

HemoSphere Nano Monitor

Operator's Manual



Edwards

HemoSphere Nano monitor Operator’s Manual

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

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

WARNING Read this operator's manual carefully before attempting to use the Edwards HemoSphere 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 monitor, or inaccurate measurements, do not use any damaged or non-compatible monitor accessories, components or cables.

Chapter	Description
1	Introduction: Provides an overview of the HemoSphere Nano monitor
2	Safety and Symbols: Includes WARNINGS, CAUTIONS, and NOTES that are found in the manual, as well as illustrations of labels found on the HemoSphere Nano monitor and accessories
3	Overview: Provides information about setting up the HemoSphere Nano monitor and connections for the first time
4	Taking a Measurement: Provides information on using the monitor
5	Settings: Provides information about the various settings

Appendix	Description
A	Specifications and Device Characteristics
B	Monitor Settings and Defaults
C	Monitor Care, Service and Support
D	Guidance and Manufacturer's Declaration
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Introduction

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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 handheld and rechargeable device that displays blood pressure measurements and is capable of supporting screening for severe aortic stenosis (sAS).

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

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 Acumen IQ finger cuff, is indicated for adult patients (≥ 18 years of age) in whom cardiac function parameters need to be intermittently evaluated as part of a patient assessment. The HemoSphere Nano Handheld monitor and compatible finger cuffs noninvasively measure blood pressure and associated hemodynamic parameters.

Additionally, HemoSphere Nano provides decision support to clinicians in their evaluation of patients and screening for severe aortic stenosis (sAS). It analyzes patient arterial pressure waveforms for signs of structural heart abnormalities and screens for severe aortic stenosis. The results provided as part of the sAS screening can be used by a clinician for decision support, in conjunction with their own evaluation and clinical judgment in consideration for referral for further diagnostic follow-up and are not intended as a sole means of diagnosis and should not be relied upon to make or confirm diagnosis.

Refer to the compatible finger cuff indication for use statements for information on target patient population specific to the finger cuff being used.

1.3 Intended Use Statement

The HemoSphere Nano monitor when used with a compatible Acumen IQ Plus finger cuff is indicated for adult patients (≥ 18 years of age) in whom cardiac function parameters need to be intermittently evaluated as part of a patient assessment. The HemoSphere Nano Handheld monitor and compatible finger cuffs noninvasively measure blood pressure and associated hemodynamic parameters. Additionally, HemoSphere Nano provides decision support to clinicians in their evaluation of patients and screening for severe aortic stenosis (sAS). It analyzes patient arterial pressure waveforms for signs of structural heart abnormalities and screens for severe aortic stenosis. The results provided as part of the sAS screening can be used by a clinician for decision support, in conjunction with their own evaluation and clinical judgment in consideration for

referral for further diagnostic follow-up and are not intended as a sole means of diagnosis and should not be relied upon to make or confirm diagnosis. Refer to the compatible finger cuff indication for use statements for information on target patient population specific to the finger cuff being used.

1.4 Contraindications for use

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

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

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, before using the monitor.

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

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

1.5 Expected Clinical Benefit

The HemoSphere Nano monitor allows intermittent non-invasive monitoring of patient hemodynamic parameters. In conjunction with the compatible sensors and decision support software to screen for symptomatic or asymptomatic severe aortic stenosis, the HemoSphere Nano monitor may aid in facilitating proactive clinical decision-making and insight for individualized patient care.

1.6 HemoSphere Monitor Connections and features available

The HemoSphere Nano monitor with a connected compatible finger cuff(s) enables non-invasive measurement of a patient's arterial pressure waveform and calculation of blood pressure and associated hemodynamic parameters. A comprehensive list of features and parameters available while monitoring with the HemoSphere Nano monitor are listed below.

Table 1-1 HemoSphere Nano features and parameters list

Parameter	Description
SYS	Average systolic blood pressure over the last minute, in mm Hg
DIA	Average diastolic blood pressure over the last minute, in mm Hg
MAP	Average mean arterial blood pressure over the last minute, in mm Hg

Table 1-1 HemoSphere Nano features and parameters list

Parameter	Description
PR	Average pulse rate in bpm
CVP	Default central venous pressure in mmHg
CI	Average continuous cardiac index over the last minute, in L/min/m ²
SVI	Average stroke volume index over the last minute, in mL/beat/m ²
SVRI	Average systemic vascular resistance index ¹ over the last minute, in dynes*sec*m ² /cm ²
sAS	Average Severe Aortic Screening Result

1.7 Documentation and Training

Available documentation and training for the HemoSphere Nano monitor includes:

- HemoSphere Nano Monitor Operator's Manual
- HemoSphere Nano Monitor Quick Start [Guide](#)

Instructions for Use are included with HemoSphere Nano Monitor. For more information on how you can receive training or available documentation for the HemoSphere Nano monitor, contact your local Edwards representative or Edwards Technical Support. See appendix [System Care, Service and Support](#).

Safety and Symbols

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2.1 Safety Signal Words Definitions

The following are definitions of alerts that can be found in this manual.

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

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

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

WARNING 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.

2.3 Cautions

2.4 UI Symbols

2.5 Product label symbols

2.6 Applicable standards

2.7 Essential performance

2.8 Critical Faults, Faults, Alerts, and Notifications

Because the system is used as a spot check device and no parameter value should trigger immediate clinical intervention, there are no physiological alarms. Therefore, all alarms are technical in nature and are visual alarms only.

There are four classifications:

- Critical Fault (red / high priority) – indicates when a system condition cannot recover automatically and requires servicing to address.
- Fault (orange / medium priority) – indicates when a system condition causes an interruption to measurement and can be cleared with user intervention.
- Alert (yellow / low priority) – indicates when the system is automatically restarting a

Overview

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3.1 Unpacking

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

3.1.1 Packaging Contents

All monitors are shipped with a regional-specific power cords. Additional items may be included and shipped based on the bundle configuration. See Table 3-1. Disposable and accessory items may be delivered separately. It is recommended that the user confirm the receipt of all ordered equipment. Refer to appendix B: Accessories, for a full list of available accessories.

3.2 Device

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

3.2.1 Monitor Front



Figure 3-1 HemoSphere Nano monitor front view

3.2.2 Monitor Side



Figure 3-2 HemoSphere Nano side view

3.2.3 Monitor Cuff Receptacle



Figure 3-3 HemoSphere Nano cuff receptacle

3.2.4 Monitor Left Panel



Figure 3-4 HemoSphere Nano monitor USB/charging port

NOTE	The HemoSphere Nano operates with the Acumen IQ Cuff Adult (AIQCA2), and data can be exported using a USB connection.
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3.3 Initial Screen

Power on the device by pressing the power button until the screen illuminates.

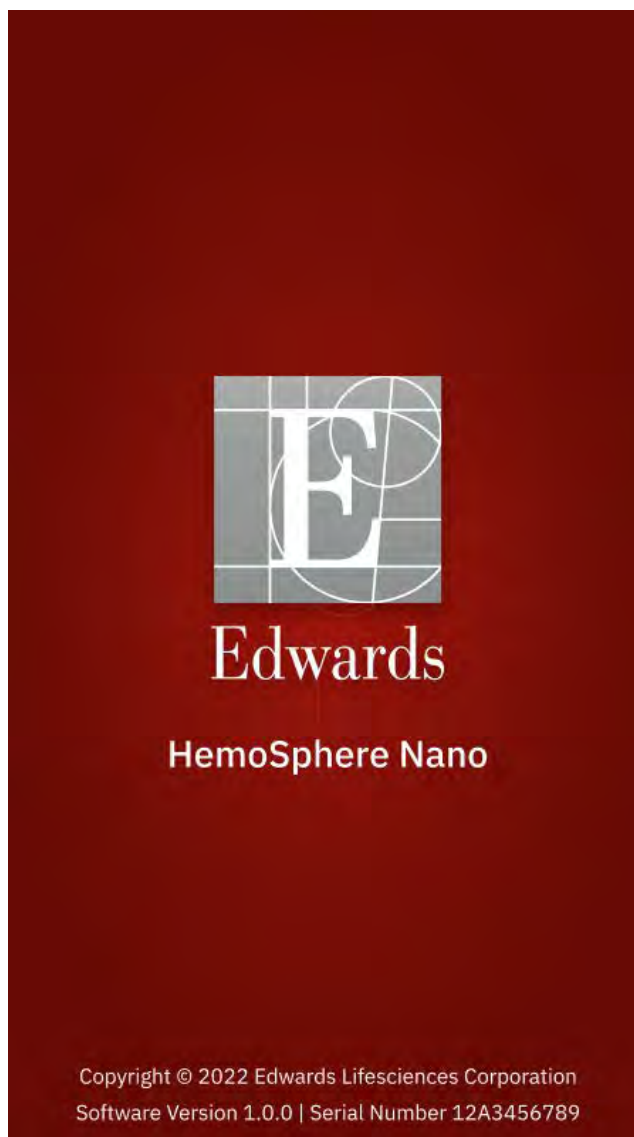


Figure 3-5 Startup screen

NOTE	If the diagnostic tests detect an error condition, a system error screen will replace the startup screen.
-------------	---

Taking a Measurement

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4.1 Preparing the Device for Use

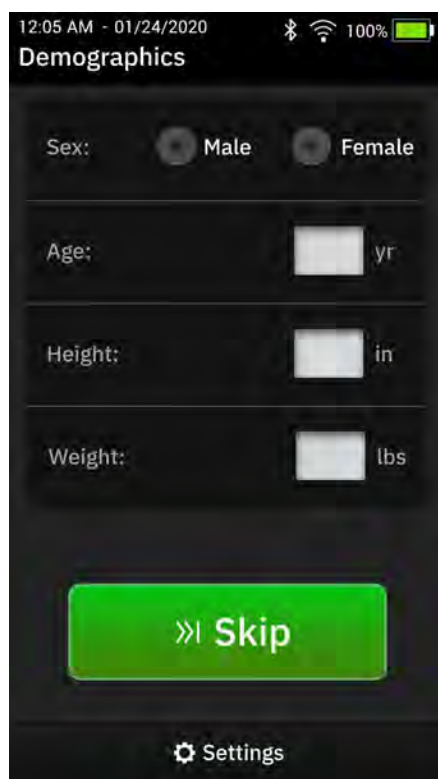
Before using the HemoSphere Nano monitor with a patient, ensure that:

- The device is powered on.
- The battery indicator displays adequate power.
- The Acumen IQ Cuff Adult (AIQCA2) is properly attached to the port.

4.2 Starting a Measurement

To take a measurement on the HemoSphere Nano monitor:

- 1 Enter the patients demographic information or choose **Skip**.
- 2 Select the patient's position – **Seated** or **Supine**.
- 3 Adjust the offset.
- 4 Press **Start** to display the Monitoring screen.
- 5 When monitoring is complete, blood pressure and advanced values are displayed.
- 6 Touch **Press to View Result** to view your severe Aortic Stenosis (sAS) result.
 - Result can be no severe AS detected, additional evaluation recommended, or results inconclusive



12:05 AM - 01/24/2020 100%

Demographics

Sex: ☒ Male ☐ Female

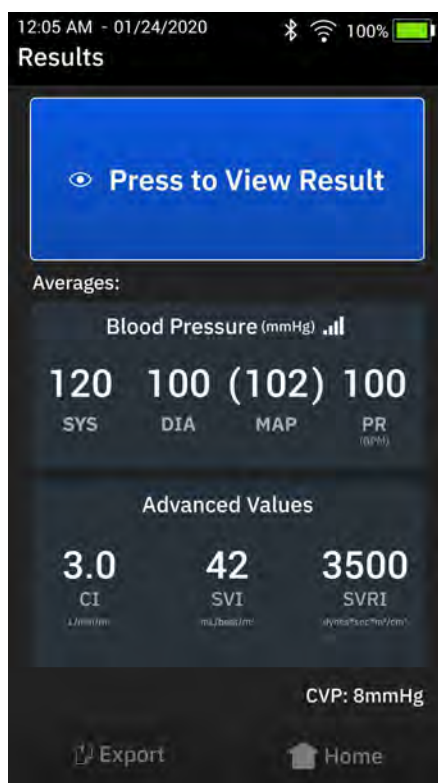
Age: yr

Height: in

Weight: lbs

» Skip

Settings

Figure 4-1 Demographics Screen

12:05 AM - 01/24/2020 100%

Results

Press to View Result

Averages:

Blood Pressure (mmHg)			
120	100	(102)	100
SYS	DIA	MAP	PR (bPM)

Advanced Values

3.0	42	3500
CI	SVI	SVRI
L/min/m²	ml/min/m²	dynes/cm⁵

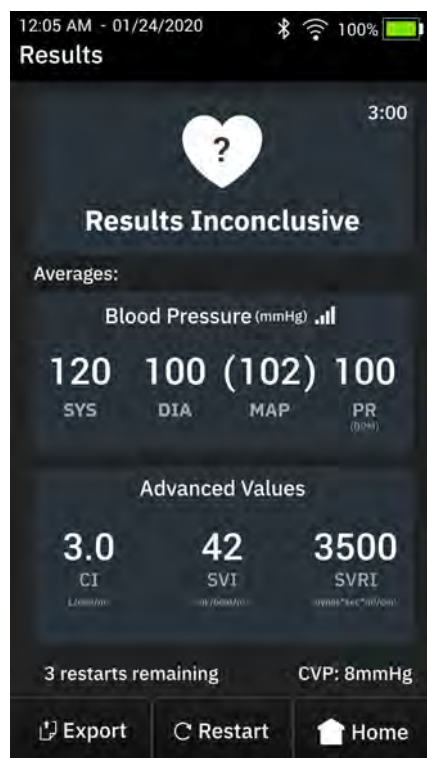
CVP: 8mmHg

Export Home

Figure 4-2 Results Screen

4.3 Ending a Monitoring Session

After you have viewed the results you have the option on ending the session and returning to the home screen (**Home**), exporting the data (**Export**), or restart the monitoring session if the results were inconclusive (**Restart**).



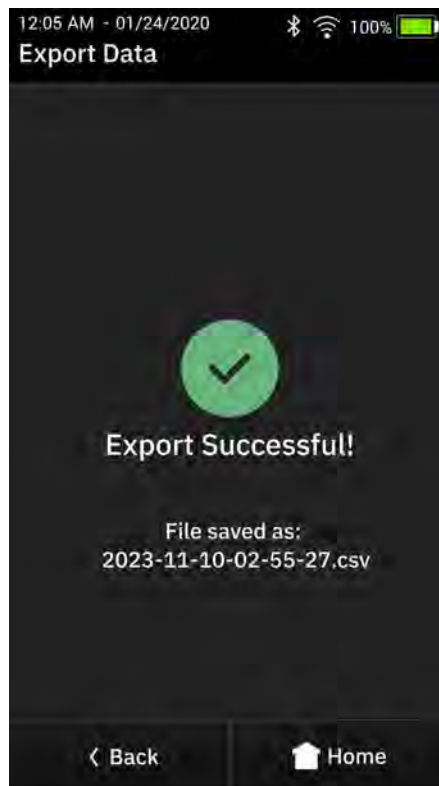
4.3.1 Exporting Data

You can export data to a USB storage device from the HemoSphere Nano monitor.

NOTE Ensure that the USB device is formatted as FAT32.

- 1 Connect a USB device to the HemoSphere Nano monitor's USB 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**), all date (**All**).
- 4 Enter the date range you want to export (if applicable).
- 5 Choose to the exported file type (**CSV** or **PDF**).
- 6 Touch **Export**.

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



Settings

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5.1 System Set Up

The HemoSphere Nano monitor displays the following settings upon initial system start up:

- Date
- Time
- Time format (12hr or 24hr)
- Units (lb/in or kg/cm)
- Manual CVP (0-50mmHg)
- Language

5.2 System Settings

HemoSphere Nano monitor System Settings are accessed by touching **Settings**.

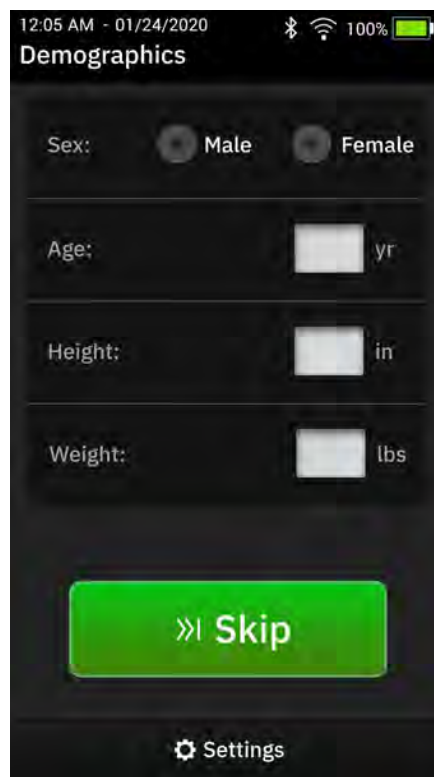


Figure 5-1 Demographics Screen

The HemoSphere Nano monitor allows for configuring the following in System Settings:

- Date
- Date Format (DD/MM/YY or MM/DD/YY or YY/MM/DD)
- Time & format (12HR or 24HR)
- Units (lbs/in or kgs/cm)
- Manual CVP Value (0- 50mmHg)
- Brightness
- Language
- Version (Current version information)
- Export (Export measurement data)
- Demographics (on/off)
- De-Identify (on/off)
- Demo Mode (simulated measurement, cuff not required)

5.3 Demo Mode

Specifications and Device Characteristics

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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 HemoSphere Alta monitor essential performance
– transient and non-transient electromagnetic phenomena**

A.2 HemoSphere Nano monitor Characteristics and Specifications

Table A-2 HemoSphere Nano monitor physical and mechanical characteristics

HemoSphere Alta advanced monitor		
Weight		
Dimensions	Height	
	Width	
	Depth	
Footprint	Width	
	Depth	
Display	Active Area	
	Resolution	1280 x 720
Operating system		
Speaker count		

Table A-3 HemoSphere Nano monitor environmental specifications

Environmental specification	Value
Temperature	0 to 45 °C
Screen temperature (active)	0 to 56 °C
Relative humidity	20 to 85% non-condensing
Altitude (Pressure)	0 to 3000m

Table A-4 HemoSphere Nano monitor transportation environmental specifications

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

Table A-5 HemoSphere Nano monitor technical characteristics

Input/Output	
Touch screen	
USB ports (1)	
Cuff port (1)	
Electrical	
Rated supply voltage	100-240VAC, 50-60Hz
Rated input	0.6A
Fuses	N/A

A.3 HemoSphere Nano Monitor Battery Characteristics and Specifications

Table A-6 HemoSphere Alta Monitor battery technical characteristics

Specification	Value
Output voltage (nominal)	7.20V
Maximum discharge current	4.5A
Cells	2

Monitor Settings and Defaults

B.1 Patient Data Input Range

Table B-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

B.2 Trend Scale Default Limits

Table B-2 Graphical trend parameter scale defaults

Parameter	Units	Minimum default value	Maximum default value	Setting increment	Minimum Gap
SYS	mmHg	0	250	2	
DIA	mmHg	0	250	2	
MAP	mmHg	0	250	2	
CVP	mmHg				
CI	L/min/m ²	1.0	20.0	20	
SVI	mL/b/m ²	0	200	20	
SVRI	dyne-s-m ² /cm ⁵	0	9950	20	

System Care, Service and Support

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C.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 monitor accessories and contains information on how to contact your local representative for support and information on repair and/or replacement.

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

CAUTION Clean and store the instrument and accessories after each use.

CAUTION Follow all cleaning instructions carefully to ensure that the monitor and cables are thoroughly cleaned. After cleaning, inspect the monitor and all accessories for any residue or foreign material. If residue is still visible after cleaning, please repeat the cleaning instructions. Follow any additional cleaning instructions provided by the manufacturer of listed approved cleaning agents.

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

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

CAUTION Do not pour or spray liquid on any portion of the HemoSphere Nano monitor, accessories or cables. Do not use any disinfecting solution other than the types specified.

DO NOT:

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

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

The Nano system allows use of the following agents while maintaining basic functionality:

- Sani-Cloth (ammonium chloride solution wipe, Super Sani-Cloth® Germicidal Disposable Wipe1 or equivalent product)
- 70% IPA
- Diversey Oxivir Tb Disinfectant Wipes:
- Clorox Healthcare Bleach Germicidal – 0.55% Sodium Hypochlorite (NaClO)
- CaviWipes Bleach – <1.5% Sodium Hypochlorite (NaClO)
- Clinell Universal – <0.5% Benzalkonium chloride (C₆H₅CH₂N(CH₃)₂Cl)
- <0.5% Didecyl dimethyl ammonium chloride (C₂₂H₄₈ClN)

C.2 Monitor Disposal

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

For single use parts and accessories, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

C.2.1 Battery Recycling

Replace the HemoSphere battery pack when it no longer holds a charge. After removal, follow your local recycling guidelines.

CAUTION Recycle or dispose of the lithium-ion battery in accordance to all federal, state, and local laws.

C.3 Preventive Maintenance

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

C.4 Warranty

Edwards Lifesciences (Edwards) 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 of merchantability or fitness for a particular purpose. This warranty does not include cables, batteries, probes, or

oximetry cables used with the HemoSphere Nano monitor. Edwards' 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' 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 catheters other than those manufactured by Edwards.

Guidance and Manufacturer's Declaration

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D.1 Electromagnetic Compatibility

Reference: IEC/EN 60601-1-2 Edition 4.1 2020-09

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, all accessory cables listed in table B-1 on page 367 comply with the EMC standards listed above.

D.2 Instructions for Use

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

WARNING

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

No modification of the HemoSphere Nano monitor is allowed.

Portable and mobile RF communication equipment and other sources of electromagnetic disturbance such as diathermy, lithotripsy, RFID, electromagnetic ant-theft systems and metal detectors can potentially affect all electronic medical equipment, including the HemoSphere Nano monitor.

Guidance on maintaining appropriate separation between communications equipment and the HemoSphere Nano monitor is provided in table D-3. The effects of other RF emitters are unknown and may interfere with the function and safety of the HemoSphere Nano monitor.

CAUTION

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

particular installation. If this equipment does cause harmful interference to other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

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

NOTE

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

Table D-1 Electromagnetic emissions

Guidance and Manufacturer's Declaration - Electromagnetic Emissions		
The HemoSphere 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.		
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	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

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

Test Frequency	Band ¹	Service ¹	Modulation ²	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
The HemoSphere Nano monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Nano 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 D-2 Guidance and Manufacturer's Declaration - Immunity to RF wireless communications equipment (continued)

Test Frequency	Band ¹			Maximum Power	Distance	Immunity Test Level
MHz	MHz	Service ¹	Modulation ²	W	Meters	(V/m)
The HemoSphere Nano monitor is intended for use in the electromagnetic environment specified below. The customer or user of the HemoSphere Nano 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 D-3 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the HemoSphere Nano 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 D-4 In band wireless coexistence – Threshold of Interference (Tol) and Threshold of Communication (ToC) between HemoSphere Alta advanced monitor (EUT) in Invasive mode and external devices **PENDING UPDATED DATA**

Test Specifications ¹	Threshold of interference (Tol) or Threshold of Communication (ToC) Results					Extrapolated Interference Thresholds based upon the Intended Signal located 3m away from the HemoSphere advanced monitor							
	Unintended Type and min level	EUT Intended Frequency (EUT)	Frequency of Unintended Signal (MHz)	Unintended Signal Level at EUT (dBm)	I/U Ratio (Tol or ToC)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)
A (Tol)	Tier 3 / 802.11n 64 qam 20MHzAdj Channel 20dBm (TRP/ EIRP)	2437	2412	25.57	3.85	10	15.80	1	5.00	0.1	1.58	0.01	0.50
A (ToC)		2437	2412	47.56	-18.14	10	1.26	1	0.40	0.1	0.13	0.01	0.04
B (Tol)		5200	5180	32.19	-15.81	10	7.37	1	2.33	0.1	0.74	0.01	0.23
B (ToC)		5200	5180	38.53	-22.15	10	3.55	1	1.12	0.1	0.36	0.01	0.11
C (Tol)		5765	5745	28.17	-12.15	10	11.70	1	3.70	0.1	1.17	0.01	0.37
C (ToC)		5765	5745	30.21	-14.19	10	9.25	1	2.93	0.1	0.93	0.01	0.29

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

A. 2.4 Ghz; Ch 6, 2437 (2412-2472) MHz – Invasive Mode

B. 5 GHz, 20 MHz; Ch 40, (5190-5210 [5180-5825] MHz) – Invasive Mode

C. 5 GHz, 20 MHz; Ch 153, (5755-5775 MHz) – Invasive Mode **ADD 6 GHz [5955-7115?]**

Table D-5 In band wireless coexistence – Threshold of Interference (ToI) and Threshold of Communication (ToC) between HemoSphere Alta advanced monitor (EUT) in Non-invasive mode and external devices **PENDING UPDATED**

DATA

Test Specifications ¹	Threshold of interference (Tol) or Threshold of Communication (ToC) Results					Extrapolated Interference Thresholds based upon the Intended Signal located 3m away from the HemoSphere advanced monitor							
	Unintended Type and min level	EUT Intended Frequency (EUT)	Frequency of Unintended Signal (MHz)	Unintended Signal Level at EUT (dBm)	I/U Ratio (Tol or ToC)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)	EIRP (W)	Distance (m)
	Tier 3 / 802.11n 64 qam 20MHzAdj Channel 20dBm (TRP/ EIRP)	2437	2412	24.06	3.05	10	18.80	1	5.94	0.1	1.88	0.01	0.59
		2437	2412	47.96	-20.85	10	1.20	1	0.38	0.1	0.12	0.01	0.04
		5200	5180	36.19	-18.7	10	4.65	1	1.47	0.1	0.47	0.01	0.15
		5200	5180	36.19	-18.7	10	4.65	1	1.47	0.1	0.47	0.01	0.15
		5765	5745	28.18	-12.1	10	11.69	1	3.70	0.1	1.17	0.01	0.37
5765		5745	32.34	-16.26	10	7.24	1	2.29	0.1	0.72	0.01	0.23	

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

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

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

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

Table D-6 Electromagnetic Immunity (ESD, EFT, Surge, Dips and Magnetic Field)

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment - Guidance
The HemoSphere 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	±2 kV for power supply lines	Mains power quality should be that of a typical commercial and/or hospital environment.
	±1 kV for input/output lines > 3 meters	±1 kV for input/output lines > 3 meters	
Surge IEC 61000-4-5	±1 kV line(s) to line(s)	±1 kV line(s) to line(s)	
	±2 kV line(s) to earth	±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply AC input lines IEC 61000-4-11	0% U_T (100% dip in U_T) for 0.5 cycle (0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°)	0% U_T	Mains power quality should be that of a typical commercial or hospital environment. If the HemoSphere 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
<i>Note: U_T is the AC mains voltage prior to application of the test level.</i>			

Table D-7 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 $d = [1.2] \times \sqrt{P}$; 150 kHz to 80 MHz $d = [1.2] \times \sqrt{P}$; 80 MHz to 800 MHz $d = [2.3] \times \sqrt{P}$; 800 MHz to 2500 MHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment with the following symbol: 
Conducted RF IEC 61000-4-6	6 Vrms (ISM band) 150 kHz to 80 MHz	6 Vrms	
Radiated RF IEC 61000-4-3	3 V/m 80 to 2700 MHz	3 V/m	

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HemoSphere 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.

D.3 Wireless Technology Information

The HemoSphere Alta monitor contains wireless communication technology that provides enterprise-class Wi-Fi 6E connectivity. HemoSphere Alta monitor wireless technology supports IEEE 802.11a/b/d/e/g/h/i/k/n/r/u/v/w/ac/ax with a fully integrated security supplicant providing 802.11i/WPA2 Enterprise authentication and data encryption. It supports dual stream Wi-Fi in the 2.4GHz and 5GHz bands as well as Bluetooth 5.0.

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

Table D-8 HemoSphere Alta monitor wireless information

Feature	Description																
Wi-Fi CERTIFIED*	Wi-Fi 4,5																
IEEE WLAN standards	IEEE 802.11a, b, e, g, h, i, k, n, r, v, w, ac																
Type of modulation	BPSK, QPSK, CCK, 16-QAM, 64-QAM, and 256-QAM.																
Supported Radios	802.11b/g/n 2.4GHz (2400.0 – 2483.5 MHz) 802.11a/n/ac 5.2GHz (5150.0 – 5350.0 MHz) 5.6GHz (5470.0 – 5725.0 MHz) 5.8GHz (5725.0 – 5895.0 MHz)																
Security methods	• WEP • WPA and WPA2 (Personal) support for powerful encryption and authentication • AES and TKIP in hardware for faster data encryption and IEEE 802.11i compatibility • Reference WLAN subsystem provides Wi-Fi Protected Setup (WPS). • CKIP																
Wi-Fi Media Access Protocol	Direct Sequence-Spread Spectrum (DSSS) Complementary Code Keying (CCK) Orthogonal Frequency Divisional Multiplexing (OFDM)																
Authentication Protocols	802.1X EAP-TLS EAP-TTLS/MSCHAPv2 PEAPv9-MSCHAPv2 (EAP-SIM, EAP-AKA)																
Encryption	WEP/WPA/TKIP/WPA2 AES-CCMP																
Bluetooth Operation Details	Bluetooth Basic Rate +EDR <table> <tr> <td>Transmit frequency</td> <td>2402 MHz to 2480 MHz</td> </tr> <tr> <td>Receive frequency</td> <td>2402 MHz to 2480 MHz</td> </tr> <tr> <td>Modulation</td> <td>GFSK, $\pi/4$ DQPSK, 8DPSK</td> </tr> <tr> <td>Transmit power</td> <td>7 dBm, e.i.r.p.</td> </tr> </table> Bluetooth Low Energy (BLE) <table> <tr> <td>Transmit frequency</td> <td>2402 MHz to 2480 MHz</td> </tr> <tr> <td>Receive frequency</td> <td>2402 MHz to 2480 MHz</td> </tr> <tr> <td>Modulation</td> <td>GFSK</td> </tr> <tr> <td>Transmit power</td> <td>7 dBm, e.i.r.p.</td> </tr> </table>	Transmit frequency	2402 MHz to 2480 MHz	Receive frequency	2402 MHz to 2480 MHz	Modulation	GFSK, $\pi/4$ DQPSK, 8DPSK	Transmit power	7 dBm, e.i.r.p.	Transmit frequency	2402 MHz to 2480 MHz	Receive frequency	2402 MHz to 2480 MHz	Modulation	GFSK	Transmit power	7 dBm, e.i.r.p.
Transmit frequency	2402 MHz to 2480 MHz																
Receive frequency	2402 MHz to 2480 MHz																
Modulation	GFSK, $\pi/4$ DQPSK, 8DPSK																
Transmit power	7 dBm, e.i.r.p.																
Transmit frequency	2402 MHz to 2480 MHz																
Receive frequency	2402 MHz to 2480 MHz																
Modulation	GFSK																
Transmit power	7 dBm, e.i.r.p.																

Table D-8 HemoSphere Alta monitor wireless information (continued)

Feature	Description
Wi-Fi Operation Details	IEEE 802.11b/g/n WLAN
	Transmit frequency 2412 MHz to 2472 MHz 2422 MHz to 2462 MHz
	Modulation 1024QAM)11b/1Mbps, 11g/6Mbps, HT20/ MCS 0, HT40/MCS 0
	Transmit power 16.5 dBm, e.i.r.p.
	IEEE 802.11a/n/ac WLAN
	Transmit frequency 5180 MHz to 5700 MHz 5190 MHz to 5670 MHz 5210 MHz to 5610 MHz
	Transmit power 16 dBm e.i.r.p.
Wi-Fi Operation Details (continued)	IEEE 802.11ax WLAN
	Transmit frequency 5995 MHz to 6415 MHz (20 MHz) 5965 MHz to 6405 MHz (40 MHz) 5985 MHz to 6385 MHz (80 MHz) 6025 MHz to 6345 MHz (160 MHz)
	Receive frequency 5995 MHz to 6415 MHz (20 MHz) 5965 MHz to 6405 MHz (40 MHz) 5985 MHz to 6385 MHz (80 MHz) 6025 MHz to 6345 MHz (160 MHz)
	Modulation OFDMA (1024QAM)
	Transmit power 22.8 dBm e.i.r.p.
Security	• WEP • WPA and WPA2 (Personal) support for powerful encryption and authentication • AES and TKIP in hardware for faster data encryption and IEEE 802.11i compatibility • Reference WLAN subsystem provides Wi-Fi Protected Setup (WPS). • CKIP

Table D-8 HemoSphere Alta monitor wireless information (continued)

Feature	Description
Compliance	ETSI Regulatory Domain EN 300 328 EN 60950-1 EN 300 328 v1.8.1 (BT 2.1) EN 55022:2006 Class B EN 301 489-1 EN 55024:1998 +A1:2001, A2:2003 EN 301 489-17 EN 61000-3-2:2006 EN 301 893 EN 61000-3-3:1995 +A1:2001, A2:2005 EN 301 489-3 EU 2002/95/EC (RoHS) FCC Regulatory Domain (Certification ID: PD9AX210D2) Industry Canada (Certification IC ID: 1000M-AX210D2) MIC (Japan) (Certification ID: )  003-200255 5.15-5.35GHz Indoor use only (Exempt communicate to high power radio) D200217003 RF: 003-200255 TEL: D200217003 KC (Korea) (Certification ID: R-C-INT-AX210D2W) NCC (Taiwan) (Certification ID:  CCAH20Y10090T9) acma (Australia)  ANATEL (Brazil) (Certification ID:  04022-21-04423) China (CMIIT ID: 2020AJ15108(M))
Certifications	Wi-Fi Alliance 802.11a, 802.11b, 802.11g, 802.11n WPA Enterprise WPA2 Enterprise Cisco Compatible Extensions (Version 4) FIPS 140-2 Level 1 Linux 3.8 running on 45 Series Wi-Fi Module with ARM926 (ARMv5TEJ) - OpenSSL FIPS Object Module v2.0 (validation certificate #1747)
Antenna Type	Chip Antenna
Antenna Dimensions	**

D.3.1 Quality of Service for Wireless and Wired Technology

Quality of service (QoS) is specified in terms of total data loss for a normal connection where the HemoSphere Alta monitor is operating at medium wireless signal strength or higher (NEED TABLE) with good network connection. HemoSphere Alta monitor wireless data transmission has been validated to have less than 5% total data loss under these conditions. HemoSphere Alta monitor wireless technology has an effective range of 150 feet, line of sight and 75 feet, non-line of sight. The effective range might be affected due to the presence of other wireless emitters.

The HemoSphere Alta monitor supports data transmission via a wired or wireless connection. All data transmitted is expected to be acknowledged by the receiving system. Data is resent if not sent successfully. The HemoSphere Alta monitor automatically tries to re-establish any HIS or Viewfinder hub connections that are interrupted. If a pre-existing connection cannot be reestablished, the HemoSphere Alta monitor alerts the user with an audible alert and message (**Alert: HIS Connectivity Loss.** [see table 14-6] or Viewfinder hub connectivity error messages [see NEED TABLE]).

CAUTION The wireless Quality of Service (QoS) may be influenced by the presence of other devices that create radio frequency interference (RFI). Such RFI devices may include electrocautery equipment, cellular telephones, wireless PC and tablets, pagers, RFID, MRI, or other electrically powered devices. When used in the presence of potential RFI devices, consideration should be taken to maximize separation distances and to observe for any potential signs of interference such as loss of communication or reduced Wi-Fi signal strength.

D.3.2 Wireless Security Measures

The wireless signals are secured using industry standard wireless security protocols (table D-8). Wireless security standards WEP and WPA have been shown to be vulnerable to intrusions and are not recommended. Edwards recommends securing wireless data transmission by enabling IEEE 802.11i (WPA2) security and FIPS mode. Edwards also recommends implementing network security measures like virtual LANs with firewalls to further secure HemoSphere Alta monitor data in transit to the HIS.

D.3.3 Troubleshooting Wireless Coexistence Issues

The instrument has been tested and complies with the limits of IEC 60601-1-2. If you experience communication issues with HemoSphere Alta monitor wireless technology, ensure a minimum distance between portable and mobile RF communications equipment (transmitters) and the HemoSphere Alta monitor are maintained. Refer to table D-3 for additional details on separation distances.

D.3.4 Federal Communication Commission (FCC) Interference Statements

NOTE To comply with FCC RF exposure compliance requirements, the antenna used for this transmitter must be installed to provide a separation distance of at least 20 cm from all persons and must not be co-located or operating in conjunction with any other antenna or transmitter.

Federal Communication Commission Interference Statement

This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- 1 Reorient or relocate the receiving antenna.
- 2 Increase the separation between the equipment and receiver.
- 3 Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- 4 Consult the dealer or an experienced radio/TV technician for help.

CAUTION Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This device is restricted to *indoor* use when operated in the 5.15 to 5.25 GHz frequency range.

FCC requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems.

This device does not permit operations on channels 116-128 (5580 – 5640 MHz) for 11na and 120-128 (5600-5640 MHz) for 11a which overlap the 5600 -5650 MHz band.

NOTE	FCC Radiation Exposure Statement: This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body.
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D.3.5 Industry Canada Statements

RF Radiation Hazard Warning

To ensure compliance with FCC and Industry Canada RF exposure requirements, this device must be installed in a location where the antennas of the device will have a minimum distance of at least 20 cm from all persons. Using higher gain antennas and types of antennas not certified for use with this product is not allowed. The device shall not be co-located with another transmitter.

Maximum Antenna Gain – If the integrator configures the device such that the antenna is detectable from the host product.

This radio transmitter (IC ID: 3147A-WB45NBT) has been approved by Industry Canada to operate with the antenna types listed below with the maximum permissible gain and required antenna impedance for each antenna type indicated. Antenna types not included in this list, having a gain greater than the maximum gain indicated for that type, are strictly prohibited for use with this device.

“To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (EIRP) is not more than that required for successful communication”

“This device has been designed to operate with an antenna having a maximum gain of [4] dBi. Antenna having a higher gain is strictly prohibited per regulations of Industry Canada. The required antenna impedance is 50 ohms.”

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

CAUTION	Industry Canada requires this product to be used indoors for the frequency range 5.15 to 5.25 GHz to reduce the potential for harmful interference to co-channel Mobile Satellite systems.
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D.3.6 European Union Radio Equipment Directive (RED) Statements

This device complies with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED). The following test methods have been applied in order to prove presumption of conformity with the essential requirements of the 2014/53/EU – Radio Equipment Directive (RED):

- **EN 62368-1:2014/A11:2017**
Safety requirements for audio/video, information, and technology equipment
- **EN 300 328 V2.2.2: (2019-07)**
Electromagnetic compatibility and Radio Spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive
- **EN 62311:2008 | EN 50665:2017 | EN 50385:2017**
RF exposure
- **EN 301 489-1 V2.2.0 (2017-03)**
Electromagnetic compatibility and Radio Spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- **EN 301 489-17 V3.2.0 (2017-03)**
Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for 2,4 GHz wideband transmission systems and 5 GHz high performance RLAN equipment
- **EN 301 893 V2.1.1 (2017-05)**
Electromagnetic compatibility and Radio spectrum Matters (ERM); Broadband Radio Access Networks (BRAN); Specific conditions for 5 GHz high performance RLAN equipment
- **EU 2015/863 (RoHS 3)**
Declaration of Compliance – EU Directive 2015/863; Reduction of Hazardous Substances (RoHS)

This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

Hereby, Edwards Lifesciences, declares that this monitor is in compliance with the essential requirements and other relevant provisions of Directive 2014/53/EU (RED).

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

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