HemoSphere Nano™ Monitor

Operator's Manual

Edwards

HemoSphere Nano™ Monitor Operator's Manual

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Technical Support
For technical assistance and customer service, call 1-800-822-9837 or +33 805 54 22 01.

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

Manufactured by	Edwards Lifesciences LLC One Edwards Way Irvine, CA 92614
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Users and/or patients should report any serious incidents to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Using This Manual

The HemoSphere Nano™ Monitor operator's manual is comprised of 6 chapters and 7 appendices. Figures in this manual are intended for reference only and may not be an exact replication of the screens as a result of continuous software improvements.

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

WARNING	Read this operator's manual carefully before attempting to use the HemoSphere Nano™ Monitor. Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Nano™ Monitor.

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

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

Chapter	Description
1	***Introduction:*** Provides an overview of the monitor
2	***Safety and Symbols:*** Includes WARNINGS and CAUTIONS that are found in the manual, as well as illustrations of labels found on the monitor
3	***Connections and Setup:*** Provides information about setting up the HemoSphere Nano™ Monitor and connections for the first time
4	***Taking a measurement:*** Provides instructions on application of patient monitoring equipment as well as how to measure noninvasive blood pressure, cardiac output, stroke volume, stroke volume variation, and systemic vascular resistance
5	***Settings:*** Provides information on screen views, about the various display settings including patient information, language and international units, SQI, battery, system time, and system date. It also provides cybersecurity information.
6	***Troubleshooting:*** Describes the Help menu and provides a list of faults, alerts, and messages, with causes and suggested actions

Appendix	Description
A	***Specifications and Device Characteristics***
B	***Accessories***
C	***Equations for Calculated Patient Parameters***
D	***Monitor Settings and Defaults***

Appendix	Description
E	***System Care, Service and Support***
F	***Guidance and Manufacturer's Declaration***
G	***Glossary***

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Introduction 1

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1.1 Intended Purpose of this Manual

This manual describes the features and monitoring options of the HemoSphere Nano™ Monitor. The HemoSphere Nano™ Monitor is a portable rechargeable device. It displays hemodynamic measurements derived from continuous arterial blood pressure waveform obtained through a non-invasive finger cuff.

This manual has been prepared for use with the HemoSphere Nano™ Monitor in an environment where healthcare is administered by trained clinicians, nurses, physicians, and healthcare professionals.

This manual provides the operator of the HemoSphere Nano™ Monitor with setup and operating instructions, device interfacing procedures, and limitations.

1.2 Indications for Use

The HemoSphere Nano™ Monitor when used with a compatible non-invasive finger cuff is indicated for adult patients (≥18 years of age) in whom cardiac function parameters need to be evaluated as part of a patient's assessment. The HemoSphere Nano™ Monitor and compatible finger cuffs non-invasively measure blood pressure and associated hemodynamic parameters.

NOTE	The effectiveness of HemoSphere Nano™ Monitor has not been evaluated in patients under 18 years of age and in pregnant and/or lactating women.

1.3 Intended Use Statement

The HemoSphere Nano™ Monitor is intended to be used in a setting where healthcare is administered by qualified personnel or trained clinicians. The HemoSphere Nano™ Monitor is intended for use with compatible non-invasive finger cuff for noninvasive measurement of blood pressure and associated hemodynamic parameters.

NOTE The HemoSphere Nano™ Monitor is not intended for residential use.

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.

1.4 Contraindications for use

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

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

1.5 Expected Clinical Benefit

The HemoSphere Nano™ Monitor enables you to monitor patient blood pressure and hemodynamic parameters continuously. In conjunction with a compatible cuff, the monitor facilitates insight for individualized patient care.

NOTE The HemoSphere Nano™ Monitor must be used in conjunction with patient clinical signs and symptoms. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting before initiating treatment options.

1.6 Connections, parameters, and features available

The HemoSphere Nano™ Monitor is equipped with one cuff connection port. When connected to a compatible finger cuff, the HemoSphere Nano™ Monitor enables non-invasive measurement of a patient's arterial pressure waveform, calculation of continuous cardiac output (CO), and associated hemodynamic parameters. For more information, see *Taking a Measurement* on page 28, and *HemoSphere Nano™ Monitor Methodology* on page 36.

Figure 1-1 The HemoSphere Nano™ Monitor with a connected compatible finger cuff

Table 1-1 HemoSphere Nano™ Monitor key parameters description

Parameter	Description	Compatible cuff(s)	Units
Systolic pressure (SYS)	Systolic blood pressure	Acumen IQ Plus finger cuff*	mmHg
Diastolic pressure (DIA)	Diastolic blood pressure		mmHg
Mean arterial pressure (MAP)	Averaged systemic blood pressure over one cardiac cycle		mmHg
Pulse rate (PR)	Number of arterial blood pressure pulses per minute		bpm
Continuous cardiac output (CO)	Continuous assessment of the volume of blood pumped by the heart measured in liters per minute using the monitored arterial pressure waveform and ClearSight algorithm		L/min
Continuous cardiac index (CI)	Continuous cardiac output relative to body surface area (BSA)		L/min/m_2
Stroke volume (SV)	Volume of blood pumped with each heartbeat		mL/beat
Stroke volume index (SVI)	Stroke volume relative to body surface area (BSA)		mL/beat/m^2
Stroke volume resistance (SVR)**	A derived measure of impedance to blood flow from left ventricle (afterload)		dyne-s/cm^5
Stroke volume resistance index (SVRI)	Systemic vascular resistance relative to body surface area (BSA)		dyne-s-m^2/cm^5

**Refer to the compatible finger cuff indication for use statements for information on target patient population specific to the finger cuff being used.*
***CVP manual entry is needed to calculate SVR.*

WARNING Improper use of the HemoSphere Nano™ Monitor could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in chapter 2, *Warnings*, before using the monitor.

This instrument must be used in conjunction with patient clinical signs and symptoms. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting before initiating treatment options.

Do not use the HemoSphere Nano™ Monitor as a heart or pulse rate monitor.

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

Only use compatible finger cuffs that have been supplied and labeled by manufacturer for use with the HemoSphere Nano™ Monitor. Using other unlabeled accessories, and/or components may affect patient safety and measurement accuracy.

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

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

The HemoSphere Nano™ Monitor is not intended for use as an apnea monitor.

1.7 Documentation and Training

Available documentation and training for HemoSphere Nano™ Monitor includes:

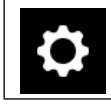
- HemoSphere Nano™ Monitor Operator's Manual

For more information on how you can receive training or available documentation for the HemoSphere Nano™ Monitor, contact your local representative or technical support.

1.8 Operator's manual style conventions

This section includes the conventions used in this operator's manual.

Table 1-2 Operator's manual style conventions

Convention	Description
Bold	Bold text indicates a software term. This word or phrase will appear on the screen as shown.
Bold button	A button is a touch screen access point for the option appearing in bold. For example, the **Start** 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.

1.9 Abbreviations in this manual

Table 1-3 Abbreviations

Abbreviations	Definition
ART	arterial blood pressure
BSA	body surface area
CO	cardiac output
CI	cardiac index
CVP	central venous pressure
DIA	arterial diastolic blood pressure
LED	light emitting diode
MAP	mean arterial pressure
SV	stroke volume
SVI	stroke volume index
SVR	systemic vascular resistance
SVRI	systemic vascular resistance index
SYS	systolic blood pressure
Touch	Interact with HemoSphere Nano™ Monitor by touching the screen.
USB-C	Universal Serial Bus Type C

Safety and Symbols 2

Contents

2.1 Safety Signal Words Definitions

The following are definitions of safety signal words that can be found in this manual. Read this operator's manual carefully before attempting to use the HemoSphere Nano™ Monitor.

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 Nano™ Monitor operator's manual. They are introduced in the manual where relevant to the function or procedure being described.

- Read this operator's manual carefully before attempting to use the HemoSphere Nano™ Monitor. (chapter 1)
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Nano™ Monitor. (chapter 1)
- To prevent injury to patient or user, damage to platform, or inaccurate measurements, do not use any damaged or non-compatible accessories, components or cables. (chapter 1)
- Improper use of the HemoSphere Nano™ Monitor could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in chapter 2, Warnings, before using the monitor. (chapter 1)
- This instrument must be used in conjunction with patient clinical signs and symptoms. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting before initiating treatment options. (chapter 1)
- Do not use the HemoSphere Nano™ Monitor as a heart or pulse rate monitor. (chapter 1)
- Refer to the directions provided with the compatible cuff for specific instructions on placement and use, and for relevant WARNINGS, CAUTIONS, and specifications. (chapter 1)
- Only use compatible finger cuffs that have been supplied and labeled by manufacturer for use with the HemoSphere Nano™ Monitor. Using other unlabeled accessories, and/or components may affect patient safety and measurement accuracy. (chapter 1)
- 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. (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. (chapter 3)
- Do not use damaged components/sensors or components/sensors with exposed electrical contacts to prevent patient or user shocks. (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 4)
- Improper use of the HemoSphere Nano™ Monitor could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in Warnings on page 17, before using the platform. (chapter 4)
- Shock hazard! Do not attempt to handle monitor while hands are wet. (chapter 4)
- Use only compatible accessories listed in Accessories List on page 55 with the HemoSphere Nano™ device. Using any other accessories may affect patient safety and measurement accuracy. (chapter 4)
- Make sure that Demo Mode is not activated in a clinical setting to ensure that simulated data is not mistaken for clinical data. (chapter 4)
- The HemoSphere Nano™ Monitor allows continuous non-invasive assessment of patient hemodynamic parameters. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting the monitor before initiating treatment options. (chapter 4)

- In cases of battery depletion, the monitor will go through a controlled shut off procedure. (chapter 5)
- Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Nano™ Monitor. (appendix B)
- Risk and Leakage current of the final system configuration must comply with IEC 60601-1/A1. It is the responsibility of the user to ensure compliance. (appendix B)
- Accessory equipment connected to the monitor must be certified according to IEC/EN 60950 for data-processing equipment or IEC 60601-1/A1 for electromedical equipment. All combinations of equipment must be in compliance with IEC 60601-1/A1 systems requirements. (appendix B)
- Use of accessories 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 B)
- The HemoSphere Nano™ Monitor contains no user-serviceable parts. Removing the cover or any disassembly will expose you to hazardous voltages. (chapter E)
- Do not drop the device. (chapter E)
- Explosion Hazard! Do not dispose of in fire, store at high temperature or short circuit. It may ignite, explode, leak or get hot, causing serious personal injury or death. (chapter E)
- 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 E)
- Do not steam, radiate, or EO sterilize the HemoSphere Nano™ system. The HemoSphere Nano™ system is provided non sterile. (chapter E)
- Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (chapter E)
- Do not immerse the HemoSphere Nano™ Monitor in any liquid solution. Do not allow any fluids to enter the instrument. Follow the cleaning instructions in the Operator's Manual. In the case of accidental spills on the unit, do not attempt to operate the instrument. Disconnect power supply, if connected, and have the device inspected by a qualified personnel. (chapter E)
- Do not clean the device with any other agents other than the ones listed. (chapter E)
- Do not sterilize any components of the system. The system is provided non sterile. Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization. (chapter E)
- Compliance to IEC 60601-1 is only maintained when the product and accessories are 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. (appendix F)
- If using the instrument during full body irradiation, keep all HemoSphere Nano™ Monitor components out of the irradiation field. If a component is exposed to the irradiation, the readings may be affected. (appendix F)
- This product contains metallic components. Do NOT use in a Magnetic Resonance (MR) environment. (appendix F)
- Do not use the device when using an electrosurgical unit (ESU). (appendix F)
- 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. (appendix F)
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the HemoSphere Nano™ Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result. (appendix F)

- Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic anti-theft systems, EAS (electronic article surveillance) and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Nano™ Monitor. (appendix F)
- The effects of other RF emitters are unknown and may interfere with the function and safety of the monitor. (appendix F)
- The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures: • Reorient or relocate the receiving device. • Increase the separation between the equipment. • Consult the manufacturer for help. (appendix F)

2.3 Cautions

The following are cautions that are used in the HemoSphere Nano™ Monitor operator's manual. They are introduced in the manual where relevant to the function or procedure being described.

- Federal (USA) law restricts this device to sale by or on the order of a physician. (chapter 1)
- Inspect the HemoSphere Nano™ Monitor and all accessories and equipment used with the monitor for damage prior to use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised. (chapter 1)
- The pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse rate should not be used as a replacement or substitute for ECG based arrhythmia analysis. (chapter 1)
- The effectiveness of the compatible finger cuffs has not been established in pre-eclamptic patients. (chapter 1)
- The HemoSphere Nano™ Monitor is not intended for use as an apnea monitor. (chapter 1)
- Device contains electronics. Handle with care. (chapter 3)
- Do not twist or bend the connectors. (chapter 4)
- Inspect power cable connector for any visual defects prior to use. Do not coil the cable tightly when storing. (chapter 4)
- Inspect the HemoSphere Nano™ Monitor for damage prior to each use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised. (chapter 4)
- Always disconnect the finger cuff when it is not wrapped around a finger, to prevent damage by accidental over-inflation. (chapter 4)
- Always grasp the connector, not the cable, when connecting or disconnecting the cuff. Do not twist or bend the connectors. Confirm that the finger cuff is connected correctly and completely before use. (chapter 4)
- Ensure patient remains still and that the entered height of finger to heart offset is accurate during measurement. (chapter 4)

- Inaccurate non-invasive measurements 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, or 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. • Inaccurate position and offset entry. In patients with extreme contraction of the smooth muscle in the arteries and arterioles in the lower arm and hand, such as may be present in patients with Raynaud's disease, blood pressure measurement can become impossible. (chapter 4)
- Use a virus scan on any USB stick before inserting to prevent a virus or malware infection. (chapter 4)
- Do not connect to unauthorized devices. Doing so may compromise data integrity or introduce malware. (chapter 5)
- Do not attempt to bypass authentication mechanisms. Use of incompatible cuffs will fail authentication. (chapter 5)
- Do not expose monitor to extreme temperatures. (appendix A)
- The HemoSphere Nano™ Monitor is electrostatic discharge (ESD) sensitive. Do not attempt to open the monitor housing or use if the housing has been damaged. (chapter E)
- If any electrolytic solution, for example Ringer's lactate solution, is introduced into the cable connectors while they are connected to the monitor, and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts. (chapter E)
- Recycle or dispose of the device in accordance with all federal, state, and local laws. (chapter E)
- Do not use any other cleaning agents. (chapter E)
- Do not steam, radiate, or EO sterilize platform. (chapter E)
- Do not use any disinfecting solution other than the specified types. (chapter E)
- Do not immerse the monitor in any cleaning agents or solutions or pour or spray liquid directly on any portion of the HemoSphere Nano™ Monitor or accessories. (chapter E)
- Do not expose monitor to dirty or dusty environments (chapter E)
- Do not allow any liquid to come in contact with the power connector or allow any liquid to penetrate connectors or openings in the monitor. If any liquid does come in contact with any of the items above-mentioned, DO NOT attempt to operate the monitor, immediately call your Biomedical Department or local representative. (chapter E)
- The instrument has been tested and complies with the limits of IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. (appendix F)

2.4 User Interface Symbols

The following are icons that appear on the HemoSphere Nano™ Monitor screen. Certain icons will only appear while monitoring with a specific hemodynamic technology, as specified.

Table 2-1 User Interface Symbols

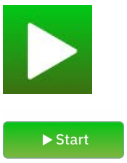
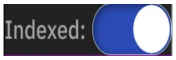
Symbol	Definition
	next
	skip
	start
	toggle to view indexed parameters (table 1-1 on page 13)
	settings
	adjust up
	adjust down
	stop or exit
	return to previous menu
	continue to next menu
	home
	export

Table 2-1 User Interface Symbols (continued)

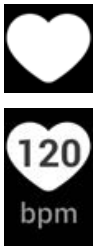
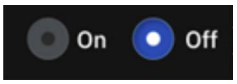
Symbol	Definition
	restart
	pause measurement
	end measurement
	beat-to-beat pulse rate
	enter or confirm
	edit
	export success
	export fail
	refer to IFU
	keypad backspace key
	keypad cancel
	keypad enter
	item enabled/selected
	item not enabled/selected

Table 2-1 User Interface Symbols (continued)

Symbol	Definition
	signal quality indicator bar
   	battery life status indicator icons, for more information, see “Battery” on page 44.

Table 2-1 User Interface Symbols (continued)

Symbol	Definition
	radio buttons used for patient demographics and to de-identify patient data.
	screen brightness

2.5 Product label symbols

This section provides the symbols that are on the HemoSphere Nano™ Monitor and accessories.

Table 2-2 Product label symbols

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 spraying water when tilted up to 15 degrees vertically.
	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.

Table 2-2 Product label symbols (continued)

Symbol	Description
	Follow instructions for use
	Follow instructions for use on the website
	Intertek ETL
	Model number
	Serial number
	Unique device identifier
	MR unsafe
	Batch code

Table 2-2 Product label symbols (continued)

Symbol	Description
	Quantity
	Lead-free
	Recyclable Lithium-Ion
	Medical device
	Importer
	Caution: Consult Instructions for use for important cautionary information
	Defibrillation proof type BF applied part or connection
	Continuous non-invasive arterial blood pressure
	Fragile, handle with care
	This end up
	Lithium ion batteries packed with or contained in equipment
	Store in a cool, dry place
	Do not use if package is damaged
	Box made from recyclable cardboard
	Use-by date
	Environment-friendly use period (EFUP) - China only

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

2.6 Applicable Standards

Table 2-3 Applicable standards

Standard	Title
ANSI/AAMI ES60601-1:2005+A1;A2/ CSA C22.2#60601-1:2014 Ed.3+A2	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2020	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010 Ed.3+A1;A2	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
IEC 60601-1-8:2006 Ed.2+A1;A2	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
IEC 60601-2-57:2011 Ed.1	Medical Electrical Equipment – Part 2-57: Particular Requirements for The Basic Safety and Essential Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use

2.7 HemoSphere Nano™ Monitor Essential Performance

The monitor shall provide display of non-invasive measurement of arterial blood pressure with a compatible Edwards finger cuff according to the specifications provided in blood pressure, according to the specifications provided in appendix A, *Specifications and Device Characteristics.*

The system shall provide alert, indicator, and/or system status when unable to provide accurate measurement of the applicable hemodynamic parameter. For more information, see *Essential Performance Characteristics* on page 51.

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.

Connections and Setup 3

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 monitor housing may be compromised. Report any evidence of external damage.

3.1.1 Packaging Contents

All monitors are shipped with a power supply and region-specific power cords. Additional items may be included and shipped based on the bundle configuration. Disposable and accessory items may be delivered separately. See appendix B: *Accessories* for more information.

NOTE	A compatible cuff is required for measurement with the HemoSphere Nano™ Monitor.

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

CAUTION	Device contains electronics. Handle with care.

3.2 Device Images and Connection Ports

The HemoSphere Nano™ Monitor can be handheld or placed on a stable flat surface during use. The operator should be in close proximity during use. The device is intended to be used by only one user at a time.

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

3.2.1 Monitor Front

Figure 3-1 Monitor front view/power button

3.2.2 Monitor Cuff Receptacle

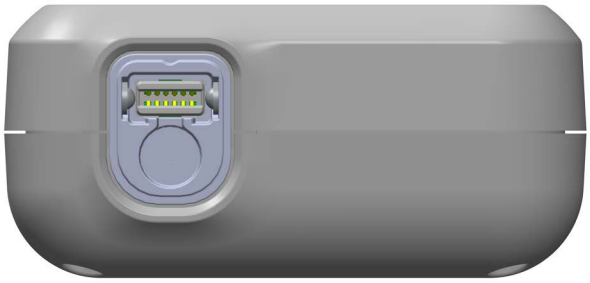


Figure 3-2 Receptacle to connect the cuff

3.2.3 Monitor USB-C/charging port

Figure 3-3 Port to connect USB-C cable or charge monitor

NOTE	The HemoSphere Nano™ operates with a compatible finger cuff, and data can be exported using a USB-C connection.

Taking a Measurement

4

Contents

4.1 HemoSphere Nano™ Monitor Screen Appearance

The HemoSphere Nano™ Monitor has a touch screen interface. All functions are initiated by touching the appropriate area on the touch screen. The HemoSphere Nano™ Monitor screen is shown below.

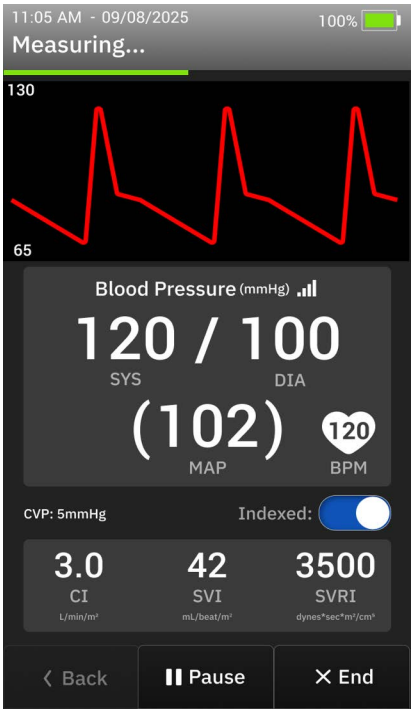


Figure 4-1 Monitor screen

4.2 Initial Start Up/System Set Up

CAUTION Do not twist or bend the connectors.

Inspect power cable connector for any visual defects prior to use. Do not coil the cable tightly when storing.

NOTE When you receive the device and use it for the first time, plug in the charger.

Before connecting the power supply to the monitor, ensure that the USB-C/charging port is not blocked.

1. Connect the detachable power supply cord to the USB-C/charging port. Ensure that the plug is secure.
2. Plug power cord into a power outlet.

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.

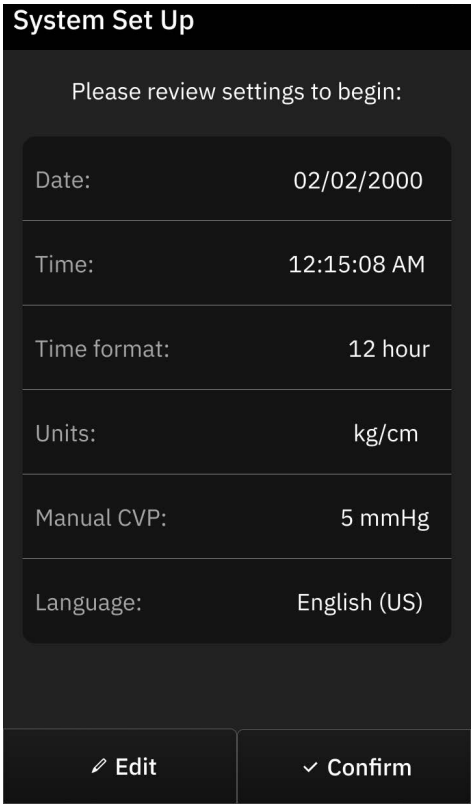


Figure 4-2 Initial Start Up

Upon initial startup, a system set up screen with default settings will be displayed to allow input and selection of date and time formats, units of measurement, manual CVP, and language. Select **Confirm** to accept the default settings or select **Edit** to edit the settings. Each of the settings can be changed later in **Settings**. See *System Settings* on page 39.

4.2.1 Start Up Procedure

To turn on the monitor, press the power button located on the front of the monitor. Refer to figure 3-1 on page 26 for power button location.

After turning on the monitor, the splash screen is displayed. During this time, a Power-On Self Test (POST) will run. The POST verifies the monitor meets basic operating requirements by exercising critical hardware components and is performed each time the system is turned on.

Figure 4-3 Startup screen

NOTE If any error conditions are detected during monitor power on, a system error will be displayed. See *Troubleshooting* on page 47. Otherwise, call your representative for assistance.

4.3 Preparing the Device for Use

A compatible cuff is required for measurement with the HemoSphere Nano™ Monitor. The HemoSphere Nano™ Monitor is compatible with the Acumen IQ Plus™ Finger Cuff, which is designed for single patient use. See figure 1-1 on page 12 for system-level illustration of the monitor with a connected finger cuff.

Before using the HemoSphere Nano™ Monitor with a patient, ensure that:

- The device is powered on.
- The compatible finger cuff is properly attached to the port (see figure 3-2 on page 27).

Refer to cuff IFU for instructions on proper finger placement, device illustrations, connection to system, and other use instructions.

WARNING Improper use of the HemoSphere Nano™ Monitor could present a hazard to the patient. Carefully read the "warnings" section of this manual, located in *Warnings* on page 17, before using the platform.

Shock hazard! Do not attempt to handle monitor while hands are wet.

Use only compatible accessories listed in *Accessories List* on page 55 with the HemoSphere Nano™ device. Using any other accessories may affect patient safety and measurement accuracy.

CAUTION Inspect the HemoSphere Nano™ Monitor for damage prior to each use. Damage may include cracks, scratches, dents, exposed electrical contacts, or any signs that the housing may be compromised.

4.4 Starting a Measurement

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

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

Always grasp the connector, not the cable, when connecting or disconnecting the cuff. Do not twist or bend the connectors. Confirm that the finger cuff is connected correctly and completely before use.

To take a measurement on the HemoSphere Nano™ Monitor:

1 Ensure a compatible finger cuff is connected to the monitor before starting measurement.

2 Enter the patient's demographic information or choose **Skip** Skip (figure 4-4).

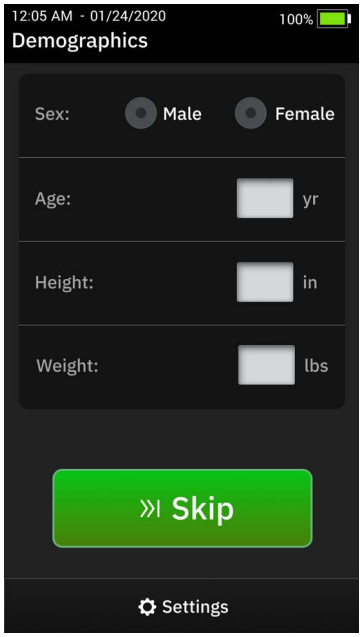


Figure 4-4 Patient demographics screen

NOTE Cardiac output (CO), cardiac index (CI), stroke volume (SV), stroke volume index (SVI), systemic vascular resistance (SVR), or systemic vascular resistance index (SVRI) are not available if patient demographics are skipped.

3 Select the patient's position: **Seated** or **Supine**.

4 Select the offset by tapping the **arrows** or dragging up and down on the offset size indicator (figure 4-5).

NOTE	The offset is the vertical distance from the heart level to the cuff on the patient's hand. The offset value must be updated each time a patient is re-positioned in this mode. If monitoring is stopped for more than one minute, the vertical offset must be verified again upon restarting monitoring.

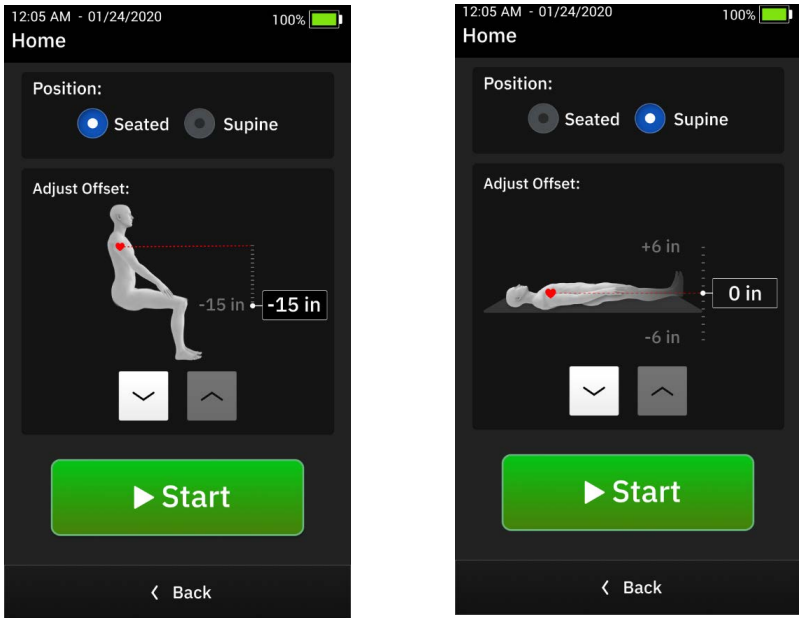


Figure 4-5 Offset entry for seated patient and supine patient

NOTE	For seated position, the offset range is 0-16 inches (0-40 cm). For supine position, the offset range is -6 inches to +6 inches (-15 cm to +15 cm).

CAUTION	Ensure patient remains still and that the entered height of finger to heart offset is accurate during measurement.

5 Press the **Start** ▶ Start button to display the monitoring screen. Before measurement begins, Physiocal™ Method interruptions occur regularly to adjust for the physiological properties of the finger artery (see *HemoSphere Nano™ Monitor Methodology* on page 36). During this time, "Measuring..." is displayed on the screen and parameter results are not displayed. Once calibration is complete, measurements will begin.

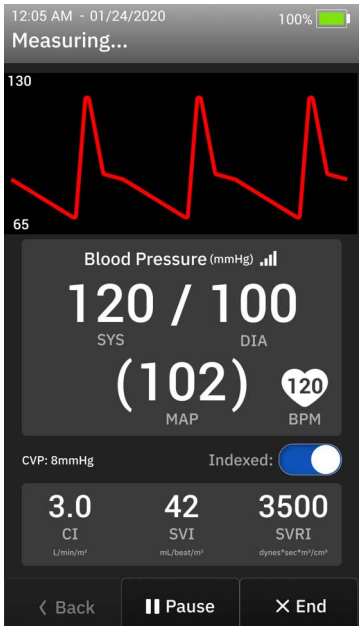


Figure 4-6 Start of monitoring and initial monitored values

6 Upon completion of the measurement, the **Assessment Summary** screen will display. Average values over the previous minute for basic blood pressure and advanced hemodynamic parameters are shown. The blood pressure based hemodynamic measurements can be displayed for up to 10 minutes or until a user selects **End** ✕.

NOTE If demographics are entered, and the toggle is set accordingly, the **Advanced Values** will display the indexed values (CI, SVI, SVRI) or non-indexed values (CO, SV, SVR).

NOTE The HemoSphere Nano™ Monitor is to be operated under the supervision of qualified personnel only.

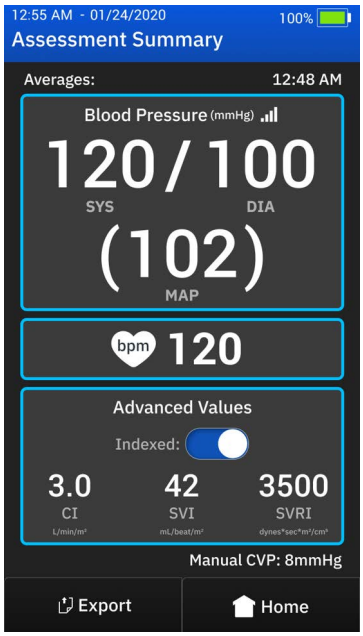


Figure 4-7 Monitoring results screen

7 After you have viewed the **Assessment Summary** screen, you have the option to:

- Touch **Home** button to end the session and start a new measurement.
- Touch **Export** button to export data. See *Exporting Data* on page 37.

NOTE Finger cuffs are designed for single patient, single session use.

CAUTION Inaccurate non-invasive measurements 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, or 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.
• Inaccurate position and offset entry.

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

WARNING The HemoSphere Nano™ Monitor allows continuous non-invasive assessment of patient hemodynamic parameters. If hemodynamic values obtained from the device are not consistent with the clinical presentation of the patient, consider troubleshooting the monitor before initiating treatment options.

4.5 HemoSphere Nano™ Monitor Methodology

The HemoSphere Nano™ Monitor utilizes ClearSight™ Technology for measurement of blood pressure and associated hemodynamic parameters. Accurate measurement of the patient's blood pressure and key hemodynamic parameters are based on the Volume Clamp method, Physiocal™ Method and ClearSight™ Algorithm.

4.5.1 Volume Clamp Method

The finger cuff uses 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.

4.5.2 The Physiocal™ Method

The Physiocal™ Method, developed by K.H. Wesseling (K.H. Wesseling et al. 1995), 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.

The Physiocal™ Method is an automatic calibration of the arterial waveform which occurs at regular intervals during non-invasive monitoring. The Physiocal™ Method can be observed on the live pressure waveform display as a stepwise increase in pressure upon startup and as brief interruptions throughout monitoring. To accurately account for changes in the finger artery characteristics throughout monitoring, Physiocal™ Method is performed at regular intervals resulting in momentary interruptions to the arterial waveform.

4.5.3 Waveform Reconstruction and Hemodynamic Analysis (ClearSight Technology)

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

Technology uses advanced processing methods to reconstruct the finger pressure waveform which yields values for cardiac output (CO), cardiac index (CI), stroke volume (SV), and stroke volume index (SVI) using an advanced pulse contour method.

Systemic vascular resistance (SVR) and systemic vascular resistance index (SVRI) are derived using MAP when a central venous pressure (CVP) value is entered manually.

All non-invasive parameters (see *Connections, parameters, and features available* on page 12) are averaged and have an update rate of 20 seconds.

4.5.4 Discoloration, Numbness, or Tingling of the Fingertip

The Volume Clamp methodology places 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. 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.

4.5.5 Accuracy of ClearSight Technology Blood Pressure Measurements

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

The table below provides a summary of repeated measurements from the same patient to provide accuracy of ClearSight non-invasive technology blood pressure outputs.

Table 4-1 95% Confidence interval results for repeated blood pressure measurements from the same patient (Bootstrap Re-sampling)

Adult	Bias [95% CI]	Precision [95% CI]
SYS (mmHg)	-2.74 [-4.95, -0.72]	6.15 [4.25, 7.82]
MAP (mmHg)	-1.29 [-2.33, -0.22]	3.14 [2.15, 4.14]
DIA (mmHg)	-1.07 [-2.26, 0.21]	3.71 [2.43, 5.29]
PR (bpm)	RMSE- Radial 0.59 [0.23,0.91]	N/A

4.5.6 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.

4.6 Exporting Data

You can export data from the HemoSphere Nano™ Monitor to a USB-C storage device. USB-A and USB-B devices can not be used with the HemoSphere Nano™ Monitor.

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

NOTE Ensure that the USB device is formatted as FAT32.

1. Connect a USB device to the HemoSphere Nano™ Monitor's USB-C port.
2. Touch **Export** on the **Results** screen or **Settings** from the **Demographics** screen (if you are starting an export without first running a monitoring session).
3. Choose to export the most recent results (**Last**), results from a specific date range (**Range**), or the last 1000 results (**All**).
4. Enter the date range you want to export (if applicable).
5. Choose the desired file type to export (**CSV** or **PDF**).
   - When CSV is selected, the data exported includes date/time, demographics (if entered), averages of blood pressure parameters including SYS, DIA, MAP, PR, CO, SV, and SVR as well as the indexes for CI, SVI, SVRI.
   - When PDF is selected, the data exported includes date/time, demographics (if entered), averages of blood pressure parameters including SYS, DIA, MAP, PR as well as indexes for CI, SVI, and SVRI.
6. Touch **Export**.

If the export was successful, you will receive a message with the file name. If it was unsuccessful, you will receive an error message.

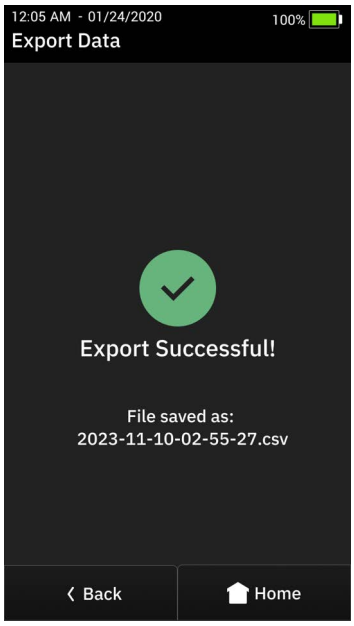


Figure 4-8 Successful data export

Settings 5

Contents

5.1 System Settings

The system settings are those that affect every screen: display language, units used, date/time settings, and monitoring screen display settings.

A language selection screen appears the first time the monitor is started. The selected language determines the default time and date format. These and other settings can be changed independently.

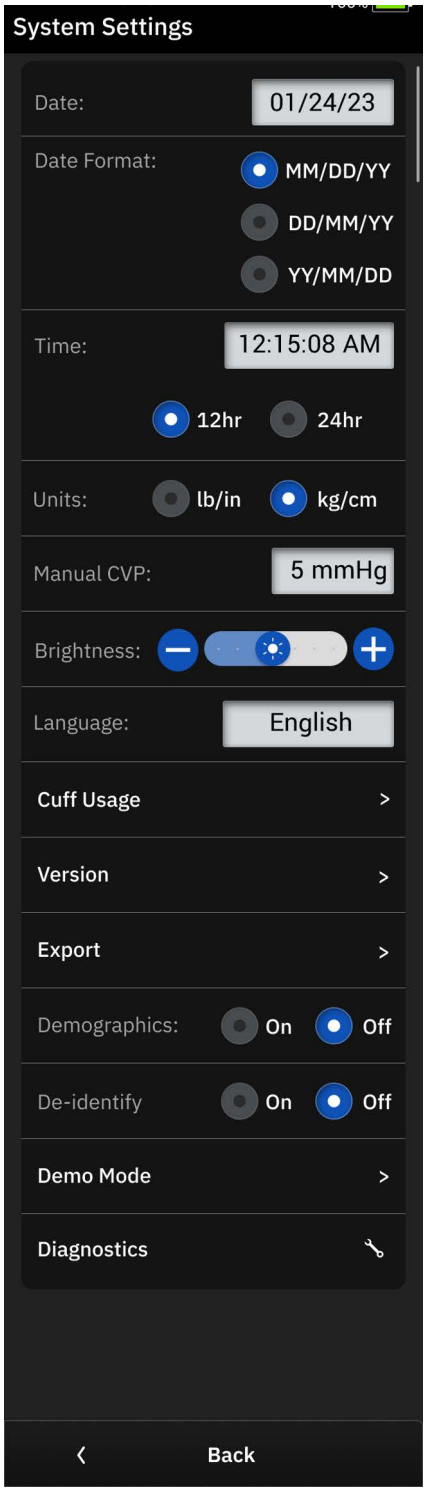


Figure 5-1 System Settings

To change the system settings of the monitor:

1 Touch **Settings** .

2 Configure one or all of the following (options described in the order they appear):

- **Date:** Touch the date displayed and follow the prompts on the screen.
- **Date Format:** Select **DD/MM/YY**, **MM/DD/YY**, or **YY/MM/DD**.
- **Time:** Touch the current time displayed and follow the prompts to change the time. Toggle between **12HR** or **24HR**.
- **Units:** Select **lbs/in** or **kgs/cm**.
- **Manual CVP:** Touch the CVP value displayed and follow the prompts to set a value between 0- 50 mmHg (5 mmHG is the default). When set to 0 mmHg, the SVRI parameter is not available.
- **Brightness:** Slide the sun icon or touch -/+ to set your desired brightness.
- **Language:** Touch the language displayed and following the prompts to choose a language.
- **Version:** Touch the **arrow** ❯ to view the information on device serial number, hardware version, and current software version.
- **Export:** Touch the **arrow** ❯ to export measurement data. See figure 4-6 on page 34.
- **Demographics:** Touch **On** or **Off** to show or hide the patient demographics screen prior to starting measurement.
- **De-Identify:** Touch **On** or **Off** to exclude demographic data from export. When the De-Identify toggle is enabled, the patient age will appear as >89 in the exported data.
- **Demo Mode:** Touch the **arrow** ❯ to perform a simulated measurement (cuff cannot be connected). See *Demo Mode* on page 42.
- **Diagnostics:** Touch the **arrow** ❯ to enter a password and access detailed System Info, Configuration settings, Export Diagnostics Data, and Engineering Mode. See *Diagnostics Settings* on page 41.

5.1.1 Diagnostics Settings

Diagnostics settings and features require a password. The Secure User password requires a reset during system initialization the first time a password screen is accessed. If a password is entered incorrectly ten times, the password keypad will become locked for a certain time period. Monitoring will remain active. In the event of forgotten passwords, contact your local representative.

To access **Diagnostics** features, touch the **Settings** ⚙ icon → **Diagnostics** button → enter password.

Table 5-1 HemoSphere Nano™ Monitor password levels

Level	Digits Required	User Description
Secure User	Eight	Hospital authorized personnel
Edwards User	Ten (rolling password)	Internal Edwards use only

Table 5-2 HemoSphere Nano™ Monitor diagnostic access

Diagnostics Menu	Sub-Menu Selection	Secure User	Edwards User
System Info	Version	•	•
	Manufacturing	•	•
	Usage	•	•

Table 5-2 HemoSphere Nano™ Monitor diagnostic access (continued)

Diagnostics Menu	Sub-Menu Selection	Secure User	Edwards User
Configuration	Sleep Mode	•	•
	Battery Shipping Mode[1]	•	•
	Change Password	•	•
	Restore Factory Settings[1]	•	•
Export Data		•	•
Engineering Mode	Engineering Testing	•	•
	Reliability Testing	no access	•
	Battery	•	•

[1] *This setting requires power cycling the monitor.*

5.2 Demo Mode

Demonstration Mode is used to simulate measurement to assist in training and demonstration. Demonstration Mode displays data and final measurement results from a stored set. It is intended to simulate the graphical user interface screens that users would normally see and interact with during regular measurement. Demo Mode only displays simulated Data and should not mistaken for clinical data. A connected cuff is not required to utilize Demo Mode. During **Demo Mode**, the HemoSphere Nano™ Monitor user interface retains the same functionality as a fully operational platform. Simulated patient demographics information is optional. They can either be entered or skipped prior to starting Demo Mode. The user can touch the controls as if a patient was being monitored.

NOTE Demo Mode will not be run when a cuff is connected. If a cuff is connected to the unit, the system will ask that the cuff be removed.

When **Demo Mode** is entered, trended data and events are cleared from being displayed.

1. Touch **Settings** button.
2. Touch the **Demo Mode**.
3. Touch **Confirm** on the **Demo Mode** confirmation screen.

4 The HemoSphere Nano™ Monitor must be exited out of Demo Mode prior to monitoring a patient.

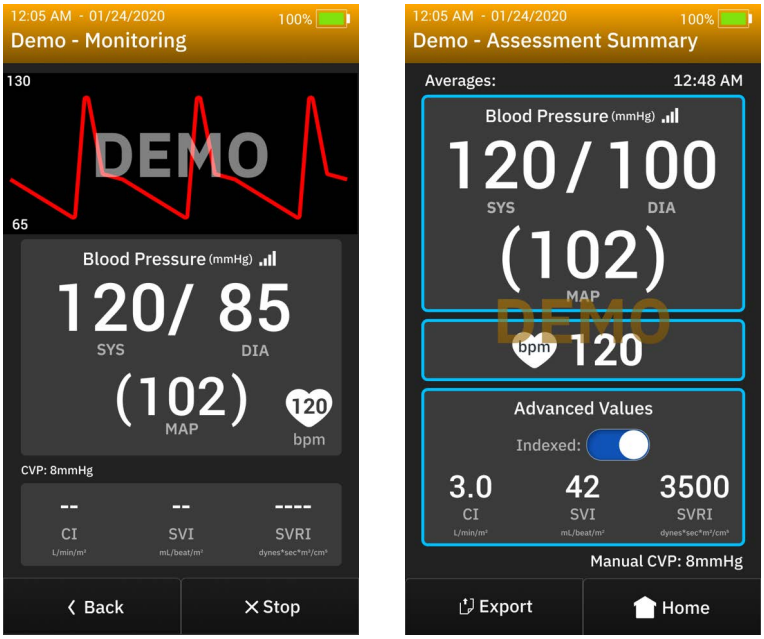


Figure 5-2 Monitoring in Demo Mode

NOTE When the HemoSphere Nano™ Monitor runs in **Demo Mode**, a "**Demo - Monitoring**" or "**Demo - Assessment Summary**" banner will appear at the top of the screen. A "**Demo**" watermark will also appear across the screen.

5.3 Power Off and Power Saving Modes

To power the monitor off, touch the power button. See figure 3-1 on page 26. The following options will be displayed:

- **Pause** ⏸: Pauses measurement for 3 seconds before ending. You can then hit "Back" to return to setup screen.
- **End** ✕: Ends measurement session.

Power saving mode can occur if the system is left idle for:

- 15 minutes without a charger connected
- 20 minutes with a charger connected

If the system is left idle for 5 hours regardless of charging status, the unit will power off. To wake from power saving mode, press the power button or connect the charger.

5.4 Signal Quality Indicator (SQI)

A signal quality indicator (SQI) is present on screens with parameters during HemoSphere Nano™ Monitoring. SQI level is calculated with each parameter update every 20 seconds. See Table 5-3 for a description of arterial waveform SQI levels.

Table 5-3 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)
	0	Pressure waveform unavailable

An SQI level of zero is shown when monitoring is initializing (starting or resuming). A zero SQI value can also be associated with a fault condition.

5.5 Battery

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

The HemoSphere Nano™ Monitor is battery operated. The USB-C port is used to charge the built-in rechargeable battery. It also supports connection with a computer for data and file transfers. For additional information, see *Exporting Data* on page 37.

Battery life is indicated on the status bar by the symbols shown in the below table. Ensure that the monitor has adequate battery life before starting a measurement. For additional information, see *Troubleshooting* on page 47.

Table 5-4 Battery status

Battery symbol	Indication
	The battery has 100% charge
	The battery has less than 20% charge remaining.
	The battery is charging and connected to mains power.
	The battery is depleted

NOTE Numerical battery percentage indicator appears next to the battery symbol.

User should not attempt to remove or replace the built-in battery. For additional information, see *General Maintenance* on page 59.

5.6 Cybersecurity

This section outlines cybersecurity. It is important to note that any facility 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 general security include:

- **Physical Access**: Limit use to authorized users.
- **Active Use**: Take measures to limit patient data storage. Patient data should be removed from the monitor after a patient is discharged and patient monitoring has ended.
- **Device Security**: Users should only use approved accessories. In addition, ensure that any connected device is free of malware.

The use of any device outside of its intended purpose could pose cybersecurity risks.

5.6.1 Cybersecurity Updates

When a cybersecurity update to the HemoSphere Nano™ Monitor is required, emergency patches will be issued within 60 days after the identification of a cybersecurity incident and cybersecurity patches within 120 days after the identification of a cybersecurity incident. All other vulnerabilities will be addressed in routine updates and communicated to customers upon request. To maintain device security, it is recommended that cybersecurity controls are implemented such as, but not limited to, internal hardening methodologies, role-based access control (RBAC). For additional recommendations on maintaining devices security please contact your local representative or technical support.

5.6.2 Cybersecurity and Electronic Interfaces

This device includes multiple electronic interfaces designed with security controls to protect patient data and ensure safe operation. These measures are implemented to prevent unauthorized access, maintain data integrity, and ensure patient safety. Improper use of these interfaces may result in compromised monitoring data or device performance.

5.6.2.1 USB-C Interface

For secure transfer of patient monitoring data and transfer of software upgrade files during servicing and maintenance. See below for Security Specifications:

- Encrypted data exchange using AES-256.
- De-Identified clinical data

CAUTION Do not connect to unauthorized devices. Doing so may compromise data integrity or introduce malware.

5.6.2.2 Cuff Connector Interface

Supports Acumen IQ Plus cuffs only. See below for Security Specifications:

- Utilizes a secure element for cryptographic authentication.

CAUTION Do not attempt to bypass authentication mechanisms. Use of incompatible cuffs will fail authentication.

5.6.3 Vulnerability Management

Vulnerability scans are performed on the monitor on a routine basis to ensure HemoSphere Nano™ Monitor 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 the product security website at https://www.edwards.com/healthcareprofessionals/products-services/support/product-security to review cybersecurity bulletins. For additional inquiries, please contact your local representative or technical support.

5.6.4 Cybersecurity Incident Response

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

5.6.5 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 monitor use.

Troubleshooting 6

Contents

6.1 On Screen Help

The help topics outlined in this chapter and displayed on monitor help screens are associated with common error conditions. In addition to these error conditions, a list of unresolved anomalies and troubleshooting steps are available at eifu.edwards.com. This list is associated with the HemoSphere Nano™ Monitor model number (HSNANO1) and software version indicated on the systems setting (see *System Settings* on page 39). These issues are continually updated and compiled as a result of ongoing product improvements.

6.2 Monitoring Faults/Alerts

Table 6-1 Monitoring faults/alerts

Message	Possible Causes	Suggested Actions
Battery Fault. Service Battery.	Battery voltage is out of range. Battery charge current is out of range. Battery capacity is low. Internal battery fault occurred.	Power cycle recommended. If the issue persists, servicing is required.
Battery Overheated.	Battery temperature is too high.	Power cycle recommended. If the issue persists, servicing is required.
Low Battery Health. Service Battery.	Battery health is at or below 70%.	Power cycle recommended. If the issue persists, servicing is required.
Low Battery. Connect Charger.	Battery percentage is at or below 20%.	Connect charger. If the issue persists, servicing is required.
Error Detected. Retrying Measurement.	Internal system calibration cannot be performed. Power cycle recommended. If issue persists, Servicing required. Calibration cannot be performed. Power cycle recommended. If issue persists, Servicing required. Blood pressure waveform is inadequate to measure accurately. Poor pressure waveform over extended period of time. Systolic pressure too high or diastolic pressure too low.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement. Allow the system to automatically resolve the issue. Warm the hand. Apply cuff to a different finger. Replace cuff. Re-start measurement. Export data to USB drive to view measurement details.
Initialization Error. Measurement Restarting.	Internal system calibration cannot be performed. Power cycle recommended. If the issue persists, Servicing required. System hardware initialization error. Application initialization error.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement. If the issue persists, servicing is required.
Insufficient Pressure. Check Cuff.	Cuff air tube kinked. Cuff leaking. Defective system.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement.
Pressure Unstable. Check Cuff.	Cuff too loose.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement.
Cuff Overpressured. Check Cuff.	Defective system.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement.
Defective Cuff. Replace Cuff.	Defective cuff detected by the system.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement.
System Issue Detected. Service Required.	Defective pressure controller. Defective system.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement.
Cuff Expired. Replace Cuff.	Cuff has exceeded maximum use time.	Replace cuff. Restart measurement.
Cuff Not Detected. Connect Cuff.	Previously connected cuff is not detected. Poor cuff connection. Cuff connector is damaged or defective.	Replace cuff.
Incompatible Cuff. Replace Cuff.	Incompatible cuff detected by the system.	Replace cuff.

Table 6-1 Monitoring faults/alerts (continued)

Message	Possible Causes	Suggested Actions
System Issue Detected. Service Required.	Analog (Front End AFE) access failure. Output pressure sensor nulling is out of range. Output pressure sensor is not nulled. Cryptochip connection error. Firmware image error. Current is too low or too high. Pump voltage too low or too high. Pump current too low or too high. Valve voltage too high or too low. Input pressure sensor cannot be accessed. Output pressure sensor cannot be accessed. Output pressure zero signals out of range.	Power cycle recommended. If the issue persists, servicing is required.
Internal Temp Out of Range. Service Required.	System temperature is either too low or too high.	Power cycle recommended. If the issue persists, servicing is required.
Screen Issue Detected. Service Required.	System communication error with the touchscreen.	Power cycle recommended. If the issue persists, servicing is required.
Air Supply Error. Service Required.	Defective pressure controller. Defective system. Input pressure is too low.	Check cuff. Replace cuff. Power cycle the system. Re-start measurement. If the issue persists, servicing is required.
Measurement Stopped. Press Start.	End button on the measurement screen has been pressed.	Monitoring will stop when End button is pressed. To begin monitoring, press start.
Export Canceled	Data export has been canceled.	Re-try export.
Connect USB-C to Export	Previously connected USB-C drive is detected as incompatible. Data export cannot be initiated. Filesystem format is incompatible.	Disconnect and reconnect USB-C drive. Re-try export. Connect a different USB-C drive. Ensure USB-C drive is formatted as FAT32 filesystem. Power cycle the system. If the issue persists, servicing is required.
Failed to Export to USB-C	Data export has failed. Exporting process was interrupted. Incompatible USB-C drive.	Disconnect and reconnect USB-C drive. Re-try export. Connect a different USB-C drive. Ensure USB-C drive is formatted as FAT32 filesystem. Power cycle the system. If the issue persists, servicing is required.
Restore Unsuccessful. Retry Restore.	Factory settings restoration was interrupted and/or unsuccessful.	Re-try to restore the factory settings. If the issue persists, servicing is required.
Upgrade Unsuccessful. Retry Upgrade.	Unsuccessful software upgrade or incompatible software version detected.	Disconnect and reconnect USB-C drive. Re-try upgrade. If the issue persists, servicing is required.
OTP Not Locked. Please check.	Internal component needs to be checked.	If the issue persists, servicing is required.

Table 6-2 Priority levels

Message	Color	Priority
Fault	Red	High
Fault	Orange	Medium
Alert	Yellow	Low
Notification	Grey	Low

Appendix A

Specifications and Device Characteristics

Contents

A.1 Essential Performance Characteristics

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

The table below represents the minimum performance when operating under non-transient electromagnetic phenomena, such as radiated and conducted RF, according to IEC 60601-1-2. This table 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 Monitor essential performance – transient and non-transient electromagnetic phenomena

Module or cable	Essential Performance
General	Non-invasive measurement of blood pressure (SYS, DIA, MAP) within specified accuracy (±1% of full scale with a maximum of ±3 mmHg). While exposed to transient and non-transient electromagnetic phenomena: Ensure all measurements & parameters behave as expected. No interruption of any given monitoring mode. No unexpected reboots or disruption of operation. No spontaneous triggering of events that require user interaction to mitigate. Patient connections provide defibrillator protection. Following exposure to defib voltages, the system shall return to an operational state within 10 seconds. Minimum performance when operating under non-transient electromagnetic phenomena, such as radiated and conducted RF, according to IEC 60601-1-2. Also identifies the minimum performance for transient electromagnetic phenomena, such as electrical fast transients & surges, according to IEC 60601-1-2. 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.

A.2 HemoSphere Nano™ Monitor Characteristics and Specifications

Table A-2 Physical and mechanical characteristics

HemoSphere Nano™ Monitor		
Weight	1.4 lbs (637 g)	
Dimensions	Height	1.85 in (47 mm)
	Width	3.96 in (100 mm)
	Depth	9.95 in (177 mm)
Display	Resolution	1280 x 720

Table A-3 HemoSphere Nano™ Monitor specifications

HemoSphere Nano™ Monitor	
Ingress Protection	IPX2
Applied Part Classification	Type BF Defibrillation Proof
Operating System	Linux

Table A-4 Environmental specifications

Environmental specification	Value
Temperature	0 to 45 °C
Relative humidity	20 to 85% non-condensing
Altitude (Pressure)	0 to 3000m

CAUTION Do not expose monitor to extreme temperatures.

Table A-5 Transportation environmental specifications

Environmental specification	Value
Temperature	-18 to 45 °C
Relative humidity	20 to 90% RH non-condensing
Atmospheric pressure range	465 hPa (20000ft/6096m) to 1013 hPa (0ft/0m)

Table A-6 Technical characteristics

Electrical	
Rated supply voltage	100-240VAC, 50-60Hz
Rated input	0.6A
Battery Model	RRC2037
Battery life	8 hours (lifespan can vary depending on usage)

Table A-7 HemoSphere Nano™ parameter measurement specifications

Parameter	Specification	
arterial blood pressure	display range	0 to 250 mmHg
	accuracy[1]	Bias systolic pressure (SYS) ≤ ±5.0 mmHg Bias diastolic pressure (DIA) ≤ ±5.0 mmHg Precision (1σ) systolic pressure (SYS) ≤ ±8.0 mmHg Precision (1σ) diastolic pressure (DIA) ≤ ±8.0 mmHg
cardiac output (CO)	range[2]	1.0 to 20.0 L/min

[1]Accuracy tested under laboratory conditions compared to a calibrated pressure gauge

[2]Cardiac Output is used for calculating the displayed Cardiac Index (CI) value.

NOTE The expected useful life of the HemoSphere Nano™ Monitor is 3 years from date of purchase. If your equipment experiences a malfunction, please contact Technical Support or your local sales representative for further assistance.

A.3 Acumen IQ™ Plus cuff Characteristics and Specifications

Table A-8 Acumen IQ™ Plus cuff characteristics

Specification	Value
Maximum weight	11 g (0.02 lbs)
LED spectrial irradiance	See figure below
Max optical output	0.013 mWatts
Max variation of output over treatment area	50%
Length	13 inches

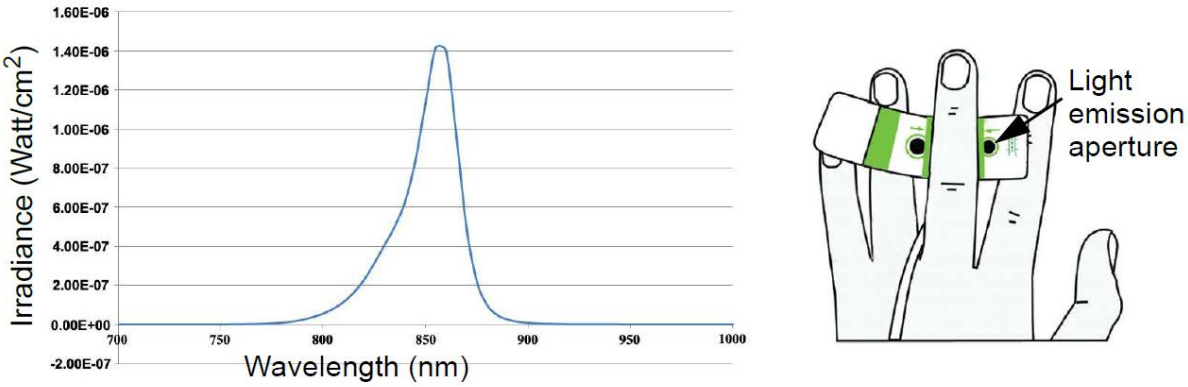


Figure A-1 Spectral Irradiance and location of light emission aperture

Appendix B

Accessories

Contents

B.1 Accessories List

Table B-1 Accessories List

Description	Model number
HemoSphere Nano™ Monitor	HSNANO1
Acumen IQ™ Plus cuff	AIQCA2
HemoSphere Nano™ Power Supply	*
Regional Power Cord	**
**Please contact your representative for model and ordering information.* ***For more information, see Unpacking on page 25*	

WARNING Refer to the instructions for use provided with each compatible accessory before using it with the HemoSphere Nano™ Monitor.

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

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

Use of accessories 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 C

Equations for Calculated Patient Parameters

Contents

C.1 Calculated Patient Parameters

This section describes the equations used to calculate continuous and intermittent patient parameters displayed on the HemoSphere Nano™ Monitor.

NOTE Patient parameters are calculated to more decimal places than are displayed on the screen. For example, a screen CO value of 2.4 may actually be a CO of 2.4492. Consequently, attempts to verify the accuracy of the monitor's display using the following equations may produce results that are slightly different from the data computed by the monitor.

Subscript SI = Standard International Units

Table C-1 Calculated Patient Parameters

Parameter	Description and formula	Units
BSA	Body Surface Area (DuBois formula) BSA = 71.84 x (WT0.425) x (HT0.725) / 10,000 where: WT – Patient Weight, kg HT – Patient Height, cm	m^2
CI	Cardiac Index CI = CO/BSA where: CO – Cardiac Output, L/min BSA – Body Surface Area, m^2	L/min/m^2
SV	Stroke Volume SV = (CO/PR) x 1000 where: CO – Cardiac Output, L/min PR – Pulse rate, beats/min	mL/beat

Table C-1 Calculated Patient Parameters (continued)

Parameter	Description and formula	Units
SVI	Stroke Volume Index SVI = (CI/PR) x 1000 where: CI – Cardiac Index, L/min/m^2 PR – Pulse rate, beats/min	mL/beat/m^2
SVR	Systemic Vascular Resistance SVR = {(MAP - CVP) x 80} /CO (dyne-sec/cm5) SVR = {(MAPSI – CVPSI) x 60} /CO where: MAP – Mean Arterial Pressure, mmHg MAPSI – Mean Arterial Pressure, kPa CVP – Central Venous Pressure, mmHg CVPSI – Central Venous Pressure, kPa CO – Cardiac Output, L/min	dyne-s/cm^5 $(kPa\text{-}s/L)_{SI}$
SVRI	Systemic Vascular Resistance Index SVRI = {(MAP - CVP) x 80} /CI where: MAP – Mean Arterial Pressure, mmHg MAP_{SI} – Mean Arterial Pressure, kPa CVP – Central Venous Pressure, mmHg CVP_{SI} – Central Venous Pressure, kPa CI – Cardiac Index, L/min/m^2	dyne-s-m^2/cm^5 $(kPa\text{-}s\text{-}m2/L)_{SI}$

Appendix D

Monitor Settings and Defaults

Contents

D.1 Patient Data Input Range

Table D-1 Patient information

Parameter	Minimum	Maximum	Available units
Gender	**M** (Male) / **F** (Female)	N/A	N/A
Age	18	120	years
Height	12 in / 30 cm	98 in / 250 cm	inches (in) or cm
Weight	2 lbs / 1.0 kg	881 lbs / 400.0 kg	lbs or kg
Seated offset	0 inches (0 cm)	16 inches (40 cm)	inches (in) or cm
Supine offset	-6 inches (-15cm)	6 inches (15cm)	inches (in) or cm

D.2 Parameter Display Ranges and Update Rates

Table D-2 Parameter display ranges and update rates

Parameter	Units	Display Range	Update Rates
CO	L/min	1.0 to 20.0	20 seconds
CI	$L/min/m^2$	0.0 to 20.0	20 seconds
SV	mL/b	0 to 250	20 seconds
SVI	$mL/b/m^2$	0 to 200	20 seconds
SVR	$dyne\text{-}s/cm^5$	0 to 5000	20 seconds
SVRI	$dyne\text{-}s\text{-}m^2/cm^5$	0 to 9950	20 seconds
CVP	mmHg	0 to 50	N/A
MAP	mmHg	0 to 250	2 seconds
SYS	mmHg	0 to 250	2 seconds
DIA	mmHg	0 to 250	2 seconds
PR	bpm	20 to 200	2 seconds

Appendix E

System Care, Service and Support

Contents

CAUTION The HemoSphere Nano™ Monitor is electrostatic discharge (ESD) sensitive. Do not attempt to open the monitor housing or use if the housing has been damaged.

If any electrolytic solution, for example Ringer's lactate solution, is introduced into the cable connectors while they are connected to the monitor, and the monitor is turned on, the excitation voltage can cause electrolytic corrosion and rapid degradation of the electrical contacts.

Recycle or dispose of the device in accordance with all federal, state, and local laws.

WARNING The HemoSphere Nano™ Monitor contains no user-serviceable parts. Removing the cover or any disassembly will expose you to hazardous voltages.

Do not drop the device.

Explosion Hazard! Do not dispose of in fire, store at high temperature or short circuit. It may ignite, explode, leak or get hot, causing serious personal injury or death.

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 steam, radiate, or EO sterilize the HemoSphere Nano™ system. The HemoSphere Nano™ system is provided non sterile.

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

E.1 General Maintenance

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

Technical Support
For technical assistance and customer service, call 1-800-822-9837 or +33 805 54 22 01.

E.2 Cleaning the Monitor

Follow all cleaning instructions carefully to ensure that the monitor is thoroughly cleaned. Follow any additional cleaning instructions provided by the manufacturers of listed approved cleaning agents.

NOTE Before cleaning, disconnect and power down the monitor.

The HemoSphere Nano™ Monitor can be cleaned using a lint-free cloth dampened with cleaning agents that are based on the following chemical content:

- Sani-Cloth®
- 70% isopropyl alcohol

CAUTION Do not use any other cleaning agents.

Do not steam, radiate, or EO sterilize platform.

Do not use any disinfecting solution other than the specified types.

Do not immerse the monitor in any cleaning agents or solutions or pour or spray liquid directly on any portion of the HemoSphere Nano™ Monitor or accessories.

Do not expose monitor to dirty or dusty environments

Do not allow any liquid to come in contact with the power connector or allow any liquid to penetrate connectors or openings in the monitor. If any liquid does come in contact with any of the items above-mentioned, DO NOT attempt to operate the monitor, immediately call your Biomedical Department or local representative.

WARNING Do not immerse the HemoSphere Nano™ Monitor in any liquid solution. Do not allow any fluids to enter the instrument. Follow the cleaning instructions in the Operator's Manual. In the case of accidental spills on the unit, do not attempt to operate the instrument. Disconnect power supply, if connected, and have the device inspected by a qualified personnel.

Do not clean the device with any other agents other than the ones listed.

Do not sterilize any components of the system. The system is provided non sterile. Refer to cleaning instructions. Do not disinfect the instrument by autoclave or gas sterilization.

E.3 Monitor Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure the HemoSphere Nano™ Monitor is disinfected and decontaminated appropriately in accordance with your country's laws for equipment containing electrical and electronic parts prior to disposal.

For the device and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

E.4 Preventive Maintenance

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

Routinely inspect cords for fraying and cracks, and make sure there are no exposed conductors.

NOTE The expected useful life of the HemoSphere Nano™ Monitor is 3 years from date of purchase. If your equipment experiences a malfunction, please contact Technical Support or your local sales representative for further assistance.

E.5 Warranty

Edwards Lifesciences™ warrants that the HemoSphere Nano™ Monitor is fit for the purposes and indications described in the labeling for a period of one (1) year from the date of purchase when used in accordance with the directions for use. Unless equipment is used in accordance with such instructions, this warranty is void and of no effect. No other express or implied warranty exists, including any warranty for merchantability or fitness for a particular purpose. This warranty does not include cables, or batteries used with the HemoSphere Nano™ Monitor. Edward's sole obligation and purchaser's exclusive remedy for breach of any warranty shall be limited to repair or replacement of the HemoSphere Nano™ Monitor at Edwards's option.

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

Appendix F

Guidance and Manufacturer's Declaration

Contents

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.

F.1 Electromagnetic Compatibility

Reference: IEC 60601-1-2:2020

The HemoSphere Nano™ Monitor is intended for use in the electromagnetic environment specified in this appendix. The customer or the user of the HemoSphere Nano™ Monitor should assure that it is used in such an environment. When connected to the HemoSphere Nano™ Monitor, ensure all accessory cables comply with the EMC standards listed above.

F.2 Instructions for Use

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

WARNING Compliance to IEC 60601-1 is only maintained when the product and accessories are 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.

If using the instrument during full body irradiation, keep all HemoSphere Nano™ Monitor components out of the irradiation field. If a component is exposed to the irradiation, the readings may be affected.

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

Do not use the device when using an electrosurgical unit (ESU).

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.

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

Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic anti-theft systems, EAS (electronic article surveillance) and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Nano™ Monitor.

The effects of other RF emitters are unknown and may interfere with the function and safety of the monitor.

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

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

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

Table F-1 Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The monitor is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should ensure that it is used in such an environment.		
Emissions	**Compliance**	**Description**
RF emissions CISPR 11	Group 1	The HemoSphere Nano™ Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment.
RF emissions CISPR 11	Class A	The HemoSphere Nano™ Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table F-2 Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
The monitor is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should ensure that it is used in such an environment.						
385	380 - 390	TETRA 400	Pulse modulation ² 18 Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ³ ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704 - 787	LTE Band 13, 17	Pulse modulation ² 217 Hz	0.2	0.3	9
810 870 930	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation ² 18 Hz	2	0.3	28
1720 1845 1970	1700 - 1900	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation ² 217 Hz	2	0.3	28
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation ² 217 Hz	2	0.3	28

Table F-2 Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment (continued)

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
The monitor is intended for use in the electromagnetic environment specified below. The customer or user of the monitor should ensure that it is used in such an environment.						
5240 5500 5785	5100 - 5800	WLAN 802.11a/n	Pulse modulation ² 217 Hz	0.2	0.3	9
Note: *If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.*						
[1]For some services, only the uplink frequencies are included.						
[2]The carrier shall be modulated using a 50 % duty cycle square wave signal.						
[3]As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.						

Table F-3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the monitor

The HemoSphere Nano™ Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. To help prevent electromagnetic interference, maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the HemoSphere Nano™ Monitor as recommended below, according to the maximum output power of the communications equipment.				
Transmitter Frequency	**150 kHz to 80 MHz**	**80 to 800 MHz**	**800 to 2500 MHz**	**2.5 to 6.5 GHz**
Equation	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$	$d = 2.3\sqrt{P}$
Rated Maximum Output Transmitter Power (watts)	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**	**Separation Distance (meters)**
0.01	0.12	0.12	0.24	0.24
0.1	0.37	0.37	0.74	0.74
1	1.2	1.2	2.3	2.3
10	3.7	3.8	7.4	7.4
100	12	12	23	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d can be estimated using the equation in the corresponding column, where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer. *Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.* *Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.*				

Table F-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 Nano™ Monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Nano™ Monitor should assure that it is used in such an environment.			
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact	±8 kV	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	±15 kV air	±15 kV	
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines > 3 meters	±2 kV for power supply lines ±1 kV for input/ output lines > 3 meters	Mains power quality should be that of a typical commercial and/or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	
	±2 kV line(s) to earth	±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply AC input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°,and 315°)	0% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the HemoSphere Nano™ Monitor user requires continued operation during power mains interruptions, it is recommended that the HemoSphere Nano™ Monitor be powered by an uninterruptible power supply or battery.
	0% U_T (100% dip in U_T) for 1 cycle (single phase at 0°)	0% U_T	
	70% U_T (30% dip in U_T) for 25/30 cycles (single phase at 0°)	70% U_T	
	Interrupt: 0% U_T (100% drop in U_T) for 250/300 cycles	0% U_T	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A(rms)/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Field IEC 61000-4-39	134.2 kHz with modulation at 2.1 kHz at 65 A/m 13.56 Mhz with modulation at 50 kHZ at 7.5 A/m	65 A/m 7.5 A/m	Proximity Magnetic Field should be at levels characteristic of a typical location in a typical commercial or hospital environment
Note: U_T is the AC mains voltage prior to application of the test level.			

Table F-5 Electromagnetic Immunity (RF Radiated and Conducted)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere Nano™ Monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Nano™ Monitor should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should be used no closer to any part of the HemoSphere Nano™ Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance d = [1.2] x $\sqrt{P}$; 150 kHz to 80 MHz
Conducted RF IEC 61000-4-6	6 Vrms (ISM band) 150 kHz to 80 MHz	6 Vrms	d = [1.2] x $\sqrt{P}$; 80 MHz to 800 MHz d = [2.3] x $\sqrt{P}$; 800 MHz to 2500 MHz
Radiated RF IEC 61000-4-3	3 V/m 80 to 2700 MHz	3 V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment with the following symbol: 

[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 Nano™ *Monitor is used exceeds the applicable RF compliance level above, the* HemoSphere Nano™ *Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the* HemoSphere Nano™ *Monitor.*

[b] *Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.*

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix G

Glossary

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

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

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

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

Default Settings
Initial operating conditions assumed by the system.

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

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

Physiocal
A physiological calibration procedure used to obtain accurate blood pressure readings from the artery of the finger.

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

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

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

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

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

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

USB-C
Universal Serial Bus Type C.

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

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. See instructions for use for full prescribing information.

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