HemoSphere Stream Module

Operator's manual

HemoSphere Stream™ Module 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 Technical Support or your local sales representative.

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CAUTION

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

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HemoSphere Stream™ Module with 1.5 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 BD HemoSphere Stream™ Module operator's manual is comprised of seven chapters and four 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 HemoSphere Stream™ Module.

Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Stream™ Module.

CAUTION

Inspect the HemoSphere Stream™ Module and all accessories and equipment used with the module 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 module, or inaccurate waveform transmission, do not use any damaged or non-compatible accessories, components or cables.

Chapter	Description
1	***Introduction***: Provides an overview of the HemoSphere Stream™ Module
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 Stream™ Module and accessories
3	***Installation and Setup***: Provides information about setting up the HemoSphere Stream™ Module and connections for the first time
4	***HemoSphere Stream™ Module Waveform Transmission***: Provides steps for transmitting a patient's arterial waveform to a patient monitor
5	***User Interface Settings***: Provides information about the various display settings including language, international units, system time, and system date
6	***Data Export***: Provides information on transferring system data
7	***Help and Troubleshooting***: Provides a list of system messages

Appendix	Description
A	***Specifications***
B	***Accessories***

Appendix	Description
C	***Module Care, Service and Support***
D	***Guidance and Manufacturer's Declaration***

1

Introduction

Contents

1.1 Intended Purpose of this Manual

This manual describes the features and technology connections of the HemoSphere Stream™ Module. The HemoSphere Stream™ Module transmits a continuous arterial blood pressure waveform obtained through non-invasive finger cuff technology to a connected multi-parameter patient monitor.

This operator's manual provides comprehensive instructions for the safe setup, operation, troubleshooting, device interfacing procedures, and limitations of the HemoSphere Stream™ Module. This manual has been prepared for use with the HemoSphere Stream™ Module by trained professionals.

1.2 Indications for Use

The HemoSphere Stream™ Module when used with a Smart pressure controller (PC1Q) and VitaWave™ Plus Finger Cuff is indicated for use in adult patients to provide continuous, non-invasive arterial pressure waveform output to a compatible multi-parameter patient monitor. The device is designed for use in clinical environments requiring continuous assessment of blood pressure waveform morphology, without the need for an invasive catheter.

Refer to the VitaWave™ Plus Finger Cuff indications for use statements for information on target patient population specific to the finger cuff being used.

1.3 Contraindications For Use

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

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

1.4 Intended Use Statement

The HemoSphere Stream™ Module is intended to be used by qualified personnel or trained professionals in a hospital setting.

The HemoSphere Stream™ Module is intended for use with compatible VitaWave™ Plus Finger Cuffs.

The HemoSphere Stream™ Module is intended to transmit a continuous, non-invasive blood pressure waveform to a compatible patient monitor. For more information, see Waveform Reconstruction and Hemodynamic Analysis (Non-Invasive Finger Cuff Technology) on page 32.

WARNING

Improper use of the HemoSphere Stream™ Module may affect the accuracy or reliability of waveform transmission data. Carefully read the "warnings" section of this manual, located in chapter 2, before using the module.

The HemoSphere Stream™ Module 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 the blood pressure waveform transmitted from the device is not consistent with the clinical presentation of the patient, verify system setup and signal quality before proceeding with any clinical interventions.

1.5 Expected Clinical Benefit

The HemoSphere Stream™ Module allows you to see and interact with a patient's blood pressure waveform on a connected multi-parameter patient monitor.

1.6 HemoSphere Stream™ Module Technology Connections and Overview

The HemoSphere Stream™ Module is equipped with two cable connection ports. The HemoSphere Stream™ connects to the Smart pressure controller (PC1Q) to provide non-invasive arterial blood waveform data from the VitaWave™ Plus Finger Cuff and transmit that to a patient monitor with a compatible pressure-out cable. Both cable connection points are located on the bottom of the device. See Figure 1-1 on page 11.

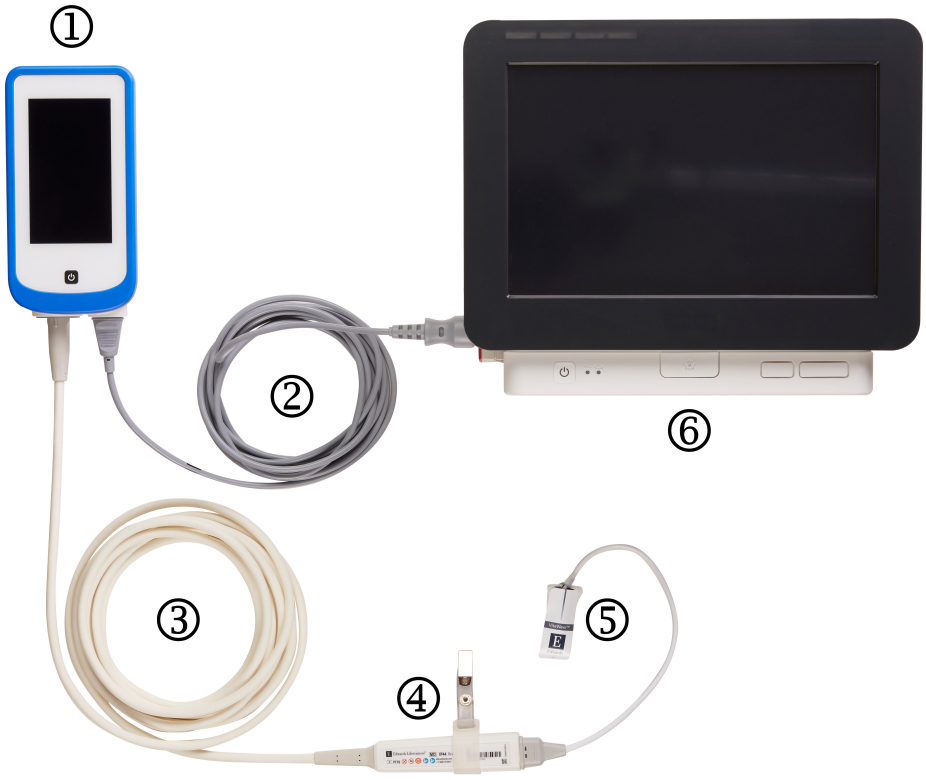


Figure 1-1: HemoSphere Stream ™ Module technology connections

1. HemoSphere™ Stream Module
2. compatible pressure-out cable to patient monitor
3. Smart pressure controller (PC1Q) cable
4. Smart pressure controller (PC1Q)
5. VitaWave™ Plus Finger Cuff (or compatible)
6. patient monitor

The HemoSphere Stream™ Module is ideal for environments where arterial waveform data is clinically valuable, but full invasive pressure monitoring is not needed.

The module integrates directly with an existing patient monitor and clinicians can continue using their preferred display systems and alarm infrastructure with no required software integration.

1.7 Manual Style Conventions

Table 1-1 on page 11 lists the style conventions used in this manual.

Table 1-1: 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.

Convention	Description
Bold button	A button is a touch screen access point for the option appearing in bold. For example, the **Advanced Settings** 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 17 for full list of menu icons shown on the HemoSphere Stream™ Module.

1.8 Abbreviations Found in This Manual

Table 1-2: Acronyms, Abbreviations

Abbreviation	Definition
DPT	disposable pressure transducer
IEC	International Electrotechnical Commission
MAP	mean arterial pressure
MPM	multi-parameter monitor
PC1Q	model code for Smart pressure controller which regulates pressure to the finger cuff
SQI	signal quality indicator
Touch	Interact with the HemoSphere Stream™ Module by touching the screen
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 Stream™ Module 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 HemoSphere Stream™ Module.
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Stream™ Module.
- To prevent injury to patient or user, damage to module, or inaccurate waveform transmission, do not use any damaged or non-compatible accessories, components or cables.
- Improper use of the HemoSphere Stream™ Module may affect the accuracy or reliability of waveform transmission data. Carefully read the "warnings" section of this manual, located in chapter 2, before using the module. (chapter 1)
- The HemoSphere Stream™ Module 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 the blood pressure waveform transmitted from the device is not consistent with the clinical presentation of the patient, verify system setup and signal quality before proceeding with any clinical interventions. (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)
- The device is not intended for use in oxygen-enriched environments (defined as atmospheres containing more than 25% oxygen by volume or where the partial pressure of oxygen exceeds 27.5 kPa). Use of this device in such conditions may pose a fire or explosion hazard. The device has not been evaluated or tested for operation in oxygen-rich environments and must only be used in accordance with the environmental conditions specified. (chapter 3)
- This product contains metallic components. Do NOT use in a Magnetic Resonance (MR) environment. (chapter 3)
- Make sure the HemoSphere Stream™ Module is securely positioned or mounted with weight considerations 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)
- Do not allow any liquids to splash onto the module screen. Liquid buildup may disable the touchscreen functionality. (chapter 3)
- Do not position the module so that it is difficult to access bottom 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)
- 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 Stream™ Module, including cables specified by the manufacturer. Otherwise, degradation of the performance this equipment could result. (chapter 3)
- Do not use the HemoSphere Stream™ Module without an installed power supply 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 Stream™ Module 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 module from the AC source by unplugging mains power cable from the AC Mains. The On/Off button on the module does not disconnect the system from the AC mains supply. (chapter 3)
- HemoSphere Stream™ Module technology use not recommended for patients age < 18 years of age. (chapter 4)
- 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 4)
- Compliance to IEC 60601-1 is only maintained when the HemoSphere Stream™ 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 4)
- 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 4)
- Do not sterilize any components of the HemoSphere Stream™ Module. The system is provided non sterile. (chapter 4)
- Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (chapter 4)
- Refer to the directions provided with each accessory for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (chapter 4)
- Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks. (chapter 4)
- Only use compatible finger cuffs and other HemoSphere Stream™ Module accessories, cables and or components that have been supplied and labeled as compatible. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy. (chapter 4)
- Always remove non-invasive cuffs and system components from the patient and completely disconnect the patient from the module before bathing the patient. (chapter 4)
- Improper finger cuff placement can lead to inaccurate waveform transmission. (chapter 4)
- If using the instrument during full body irradiation, keep all HemoSphere Stream™ Module components out of the irradiation field. If a module component is exposed to the irradiation, the waveform transmission may be affected. (chapter 4)
- 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 4)
- Only use approved HemoSphere Stream™ Module accessories, cables and or components that have been supplied and labeled by BD. Using unapproved accessories, cables and or components may affect patient safety and measurement accuracy. (appendix B)
- The HemoSphere Stream™ Module contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages. (appendix C)
- **Shock or fire hazard!** Do not immerse the HemoSphere Stream™ Module or system cables in any liquid solution. Do not allow any fluids to enter the instrument. (appendix C)
- Use of accessories 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 D)
- No modification of the HemoSphere Stream™ Module is allowed. (appendix D)
- 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 Stream™ Module. Guidance on maintaining

appropriate separation between communications equipment and the HemoSphere Stream™ Module is provided in Table D-3 on page 67. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere Stream™ Module. (appendix D)

2.3 Cautions

The following are cautions that are used in the HemoSphere Stream™ Module 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 Stream™ Module and all accessories and equipment used with the module 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 Stream™ Module to extreme temperatures. Refer to environmental specifications in appendix A. (chapter 3)
- Do not expose the HemoSphere Stream™ Module to dirty or dusty environments. (chapter 3)
- Do not obstruct the HemoSphere Stream™ Module ventilation openings. (chapter 3)
- Do not use the HemoSphere Stream™ Module in environments where strong lighting makes the LCD screen difficult to view. (chapter 3)
- Do not use any power cords not labeled for use with the HemoSphere Stream™ Module. Only use the power cord included with the module. (chapter 3)
- The HemoSphere Stream™ Module displays and transmits a reconstructed radial arterial waveform. Clinicians should consider this waveform reconstruction, especially if they are experienced with viewing a brachial arterial pressure waveform. (chapter 4)
- The effectiveness of HemoSphere Stream™ Module has not been evaluated in patients under 18 years of age. (chapter 4)
- 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 4)
- Do not wrap Smart pressure controller cable. (chapter 4)
- Do not attach the Smart pressure controller to patient's skin. (chapter 4)
- 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, arterial blood pressure waveform transmission can become impossible. (chapter 4)
- Inaccurate arterial waveform transmission can be caused by factors such as:

    - 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 4)

- Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation. (chapter 4)
- The effectiveness of compatible finger cuffs has not been established in pre-eclamptic patients. (chapter 4)
- In cases of power failure and battery depletion, the module will go through a controlled shut off procedure. (chapter 5)
- Clean and store the module and accessories after each use. (appendix C)
- The HemoSphere Stream™ Module is electrostatic discharge (ESD) sensitive. Do not attempt to open module housing or use if the housing has been damaged. (appendix C)
- Do not pour or spray liquid on any portion of the HemoSphere Stream™ Module, accessories or cables. (appendix C)
- Do not use any other cleaning agents aside from those listed. (appendix C)
- DO NOT:

  - Allow any liquid to come in contact with the power connector
  - Allow any liquid to penetrate connectors or openings in the module case

  If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the module. Disconnect power immediately and call your Biomedical Department or local sales representative. (appendix C)
- Do not disinfect the Smart pressure controller by autoclave or gas sterilization. (appendix C)
- Do not immerse the Smart pressure controller, or any cable connectors in fluid. (appendix C)
- 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.

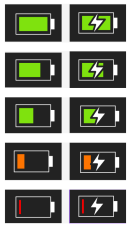
  (appendix D)

2.4 User Interface Symbols

The following are icons that appear on the HemoSphere Stream™ Module screen. For more information about screen appearance and navigation, see chapter 4, Waveform Transmission on page 31.

Table 2-1: Module display symbols

Symbol	Description
Setup Status Icons	
	setup step waiting for connection
	setup step complete

Symbol	Description
Setup Status Icons	
	setup step incomplete
	setup step error
Waveform Transmission Control Icons	
	start non-invasive waveform transmission
	stop non-invasive waveform transmission
	postpone cuff pressure release
Information Bar Icons	
	battery life indicator icons on information bar See Table 5-3 on page 49
Menu Navigation Icons	
	settings menu
	finger cuff placement help screen
	password protected menu
	decrease setting
	increase setting
	return to home screen

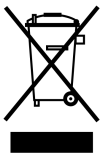
Menu Navigation Icons	
	accept (confirm action)
	cancel action
	back
	edit setting
	export
	signal quality indicator bar See SQI on page 41
	power off device

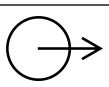
2.5 Symbols on Product Labels

This section provides the symbols that are on the HemoSphere Stream™ Module and other available module 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.
IPX2	Provides protection against dripping water when device is tilted up to a 15° from vertical
Input: 5V	Required input voltage is 5V
	Defibrillation proof type BF applied part or connection

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.
	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)
	Quantity
	Medical device
	Unique device identifier
	Importer

Connector Identification Labels	
	USB 3.0
	Pressure (DPT) output

Additional Packaging Labels	
	Keep dry
	Fragile, handle with care
	Do not use if package is damaged and consult instructions for use
	Box made from recyclable cardboard
	Follow instructions for use
	Follow instructions for use on the website
	Store in a cool, dry place
	Lithium-ion batteries contained in equipment (UN3481)
	Use-by date

Note

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

2.6 Applicable Standards

Table 2-3: Applicable standards

Standard	Title
IEC 60601-1:2005/AMD1:2012/ AMD2:2020	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance; amendment 1 (2012); amendment 2 (2020)
IEC 60601-1-2: 2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility - Requirements and tests

Standard	Title
IEC 60601-1-8/AMD1:2012/ AMD2:2020	Medical Electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

2.7 HemoSphere Stream™ Module Essential Performance

The module shall provide transmission of a blood pressure waveform to a compatible patient monitor with a compatible non-invasive finger cuff according to the specifications provided in appendix A. The module shall provide an indicator, and/or system status when unable to provide accurate measurement of the blood pressure signal. For more information, see Essential Performance Characteristics on page 57.

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 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 module may be compromised. Report any evidence of external damage.

3.1.1 Packaging Contents

In addition to the HemoSphere Stream™ Module, packages also contain a mains power cord. It is recommended that the user confirm the receipt of all ordered equipment. Refer to appendix B: Accessories on page 61, for a full list of available accessories.

3.1.2 Required Components

The following accessories are required to transmit non-invasive blood pressure with the HemoSphere Stream™ Module:

- Smart pressure controller (PC1Q)
- VitaWave™ Plus Finger Cuff
- compatible pressure output cable

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.

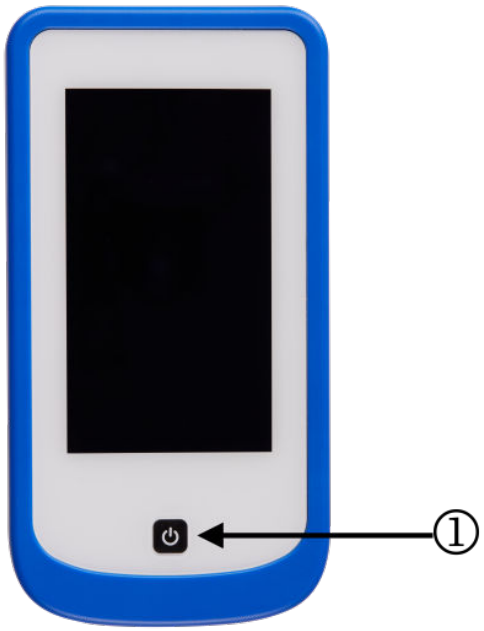
CAUTION

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 Stream™ Module Connection Ports

The following module views illustrate the connection ports and other key features of the front, rear, and bottom panels of the HemoSphere Stream™ Module.

3.2.1 Module Front



1. power button

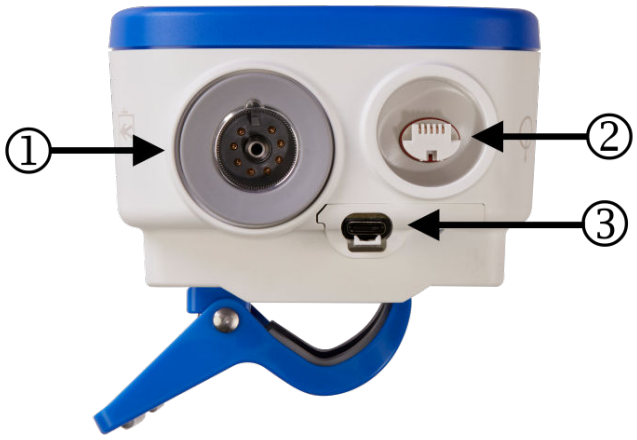
Figure 3-1: HemoSphere Stream ™ Module front view

3.2.2 Module Rear

1. pole or rail clip

Figure 3-2: HemoSphere Stream ™ Module rear view

3.2.3 Module Bottom Panel



1. PC1Q port
2. pressure-out
3. usb-c port/power receptacle

Figure 3-3: HemoSphere Stream ™ Module bottom panel

3.3 HemoSphere Stream™ Module Setup

3.3.1 Mounting Options and Recommendations

The HemoSphere Stream™ Module should be securely mounted on an IV pole or bed rail via the included clip according to your institution's practices. The operator should be positioned in front of the module and at close proximity during use. The device is intended to be used by only one user at a time. See Table B-1 on page 61 for more information.

WARNING

The device is not intended for use in oxygen-enriched environments (defined as atmospheres containing more than 25% oxygen by volume or where the partial pressure of oxygen exceeds 27.5 kPa). Use of this device in such conditions may pose a fire or explosion hazard. The device has not been evaluated or tested for operation in oxygen-rich environments and must only be used in accordance with the environmental conditions specified.

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

Make sure the HemoSphere Stream™ Module is securely positioned or mounted with weight considerations 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.

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

Do not position the module so that it is difficult to access bottom 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.

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 Stream™ Module, including cables specified by the manufacturer. Otherwise, degradation of the performance this equipment could result.

CAUTION

Do not expose the HemoSphere Stream™ Module to extreme temperatures. Refer to environmental specifications in appendix A.

Do not expose the HemoSphere Stream™ Module to dirty or dusty environments.

Do not obstruct the HemoSphere Stream™ Module ventilation openings.

Do not use the HemoSphere Stream™ Module in environments where strong lighting makes the LCD screen difficult to view.

3.3.2 Connecting Power Cord

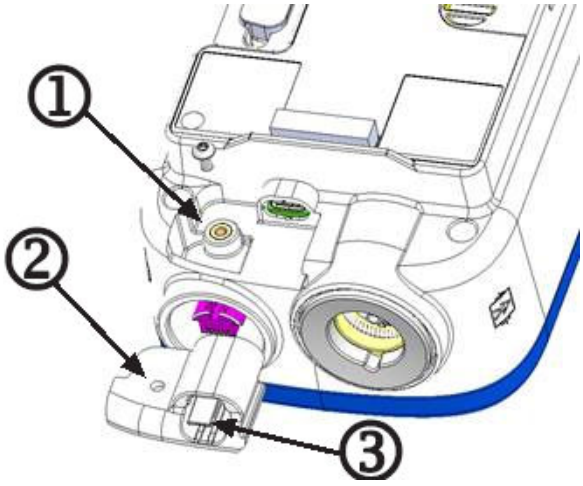
Before connecting the power cord to the bottom panel of the module, ensure that the power supply cover is installed. A single screw can be used to attach the power supply cover. See Figure 3-4 on page 28.

If the power supply cover is already installed, and access is needed to the USB port, remove the one screw (Figure 3-4 on page 28) that attaches the power supply cover to the module.

The power cord cover does not need to be removed to detach the power cord from the module. To detach the power cord from the module, depress the latch (see (3) in Figure 3-4 on page 28) and gently pull the cord out of the USB port.

WARNING

Do not use the HemoSphere Stream™ Module without an installed power supply cover. Failure to do so may result in fluid ingress.



1. screw hole in module
2. screw through hole on power supply cover
3. power cord release tab

Figure 3-4: HemoSphere Stream ™ Module power supply and cover - screw location

3.3.2.1 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.

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 Stream™ Module 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 module from the AC source by unplugging mains power cable from the AC Mains. The On/Off button on the module does not disconnect the system from the AC mains supply.

CAUTION

Do not use any power cords not labeled for use with the HemoSphere Stream™ Module. Only use the power cord included with the module.

3.3.3 Battery

The HemoSphere Stream™ Module contains a rechargeable battery. The battery supports temporary use during transport or brief disconnections.

Note

The HemoSphere Stream™ Module internal battery is intended as a backup power source during power-loss and can only support waveform transmission for a limited time period. Connect the power supply to a medical-grade AC outlet during use whenever possible.

The system will display a warning if the battery charge falls below minimum operating threshold.

3.4 Initial Start Up

3.4.1 Start Up Procedure

To turn on and off the module, press the power button located on the front panel. After turning on the module, the BD screen is displayed.

Figure 3-5: Startup screen

3.4.2 Initial Settings

Upon initial HemoSphere Stream™ Module startup, setting options are offered which affect the displayed language, time and date formats, and units of measurement. The review settings screen appears after the initial boot-up process is complete. This occurs after the first time the module is powered on.

Review the displayed settings for Date, Time, Time format, Units and Language. Touch the edit icon to change any of the displayed settings. Touch the check icon to accept the displayed settings.

Each of the display-related settings can be changed later in the Settings menu by touching the settings icon.

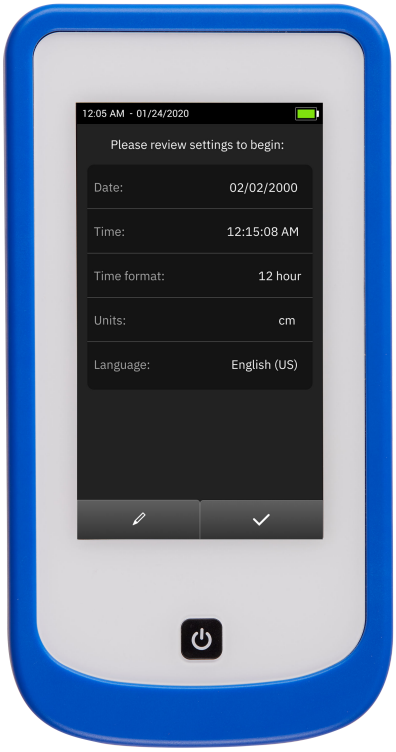


Figure 3-6: Initial startup settings screen

3.5 Power Off

To power the module off, touch the power button. See (1) in Figure 3-1 on page 24. The following option will be displayed:

- Returns you to the screen displayed prior to touching the power button.

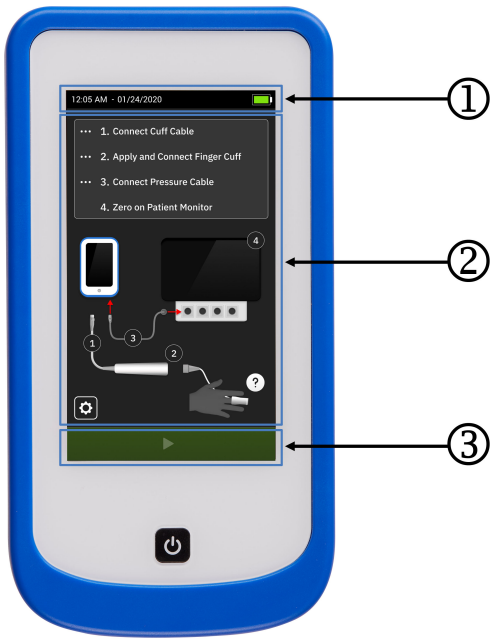
4

Waveform Transmission

Contents

4.1 HemoSphere Stream™ Module Screen Appearance

All functions are initiated by touching the appropriate area on the touch screen. The main components of the HemoSphere Stream™ Module screen are shown in Figure 4-1 on page 31. The main window displays the current instructional, status, menu, or settings screen.



1. Information bar
2. Main window for status, instructions and settings
3. Navigation buttons

Figure 4-1: HemoSphere Stream ™ Module screen features

4.2 HemoSphere Stream™ Module Methodology

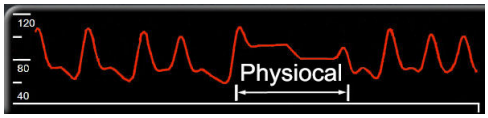
The HemoSphere Stream™ Module when used with a connected pressure controller, compatible finger cuff, and compatible pressure-out cable provides a continuous non-invasive arterial pressure waveform output to a compatible bedside patient monitor. See system connections shown in Figure 4-1 on page 31 and Figure 4-2 on page 35. Accurate waveform transmission of the patient's blood pressure is based on the Volume Clamp method, Physiocal™ Method and non-invasive finger cuff technology.

4.2.1 Volume Clamp Method

The VitaWave™ Plus 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.

4.2.2 Physiocal™ Method

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



The Physiocal™ Method adjusts for changes in the "un-stretched" volume during a normal measurement period. Cuff pressure is kept constant for one or more heart beats and blood pressure measurement is momentarily interrupted to observe the physiological properties of the finger artery. Early in the measurement period, these interruptions occur regularly. If the properties of the artery are sufficiently constant over time, the interval between Physiocal™ Method adjustments will be increased up to 70 heart beats, with higher intervals representing increased measurement stability.

4.2.3 Waveform Reconstruction and Hemodynamic Analysis (Non-Invasive Finger Cuff Technology)

The arterial blood pressure waveform is known to change between the arm and finger arteries due to physiological reasons. Non-invasive finger cuff technology uses advanced processing methods to reconstruct the finger pressure waveform into a radial arterial pressure waveform.

CAUTION

The HemoSphere Stream™ Module displays and transmits a reconstructed radial arterial waveform. Clinicians should consider this waveform reconstruction, especially if they are experienced with viewing a brachial arterial pressure waveform.

4.2.4 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 cuff use (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.

4.2.5 Waveform Transmission from a Single Cuff

A single compatible finger cuff can be used for accumulated waveform transmission from the same patient for up to 8 hours on a single finger. The HemoSphere Stream™ Module will automatically release the pressure in the cuff at 4 hours intervals. See Figure 4-7 on page 42.

Note

After 8 hours of accumulated active finger cuff use on the same finger, the HemoSphere Stream™ Module will stop waveform transmission and display a warning message ("**Switch Finger**") to place the cuff on another finger if continued waveform transmission is desired.

4.2.6 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.

4.3 Measurement Setup

After the module is powered on, the following instructional steps are provided on the module screen and are needed to begin a non-invasive measurement and waveform transmission:

1. **Connect Cuff Cable.** Connect the PC1Q Smart pressure controller to the HemoSphere Stream™ Module. See Connect the PC1Q Smart Pressure Controller to the HemoSphere Stream™ Module on page 35.
2. **Apply and Connect Finger Cuff.** Apply the finger cuff to the patient and connect the cuff to the PC1Q. See Apply and Connect the Finger Cuff on page 37.
3. **Connect Pressure Cable.** Connect the compatible pressure-out cable from the HemoSphere Stream™ Module to the patient monitor. See Connect the Compatible Pressure-Out Cable to the Patient Monitor on page 38.
4. **Zero on Patient Monitor.** Zero the arterial channel of the patient monitor. See Zero the Patient Monitor on page 39.
5. **Set Hand to Heart Offset.** (If Enabled) Provide the patient's finger to heart offset (If applicable). See Patient Finger to Heart Offset Entry (If Applicable) on page 39.

Further details on these steps are outlined below. As the steps are completed, a check icon  appears next to the on-screen step and the instructional diagram is updated to indicate the completed connection step.

Note

Once complete, a check icon will not appear next to step 4, Zero the arterial channel of the patient monitor.

Once all these steps are completed, the start waveform transmission navigation button will be enabled:

WARNING

HemoSphere Stream™ Module technology use not recommended for patients age < 18 years of age.

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 Stream™ 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 Stream™ Module. The 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.

Only use compatible finger cuffs and other HemoSphere Stream™ Module accessories, cables and or components that have been supplied and labeled as compatible. Using other unlabeled accessories, cables and or components may affect patient safety and measurement accuracy.

Always remove non-invasive cuffs and system components from the patient and completely disconnect the patient from the module before bathing the patient.

CAUTION

The effectiveness of HemoSphere Stream™ Module has not been evaluated in patients under 18 years of age.

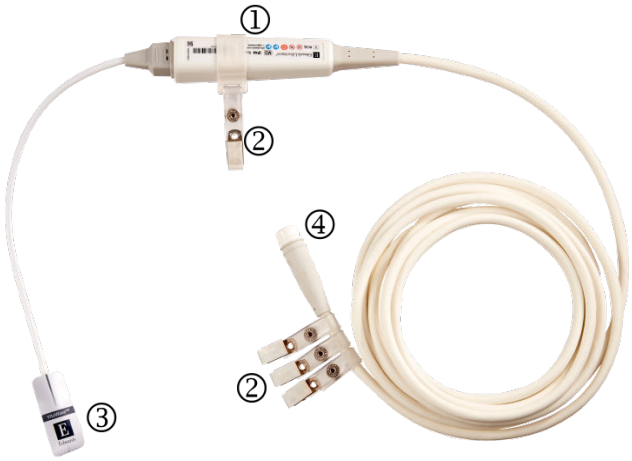
Always grasp the connector, not the cable, when connecting or disconnecting cables. Do not twist or bend the connectors. Confirm that all sensors and cables are connected correctly and completely before use.

Figure 4-2: HemoSphere Stream ™ Module on-screen connection instructions

4.3.1 Connect the PC1Q Smart Pressure Controller to the HemoSphere Stream™ Module

Connect the Smart pressure controller to the bottom panel of the module. See (1) in Figure 3-3 on page 26.

The Smart pressure controller is clipped near the patient and connects to the PC1Q cable port on the module on one end and compatible finger cuff on the other end. See Figure 4-3 on page 36.



1. Smart pressure controller
2. pressure controller clip(s)
3. finger cuff
4. connection to module

Figure 4-3: Smart pressure controller connections and clips

1. Insert the Smart pressure controller cable ((4) in Figure 4-3 on page 36) into the PC1Q cable port of the module ((1) in Figure 3-3 on page 26).
2. Use the Smart pressure controller cable clip(s) to place the Smart pressure controller near the patient's forearm. See Figure 4-4 on page 36 (preferred location).

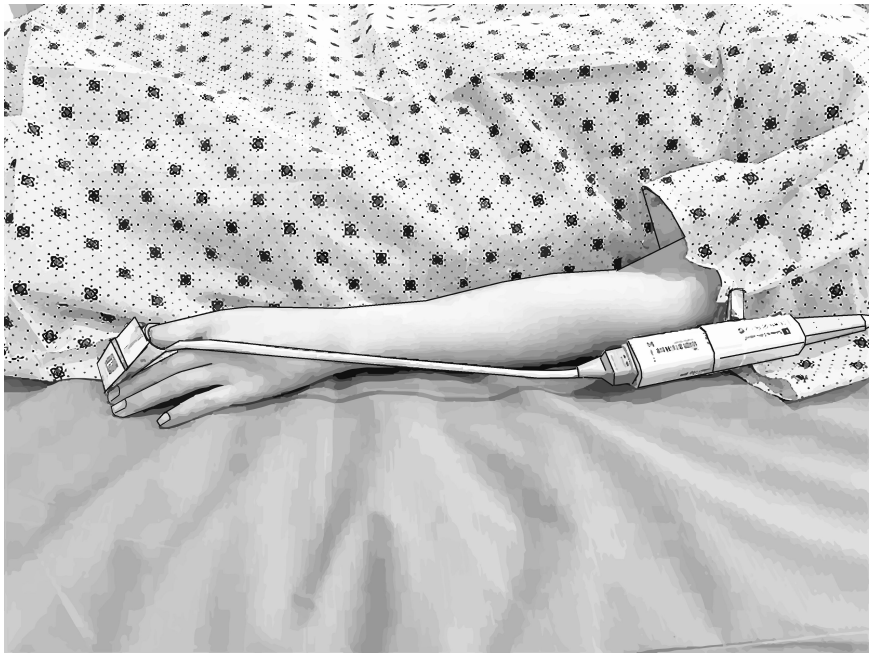


Figure 4-4: Smart pressure controller application

Note

Do not clip cable directly next to patient's skin.

3. Remove the plastic connector plug in order to connect the finger cuff.

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 the device is not in use.

4. Apply the finger cuff to the patient and connect to the Smart pressure controller according to the Instructions for Use supplied with the finger cuff unit.

CAUTION

Do not wrap Smart pressure controller cable.

Do not attach the Smart pressure controller to patient's skin.

4.3.2 Apply and Connect the Finger Cuff

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

Single Patient Use. The VitaWave™ Plus Finger Cuffs is designed for single patient use. Upon starting a measurement, the finger cuff will expire after 72 hours for a single patient.

Use the help icon for finger cuff application instructions.

1. Position the cuff on the middle phalanx of the patient's non-dominant hand.
2. Ensure the cable coming out of the cuff starts on the bottom side of the hand and is then fed between fingers to top side of hand.

WARNING

Improper finger cuff placement can lead to inaccurate waveform transmission.

4.3.2.1 General Troubleshooting of HemoSphere Stream™ Module Waveform Transmission

Listed below are common issues that may occur during waveform transmission and some troubleshooting steps.

- If waveform does not appear within minutes after waveform transmission is initiated, check the main window for any messages that may indicate there is a problem.
- 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 Physiocal™ Method adjustments. 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 waveform transmission. If the patient has cold hands, try to warm the hand.

WARNING

If using the instrument during full body irradiation, keep all HemoSphere Stream™ Module components out of the irradiation field. If a module component is exposed to the irradiation, the waveform transmission 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

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, arterial blood pressure waveform transmission can become impossible.

Inaccurate arterial waveform transmission can be caused by factors such as:

- 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 compatible finger cuffs has not been established in pre-eclamptic patients.

4.3.3 Connect the Compatible Pressure-Out Cable to the Patient Monitor

Connect the DPT receptacle pressure signal plug into a compatible patient monitor. Ensure that the selected connector is fully engaged. Refer to the patient monitor instructions for use.

4.3.4 Zero the Patient Monitor

Zero patient monitor and confirm 0 mmHg is displayed. Refer to the patient monitor instructions for use.

Note

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

4.3.5 Patient Finger to Heart Offset Entry (If Applicable)

Manual hand offset is a feature that can be enabled. When this feature is enabled through advanced settings, an additional step must be performed before transmitting the non-invasive arterial blood pressure waveform. The pressure controller software must account for differences in pressure due to the change in vertical level of the monitored finger relative to the heart.

Use the arrows to indicate this height difference. The allowable entered offset can be between -20 inches and 20 inches in 1 inch increments (-50 cm to 50 cm, in 1 cm increments).

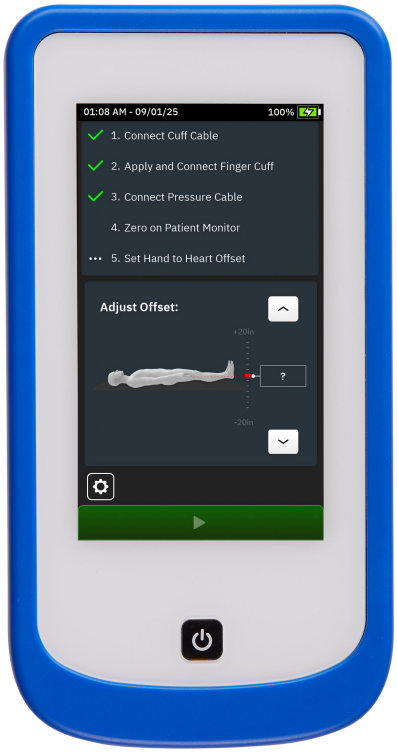


Figure 4-5: HemoSphere Stream ™ Module on-screen connection instructions

The entered offset can be updated during active waveform transmission. See Offset Update on page 43.

4.3.6 Start Waveform Transmission

Touch the start icon to begin waveform transmission:

Before active waveform transmission begins, Physiocal™ Method interruptions occur regularly to adjust for the physiological properties of the finger artery. During these adjustments, "Initializing.." is displayed on the module and a zero pressure signal is transmitted to the patient monitor. A waveform is transmitted to the patient monitor after this initialization period is completed.

4.4 Active Waveform Transmission

During active waveform transmission, the arterial waveform appears at the top of the module screen along with a stop icon. See Figure 4-6 on page 40. If there are any errors in transmission, they will appear on the screen. See Table 7-1 on page 53 for system error messages.

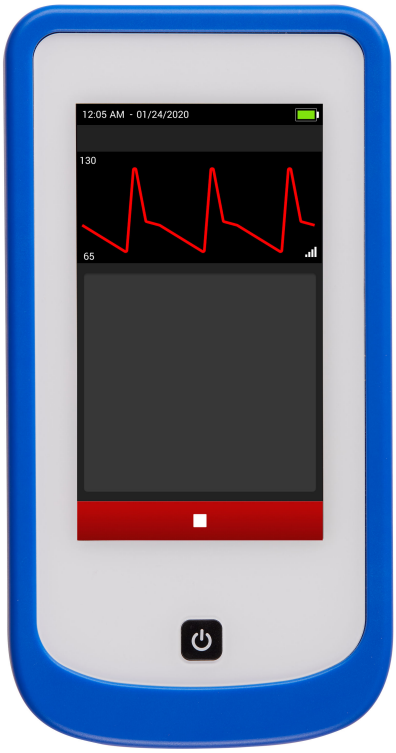


Figure 4-6: HemoSphere Stream ™ Module active waveform transmission

Touch the stop icon to end waveform transmission:

4.4.1 Waveform Transmission Considerations

4.4.1.1 SQI

A signal quality indicator (SQI) is present on the blood pressure waveform display. SQI level is calculated every 20 seconds. The SQI symbol appears next to the waveform on the waveform transmission screen. See Figure 4-6 on page 40. See Table 4-1 on page 41 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 waveform transmission is initializing (starting or resuming). A zero SQI value can also be associated with an error condition.

Table 4-1: 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 7-1 on page 53 for a list of errors)
	0	Pressure waveform unavailable (see Table 7-1 on page 53 for a list of finger cuff errors)

4.4.1.2 Cuff Pressure Release

During waveform transmission, the HemoSphere Stream™ Module will automatically release pressure from the finger for five minutes at regular four hour intervals. When ≤5 minutes remain until a cuff pressure release, a notification popup will indicate that the countdown clock has been initiated along with the time remaining until pressure release. See Figure 4-7 on page 42. Touch the snooze icon  to postpone the cuff pressure release. The cuff pressure release can be postponed up to two times for five minute increments each. Continuous waveform transmission will not be extended beyond the 8 hour cumulative monitoring limit on a single finger.

Figure 4-7: HemoSphere Stream ™ Module upcoming cuff pressure release notification

Once the countdown timer ends, pressure will be released from the cuff and waveform transmission will be temporarily suspended. A notification will appear on the screen to indicate that finger cuff pressure has been released. A five minute timer will be initiated and display time until the cuff is reinflated and waveform transmission is automatically resumed. See Figure 4-8 on page 43.

Figure 4-8: HemoSphere Stream ™ Module cuff pressure release active

4.4.1.3 Offset Update

If the manual hand offset feature is enabled the waveform transmission displays a hand offset adjust. To adjust the patient heart to hand vertical offset use the arrow buttons until the correct offset is displayed. See Figure 4-9 on page 44. Touch the check icon  to accept the adjusted hand offset value.

Figure 4-9: HemoSphere Stream ™ Module active waveform transmission with manual hand offset enabled

4.4.1.4 Power Save Mode

After 2 minutes of user inactivity (no screen touches), the module will enter power save mode. Waveform transmission will continue to the patient monitor. To wake the module up from power save mode, touch anywhere on the screen.

Figure 4-10: HemoSphere Stream ™ Module power save mode screen

Note

To conserve battery power, the module will power off after 35 minutes if it is not connected to AC power or an external patient monitor.

5

User Interface Settings

Contents

5.1 Password Protection

The HemoSphere Stream™ Module has two levels of password protection.

Table 5-1: HemoSphere Stream™ Module password levels

Level	Digits required	User description
Authorized User	eight	Hospital authorized personnel
BD User	rolling password	internal BD use only

Any settings or features described in this manual that require a password are **Authorized User** features. The **Authorized User** password requires 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. In the event of forgotten passwords, contact your local sales representative.

To access the **Advanced Settings** features described below in Table 5-2 on page 46, touch settings icon  → **Advanced Settings** button.

Table 5-2: Advanced settings menu navigation and password protection

Advanced settings menu selection	Sub-menu selection	Authorized User	BD User
Hand Offset: (radio button)		•	•
Change Password		•	•
Demo Mode		•	•
Service Info	Versions	•	•
	Manufacturing	•	•
	Usage	•	•
	Battery	•	•
Export Data	Diagnostic Data	•	•
	Engineering Data	•	•
	Security Logs	no access	•

Advanced settings menu selection	Sub-menu selection	Authorized User	BD User
Engineering Mode	Engineering Testing	•	•
	Parameter Display Mode	no access	•
	Buzzer Test	•	•
	DPT Out Test	•	•
Software Update		•	•
Battery Shipping Mode		•	•
Restore Factory Settings		•	•

For more information on these advanced settings, contact your sales representative.

5.1.1 Changing Passwords

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

1. Touch the settings icon → **Advanced Settings** button.
2. Enter the **Authorized User** password.
3. Touch the **Change Password** button.
4. Enter the new **Authorized User** password digits in both value boxes until the green check mark appears. A check mark confirms that the eight digit requirement has been met and both entries of the desired password are identical.
5. Touch the icon to confirm password change.

5.1.2 Manual Offset Toggle

Enabling the **Hand Offset** feature requires **Authorized User** access. Contact your hospital administrator or IT department for password. To enable **Hand Offset**:

1. Touch the settings icon → **Advanced Settings** button.
2. Enter the **Authorized User** password.
3. Touch the **On** radio button next to "**Hand Offset**" to enable this feature.
4. Touch the **Off** radio button next to "**Hand Offset**" to disable this feature.

5.1.3 Demo Mode

Demonstration mode is used to display simulated waveform 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 Stream™ Module displays a **Demo Mode Active** message.

1. Touch the settings icon  → **Advanced Settings** button.
2. Enter the **Authorized User** password.
3. Touch the **Demo Mode** button.
4. Touch the  icon to confirm demo mode entry.
5. The module must be power cycled to return to normal operation. The HemoSphere Stream™ Module will power off after 12 hours in Demo Mode.

5.2 General Device Settings

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

The HemoSphere Stream™ Module interface is available in several languages. A settings review screen appears the first time the HemoSphere Stream™ Module is started but the display language can be changed at any time.

The selected language does not determine the default time and date format. Time and date formatting is changed independent of the language selected. See Figure 5-1 on page 49.

Note

If power is lost and restored to the HemoSphere Stream™ Module, the system settings prior to the power loss, including alarm volume, language and unit selection, are automatically restored to last configured settings.

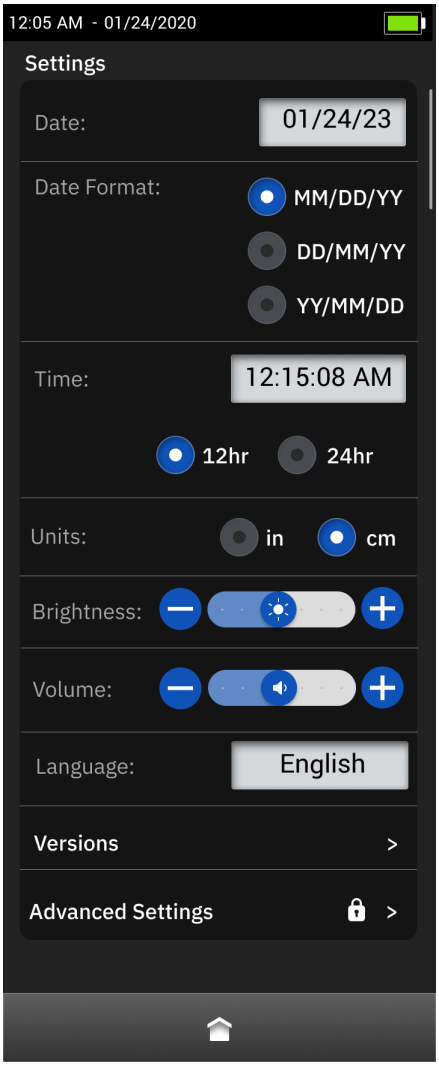


Figure 5-1: HemoSphere Stream ™ Module general settings screen

5.2.1 Battery

The HemoSphere Stream™ Module allows for uninterrupted waveform transmission during power loss. Battery life is indicated on the information bar by the symbols shown in Table 5-3 on page 49. To ensure that the battery charge status displayed on the module is correct, it is recommended to perform periodic checks of battery health through advanced settings.

Table 5-3: Battery status

Battery symbol	Indication
	The battery is fully charged.
	The battery has greater than 50% charge remaining.

Battery symbol	Indication
	The battery has less than 50% charge remaining.
	The battery has less than 20% charge remaining.
	The battery is low.
	The battery is charging.

CAUTION

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

6

Data Export

Contents

6.1 Export Data

The **Export Data** screen lists a number of data export features of the HemoSphere Stream™ Module. This screen is password protected. From this screen clinicians can export system diagnostic reports. For more on exporting system data reports, see below.

6.1.1 System Diagnostic Export

The capturing of all events, alerts and waveform transmission activity is logged if investigations or detailed troubleshooting is needed. A **Diagnostic Data** 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 technical 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 → **Advanced Settings** button.
2. Enter the **Authorized User** password.
3. Touch **Export Data** button.
4. Touch **Diagnostic Data** button.
5. Insert a USB flash drive into the module USB port. Only USB flash drives that are formatted as exFAT or FAT32 can be used.
6. Allow the diagnostic export to complete as indicated on the screen.

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

6.2 Cybersecurity

This chapter outlines ways in which system data can be transferred to and from the HemoSphere Stream™ Module. It is important to note that any facility using the HemoSphere Stream™ Module 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 Stream™ Module include:

- **Physical Access**: Limit use of the HemoSphere Stream™ Module to authorized users. The module has password protection for certain configuration screens. Passwords should be protected. See Password Protection on page 46 for more information.

- **Active Use**: Users of the module should take measures to limit patient data storage.
- **Device Security**: Users should only use approved accessories. In addition, ensure that any connected device is free of malware.

The use of any HemoSphere Stream™ Module interface outside of its intended purpose could pose cybersecurity risks. No HemoSphere Stream™ Module connections are meant to control the operations of another device. All available interfaces are shown in HemoSphere Stream™ Module Connection Ports on page 24 and specifications for these interfaces are listed in Table A-4 on page 59.

6.2.1 Cybersecurity Updates

When a cybersecurity update to the HemoSphere Stream™ Module is required, Emergency patches will be issued and provided to customers within 60 days after the identification of a cybersecurity incident and Cybersecurity patches will be issued and provided 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.

6.2.2 Deployment Environment

To maintain the security of this device, it is strongly recommended that customers implement cybersecurity best practices within the deployment environment. These practices include, but are not limited to:

- Network segmentation and internal system hardening, where applicable
- Role-Based Access Control (RBAC)
- Principle of Least Privilege, ensuring access is limited strictly to users who require it

For additional recommendations on maintaining devices security please contact your local sales representative or Technical Support.

6.2.3 Vulnerability Management

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

6.2.4 Cybersecurity Incident Response

If there is or has been a suspected cybersecurity incident(s) that has affected the HemoSphere Stream™ Module, please contact your local sales representative or 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 BD, these actions should return the product to secure operability.

6.2.5 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 module use.

7

Troubleshooting

Contents

7.1 On Screen Error Messages

The on screen error messages that appear in Table 7-1 on page 53 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 Stream™ Module model number (HEMSTRM10) and software version indicated on the startup page (see Start Up Procedure on page 29). These issues are continually updated and compiled as a result of ongoing product improvements.

Table 7-1: System error messages

Message	Priority	Possible causes	Suggested actions
Check Cuff Cable* (Smart Pressure Controller/PC1Q)	Medium	Unresponsive cuff cable* Poor connection between cuff cable and HemoSphere Stream™ Module Connection points on the cuff cable or HemoSphere Stream™ Module port are damaged Defective cuff cable Hardware failures detected on the cuff cable Defective HemoSphere Stream™ Module	Disconnect and re-connect cuff cable* Power cycle the HemoSphere Stream™ Module Replace cuff cable If problem persists, contact Technical Support

Message	Priority	Possible causes	Suggested actions
Check Finger Cuff	Medium	Blood pressure measurement failed due to movement or poor measurement conditions Finger cuff too loose or too tight Light signal too high No measurable plethysmogram detected on startup Possibly contracted arteries When the following cuff cable (PC1Q) alerts are persisting for at least 5 minutes: Unstable Pressure, Finger Too Thin, No Plethsmogram Detected, Plethysmogram Errorst*	Reapply finger cuff Apply finger cuff to a different finger Restart measurement Warm the hand Disconnect and reconnect the cuff cable to clear the alerts*
Cuff Cable Kinked*	Low	Cuff cable is bent*	Allow the system to automatically resolve issue Ensure the cuff cable is not kinked in any area* If problem persists, contact Technical Support
Incompatible Cuff Cable*	Medium	Unsuccessful software upgrade or incompatible software version detected Incompatible cuff cable detected* Cuff cable authentication failure Non-BD cuff cable detected	Verify that a genuine BD cuff cable has been used* Disconnect and re-connect cuff cable Replace cuff cable with a genuine BD cuff cable If problem persists, contact Technical Support
No Pulsation - Check Patient	Medium	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 Allow System to automatically resolve issue Reapply finger cuff(s) Restart measurement
Replace Finger Cuff	Medium	Finger cuff has exceeded the maximum use time (Expired) Non-BD finger cuff detected Invalid finger cuff connected Defective finger cuff connected Cuff connector on the cuff cable is damaged or defective*	Replace finger cuff Disconnect and reconnect finger cuff Verify that a genuine finger cuff has been used Restart measurement If problem persists, contact Technical Support

Message	Priority	Possible causes	Suggested actions
Severe Vasoconstriction - Warm Hands	Medium**	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
Switch Finger	Medium	Cumulative measurement time on the same finger exceeded maximum duration of 8 hours	Remove cuff from finger Apply finger cuff to a different finger Restart measurement
System Service Recommended	Medium	HemoSphere Stream™ Module service time is overdue Defective HemoSphere Stream™ Module Internal temperature out of range Battery health or lifetime alerts	Power cycle the HemoSphere Stream™ Module If problem persists, contact Technical Support
System Service Required	Medium	Defective HemoSphere Stream™ Module Defective cuff cable* Kinked or damaged cuff cable Damaged finger cuff	Power cycle the HemoSphere Stream™ Module Verify that connection between cuff cable and HemoSphere Stream™ Module is not kinked or damaged* Replace the cuff cable If problem persists, contact Technical Support
Low Battery	Medium ((🔔))†	The battery has less than 20% charge remaining	Connect the HemoSphere Stream™ Module to an alternate source of power (connect charger) to avoid loss of power and continue monitoring
Warm Patient's Hand or Adjust Cuff	Low	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

**Note: Cuff cable refers to the Smart pressure controller (PC1Q)*

***Indicates visual alarm (entire module screen will flash in brightness between dark and bright)*

† ((🔔)) *Indicates audible and visual alarm*

7.2 Technical Alarms

All of the error messages listed in Table 7-1 on page 53 are considered technical alarms.

Certain technical alarms have additional audible or visual indicators to the user. These are noted in the priority indication in Table 7-1 on page 53.

- Audible indicator: The user needs to be within a certain distance to hear.

- Visual indicator: The user needs to be able to view the module screen to see this visual alarm indicator. The module screen will flash in brightness until any touch input to the screen by the user is registered.

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 57 is provided or failure to provide this performance is readily identifiable by the user (e.g., technical alarm, distorted waveforms or delay in waveform update, complete failure of the module, etc.).

Table A-1 on page 57 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 57 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 Stream™ Module essential performance – transient and non-transient electromagnetic phenomena

Function	Parameter	Essential Performance
General		No interruption of current waveform transmission. No unexpected reboots or halting of operation. No spontaneous triggering of events that require user interaction to initiate. 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 module shall return to operational mode within 10 seconds without loss of stored data after exposure to the field produced by the HF Surgical Equipment.
Non-invasive waveform transmission	Non-invasive blood pressure (arterial waveform)	Measurement of blood pressure within specified accuracy (±1% of full scale with a maximum of ±3 mmHg).

A.2 HemoSphere Stream™ Module Characteristics and Specifications

Table A-2: HemoSphere Stream™ Module physical and mechanical characteristics

HemoSphere Stream™ Module		
Weight (with clip)	2.54 lb (1.15 kg)	
Dimensions (with clip)	Height	8.1 in (206 mm)
	Width	4.3 in (109 mm)
	Depth	4.1 in (104 mm)
Ingress protection	IPX2	
Applied Part Classification	Type BF Defibrillation Proof	
Display	Active Area	5.0 in diagonal (127 mm)
	Resolution	1280 × 720
Operating system	Linux	
Buzzer count	1	

Table A-3: HemoSphere Stream™ 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
Altitude (Pressure)	Operational	701 hPa to 1074 hPa
**Note: Battery capacity starts to degrade with extended exposure above 35 °C.*		

Note

Unless otherwise stated, all compatible HemoSphere Stream™ Module accessories, components, and cables have the environmental specifications listed in Table A-3 on page 58.

It is recommended that after 3 years from the date of purchase, a replacement HemoSphere Stream™ Module may be considered depending on its condition and functionality at that time. If your equipment experiences a malfunction, please contact Technical Support or your local sales representative for further assistance.

MRI Information. Do not use the HemoSphere Stream™ Module and cables in an MR environment. The module, including all cables, is MR unsafe since the device contains metallic components, which can experience RF-induced heating in the MRI environment. 

Table A-4: HemoSphere Stream™ Module technical characteristics

Input/Output	
Touch screen	Projective capacitive touch
USB port	one USB-C
Pressure output	
DPT pressure out signal from non-invasive finger cuff technology is compatible with monitors and accessories intended to interface with non-invasive pressure signal	
Post-zero minimum patient monitor display range	0 mmHg to 300 mmHg
Sensitivity	5µV/V/mmHg
Excitation Frequency	DC to 5,000 Hz
Excitation Impedance	545 ohms ±1%
Signal Impedance	290 ohms ±10%
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)
Battery	
Model	RRC2037
Capacity*	30 minutes
**Note: This represents approximate run time with the system when using a fully charged battery. Contact your local sales representative if there are any technical issues with the battery.*	

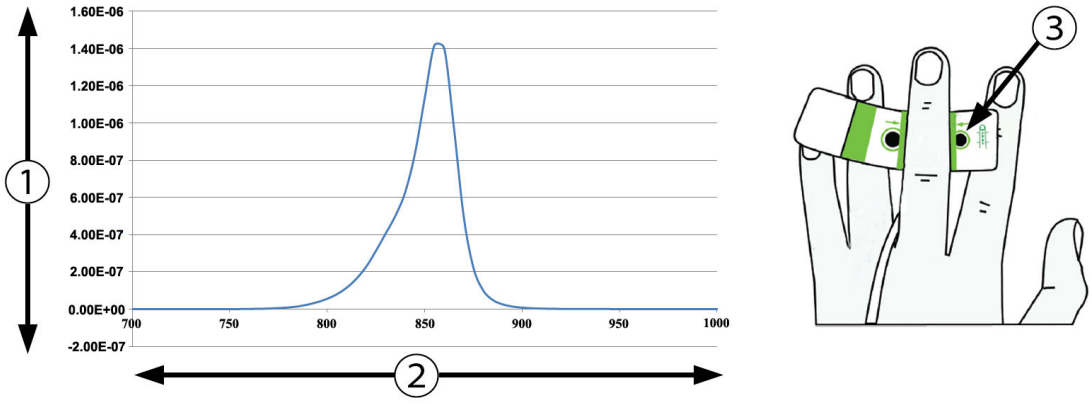
A.3 Non-Invasive Finger Cuff Technology Characteristics and Specifications

Table A-5: Smart pressure controller (cuff cable) physical characteristics

Smart pressure controller		
Weight	Housing	approximately 0.7 lb (0.32 kg)
Dimensions	Cable length	14.8 +/- 0.2 ft (4.5 +/- 0.06 m)
Ingress protection	IP44	
Applied part classification	Type BF defibrillation proof	

Table A-6: Finger cuff characteristics

Finger cuff	
Maximum weight	11 g (0.02 lb)
LED spectral irradiance	See Figure A-1 on page 60
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

Appendix B

Accessories

Contents

B.1 Accessories List

WARNING

Only use approved HemoSphere Stream™ Module accessories, cables and or components that have been supplied and labeled by BD. Using unapproved accessories, cables and or components may affect patient safety and measurement accuracy.

Table B-1: HemoSphere Stream™ Module components

Description	Model number
HemoSphere Stream™ Module	HEMSTRM10
Mounting Clip	*
Smart pressure controller kit	PC1QAK
Smart pressure controller	PC1Q
Smart pressure controller cable clip	PC1QACC
Smart pressure controller clip band	PC1QACB
Smart pressure controller plug	PC1QAP
VitaWave™ Plus Finger Cuff	VWCA2
Charger (Power Supply)	*
Power Supply Cover	*
Mains Power Cord	*
**Please contact your sales representative for model and ordering information.*	

Appendix C

Module Care, Service and Support

Contents

C.1 General Maintenance

The HemoSphere Stream™ Module contains no user-serviceable parts, and should be repaired only by qualified service representatives. This appendix provides instructions for cleaning the module and accessories and contains information on how to contact your local sales representative for support and information on repair and/or replacement.

WARNING

The HemoSphere Stream™ Module contains no user-serviceable parts. Removing the cover or any other disassembly will expose you to hazardous voltages.

CAUTION

Clean and store the module and accessories after each use.

The HemoSphere Stream™ Module is electrostatic discharge (ESD) sensitive. Do not attempt to open module housing or use if the housing has been damaged.

C.2 Cleaning the Module and Cables

WARNING

Shock or fire hazard! Do not immerse the HemoSphere Stream™ Module or system cables in any liquid solution. Do not allow any fluids to enter the instrument.

The HemoSphere Stream™ Module and cables can be cleaned using the following disinfectant wipes, or equivalent:

- Clorox HealthCare Bleach Germicidal Wipes or PDI Sani-Cloth Bleach Germicidal Disposable Wipe
- PDI Super Sani-Cloth Germicidal Disposable Wipe (Purple Cap) or Isopropyl/Isopropanol (70%)
- Metrex CaviCide1 or Metrex CaviWipes1
- Clorox HealthCare Hydrogen Peroxide Cleaner Disinfectant Wipe or Hydrogen Peroxide Solution (3%)

Do not use any other cleaning agents. Unless otherwise stated, these cleaning agents are approved for all HemoSphere Stream™ Module accessories and cables.

CAUTION

Do not pour or spray liquid on any portion of the HemoSphere Stream™ Module, accessories or cables.

Do not use any other cleaning agents aside from those listed.

DO NOT:

- Allow any liquid to come in contact with the power connector
- Allow any liquid to penetrate connectors or openings in the module case

If any liquid does come in contact with any of the above mentioned items, DO NOT attempt to operate the module. Disconnect power immediately and call your Biomedical Department or local sales representative.

C.2.1 Cleaning the Smart Pressure Controller (Cuff Cable)

The Smart pressure controller can be cleaned using the disinfectant wipes, or equivalent, listed in Cleaning the Module and Cables on page 62.

1. Grab unused wipe from container or moisten a clean cloth with disinfectant and wipe the surfaces.
2. Dry the surface with a clean, dry cloth.

CAUTION

Do not disinfect the Smart pressure controller by autoclave or gas sterilization.

Do not immerse the Smart pressure controller, or any cable connectors in fluid.

C.3 Service and Support

See chapter 7, Troubleshooting on page 53 for diagnosis and remedies. If this information does not solve the problem, contact Technical Support.

HemoSphere Stream™ Module operations support:

- Within the United States and Canada, call 1.800.822.9837.
- Outside the United States and Canada, contact your local sales representative.
- E-mail operational support questions to tech_support@edwards.com.

Have the following information before you call:

- The HemoSphere Stream™ Module's serial number, located on the rear panel;
- The text of any error message and detailed information as to the nature of the problem.

C.4 Module Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the HemoSphere Stream™ Module 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.

C.5 Preventive Maintenance

Periodically examine the HemoSphere Stream™ Module 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.

C.6 Warranty

BD warrants that the HemoSphere Stream™ Module 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 and batteries used with the HemoSphere Stream™ Module. BD's sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the module at BD's option.

BD shall not be liable for proximate, incidental, or consequential damages. BD shall not be obligated under this warranty to repair or replace a damaged or malfunctioning HemoSphere Stream™ Module if such damage or malfunction is caused by the customer's use of sensors other than those manufactured by BD.

Appendix D

Guidance and Manufacturer's Declaration

Contents

D.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 Stream™ Module is intended for use in the electromagnetic environment specified in this appendix. The customer or the user of the module should assure that it is used in such an environment. When connected to the HemoSphere Stream™ Module, all accessory cables listed in Table B-1 on page 61 comply with the EMC standards listed above.

D.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 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 Stream™ Module 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 Stream™ Module. Guidance on maintaining appropriate separation between communications equipment and the HemoSphere Stream™ Module is provided in Table D-3 on page 67. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere Stream™ Module.

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 D-1: Electromagnetic emissions

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

The HemoSphere Stream™ Module 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 Stream™ Module 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 Stream™ Module 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 Stream™ Module 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 D-4: Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
The HemoSphere Stream™ Module is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Stream™ Module 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 Stream™ Module user requires continued operation during power mains interruptions, it is recommended that the HemoSphere Stream™ Module 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	

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Stream™ Module is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Stream™ Module should assure that it is used in such an environment.			
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 D-5: Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Stream™ Module is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Stream™ Module should assure that it is used in such an environment.			
			Portable and mobile RF communication equipment should be used no closer to any part of the HemoSphere Stream™ Module, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	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
Conducted RF IEC 61000-4-6	6 Vrms (ISM band) 150 kHz to 80 MHz	6 Vrms	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).
Radiated RF IEC 61000-4-3	3 V/m 80 to 2700 MHz	3 V/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: 

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Stream™ Module is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Stream™ Module should assure that it is used in such an environment.			
[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 Stream ™ Module is used exceeds the applicable RF compliance level above, the HemoSphere Stream ™ Module 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 Stream ™ Module.* [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.*			

D.3 Open-Source Software

This product includes open-source software components that are protected by copyright and licensed under various open-source licenses. A full list of applicable licenses is available at:

https://wiki.st.com/stm32mpu/wiki/OpenSTLinux_licenses.

In accordance with applicable open-source license terms, the complete corresponding source code for the Linux kernel is available upon request. You may request a physical copy of the source code (for a fee covering costs of physical media) by mailing a written request:

BD Advanced Patient Monitoring
Legal Department
17200 Laguna Canyon Rd.
Irvine, CA 92618
USA

This source will remain available for at least three (3) years from the final distribution date of this product version.

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