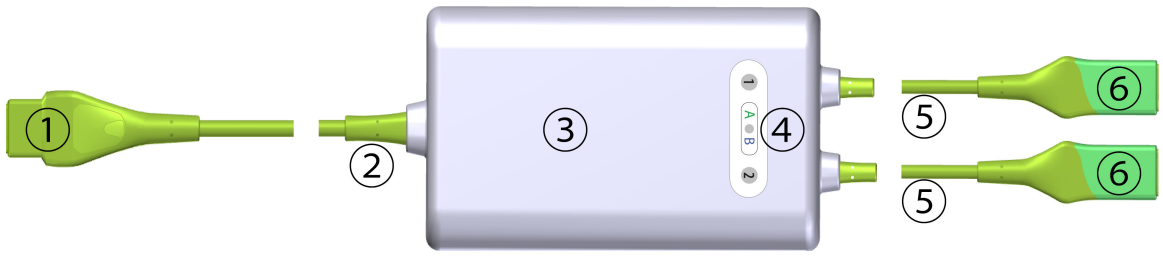
The following components may have alternative labeling conventions:

ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).

ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.

10.2 ForeSight Oximeter Cable Overview

The following diagrams provide an overview of the ForeSight oximeter cable's physical features.



1. module connector
2. module cable
3. cable housing
4. LED display
5. sensor cables
6. sensor connectors

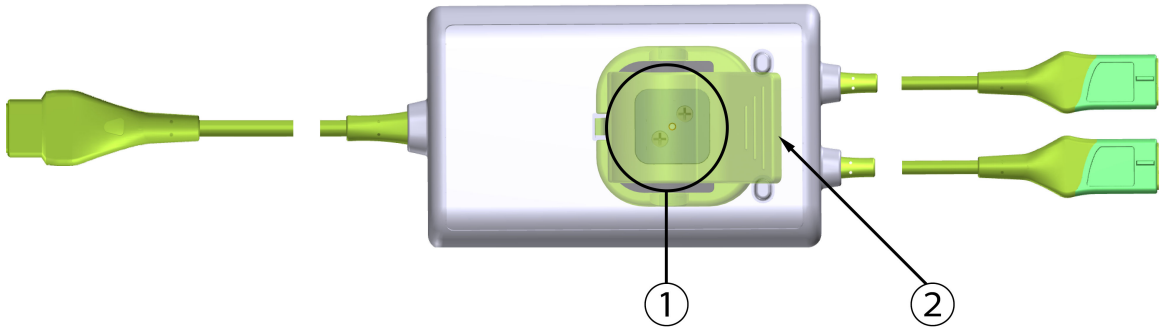
Figure 10-1: ForeSight oximeter cable front view

Note

The technology module and sensor cables are shown cut; see Table A-10 on page 166. For a description of LED status indicators, see ForeSight Oximeter Cable Sensor Communication on page 143.

CAUTION

Avoid placing the ForeSight oximeter cable where the status LED cannot be easily seen.



1. mounting clip slide (underneath)
2. mounting clip (superimposed)

Figure 10-2: ForeSight oximeter cable rear view

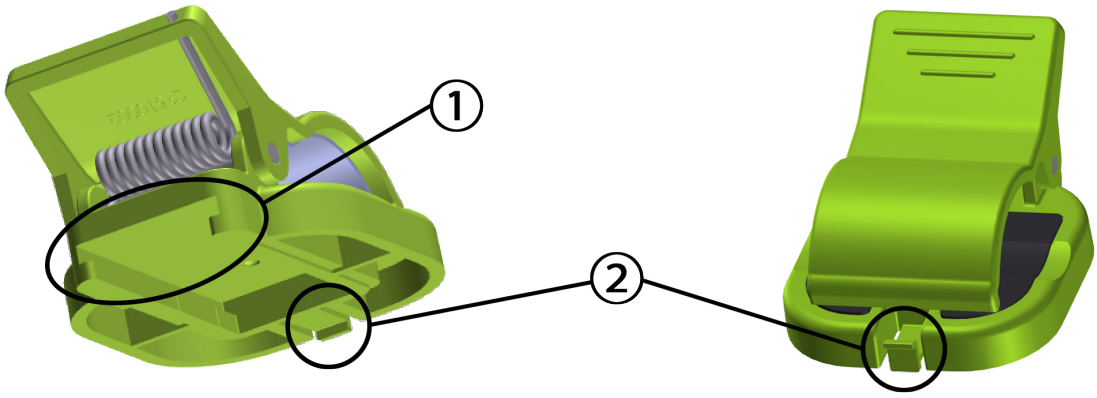
Note

Images of cable housing rear view in this manual are shown without labeling for clarity.

10.2.1 ForeSight Oximeter Cable Mounting Solutions

The ForeSight oximeter cable is packaged with a mounting clip.

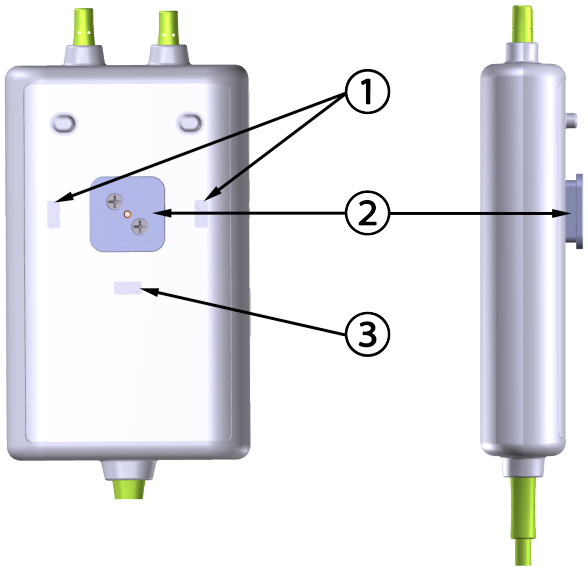
Figure 10-3 on page 120 and Figure 10-4 on page 120 identify attachment points on the mounting clip and cable housing.



1. mounting clip slot

2. mounting clip retaining tab

Figure 10-3: Mounting clip attachment points



Rear View

1. mounting clip retaining recess (horizontal)

2. mounting clip slide

3. mounting clip retaining recess (vertical)

Figure 10-4: Cable housing – mounting clip attachment points

10.2.2 Installing the Mounting Clip

The mounting clip can be attached to the ForeSight oximeter cable either vertically (typical for a bed rail – see Figure 10-5 on page 121) or horizontally (typical for a pole mount – see Figure 10-6 on page 122).

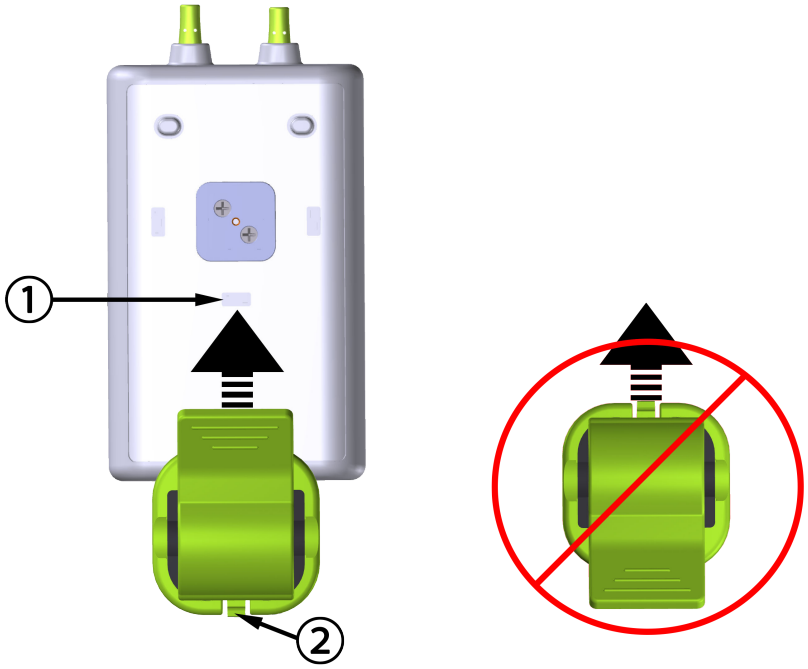
10.2.2.1 Attaching the Mounting Clip Vertically

To attach the mounting clip vertically:

1. On the rear of the cable housing, position the mounting clip with the slot facing the mounting clip slide.
2. Slide the mounting clip towards the top of the cable housing, until the mounting clip retaining tab locks in to the vertical mounting clip retaining recess.

Note

The mounting clip is not designed to be attached with the opening facing up.



1. mounting clip retaining recess (vertical) **2.** mounting clip retaining tab

Figure 10-5: Attaching the mounting clip vertically

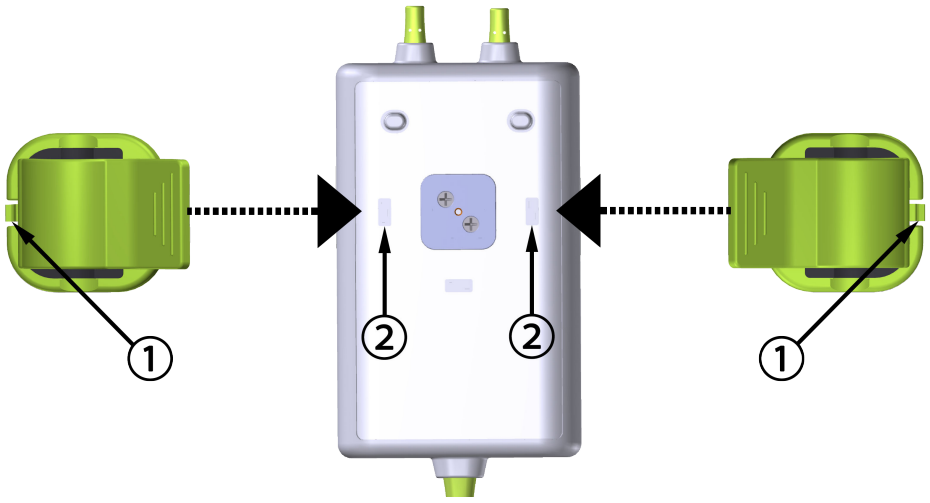
10.2.2.2 Attaching the Mounting Clip Horizontally

To attach the mounting clip horizontally:

1. Position the mounting clip with the mounting clip retaining tab facing away from the cable housing, from either the left or right.
2. Slide the mounting clip across the rear of the cable housing, until the mounting clip retaining tab locks in to the one of horizontal mounting clip retaining recesses.

Note

You may attach the mounting clip with the opening facing the left or right side.



1. mounting clip retaining tab

2. mounting clip retaining recess (horizontal)

Figure 10-6: Attaching the mounting clip horizontally

10.2.3 Removing the Mounting Clip

To remove the mounting clip from the rear of the cable housing (see Figure 10-7 on page 123):

1. Gently lift the mounting clip retaining tab until it disengages from its recess.

   CAUTION

   Applying too much pressure may break the retaining tab, which may present a risk of the cable falling on the patient, bystander, or operator.

   Note

   For information on replacement parts, technical support numbers are located on inside cover. See Table B-1 on page 170 for approved parts and accessories.

2. Slide the mounting clip in the direction of the mounting clip retaining tab until the mounting clip is free from the mounting clip slide.

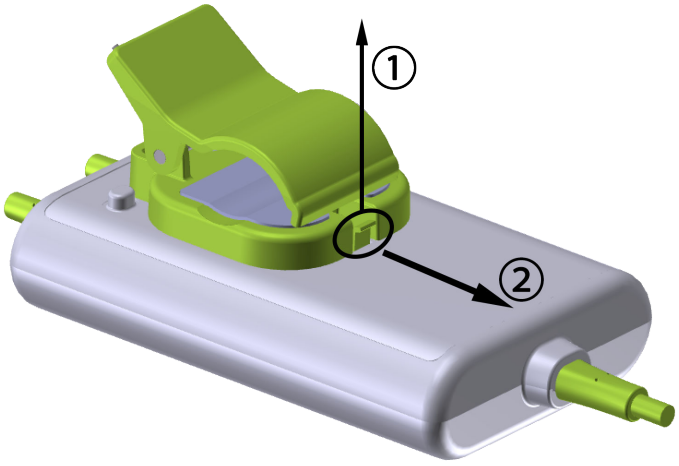


Figure 10-7: Removing the mounting clip

3. Remove the mounting clip from the rear of the cable housing.

CAUTION

Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the cable in any position that might present a risk that the cable may fall on the patient, bystander or operator.

Avoid placing the ForeSight oximeter cable under sheets or blanket that could restrict air flow around the cable that may increase the cable's case temperature and present an injury.

10.3 Connecting the HemoSphere Vita Technology Module and ForeSight Oximeter Cable

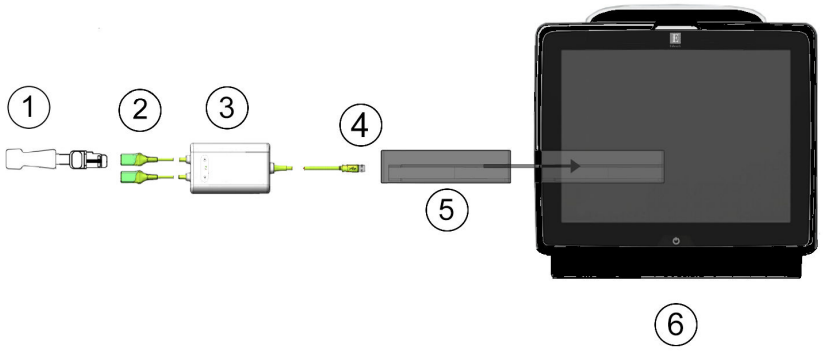
The HemoSphere Vita technology module is compatible with a ForeSight oximeter cable and ForeSight/ForeSight Jr sensors. The HemoSphere Vita technology module fits into a standard module slot.

Note

The following components may have alternative labeling conventions:

ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).

ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.



1. ForeSight/ForeSight Jr sensor
2. ForeSight/ForeSight Jr sensor connections (2)
3. ForeSight oximeter cable housing
4. Cable to module connections (2)
5. HemoSphere Vita technology module
6. HemoSphere Vita monitor

Figure 10-8: Tissue oximetry monitoring connection overview

Note

ForeSight/ForeSight Jr sensors are TYPE BF defibrillation proof APPLIED PARTS. Patient cables that attach to the sensors, such as the ForeSight oximeter cable, are not intended to be applied parts but may come into contact with the patient and meet the relevant applied part requirements per IEC 60601-1.

The ForeSight oximeter cable can remain connected to the patient during cardiac defibrillation.

The HemoSphere Vita technology module is shipped with ESD covers for the ForeSight oximeter cable connection ports. After removing them when using the system for the first time, it is recommended that they be kept and used to protect the electrical connection points when the ports are not in use.

WARNING

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

Inspect all of the ForeSight oximeter cable connections for damage prior to installation. If any damage is noted, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical support. There is a risk that damaged parts could reduce the performance of the cable or present a safety hazard.

To remove any chance of contamination between patients, the ForeSight oximeter cable and cable connections should be cleaned after each case.

To reduce the risk of contamination and cross infection, if the ForeSight oximeter cable or cable connections are grossly contaminated, with blood or other bodily fluids, it should be disinfected. If the ForeSight oximeter cable or

cable connections cannot be disinfected, it should be serviced, replaced or discarded. Contact Edwards Technical support.

To reduce the risk of damaging internal elements of the cable assemblies — within the ForeSight oximeter cable housing — avoid excessive pulling, bending or other types of stress on the cable connections.

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

CAUTION

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

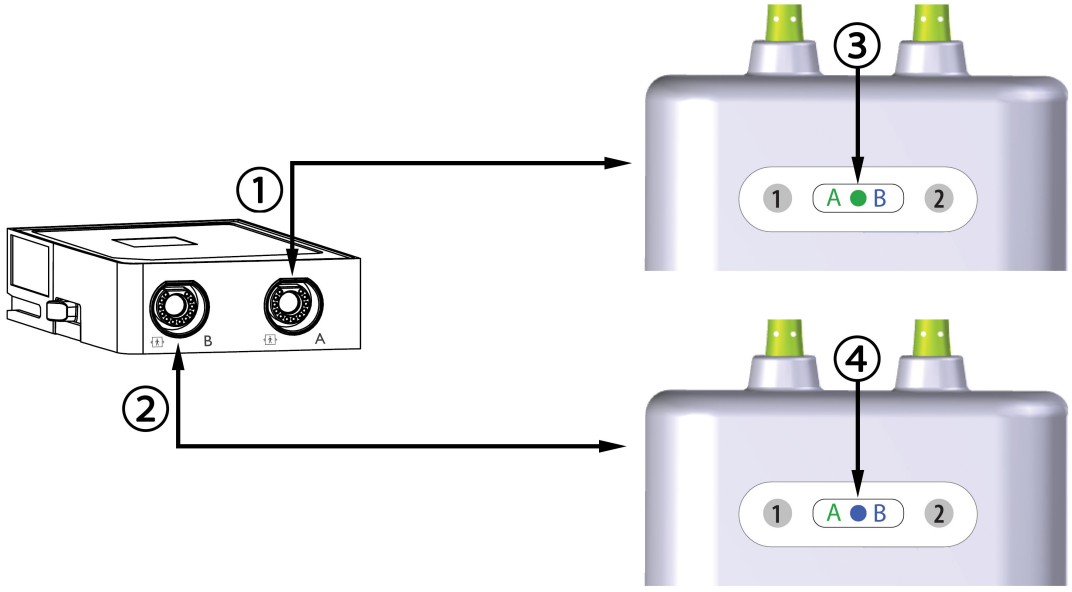
1. Press the power button to turn on the HemoSphere Vita monitor. All functions are accessed through the touch screen.
2. Ensure proper orientation, then plug the ForeSight oximeter cable into the technology module. Up to two ForeSight oximeter cables can be connected to each technology module.

   Note

   The ForeSight oximeter cable only connects one way to the HemoSphere technology module. If at first the connection does not go in, rotate the connector and try inserting it again.

   Do not pull on any part of the ForeSight oximeter cable connections when unplugging it from the HemoSphere Vita technology module. If it is necessary to remove the HemoSphere Vita technology module from the monitor, press the release button to unlatch and slide module out.

   Once the ForeSight oximeter cable connection has been made to the technology module, the channel 1 and channel 2 status LEDs should turn on. The group status LED will also turn on, indicating the module channels are group A (connected to port A on inserted technology module) or group B (connected to port B on inserted technology module).



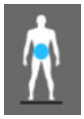
1. HemoSphere Vita technology module port A
2. HemoSphere Vita technology module port B
3. Green module group status LED: Channels associated with port A on technology module
4. Blue module group status LED: Channels associated with port B on technology module

Figure 10-9: ForeSight oximeter cable status LED

3. Select **Continue Same Patient** button or **New Patient** button and enter new patient data.
4. Connect the compatible ForeSight/ForeSight Jr sensor(s) to the ForeSight oximeter cable. Up to two sensors can be connected to each ForeSight oximeter cable. Available sensor locations are listed in Table 10-1 on page 126. See Attaching Sensors to the Patient on page 128 and refer to the ForeSight sensor and ForeSight Jr sensor instructions for use for proper sensor application directions.
5. Monitoring begins automatically once the ForeSight sensor(s) are connected to the ForeSight oximeter cable.

Table 10-1: Tissue oximetry sensor locations

Symbol (right)*	Symbol (left)*	Adult (≥40 kg) anatomical location* (sensor size)	Pediatric (<40 kg) anatomical location* (sensor size)
		brain (large)	brain (medium/small)
		shoulder (large)	n/a

Symbol (right)*	Symbol (left)*	Adult (≥40 kg) anatomical location* (sensor size) 	Pediatric (<40 kg) anatomical location* (sensor size) 
		arm (large)	n/a
		flank/abdomen (large)	flank/abdomen (medium/small)
		n/a	abdomen (medium/small)
		leg – quadriceps (large)	leg – quadriceps (medium)
		leg – calf (gastrocnemius or tibialis, large)	leg – calf (gastrocnemius or tibialis, medium)
Symbols are color coded based on ForeSight oximeter cable group channel: green for channel A and blue (shown) for channel B			

6. If **StO_2** is not a current key parameter, touch the displayed parameter label located inside of any parameter tile to select **StO_2 <Ch>** as a key parameter from the tile configuration menu, where <Ch> is the sensor channel. The channel options are **A1** and **A2** for ForeSight oximeter cable A and **B1** and **B2** for ForeSight oximeter cable B.

7. The channel will appear in the upper left corner of the parameter tile. Touch the patient figure  on the parameter tile to access the **Sensor Configuration** window.

8. Select the Patient monitoring mode: adult  or pediatric  .

Note

The sensor mode selection is automatically selected based on the patient's entered body weight. Adult sensor mode is configured for any body weight ≥40 kg.

9. Select the anatomical location of the sensor. See Table 10-1 on page 126 for a list of available sensor locations. The sensor locations are color coded based on the HemoSphere Vita technology module connection port:
   - **Green:** Sensor locations for a ForeSight oximeter cable connected to port A on HemoSphere Vita technology module
   - **Blue:** Sensor locations for a ForeSight oximeter cable connected to port B on HemoSphere Vita technology module
10. Touch the home icon  to return to the monitoring screen.

10.3.1 Attaching Sensors to the Patient

The following sections describe how to prepare the patient for monitoring. For additional information on how to apply a sensor to the patient, see the instructions included in the ForeSight/ForeSight Jr sensor packaging.

10.3.1.1 Selecting a Sensor Site

To ensure patient safety and proper data collection, consider the following items when selecting a sensor site.

WARNING

Sensors are not sterile and therefore should not be applied on abraded, cracked, or lacerated skin. Exercise caution when applying sensors to a site with delicate skin. Applying sensors, tape or pressure to such a site may reduce circulation and/or cause skin deterioration.

Do not place sensor over poorly perfused tissues. Avoid uneven skin surfaces for best adhesion. Do not place sensor over sites with ascites, cellulitis, pneumoencephalus, or edema.

If electrocautery procedures will be performed, sensors and electrocautery electrodes should be placed as far apart as possible to prevent unwanted skin burns; a distance of at least 15 cm (6 in) is recommended.

CAUTION

Sensors should not be placed on high density hair areas.

The sensor must be able to rest flush with clean, dry skin. Any debris, lotion, oil, powder, perspiration, or hair that prevents good contact between the sensor and the skin will affect the validity of the data collected and may result in an alarm message.

Note

Skin pigmentation does not affect the validity of collected data. The ForeSight oximeter cable compensates automatically for skin pigmentation.

In the event that the location of the selected tissues cannot be palpated or visualized, confirmation by ultrasound or X-ray is recommended.

Table 10-2 on page 129 provides sensor selection guidelines based on patient monitoring mode, patient weight, and body location.

Table 10-2: Sensor selection matrix

Patient Mode	Sensor	Weight	Body Location				
			Brain	Flank	Abdomen	Legs	Arms/ Deltoids
Adult	Large	≥40 kg	•	•		•	•
Pediatric	Medium	≥3 kg	•	•	•	•	
Pediatric neonatal	Small	<8 kg	•				
		<5 kg	•	•	•		
Pediatric neonatal	Small, nonadhesive	<8 kg	•				
		<5 kg	•	•	•		

Note

If you connect a sensor that is sized inappropriately for the current patient monitoring mode, that channel displays an alert on the status bar. If this is the only sensor connected, you may be prompted to switch modes (adult or pediatric).

If you connect a sensor that is sized inappropriately for the selected body location, that channel displays an alert on the status bar. If this is the only sensor connected, you may be prompted to select a different body location or use a different sensor size.

WARNING

Use only Edwards supplied accessories with the ForeSight oximeter cable. Edwards accessories ensure patient safety and preserve the integrity, accuracy, and electromagnetic compatibility of the ForeSight oximeter cable. Connecting a non-Edwards sensor will cause an appropriate alert on that channel and no StO_2 values will be recorded.

Sensors are designed for single-patient use, and are not to be reprocessed – re-used sensors present a risk of cross-contamination or infection.

Use a new sensor for each patient and discard it after use. Disposal should follow in accordance with local hospital and institution policies.

If a sensor seems damaged in any way, it must not be used.

Always read the sensor packaging.

10.3.1.2 Preparing the Sensor Site

To prepare the patient's skin for sensor placement:

1. Verify that the skin area where the sensor is to be placed is clean, dry, intact, and free of powder, oil, or lotion.
2. If necessary, shave hair from skin at the chosen site.

3. Use an appropriate cleanser to gently clean the intended sensor site.
   You may use Tegaderm or Mepitel under the sensor in patients with delicate skin or edema.

4. Allow the skin to dry completely before applying the sensors.

10.3.1.3 Applying Sensors

1. Select the appropriate sensor (see Table 10-2 on page 129) and remove it from the package.
2. Remove and discard the protective liner from the sensor (Figure 10-10 on page 130).

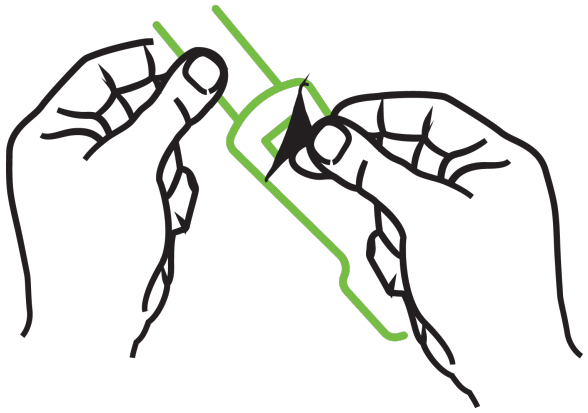


Figure 10-10: Removing protective liner from sensor

Note

When using the non-adhesive small sensor, you must size and cut the sensor band length to fit the patient.

- Shorten the sensor band away from the patient. Do not cut the sensor band while on the patient, and do not cut any other part of the sensor.
- Attach the sensor band to the patient with the print facing out.
- Do not over-tighten the sensor band, as pressure can be transferred to the baby.

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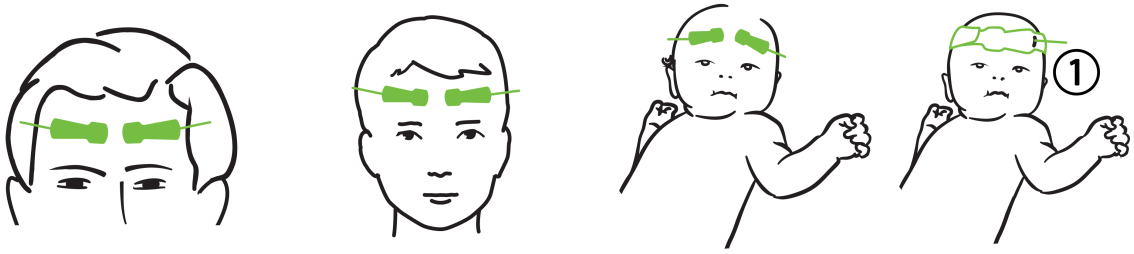
3. Affix the sensor to the patient in the chosen location.
   Cerebral Use (Figure 10-11 on page 131): Select the site on the forehead above the eyebrow and just below the hairline where the sensors will be linearly aligned.

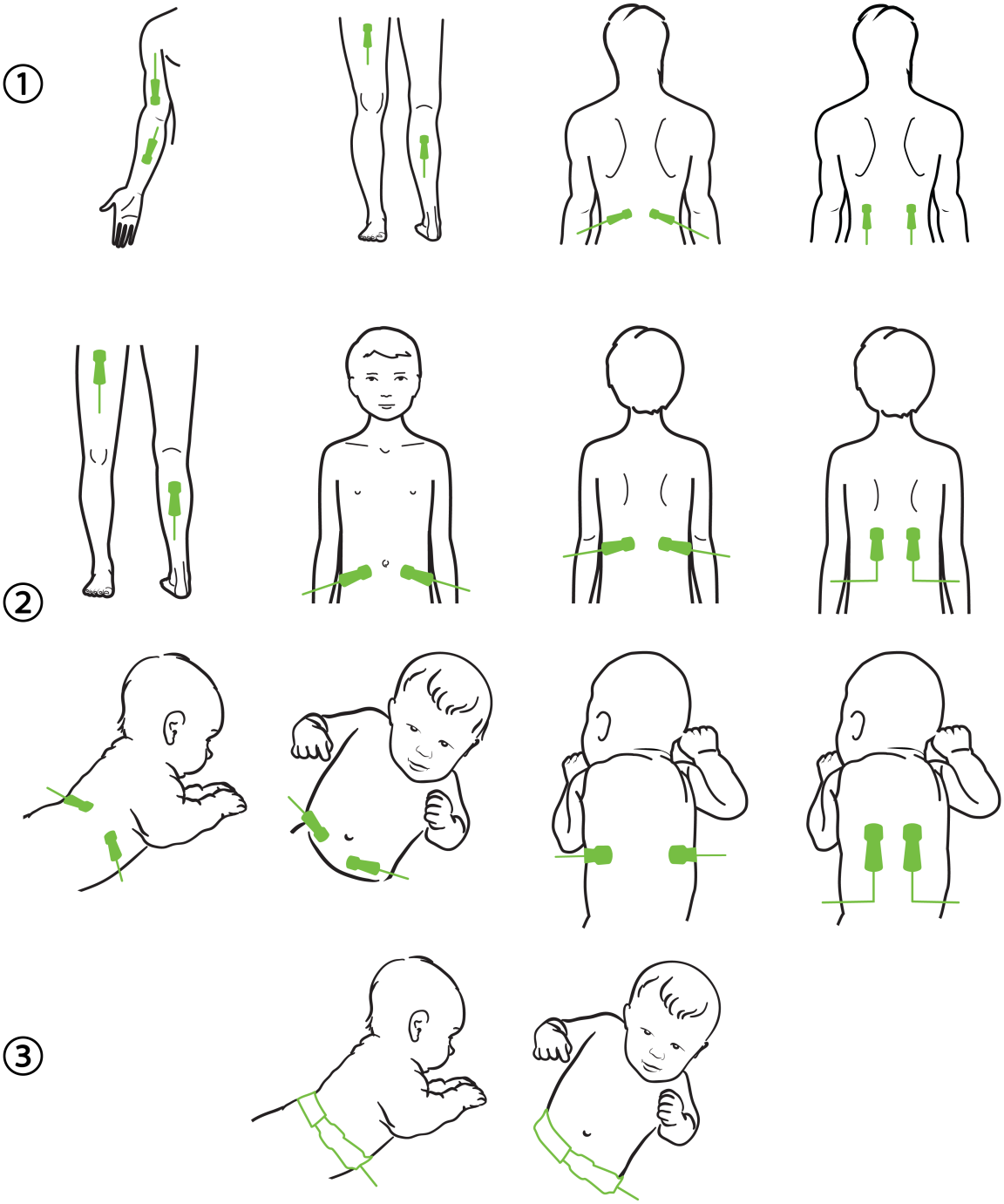


1. non-adhesive small sensor

Figure 10-11: Sensor placement (cerebral)

Non-Cerebral Use (Figure 10-12 on page 132): Select the site that provides the ideal access to the desired skeletal muscle tissue (if muscle cannot be palpated, too much adipose or edema may be present).

- Arm: Position sensor over the deltoid (shoulder), biceps (upper arm), or brachioradialis muscle.
- Leg: Position sensor over the quadriceps (upper leg), gastrocnemius (calf), or tibialis (calf) muscle. Apply the sensor with the connector towards the feet.
- Flank/Abdomen: Position sensor over the Latissimus dorsi (flank) or external oblique (abdomen) muscle.



1. adult

2. pediatric/neonatal

3. non-adhesive small sensor

Figure 10-12: Sensor placement (non-cerebral)

Note

When monitoring muscle tissue, place the sensor centrally over the selected muscle bed (e.g., middle of upper half of the lower leg as diagrammed).

A muscle bed with significant atrophy may not provide enough tissue for monitoring.

When monitoring for the effects of vascular obstruction in a limb, place a sensor on both the limb of concern and in the same location on the opposing limb.

WARNING

Exercise extreme care when applying sensors. Sensor circuits are conductive and must not come into contact with other grounded, conductive parts other than EEG or entropy monitors. Such contact would bridge the patient's isolation and cancel the protection provided by the sensor.

Failure to apply sensors properly may cause incorrect measurements. Misapplied sensors or sensors that become partially dislodged may cause either over- or under-reading of oxygen saturation.

Do not position a sensor under the weight of the patient. Prolonged periods of pressure (such as taping over the sensor or the patient lying on a sensor) transfers weight from the sensor to the skin, which can injure skin and reduce sensor performance.

The sensor site must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. If the circulatory condition or skin integrity has deteriorated, the sensor should be applied to a different site.

10.3.1.4 Connecting Sensors to Cables

1. Be sure that ForeSight oximeter cable is connected to the technology module and that sensors are placed correctly on the patient's skin.
2. Use the clips on the sensor cable to secure and prevent the cable from being pulled away from the patient.

   WARNING

   Do not connect more than one patient to the ForeSight oximeter cable. This may compromise the patient's isolation and cancel the protection provided by the sensor.

   CAUTION

   When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection.

   Do not lift or pull the ForeSight oximeter cable by any cable connections, or place the ForeSight oximeter cable in any position that might present a risk that the module may fall on the patient, bystander or operator.

3. Position the sensor connector in front of the sensor cable connector and align the marks on each (Figure 10-13 on page 134).

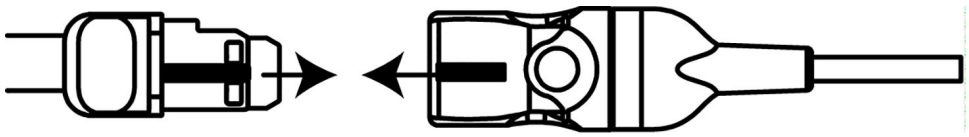
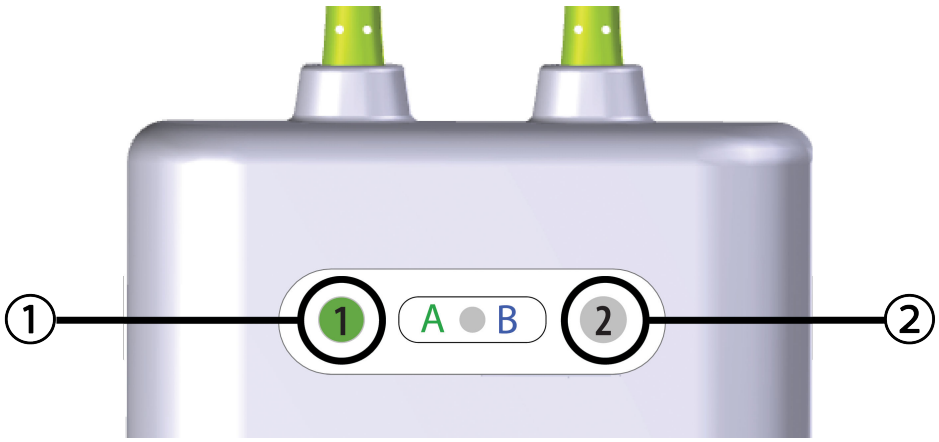


Figure 10-13: Connecting a sensor to the sensor cable connector

4. Gently push the sensor connector straight into the sensor cable connector until it snaps into place.
5. Gently pull back on the sensor to verify the sensor is fully inserted into the connector.
6. Verify that the channel status LED indicator on the ForeSight oximeter cable changes from white to green when the sensor is fully connected. See Figure 10-14 on page 134.



1. channel 1 LED is green (sensor connected) **2.** channel 2 LED is white (no sensor connected)

Figure 10-14: Connecting a sensor to the ForeSight oximeter cable - channel status LED

CAUTION

Once patient monitoring has started, do not replace the sensor or disconnect the sensor for more than 10 minutes to avoid restarting the initial StO_2 calculation.

Note

If the ForeSight oximeter cable cannot read sensor data properly after starting a new patient, a message to verify the sensors are properly applied to the patient may be displayed.

Confirm that sensors are properly adhered to the patient and dismiss the message and begin monitoring.

When displaying the parameter value change or percent change, the StO_2 parameter value from the start of monitoring is used as a Reference value. See Display Parameter Value Change on page 83. If replacing or repositioning a sensor, it is recommended to update the Reference value.

10.3.2 Disconnecting Sensors After Monitoring

Once you are done monitoring a patient, you need to remove the sensors from the patient and disconnect the sensors from the sensor cable as described in the instructions included in the ForeSight/ForeSight Jr sensor packaging.

10.3.3 Monitoring Considerations

10.3.3.1 ForeSight Oximeter Cable Use During Defibrillation

WARNING

The ForeSight oximeter cable has been designed to promote patient safety. All cable parts are "Type BF Defibrillation Proof" and are protected against the effects of the defibrillator discharge and may remain attached to the patient. Cable readings may be inaccurate during defibrillator use and up to twenty (20) seconds thereafter.

No separate actions are required when using this equipment with a defibrillator, but only Edwards-supplied sensors must be used for proper protection against the effects of a cardiac defibrillator.

Do not come into contact with patients during defibrillation, or serious injury or death could result.

10.3.3.2 Interference

CAUTION

Measurements may be affected in the presence of strong electromagnetic sources such as electrosurgery equipment, and measurements may be inaccurate during use of such equipment.

Elevated levels of carboxyhemoglobin (COHb) or methemoglobin (MetHb) may lead to inaccurate or erroneous measurements, as may intravascular dyes or any substance containing dyes that change usual blood pigmentation. Other factors that may affect measurement accuracy include: myoglobin, hemoglobinopathies, anemia, pooled blood under the skin, interference from foreign objects in the Sensor path, Bilirubinemia, externally applied coloring (tattoos), high levels of HGB or Hct and birthmarks.

When used in settings with LED lighting, sensors may need to be covered with a light blocker prior to connection to the sensor cable, as some high intensity systems can interfere with the sensor's near infrared light detection.

10.3.3.3 Interpreting StO_2 Values

WARNING

If the accuracy of any value displayed on the monitor is questionable, determine the patient’s vital signs by alternative means. The functions of the alarm system for patient monitoring must be verified at regular intervals and whenever the integrity of the product is in doubt.

Testing of the ForeSight oximeter cable operation should be done at least once every 6 months, as described in HemoSphere Vita service manual. Failure to comply may lead to injury. If the cable fails to respond, it must not be used until it has been inspected and serviced or replaced. See technical support contact information on inside cover.

CAUTION

When compared to earlier software versions, a ForeSight oximeter cable with a software version of V3.0.7 or later and used with pediatric sensors (small and medium) is more responsive in the display StO_2 values. Specifically, in the range below 60%, StO_2 measurements could be reported lower than in earlier software versions. Clinicians should consider the faster response and potentially modified StO_2 values when using V3.0.7 software, especially if they are experienced with earlier software versions of the ForeSight oximeter cable.

Note

For patients experiencing complete bilateral external carotid artery (ECA) occlusion, measurements may be lower than expected.

Table 10-3 on page 136 and Table 10-4 on page 136 summarize the validation methodology and study results associated with the ForeSight oximeter cable.

Table 10-3: StO_2 validation methodology

Patient population	ForeSight sensor	Cerebral reference	Non-cerebral reference	Type measurement	Subject weight range
Adult	Large	Co-oximetry of jugular bulb and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	≥40 kg
Pediatric — adolescents, children, infants, and neonates	Medium	Co-oximetry of internal jugular vein and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	≥3 kg
Pediatric — adolescents, children, infants, and neonates	Small	Co-oximetry of internal jugular vein and arterial blood samples	Co-oximetry of central venous and arterial blood samples	Single point	3 to 8 kg
Pediatric — neonates (term, premature, low birth weight, very low birth weight)	Small	FORE-SIGHT MC3010[1]	Co-oximetry of umbilical venous and pulse oximetry samples	StO_2 data averaged in two-minute windows[2]	<5 kg

[1]Unlike the other ForeSight validation studies, this cerebral validation study did not include invasive measurements because of the challenge for medical centers to obtain consent to insert an internal jugular venous catheter in very small subjects.

[2]StO_2 data was averaged in two-minute windows for term, premature low birth weight (LBW), and very low birth weight (VLBW) neonates for the following reasons: 1) to reduce the influence of acute changes in StO_2 due to changes in body position or touch as the hemodynamics in premature LBW and VLBW neonates are not as stable compared to normal birth weight neonates, and 2) to enable measurements for both FORE-SIGHT MC3010 and ForeSight sensors or across multiple abdominal locations at nominally the same time for the smallest neonates for which only one sensor can be fitted on the head or specific abdominal location at a time.

Table 10-4: Clinical validation study results for StO_2

StO_2 measurement location	Sensor size	Accuracy (Bias ± Precision)*
Cerebral StO_2	large	46% to 88%: -0.06 ± 3.25% at 1 SD
		46% to 88%: -0.06 ± 3.28% at 1 SD†

StO_2 measurement location	Sensor size	Accuracy (Bias ± Precision)*
	medium	44% to 91%: 0.97 ± 5.43% at 1 SD
		44% to 91%: 1.21 ± 5.63% at 1 SD†
		44% to 91%: 1.27 ± 4.93% at 1 SD ‡
	small	44% to 90%: -0.74 ± 5.98% at 1 SD
Non-cerebral StO_2 (somatic)	large	51% to 92%: -0.12 ± 4.15% at 1 SD
		51% to 92%: -0.12 ± 4.17% at 1 SD†
	medium	52% to 88%: -0.14 ± 5.75% at 1 SD
	small	66% to 96%: 2.35 ± 5.25% at 1 SD

**Not determined outside of the listed ranges*

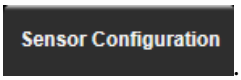
†Dependent Data Bland-Altman Analysis (DDBA)

‡Brain StO_2 values averaged versus REF CX bias and precision

Note: StO_2 accuracy is determined based on 30:70% (arterial:venous) reference measurement for REF CX. The method of evaluation for all StO_2 sensor size accuracy measurements was under human clinical evaluation studies.

10.3.4 Skin Check Timer

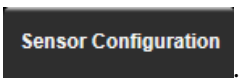
Tissue oximetry sensor sites must be inspected at least every 12 hours to reduce the risk of inadequate adhesion, circulation, and skin integrity. The **Skin Check Reminder** displays a reminder every 12 hours, by default. The time interval for this reminder can be modified:

1. Touch anywhere in the **StO_2** parameter tile → **Sensor Configuration** tab 

.
2. Touch the value button for **Skin Check Reminder** to select a time interval between skin check notifications. The options are: **2 Hours**, **4 Hours**, **6 Hours**, **8 Hours** or **12 Hours** (default).
3. To reset the timer, select **Reset** from the **Skin Check Reminder** value button.

10.3.5 Set Averaging Time

StO_2 is measured constantly and parameter display is updated every 2 seconds. The averaging time used to smooth monitored data points can be adjusted. Faster averaging times will limit the filter of irregular or noisy data points.

1. Touch anywhere in the **StO_2** parameter tile → **Sensor Configuration** tab 

.
2. Touch the value button for **Averaging** to select a time interval between skin check notifications. The options are:

   - **Slow (24 seconds)**: Higher number of samples gives slower response.
   - **Normal (16 seconds)**: Default setting for Adult Mode.
   - **Fast (8 seconds)**: Smaller numbers of samples gives a faster response. This is the default setting for Pediatric Mode.

- **None**: Displays values at measurement update rate of 2 seconds. This fastest response setting is an advanced option only available through the **Engineering** → **Tissue Oximetry** settings screen.

10.3.6 Signal Quality Indicator

The signal quality indicator (SQI), displayed on parameter tiles configured for tissue oximetry is a reflection of the signal quality based on the amount of near-infrared light tissue perfusion. The SQI bar boxes fill based on the level of oximetry signal quality. The update rate for StO_2 and SQI level is two seconds. SQI will display one of four signal levels as described in Table 10-5 on page 138.

Table 10-5: Signal quality indicator levels

SQI symbol	Bars filled	Level	Description
	four	normal	All aspects of the signal are optimal
	three	intermediate	Indicates a moderately compromised signal
	two	poor	Indicates poor signal quality
	one	unacceptable	Indicates a severe problem with one or more aspects of signal quality

10.3.7 Relative Change in Total Hemoglobin – ΔctHb

The relative change in total hemoglobin (ΔctHb) is a sub-parameter of StO_2. A trending value, ΔctHb is calculated from the sum of relative changes in oxygenated hemoglobin and deoxygenated hemoglobin (ΔO2Hb and ΔHHb). Each connected tissue oximetry sensor site StO_2 measurement has its own ΔctHb sub-parameter. ΔctHb parameters are only available if the ΔctHb parameter feature is enabled. Please contact your local Edwards representative for more information on enabling this advanced feature. For additional information, see Relative Change in Total Hemoglobin – ΔctHb on page 139.

11

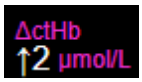
Advanced Features

Contents

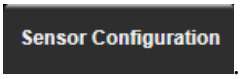
11.1 Relative Change in Total Hemoglobin – ΔctHb

The relative change in total hemoglobin (ΔctHb) is a sub-parameter of StO_2. A trending value, ΔctHb is calculated from the sum of relative changes in oxygenated hemoglobin and deoxygenated hemoglobin (ΔO2Hb and ΔHHb). Each connected tissue oximetry sensor site StO_2 measurement has its own ΔctHb sub-parameter. ΔctHb parameters are only available if the ΔctHb parameter feature is enabled. Please contact your local Edwards representative for more information on enabling this advanced feature.

11.1.1 ΔctHb Value Display

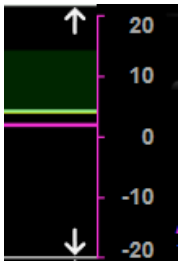


To display the value of ΔctHb on the StO_2 parameter tile:

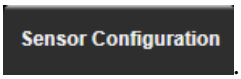
1. Touch anywhere in the **StO_2** parameter tile → **Sensor Configuration** tab 

.
2. Toggle the ΔctHb value button from **Off** to **On**.

11.1.2 ΔctHb Trend Display



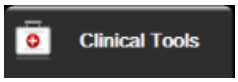
To display the trend of ΔctHb on the StO_2 parameter trend graph:

1. Touch anywhere in the **StO_2** parameter tile → **Sensor Configuration** tab 

.
2. Toggle the ΔctHb trend button from **Off** to **On**. The trend will be plotted in pink with a corresponding y-axis on the right side of the graph.

11.1.3 Reset ΔctHb

To reset the baseline value of ΔctHb to zero for all channels:

1. Touch the settings icon  → **Clinical Tools** tab 

→ **ctHb Tools** icon  .
2. Touch the **Reset ΔctHb** button.

11.1.4 Validation Methodology and Study Results

Table 11-1 on page 140 summarizes the validation methodology and study results for relative change in hemoglobin (ΔctHb).

Table 11-1: Clinical and blood bench validation study results for trending accuracy of relative change in hemoglobin (ΔctHb)

Sensor size	Bland-Altman Bias ± Precision, RSME (A_{rms})	Method of evaluation*
large	0.22 ± 2.53 µM at 1 SD, 2.53 µM	Under isovolumic hemodilution human study
	-0.26 ± 2.04 µM at 1 SD, 2.04 µM	Under mild hypoxia human study
medium	-1.10 ± 5.27 µM at 1 SD, 5.39 µM	Blood phantom study
small	-0.02 ± 5.96 µM at 1 SD, 5.96 µM	Blood phantom study
	-0.50 ± 2.09 µM at 1 SD, 2.15 µM	Under hemoglobin level desaturation blood phantom study
**Differential Pathlength factor = 5*		

12

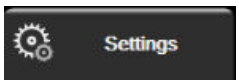
Troubleshooting

Contents

12.1 On Screen Help

The help topics outlined in this chapter and displayed on monitor help screens are associated with common error conditions. In addition to these error conditions, a list of unresolved anomalies and troubleshooting steps are available at eifu.edwards.com. This list is associated with the HemoSphere Vita monitor model number (HEMVITA1) and software version indicated on the startup page (see Start Up Procedure on page 49). These issues are continually updated and compiled as a result of ongoing product improvements.

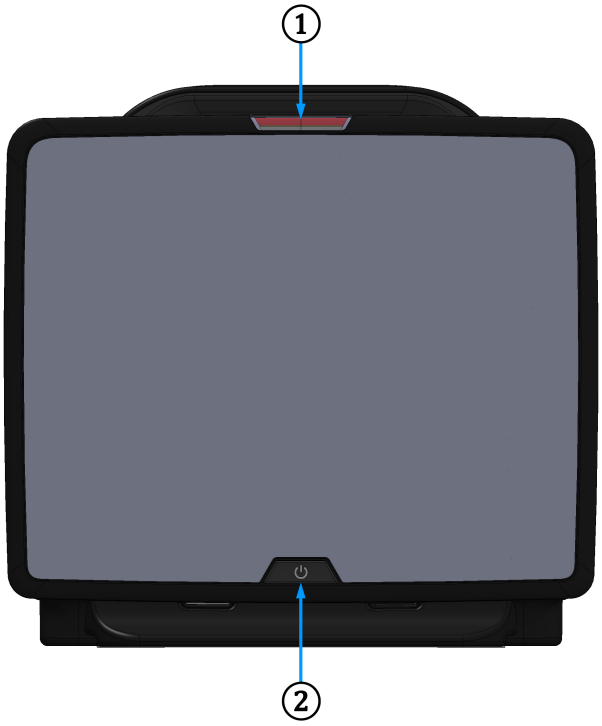
The main help screen allows the user to navigate to specific help for HemoSphere Vita monitoring platform issues. Faults, alerts and warnings notify the user of error conditions affecting parameter measurements. Faults are technical alarm conditions that suspend parameter measurement. The category help 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: **Monitoring**, **VitaWave** module, or **Tissue 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.
7. To display software versions and serial numbers for the monitor and connected technology module(s)/cable(s) touch settings icon  → **Settings** tab 

→ **Versions** button.

12.2 Monitor Status Lights

The HemoSphere Vita monitor has a visual alarm indicator to alert the user to alarm conditions. See Alarm Priorities on page 176 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.



1. visual alarm indicator

2. monitor power status

Figure 12-1: HemoSphere Vita monitor LED indicators

Table 12-1: HemoSphere Vita 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 and will remain active during an alarm pause If a particular technical alarm condition is unrecoverable, restart system If problem persists, contact Edwards Technical Support
Medium-priority technical faults and alerts	Yellow	Flashing ON/OFF	This alarm condition needs prompt attention Refer to the status bar for specific alarm condition

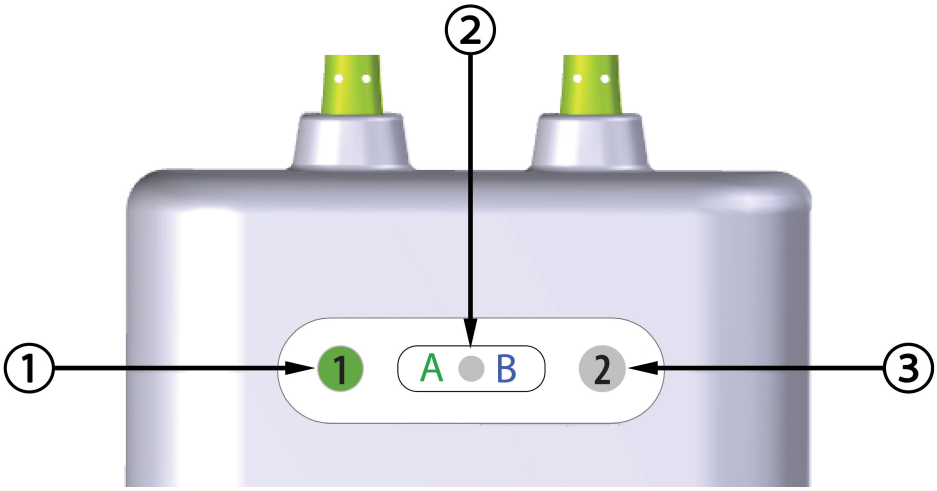
Alarm status	Color	Light pattern	Suggested action
Medium-priority physiological alarm	Yellow	Flashing ON/OFF	This alarm condition needs prompt attention Refer to the status bar for specific alarm condition
Low-priority technical alert	Yellow	Solid ON	This alarm condition requires non-urgent attention Refer to the status bar for specific alarm condition

Table 12-2: HemoSphere Vita 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

12.3 ForeSight Oximeter Cable Sensor Communication

The ForeSight oximeter cable LED indicates the status of the tissue oximetry sensor channels.



1. channel 1 status LED
2. module status LED
3. channel 2 status LED

Figure 12-2: ForeSight oximeter cable LED indicators

Table 12-3: ForeSight oximeter cable LED communication lights

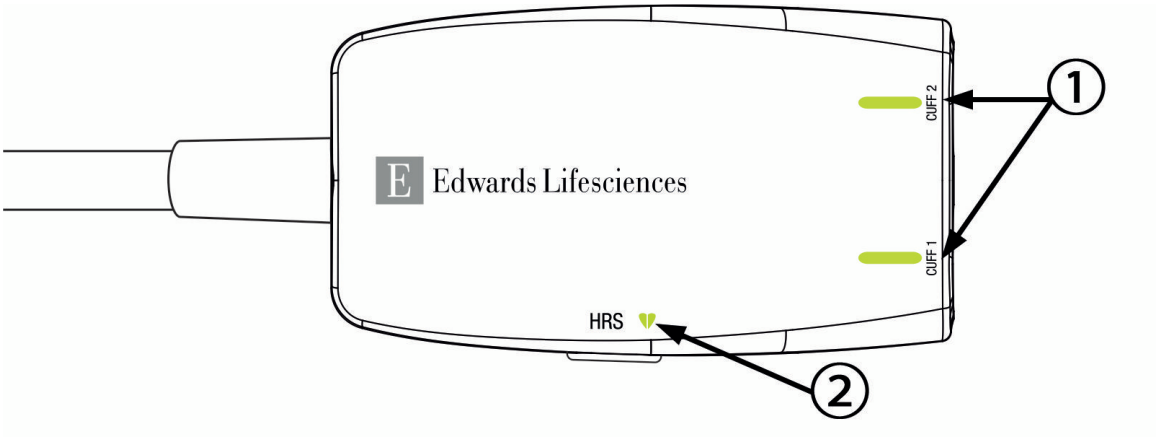
LED indicator	Color	Indication
Channel 1 status	White	No sensor connected
	Green	Sensor connected
Channel 2 status	White	No sensor connected
	Green	Sensor connected
Module status	Green	Channels are associated with port A on HemoSphere Vita technology module
	Blue	Channels are associated with port B on HemoSphere Vita technology module

CAUTION

If any of the ForeSight oximeter cable LEDs fail to turn on, the cable must not be used until it has been serviced or replaced. Contact Edwards Technical Support. There is a risk that damaged parts could reduce the performance of the cable.

12.4 Pressure Controller Communication

The pressure controller lights indicate the status of the finger cuff(s) and heart reference sensor.



1. Finger Cuff(s) Status **2.** Heart Reference Sensor Status

Figure 12-3: Pressure Controller LED Indicators

Table 12-4: Pressure controller communication lights*

Condition	Color	Light Pattern	Suggested Action
CUFF STATUS LIGHT			
No finger cuff connected	No light	Solid OFF	None

Condition	Color	Light Pattern	Suggested Action
Finger cuff connected	Green	Solid ON	None. The connected cuff is detected, authenticated, and not expired.
Active monitoring	Green	Flashing ON/OFF	None. The connected finger cuff is actively monitoring.
Defective finger cuff connected Expired finger cuff connected Non-compatible Edwards finger cuff connected	Amber	Flashing ON/OFF	Verify that a compatible Edwards finger cuff has been used. Disconnect and reconnect the finger cuff. Replace the finger cuff with a compatible Edwards finger cuff. Restart the measurement. If the problem persists, contact Edwards Technical Support.
HEART REFERENCE SENSOR STATUS LIGHT			
No heart reference sensor connected	No light	Solid OFF	None
Heart reference sensor connected	Green	Solid ON	None. The system is ready to start a measurement.
Defective heart reference sensor connected Non Edwards heart reference sensor detected	Amber	Flashing ON/OFF	Verify that an Edwards heart reference sensor has been used. Disconnect and reconnect the heart reference sensor. Replace the heart reference sensor with a genuine heart reference sensor. Restart the measurement. If the problem persists, contact Edwards Technical Support.
**Finger cuff error may also be indicated by software. See Table 12-8 on page 150.*			

12.5 HemoSphere Vita Monitor Error Messages

12.5.1 System/Monitoring Faults/Alerts

Table 12-5: 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

Message	Possible causes	Suggested actions
Fault: L-Tech Module Slot – Hardware Failure	Large technology module is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins 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	Reinsert 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: L-Tech Module Slot – Software Failure	There is a software error with the module inserted in the large technology module slot	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: L-Tech Module Slot – Communication Error	Large technology module is not inserted properly Connection points on slot or module are damaged	Reinsert the module Check for bent or broken pins 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

Message	Possible causes	Suggested actions
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
Fault: Module Slot 2 - Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: L-Tech Module Slot – 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: HemoSphere VitaWave Module	Defective HemoSphere VitaWave module	Power cycle the system Replace HemoSphere VitaWave module If problem persists, contact Edwards Technical Support
Fault: HemoSphere VitaWave Module Disconnected	HemoSphere VitaWave module removed during monitoring HemoSphere VitaWave 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 If problem persists, contact Edwards Technical Support
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

Message	Possible causes	Suggested actions
Fault: Pressure-Out – Hardware Failure	Pressure-out cable is not properly connected Connection points on cable or port are damaged	Reinsert the pressure-out cable Check for bent or broken pins If problem persists, contact Edwards Technical Support
Fault: Module Slot 1 – Incompatible Cable	The cable plugged into the technology module inserted in module slot 1 is not compatible with the HemoSphere Vita system	Remove the unsupported cable
Fault: Module Slot 2 – Incompatible Cable	The cable plugged into the technology module inserted in module slot 2 is not compatible with the HemoSphere Vita system	Remove the unsupported cable
Fault: Module Slot 1 - Incompatible Hardware	Module 1 is not compatible with the HemoSphere Vita system	Remove module 1 and replace with supported module
Fault: Module Slot 2 - Incompatible Hardware	Module 2 is not compatible with the HemoSphere Vita system	Remove module 2 and replace with supported module
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 reinsert the battery pack Change HemoSphere battery pack If problem persists, contact Edwards Technical Support
Alert: Service Battery	Internal battery fault occurred Battery can no longer sustain the system adequately on a full charge	Power cycle the system If condition persists, replace the battery pack
Alert: Advanced Feature expiring in < 2 weeks	One or more currently activated Advanced Features are expiring	Update Advanced Feature License Contact Edwards Technical Support
Alert: Advanced Feature expiring in < 4 weeks	One or more currently activated Advanced Features are expiring	Update Advanced Feature License Contact Edwards Technical Support

Message	Possible causes	Suggested actions
Alert: Transmit Pressure Not Active	Connection of new patient monitor pressure channel detected	Navigate to Zero & Waveform screen, and touch transmit pressure button (waveform icon) after zeroing patient monitor Disconnect the pressure-out cable

12.5.2 System/Monitoring Warnings

Table 12-6: HemoSphere Vita 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

12.5.3 Numeric Keypad Errors

Table 12-7: Numeric keypad errors

Message	Possible causes	Suggested actions
Value out of range (xx-yy)	The entered value is either higher or lower than the allowed range.	Displayed when the user enters a value that is out of range. The range is displayed as part of the notification replacing the xx and yy.
Value must be ≤ xx	The entered value is in range, but is higher than the high value setting such as the high scale setting. xx is the associated value.	Enter a lower value.

Message	Possible causes	Suggested actions
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.

12.6 HemoSphere VitaWave Module Error Messages

12.6.1 Faults/Alerts

Table 12-8: HemoSphere VitaWave module faults/alerts

Message	Possible causes	Suggested actions
Fault: Finger Cuff #1 - BP Measurement Error Fault: Finger Cuff #2 - BP Measurement Error	Blood pressure measurement failed due to movement or poor measurement conditions.	Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size Restart measurement
Fault: Finger Cuff #1 – Sensor Light Out of Range Fault: Finger Cuff #2 – Sensor Light Out of Range	Light signal too high.	Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size Restart measurement
Fault: Finger Cuff #1 – No Signal Detected – Low Perfusion Fault: Finger Cuff #2 – No Signal Detected – Low Perfusion	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Warm the hand. Apply Finger Cuff to a different finger. Restart measurement.
Fault: Finger Cuff #1 - No Pressure Waveforms Detected Fault: Finger Cuff #2 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Check if the blood flow in the arm of the patient is free of obstructions Check the blood pressure waveforms Reapply finger cuff(s) Restart measurement
Fault: Insufficient Pressure Build Up in Cuff #1 Fault: Insufficient Pressure Build Up in Cuff #2	Finger cuff air tube kinked Finger cuff leaking Cable between HemoSphere VitaWave module and pressure controller kinked or leaking Defective pressure controller Defective HemoSphere VitaWave module	Check finger cuff Check cable between HemoSphere VitaWave module and pressure controller Replace finger cuff Replace pressure controller Replace HemoSphere VitaWave module Restart measurement
Fault: Finger Cuff Disconnected	Previously connected Finger Cuff(s) not detected.	Disconnect and reconnect Edwards finger cuff(s) Replace finger cuff(s) Restart measurement

Message	Possible causes	Suggested actions
Fault: Accumulated Single Cuff Monitoring has reached the duration limit	Cumulative measurement time on the same finger exceeded maximum duration of 8 hours.	Remove Cuff from finger Place the Cuff on another finger and press 'Continue' on the Popup Restart Measurement
Fault: Finger Cuff #1 Has Expired. Replace Cuff	Finger Cuff #1 has exceeded maximum use time.	Replace Finger Cuff #1. Restart measurement.
Fault: Finger Cuff #2 Has Expired. Replace Cuff	Finger Cuff #2 has exceeded maximum use time.	Replace Finger Cuff #2. Restart measurement.
Fault: Invalid Finger Cuff #1 Connected	Non Edwards finger cuff #1 detected Defective finger cuff #1 connected	Verify that an Edwards finger cuff has been used Disconnect and reconnect Edwards finger cuff #1 Replace finger cuff #1 with a genuine Edwards cuff Restart measurement If problem persists, contact Edwards Technical Support
Fault: Invalid Finger Cuff #2 Connected	Non Edwards finger cuff #2 detected Defective finger cuff #2 connected	Verify that an Edwards finger cuff has been used Disconnect and reconnect Edwards finger cuff #2 Replace finger cuff #2 with a genuine Edwards cuff Restart measurement If problem persists, contact Edwards Technical Support
Fault: Finger Cuff #1 or Finger Cuff Connector Error	Finger cuff #1 is defective Cuff connector on pressure controller is damaged or defective	Disconnect and reconnect Edwards finger cuff #1. Replace finger cuff #1. Replace pressure controller. Restart measurement. If problem persists, contact Edwards Technical Support.
Fault: Finger Cuff #2 or Finger Cuff Connector Error	Finger cuff #2 is defective Cuff connector on pressure controller is damaged or defective	Disconnect and reconnect Edwards finger cuff #2. Replace finger cuff #2. Replace pressure controller. Restart measurement. If problem persists, contact Edwards Technical Support.
Fault: HRS Value Out of Physiological Range	Heart end of HRS is loose and may no longer be at heart level. HRS detached from finger cuff. HRS incorrectly calibrated. HRS is defective.	Verify HRS placement. The finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis. Vertically align the two ends of HRS and calibrate Replace HRS Restart measurement If problem persists, contact Edwards Technical Support
Fault: HRS Disconnected	Heart Reference Sensor (HRS) disconnected during monitoring HRS connection not detected	Verify HRS connection Disconnect and reconnect Edwards HRS Replace HRS If problem persists, contact Edwards Technical Support

Message	Possible causes	Suggested actions
Fault: HRS Detected	Measurement without HRS chosen but HRS is connected	Disconnect HRS Or select to measure with HRS
Fault: Invalid HRS Connected	Non Edwards HRS detected HRS is defective	Verify that an Edwards HRS has been used. Disconnect and reconnect Edwards HRS. Replace HRS with a genuine Edwards HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.
Fault: HRS or HRS Connector Error	HRS is defective HRS connector on pressure controller is damaged	Disconnect and reconnect Edwards HRS Replace HRS Replace pressure controller Restart measurement If problem persists, contact Edwards Technical Support
Fault: HRS Has Expired. Replace HRS	HRS has expired as it is past useful life.	Disconnect and reconnect Edwards HRS. Replace HRS. Restart Measurement. If problem persists, contact Edwards Technical Support.
Fault: Pressure Controller Disconnected	Pressure Controller connection not detected.	Disconnect and reconnect Edwards Pressure Controller. Replace Pressure Controller. If problem persists, contact Edwards Technical Support.
Fault: Invalid Pressure Controller Connected	Incompatible pressure controller detected Non Edwards pressure controller detected Defective pressure controller connected	Verify that an Edwards pressure controller has been used. Disconnect and re-connect Edwards pressure controller. Replace pressure controller with a genuine Edwards pressure controller. If problem persists, contact Edwards Technical Support.
Fault: Pressure Controller Communication Error	Unresponsive pressure controller Poor connection between pressure controller and HemoSphere VitaWave module Pressure controller authentication failure Defective pressure controller Defective HemoSphere VitaWave module	Disconnect and reconnect Edwards pressure controller Power cycle the system Replace pressure controller Replace HemoSphere VitaWave module If problem persists, contact Edwards Technical Support
Fault: Pressure Controller Error	Defective pressure controller Poor connection between Edwards pressure controller and HemoSphere VitaWave module	Disconnect and reconnect Edwards pressure controller Replace pressure controller If problem persists, contact Edwards Technical Support

Message	Possible causes	Suggested actions
Fault: Pressure Controller Power Failure	Defective HemoSphere VitaWave module Defective Edwards pressure controller	Disconnect and reconnect Edwards pressure controller Replace pressure controller Replace HemoSphere VitaWave module If Problem Persists, contact Edwards Technical Support
Fault: Incompatible Pressure Controller Software	Unsuccessful software upgrade or incompatible software version detected	Replace pressure controller with a genuine Edwards pressure controller If problem persists, contact Edwards Technical Support
Fault: Continuous Monitoring Has Reached the 72 Hour Limit	Continuous measurement on the same hand exceeded maximum duration of 72 hours.	Place the cuffs on fingers of opposite hand and resume monitoring.
Fault: Air Supply Error	Kinked or damaged pressure controller cable Damaged finger cuff System malfunction Defective HemoSphere VitaWave module Defective pressure controller	Verify that connection between pressure controller and HemoSphere VitaWave module is not kinked or damaged Power cycle the system Replace pressure controller Replace HemoSphere VitaWave module Replace finger cuff If problem persists, contact Edwards Technical Support
Fault: Check Arterial Waveform	Arterial waveform is inadequate to measure blood pressure accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low	Assess noninvasive system starting from patient leading to finger cuff and HemoSphere VitaWave module Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis Confirm electrical connections of cables Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size If problem persists, contact Edwards Technical Support[†]
Fault: Arterial Waveform Compromised	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Check if the blood flow in the arm of the patient is free of obstructions Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis Check the blood pressure waveforms Reapply finger cuff(s) Restart measurement If problem persists, contact Edwards Technical Support
Fault: Cuff Disconnected During Double Cuff Monitoring	Previously connected Finger Cuff(s) not detected.	Disconnect and reconnect Edwards finger cuff(s) Replace finger cuff(s) Restart measurement

Message	Possible causes	Suggested actions
Fault: Second Cuff Connected During Single Cuff Monitoring	A second finger cuff connection is detected	Disconnect one of the finger cuffs and restart measurement Restart measurement in double cuff monitoring mode
Alert: Arterial Pressure Waveform Not Stable	Arterial waveform is inadequate to measure blood pressure accurately Poor pressure waveform over extended period of time Integrity of pressure monitoring line is compromised Systolic pressure too high or diastolic pressure too low	Assess noninvasive system starting from patient leading to finger cuff and HemoSphere VitaWave module Check the arterial waveform for severe hypotension, severe hypertension, and motion artifact Make sure the heart end of Edwards HRS is aligned with the patient's phlebostatic axis Confirm electrical connections of cables Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size If problem persists, contact Edwards Technical Support†
Alert: Cuff Pressure Release Mode – Monitoring Suspended	Finger cuff pressure has been released	Monitoring will automatically resume when the Countdown Clock on the Status Bar reaches 00:00 To resume monitoring, touch the countdown clock and select "Postpone Release"
Alert: Finger Cuff #1 - BP Measurement Error – Restarting Alert: Finger Cuff #2 - BP Measurement Error – Restarting	Blood pressure measurement failed due to movement or poor measurement conditions.	Allow system to automatically resolve issue. Apply Finger Cuff to a different finger. Resize Finger Cuff and replace Finger Cuff with different size.†
Alert: Finger Cuff #1 - No Pressure Waveforms Detected Alert: Finger Cuff #2 - No Pressure Waveforms Detected	The system failed to detect pressure waveforms. Pressure pulsations in finger diminished due to pressure applied to the upper arm, elbow or wrist.	Allow System to automatically resolve issue Check if the blood flow in the arm of the patient is free of obstructions Check the blood pressure waveforms Reapply finger cuff(s)
Alert: HRS Value Out of Physiological Range	Heart end of HRS is loose and may no longer be at heart level. HRS detached from finger cuff. HRS incorrectly calibrated. HRS is defective.	Verify HRS placement. The finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis. Vertically align the two ends of HRS and calibrate Replace HRS Restart measurement If problem persists, contact Edwards Technical Support
Alert: No HRS Connected – Verify Patient Positioning Alert: Current Offset: Finger {0} {1} Above Heart* Alert: Current Offset: Finger at Heart Level Alert: Current Offset: Finger {0} {1} Below Heart*	The patient positioning mode is "Patient Sedated and Stationary" and an HRS is not connected	Verify that the displayed offset is still accurate If the patient has been re-positioned, update the offset value on the "Zero & Waveform" screen

Message	Possible causes	Suggested actions
Alert: HemoSphere VitaWave Module Service Required	HemoSphere VitaWave module service time is overdue	Replace HemoSphere VitaWave module Contact Edwards Technical Support
Alert: Updated BP Calibration Might Be Required	Updated calibration may be required due to changes to hemodynamic state	Perform new calibration Keep Calibration Clear BP Calibration
Alert: Calibrate HRS	HRS not calibrated or previous calibration failed	Ensure HRS is connected and calibrate the HRS to start measurement
**Note: {0} {1} is the specified distance where {0} is the value and {1} is the unit of measurement (CM or IN)* *†Cuff sizing may not be applicable to all cuffs*		

Table 12-9: HemoSphere VitaWave warnings

Message	Possible causes	Suggested actions
HRS Out of Range	HRS pressure offset exceeded limit during the calibrating process HRS is defective	Vertically align the two ends of HRS Calibrate HRS Replace HRS
HRS Calibration Unsuccessful – No Movement Detected	Prior to calibration, no HRS movement detected HRS is defective Defective Pressure Controller	Move heart end of HRS up and down. Next, keep both ends at same level, wait 1-2 seconds, and then calibrate while keeping both ends steady. Replace HRS and calibrate HRS If problem persists, contact Edwards Technical Support
HRS Calibration Unsuccessful – Excessive Movement Detected	During calibration, HRS movement detected Defective pressure controller	Move heart end of HRS up and down. Next, keep both ends at same level, wait 1-2 seconds, and then calibrate while keeping both ends steady. Replace HRS and calibrate HRS If problem persists, contact Edwards Technical Support
Unstable Arterial Pressure	System detecting large variability in the arterial pressure due to physiological or artificial noise.	Ensure no external or artificial noise is interfering with arterial pressure measurements. Stabilize arterial pressure.
BP Calibration Unavailable	Insufficient monitoring data has been collected Blood pressure values from past 1 minute are too variable for a reliable calibration Non-physiological noise or artifacts are detected in the pressure signal	Allow for additional monitoring time and try again Stabilize arterial pressure Ensure no external or artificial noise is interfering with arterial pressure measurements
Finger Cuff #1 - No Signal Detected – Low Perfusion – Restarting Finger Cuff #2 - No Signal Detected – Low Perfusion – Restarting	No measurable Plethysmogram detected on startup. Possibly contracted arteries.	Allow system to automatically resolve issue. Warm the hand. Apply Finger Cuff to a different finger.
Connect HemoSphere VitaWave module for pressure monitoring	Connection to the HemoSphere VitaWave module has not been detected	Insert HemoSphere VitaWave module into the large technology module slot of the monitor Remove and re-insert module

Message	Possible causes	Suggested actions
Finger Cuff #1 – Sensor Light Out of Range – Restarting Finger Cuff #2 – Sensor Light Out of Range – Restarting	Light signal too high.	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Insufficient Pressure Build Up in Cuff #1 – Restarting Insufficient Pressure Build Up in Cuff #2 – Restarting	Finger cuff air tube kinked Finger cuff leaking Cable between HemoSphere VitaWave module and pressure controller kinked or leaking Defective pressure controller Defective HemoSphere VitaWave module	Check finger cuff Check cable between HemoSphere VitaWave module and pressure controller Replace finger cuff Replace pressure controller Replace HemoSphere VitaWave module Restart measurement
Severe Vasoconstriction	Very small arterial volume pulsations detected, possibly contracted arteries.	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Moderate Vasoconstriction	Very small arterial volume pulsations detected, possibly contracted arteries.	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Finger Cuff #1 - Pressure Waveform Oscillations Detected Finger Cuff #2 - Pressure Waveform Oscillations Detected	Possibly contracted arteries. Finger cuff too loose.	Allow system to automatically resolve issue Warm the hand Apply finger cuff to a different finger Resize finger cuff and replace finger cuff with different size†
Connect Pressure Controller	Pressure Controller not connected. Defective Pressure Controller connected.	Connect Pressure Controller. Replace Pressure Controller. If problem persists, contact Edwards Technical Support.
Finger Cuff #1 Expiration in < 5 Minutes	Finger Cuff #1 approaching maximum use time.	Replace finger cuff #1 to ensure uninterrupted measurement
Finger Cuff #2 Expiration in < 5 Minutes	Finger Cuff #2 approaching maximum use time.	Replace finger cuff #2 to ensure uninterrupted measurement
Finger Cuff #1 Has Expired	Finger Cuff #1 has exceeded maximum use time.	Replace Finger Cuff #1. Restart measurement.
Finger Cuff #2 Has Expired	Finger Cuff #2 has exceeded maximum use time.	Replace Finger Cuff #2. Restart measurement.
Connect Finger Cuff	No finger cuff(s) detected Defective finger cuff(s) connected	Connect finger cuff(s) Replace finger cuff(s)
Finger Cuff #1 Approaching Maximum Use Time	Finger Cuff #1 approaching maximum use time.	Replace finger cuff #1 to ensure uninterrupted measurement

Message	Possible causes	Suggested actions
Finger Cuff #2 Approaching Maximum Use Time	Finger Cuff #2 approaching maximum use time.	Replace finger cuff #2 to ensure uninterrupted measurement
Connect HRS	HRS connection not detected.	Connect HRS. Replace HRS.
HRS Expires in < 2 weeks	HRS will expire in less than 2 weeks.	Replace HRS to prevent delay in start of monitoring.
HRS Expires in < 4 weeks	HRS will expire in less than 4 weeks.	Replace HRS to prevent delay in start of monitoring.
HemoSphere VitaWave Module Service Required	HemoSphere VitaWave module service time is approaching	Replace HemoSphere VitaWave module Contact Edwards Technical Support
[†]*Cuff sizing may not be applicable to all cuffs*		

Table 12-10: HemoSphere VitaWave general troubleshooting

Message	Possible causes	Suggested actions
Pressure Difference: VitaWave BP vs. Other BP	HRS detached from finger cuff or phlebostatic axis HRS not properly calibrated Possibly contracted arteries (due to cold fingers) Finger cuff too loose Other BP measurement device not zeroed Other BP measurement sensor incorrectly applied	Verify HRS placement. The finger end should be attached to finger cuff and heart end should be placed at phlebostatic axis. In case of invasive BP reference, HRS heart end and the transducer should be at the same level Calibrate HRS Warm the hand Reapply finger cuff (to a different finger) or replace finger cuff with proper size Re-zero other BP measurement device Remove and reapply other BP measurement sensor[†]
[†]*Cuff sizing may not be applicable to all cuffs*		

12.7 Tissue Oximetry Error Messages

12.7.1 Tissue Oximetry Faults/Alerts

Table 12-11: Tissue oximetry faults/alerts

Message	Possible causes	Suggested actions
Fault: Second Technology Module Detected	Multiple technology module connections detected	Remove one of the technology modules from the monitor slots
Fault: StO_2 – Technology Module Disconnected	HemoSphere technology module removed during monitoring HemoSphere technology 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

Message	Possible causes	Suggested actions
Fault: StO_2 – ForeSight Oximeter Cable A Disconnected	FSOC A has become disconnected	Connect FSOC to port A of the inserted HemoSphere technology module
Fault: StO_2 – ForeSight Oximeter Cable B Disconnected	FSOC B has become disconnected	Connect FSOC to port B of the inserted HemoSphere technology module
Fault: StO_2 {0} – Sensor Disconnected*	Edwards Sensor on the indicated channel has become disconnected	Connect Edwards Sensor
Fault: StO_2 – Technology Module	Internal system malfunction	Remove and re-insert module to reset If problem persists, contact Edwards Technical Support
Fault: StO_2 – ForeSight Oximeter Cable A	FSOC A is defective	If condition persists, contact Edwards to replace the FSOC
Fault: StO_2 – ForeSight Oximeter Cable B	FSOC B is defective	If condition persists, contact Edwards to replace the FSOC
Fault: StO_2 – ForeSight Oximeter Cable A Communication Error	The technology module has lost communication with the indicated FSOC	Reconnect the cable Check for bent or broken pins Try switching FSOC to other port of technology module If problem persists, contact Edwards Technical Support
Fault: StO_2 – ForeSight Oximeter Cable B Communication Error	The technology module has lost communication with the indicated FSOC	Reconnect the cable Check for bent or broken pins Try switching FSOC to other port of technology module If problem persists, contact Edwards Technical Support
Fault: StO_2 – ForeSight Oximeter Cable A Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: StO_2 – ForeSight Oximeter Cable B Incompatible Software Version	Unsuccessful software upgrade or incompatible software version detected	Contact Edwards Technical Support
Fault: StO_2 {0} – Faulty Sensor*	Sensor is defective or Non-Edwards Sensor in use	Replace with Edwards Sensor
Fault: StO_2 {0} – Ambient Light Too High*	Sensor is not in correct contact with patient	Check that Sensor is in direct contact with skin Apply a light blocker or drape over the Sensor to limit exposure to light
Fault: StO_2 {0} – Sensor Temperature High*	Temperature under Sensor is > 45 °C (Adult Mode) or > 43 °C (Pediatric/ Neonatal Mode)	Cooling of patient or environment may be required

Message	Possible causes	Suggested actions
Fault: StO_2 {0} – Signal Level Too Low*	Insufficient light detected from patient Tissue under the sensors may have conditions such as excessive skin pigmentation, elevated hematocrit, birth marks, hematoma, or scar tissue A large (adult) sensor is being used on a pediatric patient (<18 years of age)	Verify that sensor is well adhered to patient's skin Move sensor to a location where SQI is 3 or 4 In the case of edema, remove the sensor until tissue condition returns to normal Replace large sensor with medium or small sensor in pediatric patients (<18 years of age)
Fault: StO_2 {0} – Signal Level Too High*	Very unusual condition that is likely caused by optical shunting, where most of the light emitted is directed to the detectors Certain non-physiological materials, anatomical characteristics or scalp edema may trigger this message	Check that sensor is in direct contact with skin and that the clear liner has been removed
Fault: StO_2 {0} – Check Tissue Under Sensor*	Tissue under Sensor may have fluid accumulation/edema	Check patient for edema under Sensor When tissue condition returns to normal range (e.g., patient is no longer edematous) the Sensor may be reapplied
Fault: StO_2 {0} – Stool Interference High*	The Sensor is interrogating primarily stool versus perfused tissue and StO_2 cannot be measured	Move the Sensor to a location where the relative amount of intestinal tissue is less, such as the flank
Fault: StO_2 {0} – Sensor Off*	Computed StO_2 not in valid range or sensor placed on an inappropriate object Low sensor temperature Poorly adhered or detached sensor Ambient light	Sensor may need to be repositioned
Fault: StO_2 {0} – Not Physiological*	The measured value is out of physiological range Sensor malfunction	Verify correct placement of Sensor Check Sensor connection
Fault: StO_2 {0} – Incorrect Sensor Size*	The sensor size is incompatible with either the Patient Mode or body location	Use a different sensor size (Refer to Sensor Instructions for Use for sensor size table) Change the Patient Mode or body location on the tile configuration menu accordingly
Fault: StO_2 {0} – Algorithm Fault*	A processing error has occurred in the calculation of StO_2 for the indicated channel	Disconnect and reconnect the indicated sensor channel Replace the FSOC Replace the technology module If problem persists, contact Edwards Technical Support
Fault: ΔctHb {0} – Out Of Range*	ΔctHb went outside of display range	Reset ctHb to re-baseline all applicable channels
Alert: StO_2 {0} – Unstable Signal*	Interference from outside source	Move Sensor away from interfering source

Message	Possible causes	Suggested actions
Alert: StO_2 {0} – Reduce Ambient Light*	Ambient light approaching maximum value	Check that Sensor is in direct contact with skin Apply a light blocker or drape over the Sensor to limit exposure to light
Alert: StO_2 {0} – Stool Interference*	Stool Interference is approaching maximum acceptable level The Sensor is interrogating some perfused tissue to make a StO_2 measurement, but there is also a high concentration of stool in the Sensor's interrogation path	Consider moving the Sensor to a different abdominal location with less stool interference
Alert: StO_2 {0} – Sensor Temperature Low*	Temperature under Sensor < -10 °C	Warming of patient or environment may be required
Alert: StO_2 {0} – Configure location for tissue oximetry sensor*	An anatomical location on the patient has not been configured for the connected sensor	Use the tissue oximetry configuration menu to select a body location for the indicated sensor channel
Alert: ΔctHb {0} – Reset Failed*	One of the connected channels produced a fault or alert during Reset	Check the information bar or event review screen for any faults or alerts associated with the tissue oximetry sensors Follow suggested actions for given faults or alerts
**Note: {0} is the sensor channel. The channel options are A1 and A2 for ForeSight cable A and B1 and B2 for ForeSight cable B. FSOC indicates ForeSight oximeter cable.* *The following components may have alternative labeling conventions:* *ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).* *ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.*		

12.7.2 Tissue Oximetry General Troubleshooting

Table 12-12: Tissue oximetry general troubleshooting

Message	Possible causes	Suggested actions
Connect Technology Module for StO_2 Monitoring	Connection between the HemoSphere advanced monitor and technology module has not been detected	Insert the HemoSphere technology module into slot 1 or slot 2 of the monitor Remove and re-insert module
Connect ForeSight Oximeter Cable A for StO_2 Monitoring	Connection between the HemoSphere technology module and FSOC at the indicated port has not been detected	Connect a FSOC to the indicated port of the HemoSphere technology module Reconnect the FSOC
Connect ForeSight Oximeter Cable B for StO_2 Monitoring	Connection between the HemoSphere technology module and FSOC at the indicated port has not been detected	Connect a FSOC to the indicated port of the HemoSphere technology module Reconnect the FSOC

Message	Possible causes	Suggested actions
Connect Tissue Oximetry Sensor for StO_2 Monitoring – {0}*	Connection between the FSOC and tissue oximetry sensor has not been detected on the channel for which StO_2 has been configured	Connect a tissue oximetry sensor to the indicated channel Reconnect the tissue oximetry sensor on the indicated channel
StO_2 {0} - Sensor Temperature Below Expected Range	Temperature under Sensor < 28°C	Verify correct placement of sensor If patient is cooled intentionally, no action is required
**Note: {0} is the sensor channel. The channel options are A1 and A2 for ForeSight cable A and B1 and B2 for ForeSight cable B. FSOC indicates ForeSight oximeter cable.* *The following components may have alternative labeling conventions:* *ForeSight oximeter cable (FSOC) may also be labeled as FORE-SIGHT ELITE tissue oximeter module (FSM).* *ForeSight sensors or ForeSight Jr sensors may also be labeled as FORE-SIGHT ELITE tissue oximetry sensors.*		

Appendix A

Specifications and Device Characteristics

Contents

A.1 Essential Performance Characteristics

Under normal and single fault conditions either the essential performance listed in Table A-1 on page 162 is provided or failure to provide this performance is readily identifiable by the user (e.g., no display of parameter values, technical alarm, distorted waveforms or delay in parameter value update, complete failure of the monitor, etc.).

Table A-1 on page 162 represents the minimum performance when operating under non-transient electromagnetic phenomena, such as radiated and conducted RF, according to IEC 60601-1-2. Table A-1 on page 162 also identifies the minimum performance for transient electromagnetic phenomena, such as electrical fast transients and surges, according to IEC 60601-1-2.

Table A-1: HemoSphere Vita monitor essential performance – transient and 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 10 seconds. After the transient electromagnetic phenomena, the system shall return to an operational state within 30 seconds. The system shall exhibit no loss of any stored data following the transient electromagnetic phenomena. When used with HF Surgical Equipment, the monitor shall return to operational mode within 10 seconds without loss of stored data after exposure to the field produced by the HF Surgical Equipment.

Module or cable	Parameter	Essential Performance
HemoSphere VitaWave module	non-invasive blood pressure (SYS, DIA, MAP)	Measurement of blood pressure within specified accuracy (±1% of full scale with a maximum of ±3 mmHg). Alarm if blood pressure outside alarm ranges. Alarm delay of approximately 10 seconds based on averaging window of 5 heartbeats (at 60 bpm this would be 5 seconds but will vary based on heart rate) and 5 consecutive seconds outside of alarm ranges.
HemoSphere Vita technology module with ForeSight oximeter cable	tissue oxygen saturation (StO_2)	The ForeSight oximeter cable shall recognize attached sensor and issue an appropriate equipment status if inoperable or disconnected. When a sensor is properly positioned on the patient and connected to the ForeSight oximeter cable, the ForeSight oximeter cable shall measure StO_2 values within system specifications (refer to Table A-11 on page 167) and correctly output values to HemoSphere Vita technology module. In response to a defibrillation event, the ForeSight oximeter cable shall not be electrically damaged. In response to an external noise event, the values may continue to report as pre-event values or may be reported as indeterminate value (dashed). The ForeSight oximeter cable shall automatically recover and resume reporting appropriate values within 20 seconds after the noise event.

A.2 HemoSphere Vita Monitor Characteristics and Specifications

Table A-2: HemoSphere Vita monitor physical and mechanical characteristics

HemoSphere Vita monitor		
Weight	10 ± 0.2 lb (4.5 ± 0.1 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)
Ingress protection	IPX1	
Display	Active Area	12.1 in (307 mm)
	Resolution	1024 × 768 LCD
Operating system	Windows 10 IoT	
Speaker count	1	

Table A-3: HemoSphere Vita monitor environmental specifications

Environmental specification		Value
Temperature	Operational	10 to 32.5 °C

Environmental specification		Value
	Non-operational/storage*	-18 to 45 °C
Relative humidity	Operational	20 to 90% non-condensing
	Non-operational/storage	90% non-condensing at 45 °C
Altitude	Operational	0 to 10,000 ft (3048 m)
	Non-operational/storage	0 to 20,000 ft (6096 m)
**Note: Battery capacity starts to degrade with extended exposure above 35 °C.*		

Table A-4: HemoSphere Vita monitor transportation environmental specifications

Environmental specification	Value
Temperature*	-18 to 45 °C
Relative humidity*	20 to 90% RH non-condensing
Altitude	maximum of 20,000 ft (6096 m) for up to 8 hours
Standard	ASTM D4169, DC13
**Note: Pre-conditioning temperature and humidity*	

Note

Unless otherwise stated, all compatible HemoSphere Vita monitor accessories, components, and cables have the environmental specifications listed in Table A-3 on page 163 and Table A-4 on page 164.

MRI Information. Do not use the HemoSphere Vita monitor or platform modules and cables in an MR environment. The HemoSphere Vita monitoring platform, including all modules and cables, is MR unsafe since the device contains metallic components, which can experience RF-induced heating in the MRI environment.

Table A-5: HemoSphere Vita monitor technical characteristics

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
Pressure output (1)	DPT pressure out signal is compatible with monitors and accessories intended to interface with Edwards minimally-invasive pressure transducers Post-zero minimum patient monitor display range: -20 mmHg to 270 mmHg

Input/Output	
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
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)
**While Analog and ECG monitor inputs are available on the monitor, their use is not supported within the current software release.*	

A.3 HemoSphere Battery Pack Characteristics and Specifications

Table A-6: HemoSphere battery pack physical characteristics

HemoSphere battery pack		
Weight	1.1 lb (0.5 kg)	
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
	Minimum long term storage	0 °C
Relative humidity	Operational	5 to 95% non-condensing at 40 °C

Table A-8: HemoSphere battery pack technical characteristics

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

A.4 HemoSphere Tissue Oximetry Characteristics and Specifications

Table A-9: HemoSphere Vita technology module physical characteristics

HemoSphere Vita technology module		
Weight	approximately 1.0 lb (0.4 kg)	
Dimensions	Height	1.4 in (3.5 cm)
	Width	3.5 in (9.0 cm)
	Depth	5.4 in (13.6 cm)
Ingress protection	IPX1	
Applied part classification	Type BF defibrillation proof	

Note

For HemoSphere Vita technology module and ForeSight oximeter cable environmental specifications, see Table A-3 on page 163.

Table A-10: ForeSight oximeter cable physical characteristics

ForeSight oximeter cable characteristics		
Weight	mounting clip	0.1 lb (0.05 kg)
	case, cables, and clip	2.3 lb (1.0 kg)
Dimensions	technology module cable length	15 ft (4.6 m)[1]
	sensor cable length (2)	4.9 ft (1.5 m)[1]

ForeSight oximeter cable characteristics		
	cable housing (H × W × D)	6.0 in (15.24 cm) x 3.75 in (9.52 cm) x 2.75 in (6.00 cm)
	mounting clip (H × W × D)	2.4 in (6.2 cm) x 1.75 in (4.47 cm) x 3.2 in (8.14 cm)
Ingress protection	IPX4	
Applied part classification	Type BF defibrillation proof	
[1]*The length of the technology module and sensor cables are nominal lengths.*		

Table A-11: HemoSphere Vita technology module with ForeSight oximeter cable parameter measurement characteristics

Parameter	Sensor	Specification
StO_2 (all locations)	all sensor sizes	display range: 0 to 99% update rate: 2 seconds
Cerebral StO_2	large sensors	A_{rms}* < 3.4% StO_2
	small/medium sensors	A_{rms}* < 6.1% StO_2
Somatic StO_2	large sensors	A_{rms}* < 4.3% StO_2
	small/medium sensors	A_{rms}* < 6.1% StO_2
**Note 1: A_{rms} from 50 to 85% StO_2. See Interpreting StO_2 Values on page 135 for more information.* *Note 2: Measurements are statistically distributed, and therefore about two-thirds of tissue oximeter equipment measurements are expected to fall within ±A_{rms} of the reference measurement over the measurement range.*		

Note

The expected useful life of the HemoSphere Vita technology module and ForeSight oximeter cable is 5 years from date of purchase. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

A.5 HemoSphere VitaWave Module Characteristics and Specifications

Table A-12: HemoSphere VitaWave module physical characteristics

HemoSphere VitaWave module		
Weight	approximately 2 lb (0.9 kg)	
Dimensions	Height	5.1 in (13 cm)
	Width	5.6 in (14 cm)
	Depth	3.9 in (10 cm)
Ingress protection	IPX1	
Applied part classification	Type BF	

Table A-13: HemoSphere VitaWave module environmental specifications

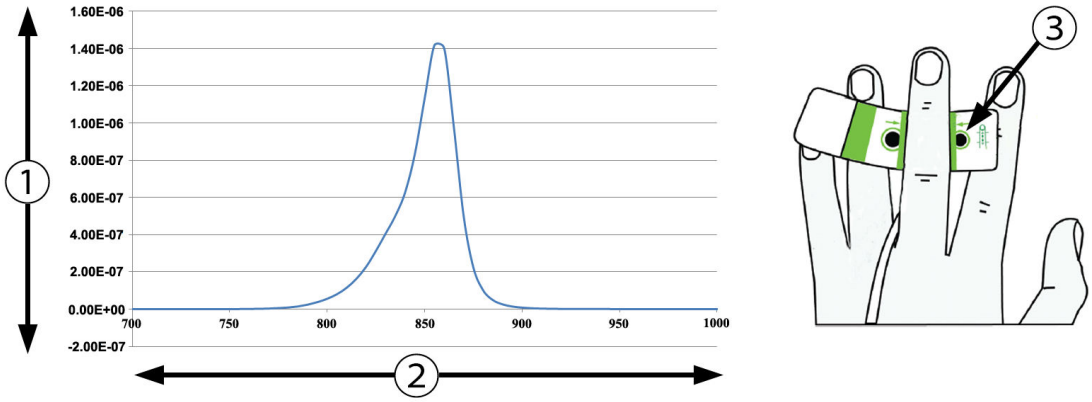
Environmental specification		Value
Temperature	Operational	10 to 37 °C
	Non-operational/storage	-18 to 45 °C
Relative humidity	Operational	20 to 85% non-condensing
	Non-operational/storage	20 to 90% non-condensing at 45 °C
Altitude	Operational	0 to 9,483 ft (3000 m)
	Non-operational/storage	0 to 19,685 ft (6000 m)

Table A-14: HemoSphere VitaWave module parameter measurement specifications

Parameter	Specification	
Arterial blood pressure	Display range	0 to 300 mmHg
	Accuracy[1]	Bias systolic pressure (SYS) ≤ ±5.0 mmHg Bias diastolic pressure (DIA) ≤ ±5.0 mmHg Precision (1σ) systolic pressure (SYS) ≤ ±8.0 mmHg Precision (1σ) diastolic pressure (DIA) ≤ ±8.0 mmHg
Finger cuff pressure	Range	0 to 300 mmHg
	Accuracy	1% of full scale (max 3 mmHg), zeroing automatically
[1]*Accuracy tested under laboratory conditions compared to a calibrated pressure gauge*		

Table A-15: Edwards finger cuff characteristics

Finger cuff	
Maximum weight	11 g (0.02 lb)
LED spectral irradiance	See figure A-1
Max optical output	0.013 mWatts
Max variation of output over treatment area	50%



1. Irradiance (Watt/cm^2)
2. Wavelength (nm)
3. Light emission aperture

Figure A-1: Spectral Irradiance and location of light emission aperture

Note

The expected useful life of the HemoSphere VitaWave module is 5 years from date of purchase. If your equipment experiences a malfunction, please contact Technical Support or your local Edwards representative for further assistance.

Appendix B

Accessories

Contents

B.1 Accessories List

WARNING

Only use approved HemoSphere Vita 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 Vita monitor components

Description	Model number
HemoSphere Vita monitor	
HemoSphere Vita monitor	HEMVITA1
HemoSphere battery pack	HEMBAT10
HemoSphere Vita expansion module	HEMVEXPM1
HemoSphere Vita L-Tech expansion module	HEMVLTECHM1
HemoSphere Vita monitor roll stand	HEMRLSTD1000
HemoSphere tissue oximetry monitoring	
HemoSphere Vita technology module	HEMVTOM1
ForeSight oximeter cable (May also be labeled as FORE-SIGHT ELITE oximeter module)	HEMFSM10
ForeSight Jr sensors (size: non-adhesive small and small) (May also be labeled as FORE-SIGHT ELITE oximetry sensors)	*
ForeSight sensors (sizes: medium and large) (May also be labeled as FORE-SIGHT ELITE oximetry sensors)	*
HemoSphere VitaWave module monitoring	
HemoSphere VitaWave module	HEMVWM1
Pressure controller kit	PC2K HEMPC2K
Pressure controller	PC2 HEMPC

Description	Model number
Pressure controller band multi pack	PC2B
Pressure controller cuff connector caps multi pack	PC2CCC
Pressure controller cover	PCCVR
Heart reference sensor	HRS
HemoSphere VitaWave module upgrade; HemoSphere ForeSight module upgrade	*
VitaWave finger cuff	*
HemoSphere Vita monitor cables	
Mains power cord	*
Pressure-out cable	HEMDPT1000
Additional HemoSphere Accessories	
HemoSphere Vita monitor operator's manual	**
HemoSphere Vita monitor service manual	**
HemoSphere Vita monitor quick start guide (contains HemoSphere Vita monitor operator's manual)	HEMVITAQG1
**Please contact your Edwards representative for 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 Vita monitor roll stand is intended for use with the HemoSphere Vita 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.

B.2.2 Pressure Controller Cover

The pressure controller cover secures the heart reference sensor into the pressure controller. The pressure controller cover is intended for limited reuse. The operator shall assess whether reuse is appropriate. When reused, follow the platform cleaning instruction listed in Cleaning the Monitor and Modules on page 178. Replace if damaged.

To apply the pressure controller cover:

1. Ensure the heart reference sensor (HRS) is attached prior to attaching the pressure controller cover to the pressure controller.
2. Place the pressure controller cover's back mounting notch around the pressure controller cable. See step 1 in Figure B-1 on page 172.
3. Snap the pressure controller cover over the pressure controller, making sure that the pressure controller cover does not interfere with the heart reference sensor (HRS) connection. See step 2 in Figure B-1 on page 172.

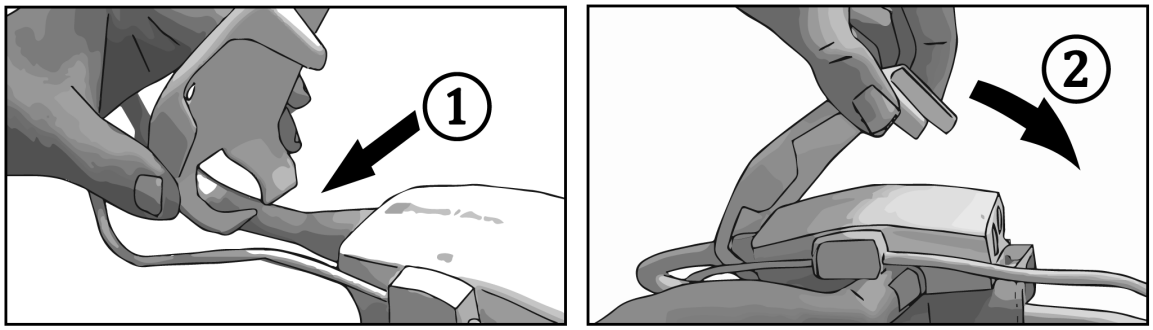


Figure B-1: Applying pressure controller cover

4. To remove the pressure controller cover, pull upwards from the front tab. This is indicated by the arrows symbol . Do not remove the pressure controller cover from the side by HRS connection indicated by the do not remove symbol .

CAUTION

Do not pinch any heart reference sensor tubes or wires under the pressure controller cover during application. Be careful the only wire between the back mounting notch is the pressure controller cable.

Do not lift PCCVR from any other point than the front tab.

Appendix C

Equations for Calculated Patient Parameters

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

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
StO_2	Tissue Oxygen Saturation $StO_2 = [HbO_2/(HbO_2 + Hb)] \times 100$ where: HbO_2 – Oxygenated Hemoglobin Hb – De-Oxygenated Hemoglobin	%

Appendix D

Monitor Settings and Defaults

Contents

D.1 Patient Data Input Range

Table D-1: Patient information

Parameter	Minimum	Maximum	Available units
Gender	**M** (Male) / **F** (Female)	N/A	N/A
Age	2	120	years
Height	12 in / 30 cm	98 in / 250 cm	inches (in) or cm
Weight	2 lbs / 1.0 kg	881 lbs / 400.0 kg	lbs or kg
BSA	0.08	5.02	m^2
ID	0 digits	40 characters	None

D.2 Trend Scale Default Limits

Table D-2: Graphical trend parameter scale defaults

Parameter	Units	Minimum default value	Maximum default value	Setting increment
StO_2	%	1	99	10
SYS_{ART}	mmHg	80	160	5
DIA_{ART}	mmHg	50	110	5
MAP	mmHg	50	130	5
PR	bpm	40	130	5
ΔctHb	none	-20	20	5

Note

The HemoSphere Vita 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	Display Range	Configurable Alarm/ Target Range
Tissue oximetry (StO_2)*	%	0 to 99	0 to 99
ΔctHb*	none	0 to 20	N/A^
MAP*	mmHg	0 to 300	10 to 300
ART* (live pressure waveform display)	mmHg	-34 to 312	0 to 300
SYS_{ART}	mmHg	0 to 300	10 to 300
DIA_{ART}	mmHg	0 to 300	10 to 300
PR	bpm	0 to 220	0 to 220
Parameter is available in Non-Pulsatile mode. ^ΔctHb is a non-alarming parameter. Ranges shown here are for display only.			

D.4 Alarm and Target Defaults

Table D-4: Parameter alarm red zone and target defaults

Parameter	Units	EW default lower alarm (red zone) setting	EW default lower target setting	EW default upper target setting	EW default upper alarm (red zone) setting
StO_2	%	50	60	85	90
SYS_{ART}	mmHg	90	100	130	150
DIA_{ART}	mmHg	60	70	90	100
MAP	mmHg	60	70	100	120
PR	bpm	60	70	100	120

Note

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

D.5 Alarm Priorities

Table D-5: Parameter alarms, faults, and alerts priorities

Physiologic parameter (alarms)/ message type	Lower physiological alarm (red zone) priority	Upper physiological alarm (red zone) priority	Message type priority
StO_2	High	N/A	
SYS_{ART}	High	High	
DIA_{ART}	High	High	
MAP	High	High	
PR	High	High	
Fault			Medium/High
Alert			Low

Note

The alarm signal generation delay is parameter dependent. For oximetry associated parameters, the delay is less than 2 seconds after the parameter is out of range continuously for 5 or more seconds. For HemoSphere VitaWave module non-invasive hemodynamic parameters, the delay is 20 seconds. For real-time blood pressure waveform display while monitoring with the HemoSphere VitaWave module, the delay is 5 heartbeats after the parameter is out of range continuously for 5 or more seconds.

The parameter value will flash at a higher frequency for a high priority physiological alarm as compared to a medium physiological alarm. If medium and high priority alarms are sounding at the same time, the physiological high priority alarm tone will be heard. If a low priority alarm is active and a medium or higher priority alarm is generated, the low priority alarm visual indicator will be replaced by the higher priority alarm visual indicator.

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

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

Language	Default display units				Time format	Date format	CO trend averaging time
	PaO_2	HGB	Height	Weight			
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

System Care, Service and Support

Contents

E.1 General Maintenance

The HemoSphere Vita monitor contains no user-serviceable parts, and should be repaired only by qualified service representatives. Hospital biomeds or service technician can refer to the HemoSphere Vita monitor service manual for information on maintenance and recurrent testing. 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 Vita 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.

The HemoSphere Vita monitor modules and platform cables are electrostatic discharge (ESD) sensitive. Do not attempt to open cable or module housing or use if the housing has been damaged.

E.2 Cleaning the Monitor and Modules

WARNING

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

The HemoSphere Vita 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 alcohol
- 2% glutaraldehyde
- 10% bleach solution (sodium hypochlorite)
- quaternary ammonium solution

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

Note

Once inserted, modules do not need to be removed unless maintenance or cleaning is necessary. If it is necessary to remove platform modules, store them in a cool, dry place in original packaging to prevent damage.

CAUTION

Do not pour or spray liquid on any portion of the HemoSphere Vita 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.

E.3 Cleaning the Platform Cables

Platform cables, such as the pressure-out cable, can be cleaned using the cleaning agents listed in Cleaning the Monitor and Modules on page 178 and the following methods.

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.

Store platform cables in a cool, dry place in original packaging to prevent damage. Additional instructions specific to certain cables are listed in the following sub-sections.

CAUTION

Do not use any other cleaning agents, spray, or pour cleaning solution directly on platform cables.

Do not steam, radiate, or EO sterilize platform cables.

Do not immerse platform cables.

E.3.1 Cleaning the ForeSight Oximeter Cable

Regular cleaning and preventive maintenance of the ForeSight oximeter cable is an important function that should be performed routinely to ensure safe and efficient cable operation. The cable does not require calibration, but following maintenance intervals are recommended:

- The cable should be tested upon installation and every six (6) months thereafter. Please contact Edwards Technical Support for more information.

WARNING

Do not, under any circumstances, perform any cleaning or maintenance of the ForeSight oximeter cable, while the cable is being used to monitor a patient. The cable must be turned off and the HemoSphere Vita monitor power cord disconnected, or the cable must be disconnected from the monitor and the sensors removed from the patient.

Before starting cleaning or maintenance of any sort, check the ForeSight oximeter cable, cable connections, ForeSight sensors, and other accessories for damage. Check the cables for bent or broken prongs, cracks, or fraying. If any damage is noted, the cable must not be used until it has been inspected and serviced or replaced. Contact Edwards Technical Support.

There is a risk of serious injury or death if this procedure is not followed.

The following cleaning agents are recommended to clean the ForeSight oximeter cable:

- Aspeti-Wipe
- 3M Quat #25
- Metrex CaviCide
- Phenolic germicidal detergent solution (per manufacturer's recommendations)
- Quaternary ammonium germicidal detergent solution (per manufacturer's recommendations)

See the product directions for use and labeling for detailed information on active ingredients and any disinfecting claims.

The ForeSight oximeter cable is designed to be cleaned using wipes or towelettes designed for that purpose. When all surfaces have been cleaned, wipe the entire surface of the cable using a soft cloth dampened with fresh water to remove any trace residue.

The sensor cables may be cleaned using wipes or towelettes designed for that purpose. They may be cleaned by wiping from the ForeSight oximeter cable housing end towards the sensor connections.

E.3.2 Cleaning the Heart Reference Sensor and Pressure Controller

The heart reference sensor (HRS) and pressure controller can be cleaned using the following disinfectants:

- 70% isopropyl alcohol solution
- 10% sodium hypochlorite water solution

1. Moisten a clean cloth with disinfectant and wipe the surfaces.

2. Dry the surface with a clean, dry cloth.

CAUTION

Do not disinfect the heart reference sensor or pressure controller by autoclave or gas sterilization.

Do not immerse any cable connectors in fluid.

Clean and store the heart reference sensor after each use.

E.3.2.1 Removing the Pressure Controller Band

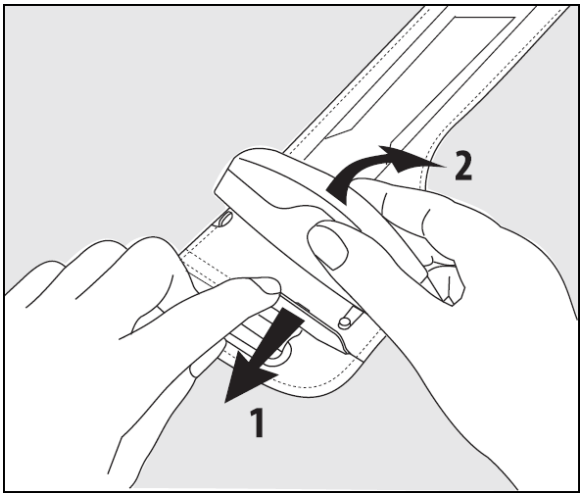


Figure E-1: Removing pressure controller from band

To remove the pressure controller from the pressure controller band, pull the sleeve slightly outwards (see step 1 in Figure E-1 on page 181) and tilt the pressure controller to remove it from the sleeve (see step 2 in Figure E-1 on page 181). The pressure controller band is intended for limited reuse. The operator shall assess whether reuse is appropriate. When reused, follow the platform cleaning instruction listed in Cleaning the Monitor and Modules on page 178. Replace if damaged.

E.4 Service and Support

See chapter 12: Troubleshooting on page 141 for diagnosis and remedies. If this information does not solve the problem, contact Edwards Lifesciences.

Edwards provides HemoSphere Vita 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 Vita 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.

E.5 Edwards Lifesciences Regional Headquarters

USA: Edwards Lifesciences LLC
One Edwards Way
Irvine, CA 92614 USA
949.250.2500
800.424.3278
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E.6 Monitor Disposal

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

E.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.

E.7 Preventive Maintenance

Periodically examine the HemoSphere Vita monitor exterior for general physical condition. Make sure the housing is not cracked, broken or dented, and that everything is present. Make sure there is no sign of spilled liquids or signs of abuse.

Routinely inspect cords and cables for fraying and cracks, and make sure there are no exposed conductors. In addition, check that the enclosure door at catheter connection point of the oximetry cable moves freely and latches properly.

E.7.1 Battery Maintenance

E.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 Vita 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.

E.7.1.2 Battery Storage

The battery pack can remain stored in the HemoSphere Vita monitor. Refer to HemoSphere Vita Monitor Characteristics and Specifications on page 163 for environmental specifications for storage.

Note

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

E.7.2 HemoSphere VitaWave Module Maintenance

Do not pull on the pressure controller cable when unplugging it from the HemoSphere VitaWave module. If it is necessary to remove the module from the HemoSphere Vita monitor, press the release button to unlatch and slide module out. It is recommended to send the HemoSphere VitaWave module to a qualified Edwards Service Center for routine service and preventive maintenance checks every two years. Additional testing includes a visual inspection, a software inspection, safety testing and functional testing. For more information on the testing contact your local Edwards Lifesciences representative.

E.7.3 HRS Preventive Maintenance

The finger component of the heart reference sensor (HRS) may be damaged if subjected to moderate to significant surface impact. Although the likelihood of damage is small, the resulting displayed values would be biased by the difference in height from the heart to the finger cuff. Even though this damage cannot be seen by looking at the heart reference sensor, it is possible to confirm whether the damage has occurred by following the below procedure prior to each use:

1. Connect the heart reference sensor to the pressure controller connected to the HemoSphere Vita monitor and go to the zeroing screen.
2. As instructed in Calibrate the Heart Reference Sensor on page 112, bring the two ends of the heart reference sensor level with each other.

3. Observe the value shown on the zeroing screen.
4. Raise one end of the heart reference sensor 6 inches (15 cm) above the other end.
5. Observe that the value shown has changed by at least 5 mmHg.
6. Reverse the ends such that the other end is now 6 inches (15 cm) above the first end.
7. Observe the value shown changed in the opposite direction by at least 5 mmHg from the original value.

If the value does not change as described, then the heart reference sensor may have been damaged. Contact your local Technical Support office as indicated on the inside cover or Service and Support on page 181. A replacement unit shall be provided. If the value does change, the heart reference sensor is functioning normally and can be used for hemodynamic monitoring.

E.8 Testing of Alarm Signals

Each time the HemoSphere Vita 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.

E.9 Warranty

Edwards Lifesciences (Edwards) warrants that the HemoSphere Vita 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 Vita monitor. Edwards' sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the HemoSphere Vita 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 Vita monitor if such damage or malfunction is caused by the customer's use of catheters other than those manufactured by Edwards.

Appendix F

Guidance and Manufacturer's Declaration

Contents

F.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 Vita monitor is intended for use in the electromagnetic environment specified in this appendix. The customer or the user of the HemoSphere Vita monitor should assure that it is used in such an environment. When connected to the HemoSphere Vita monitor, all accessory cables listed in Table B-1 on page 170 comply with the EMC standards listed above.

F.2 Instructions for Use

Medical electrical equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the following information and tables.

WARNING

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

No modification of the HemoSphere Vita monitor is allowed.

Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic ant-theft systems and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Vita monitor. Guidance on maintaining appropriate separation between communications equipment and the HemoSphere Vita monitor is provided in Table F-3 on page 187. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere monitoring platform.

CAUTION

The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be

determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Consult the manufacturer for help.

Note

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table F-1: Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HemoSphere Vita monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Vita monitor should assure that it is used in such an environment.		
Emissions	**Compliance**	**Description**
RF emissions CISPR 11	Group 1	The HemoSphere Vita 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 Vita 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 F-2: Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	**MHz**			**W**	**Meters**	**(V/m)**
The HemoSphere Vita monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Vita 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

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
The HemoSphere Vita monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Vita monitor should ensure that it is used in such an environment.						
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 F-3: Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HemoSphere Vita monitor

The HemoSphere Vita 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 Vita 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**

The HemoSphere Vita 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 Vita monitor as recommended below, according to the maximum output power of the communications equipment.				
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 F-4: In band wireless coexistence – Threshold of Interference (ToI) and Threshold of Communication (ToC) between HemoSphere Vita monitor (EUT) in Non-Invasive mode and external devices

Test Specifications[1]	**Threshold of interference (ToI) or Threshold of Communication (ToC) Results**				
	Unintended Type and min level	**EUT Intended Frequency (EUT)**	**Frequency of Unintended Signal (MHz)**	**Unintended Signal Level at EUT (dBm)**	**I/U Ratio (ToI or ToC)**
A (ToI)	Tier 3 / 802.11n 64 qam 20 MHz Adj Channel 20 dBm (TRP/EIRP)	2437	2412	24.06	3.05
A (ToC)		2437	2412	47.96	-20.85
B (ToI)		5200	5180	36.19	-18.7
B (ToC)		5200	5180	36.19	-18.7
C (ToI)		5765	5745	28.18	-12.1
C (ToC)		5765	5745	32.34	-16.26
[1]Test Specifications [Threshold of interference (ToI) or Threshold of Communication (ToC) results]:					
***A**. 2.4 GHz; Ch 6, 2437 MHz – Non-Invasive Mode*					
***B**. 5 GHz, 20 MHz; Ch 40, (5190-5210 MHz) – Non-Invasive Mode*					
***C**. 5 GHz, 20 MHz; Ch 153, (5755-5775 MHz) – Non-Invasive Mode*					

Test Specifications[1]	**Extrapolated Interference Thresholds based upon the Intended Signal located 3 m away from the HemoSphere Vita monitor**							
	EIRP (W)	**Distance (m)**	**EIRP (W)**	**Distance (m)**	**EIRP (W)**	**Distance (m)**	**EIRP (W)**	**Distance (m)**
A (ToI)	10	18.80	1	5.94	0.1	1.88	0.01	0.59
A (ToC)	10	1.20	1	0.38	0.1	0.12	0.01	0.04

Test Specifications[1]	Extrapolated Interference Thresholds based upon the Intended Signal located 3 m away from the HemoSphere Vita monitor							
	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)
B (TOI)	10	4.65	1	1.47	0.1	0.47	0.01	0.15
B (ToC)	10	4.65	1	1.47	0.1	0.47	0.01	0.15
C (TOI)	10	11.69	1	3.70	0.1	1.17	0.01	0.37
C (ToC)	10	7.24	1	2.29	0.1	0.72	0.01	0.23

[1]Test Specifications [Threshold of interference (TOI) or Threshold of Communication (ToC) results]:

***A**. 2.4 GHz; Ch 6, 2437 MHz – Non-Invasive Mode*

***B**. 5 GHz, 20 MHz; Ch 40, (5190-5210 MHz – Non-Invasive Mode)*

***C**. 5 GHz, 20 MHz; Ch 153, (5755-5775 MHz – Non-Invasive Mode)*

Table F-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 Vita monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Vita 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	0% U_T (100% dip in U_T) for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°)	0% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the HemoSphere Vita monitor user requires continued operation during power mains interruptions, it is recommended that the HemoSphere Vita monitor be powered by an uninterruptible power supply or battery.
	0% U_T (100% dip in U_T) for 1 cycle (single phase at 0°)	0% U_T	
	70% U_T (30% dip in U_T) for 25/30 cycles (single phase at 0°)	70% U_T	
	Interrupt: 0% U_T (100% drop in U_T) for 250/300 cycles	0% U_T	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A(rms)/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Table F-6: Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Vita monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Vita 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 Vita monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d = [1.2] \times \sqrt{P}$; 150 kHz to 80 MHz $d = [1.2] \times \sqrt{P}$; 80 MHz to 800 MHz $d = [2.3] \times \sqrt{P}$; 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 Vita monitor is used exceeds the applicable RF compliance level above, the HemoSphere Vita 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 Vita 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.

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.

Blood Pressure (BP)
Blood pressure measured with HemoSphere pressure cable.

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

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

Default Settings
Initial operating conditions assumed by the system.

Heart Rate (HR)
Number of ventricular contractions per minute. HR data from an external monitor using an analog input is averaged over time and displayed as HR_{avg}.

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.

Intervention
Steps taken to change a patient's condition.

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

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

Phlebostatic Axis
Reference axis in the patient that passes through the patient's right atrium in any anatomical plane.

Plethysmograph Sensor
A device built into the ClearSight finger cuff that measures fluctuations of volume within the finger artery.

Pressure Controller (PC2/HEMPC)
The unit worn on the patient's wrist that connects the heart reference sensor and compatible Edwards finger cuffs to the HemoSphere VitaWave module.

Pulse Rate (PR)
Number of arterial blood pressure pulses per minute.

Sensitivity
The ability of a test to correctly identify those with the condition (true positive rate). Mathematically defined as: (number of true positives/[number of true positives + number of false negatives])× 100

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

Specificity
The ability of a test to correctly identify those without the condition (true negative rate). Mathematically defined as: (number of true negatives/[number of true negatives + number of false positives])× 100

USB
Universal Serial Bus.

Volume Clamp Method
Arterial blood volume is kept constant using the signal from the photo-plethysmograph and a rapidly changing pressure in the air bladder.

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.

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