GE HealthCare

Portrait™ VSM Vital Signs Monitor

User's Manual

Software Version 1.0

CE 0197

5975000-EN-US
Revision 2
English

Notice

The information in this manual applies to the software version listed on the first page of the manual. Due to continuing product innovation, specifications in this manual are subject to change without notice.

Revision history

Revision	Date	Reason for change
1	2024-3-15	Initial release.
2	2024-4-25	Update the graphical plots for SpO_2 specifications and add Symbols glossary.

Contents

Standards and Regulations

Standards compliance

The system complies with the following standards.

- IEC 60601-1: General safety standard for medical devices
- IEC 60601-1-2: EMC safety standard
- IEC 80601-2-49: Particular safety standard for multifunction patient monitoring equipment
- IEC 60601-1-6: Usability safety standard
- IEC 62366-1: Application of usability engineering to medical device
- EN/ISO 14971: Application of risk management analysis to medical device
- IEC 62304: Software life cycle processes
- The alarm systems of the monitor conform to IEC 60601-1-8.
- The SpO_2 parameter conforms to ISO 80601-2-61.
- The NIBP parameter conforms to IEC 80601-2-30 and ISO 81060-2.
- The temperature parameter conforms to ISO 80601-2-56 and ASTM E1112-00.

IEC 60601-1

Monitor

- Type of protection against electrical shock: Class I. Internally powered ME equipment.
- Degree of protection against electrical shock: applied parts are marked with a symbol indicating degree of protection.
- Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide: Not suitable.
- Degree of protection against harmful ingress of water: IP22.
- Mode of operation: Continuous.
- Method(s) of sterilization or disinfection recommended by the manufacturer: see the Instructions for Use.
- Portable monitor.

EU Medical Device Regulation

Classification in accordance with the Regulation (EU) 2017/745 concerning Medical Devices: Class IIb

- The CE Mark CE-0197 indicating its conformity with the provisions of the Regulation (EU) 2017/745 concerning Medical Devices. The country of manufacture can be found on the equipment labeling.

CISPR 11

Classification in accordance with the CISPR (International Special Committee on Radio Interference) 11: Group 1, Class A.

- Group 1 contains all ISM (Industrial, scientific and medical) equipment in which there is intentionally generated and/or used conductively coupled radio-frequency energy which is necessary for the internal functioning of the equipment itself.
- Class A equipment is equipment suitable for use in all establishments other than domestic and those directly connected to a low-voltage power supply network which supplies buildings used for domestic purposes.

FCC

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.

   NOTE
   Harmful interference means interference which endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with the International Telecommunications Union (ITU) Radio Regulations.

2. This device must accept any interference received, including interference that may cause undesired operation.

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

Please notice that if the FCC identification number is not visible when the module is installed inside another device, then the outside of the device into which the module is installed must also display a label referring to the enclosed module. This exterior label can use wording such as the following: "Contains FCC ID:OU5VSM01". Any similar wording that expresses the same meaning may also be used.

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 cm between the radiator and your body. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The module is limited to OEM installation ONLY.

The OEM integrator is responsible for ensuring that the end-user has no manual instruction to remove or install module.

The module is limited to installation in mobile applications.

A separate approval is required for all other operating configurations, including portable configurations with respect to Part 2.1093 and different antenna configurations.

There is a requirement that the grantee provide guidance to the host manufacturer for compliance with Part 15B requirements.

Radio Equipment Directive

The wireless network feature of the monitor bears a CE mark indicating its conformity with the provisions of the Radio Equipment Directive 2014/53/EU.

The CE mark can be found from the monitor's labeling.

GE Medical Systems *Information Technologies*, Inc. hereby, declares that the radio equipment type device is in compliance with Directive 2014/53/EU. Only indoors usage is permitted with 5150 to 5350 MHz WLAN.

The full text of the EU DoC is available at the following internet address: https://www.gehealthcare.com/documentationlibrary

CE manufacturer and EU Representative

Manufacturer name and address	European authorized representative
	
GE Medical Systems *Information Technologies*, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA	GE Medical Systems SCS 283 Rue de la Miniere 78530 BUC, France

CE marking application year

CE marking application year: 2023.

About this manual

Intended use of this manual

This manual is an integral part of the device and describes its intended use. It should always be kept in a place accessible to users, and information indicating that place should be available close to the equipment. Observance of the manual is mandatory for proper performance and correct operation and ensures patient and user safety. Information which refers only to certain versions of the product(s) is accompanied by the model number(s) of the product(s) concerned. The model number is given on the device plate of the product.

Use the manual for important safety information and detailed instructions for clinical use of these products. Devices and versions not specifically stated are not supported and should not be used.

As the monitor configuration may vary, some menus, displays and functions described may not be available in the monitor you are using.

Intended audience of this manual

This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology required to provide patient care. Using the device should never replace nor impede the human intervention and required patient care provided by clinical professionals.

This manual is also intended for service representatives and technical personnel who install, maintain, troubleshoot, or repair this device.

Manual conventions

This manual uses the following styles to emphasize text or indicate action.

Item	Description
`Courier`	Indicates hardware terms.
bold	Indicates software terms.
italic	Indicates terms for emphasis.
select	The word select means choosing and confirming.
supplemental information	Indicates information that appears in the supplements provided.
NOTE	Note statements provide application tips or other useful information.

Naming conventions

In this manual, the following naming conventions are used:

- Portrait^{TM} HUBXB, Mobile Patient Monitor Hardware: Hub
- Portrait^{TM} HSWXB, Mobile Patient Monitor Software: Hub

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all system settings, features, configurations, or displayed data.

Names of persons, institutions, and places and related information are fictitious; any similarity to actual persons, entities, or places is purely coincidental.

Related documents

- Portrait™ VSM Vital Signs Monitor Technical Manual
- Supplies and Accessories
- Portrait Network Infrastructure - Enterprise Configuration Guide
- HL7 Reference Manual
- Privacy and Security Manual
- B1X5-REC Recorder Instruction for Use
- B1X5-REC Recorder Service Manual
- Portrait™ Mobile Monitoring Solution User Manual
- Wireless LAN Network Configuration Guide

Ordering manuals

Paper copies of the medical device IFU will be provided within 7 days of receiving the request, at no additional cost. Contact your local GE HealthCare representative and request the part number on the first page of the eIFU.

Accessing manuals online

To obtain the latest version of the manual:

1. Go to https://www.gehealthcare.com/documentationlibrary.
2. Enter the Customer Documentation Portal.
3. Select **Modality** > **Monitoring Solutions (MS)**.
4. Select **Products** > the products you want to search.

   You may also select the **Document Type** and **Language** to narrow down the search.
5. Launch the search.
6. Identify and download the manual.

The manuals are in PDF format. Make sure that your viewing device (for instance, computer) has software to open the PDF files (for instance, Adobe® Acrobat® Reader).

Security related documents can be downloaded from https://securityupdate.gehealthcare.com.

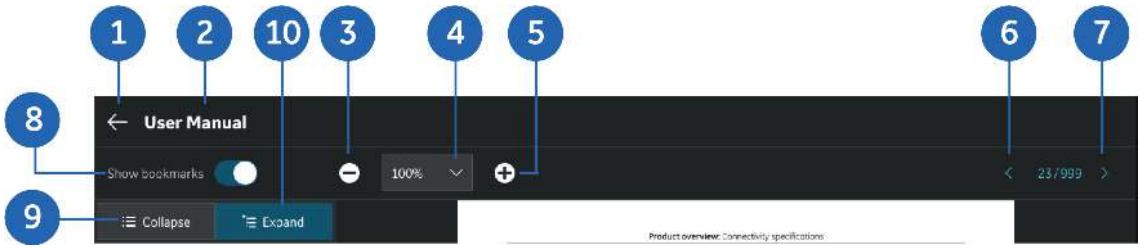
Accessing manuals on monitor

To access manuals on monitor:

1. Press the `On/Off` button (more than 3 seconds) to turn on the monitor.
2. Select the **Configurations** > **E-Manual** tab.
3. Select **View** for the relevant manual.

Using E-manuals on monitor

The E-manual can be navigated from the top of the menu.



1.	←	Return to the **E-Manual** menu.
2.	User Manual (**User manual**)	Title of the selected manual
3.	⊖	Zoom out
4.	∨	Select the key to open the list of all display scales.
5.	⊕	Zoom in
6.	<	Turn to previous page
7.	>	Turn to next page
8.	Show bookmarks (**Show bookmarks**)	Select or to display or hide bookmarks.
9.	Collapse (**Collapse**)	Collapse bookmark
10.	Expand (**Expand**)	Expand bookmark

1. Swipe down and up to scroll the page.
2. Select ⊖ or ⊕ or ∨ to set the scale.
3. Select < or > to turn pages.
4. Select **Show bookmarks** or to display or hide the bookmark on the left.
5. Select to collapse bookmark.
6. Select to expand bookmark.

Trademarks

Portrait and Round Advisor are trademarks of GE HealthCare.

GE and GE Monogram are trademarks of General Electric Company used under trademark license.

DINAMAP is trademark of General Electric Company or one of its subsidiaries used under trademark license.

Third party trademarks

Masimo and SET are trademarks of Masimo Corporation.

Covidien, Nellcor and OxiMax are trademarks of Medtronic.

HL7 is a registered trademark of Health Level Seven (HL7), Inc.

Welch Allyn and SureTemp Plus are trademarks of Welch Allyn, Inc.

Exergen and TAT-5000S-USB are trademarks of Exergen Corporation.

HeTaida is the trademark of HeTaida Technology Company.

All other third-party trademarks are the property of their respective owners.

Manufacturer responsibility

GE HealthCare is responsible for the effects on safety, reliability, and performance of the equipment only if:

- Assembly operations, extensions, readjustments, modifications, servicing, or repairs are carried out by authorized service personnel.
- The electrical installation of the relevant room complies with the requirements of the appropriate regulations.
- The equipment is used in accordance with the instructions for use.

Product availability

NOTE
Due to continual product innovation and design, specifications for these products are subject to change without notice.

Some of the products mentioned in this manual may not be available in all countries. Please consult your local representative about availability.

Safety and intended use

Safety message signal words

Safety message signal words designate the severity of a potential hazard.

DANGER

Indicates a hazardous situation that, if not avoided, will result in death or serious injury.

WARNING

Indicates a hazardous situation that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.

NOTICE

Indicates a hazardous situation not related to personal injury that, if not avoided, could result in property damage.

System safety

System safety messages apply to the entire system. Safety messages specific to parts of the system are found in the relevant section.

System warning safety messages

The following warning safety messages apply to this monitoring system.

Indications for use warnings

WARNING

PATIENT SAFETY.

Read all the safety information before using the device for the first time. This manual contains instructions necessary to operate this device safely and in accordance with its functions and intended use. This manual is intended for clinical professionals. Clinical professionals are expected to have a working knowledge of medical procedures, practices and terminology, as required for the monitoring of all patients.

WARNING

SINGLE PATIENT USE.

This equipment is designed for use on one patient at a time. Using this equipment to monitor different parameters on different patients at the same time compromises the accuracy of data acquired.

WARNING

INSTRUCTIONS FOR USE.

For continued safe use of this equipment, it is necessary that the listed instructions are followed. However, instructions listed in this manual in no way supersede established medical practices concerning patient care.

WARNING

INTRAHOSPITAL TRANSPORT.

Vibrations during intrahospital transport may disturb SpO_2 and NIBP measurements.

Accessories warnings

WARNING

PATIENT SAFETY.

Single-use products are not designed to be reused. Reuse may cause a risk of cross-contamination, affect the measurement accuracy and/or system performance, and cause a malfunction as a result of the product being physically damaged due to cleaning, disinfection, re-sterilization and/or reuse.

WARNING

PATIENT SAFETY.

Use only approved accessories. For a list of approved accessories, see the Supplies and Accessories provided. Other accessories may cause a safety hazard, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system or interfere with the measurement.

WARNING

ELECTRIC SHOCK.

Only use protected patient cables with this device. The use of unprotected patient cables creates the potential for making an electrical connection to ground or to a high voltage power source, which can cause serious injury or death to the patient.

WARNING

PATIENT SAFETY.

When using any supply or accessory, make sure that you are familiar with their use to avoid any risk to the patient. For detailed instructions and information regarding supplies and accessories, always refer to their own instructions for use.

Cables warnings

WARNING

CABLES.

Route all cables away from patient’s throat to avoid possible strangulation.

WARNING

CABLES.

Route all cables in such a way that they are not under the patient to avoid the risk of possible pressure sores.

WARNING

PERSONAL INJURY.

To avoid personal injury to users or any other persons moving in the vicinity of the cables or tubing, route all cables and tubing in such a way that they do not present a tripping hazard.

WARNING

SAFETY GROUND.

Remove power cord from the mains source by grasping the plug. Do not pull on the cable.

Defibrillation warnings

WARNING

ELECTRIC SHOCK.

To avoid the risk of electric shock, do not touch the patient, table, bed, instruments, or system parts during defibrillation.

WARNING

DEFIBRILLATOR PRECAUTIONS.

Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cable and sensor.

Electrical warnings

WARNING

POWER SUPPLY.

Always connect the device power cable to a properly installed power outlet with protective earth contacts before connecting any other interface cables. If the integrity of the protective earth conductor is in doubt, disconnect the monitor from the power line. If the installation does not provide for a protective earth conductor, disconnect the monitor from the power line after having disconnected all other interface cables. All devices of a system must be connected to the same power supply circuit. Devices which are not connected to the same circuit must be electrically isolated when operated.

WARNING

EXCESSIVE LEAKAGE CURRENT.

Do not use a multiple socket outlet or extension cord. A failure in a multiple socket outlet or extension cord may cause increased leakage current when many devices are sharing the same multiple socket outlet or extension cord.

WARNING

EXCESSIVE LEAKAGE CURRENT.

To avoid summation of leakage currents when interfacing the device with other equipment, the devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer’s instructions for use, and system standards IEC 60601-1 clause 16, and the requirements of the local authorities must be complied with.

WARNING

EXCESSIVE TOUCH CURRENT.

To avoid excessive patient leakage current, do not simultaneously touch the patient and the electrical connectors in the monitor, or within the module housing or frame.

WARNING

INTERFACING OTHER EQUIPMENT.

Connect only items that are specified as part of the system and as compatible.

WARNING

INTERFACING OTHER EQUIPMENT.

Devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC60601-1 must be complied with.

WARNING

ELECTRIC SHOCK.

To avoid the risk of electric shock, do not under any circumstances remove the grounding conductor from the power plug. Always check that power cord and plug are intact and undamaged.

WARNING

EQUIPMENT DAMAGE.

If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply and have the equipment serviced by qualified service personnel. Otherwise, there is a risk of damage to the equipment.

WARNING

DISCONNECTION FROM MAINS.

When disconnecting the device from the power line, remove the plug from the wall outlet first. Then you may disconnect the power cord from the device. If you do not observe this sequence, there is a risk of coming into contact with line voltage by inserting metal objects into the sockets of the power cord by mistake.

EMC warnings

WARNING

EMC.

Other equipment may interfere with the system, even if that other equipment complies with CISPR emission requirements.

WARNING

ESD.

Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless electrostatic discharge (ESD) precautions are used.

WARNING

EQUIPMENT DAMAGE AND PATIENT SAFETY.

Do not use the device in high electromagnetic fields (for example, during magnetic resonance imaging).

WARNING

EMC.

Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Changes or modifications to this device/system not expressly approved by GE HealthCare may cause EMC issues with this or other equipment. This device/system is designed and tested to comply with applicable standards and regulations regarding EMC and needs to be installed and put into service according to the EMC information stated as follows: This device/system 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. Mains power should be that of a typical commercial or hospital environment. Device is compliant to Class A.

WARNING

ERRONEOUS READINGS.

The device/system should not be used adjacent to, or stacked with, other equipment. Consult qualified personnel regarding device/system configuration.

WARNING

DEGRADED PERFORMANCE.

Do not use portable RF communications equipment (including peripherals such as antenna cables and external antennas) closer than 30 cm (12 inches) to any part of this device/system, including cables specified by the manufacturer. Otherwise, the performance of this device/system may degrade.

System warnings

WARNING

EXPLOSION.

Do not use this system in the presence of flammable anesthetics, vapors or liquids.

WARNING

PATIENT SAFETY.

If an error message appears during operation, it is the licensed medical practitioner's responsibility to decide whether the device is still suitable for patient monitoring. As a general rule, monitoring should only continue in extremely urgent cases and under the direct supervision of a licensed healthcare practitioner. The device must be repaired before being used again on a patient. If an error message appears after power-up, the device must be repaired before being used on a patient.

WARNING

PATIENT SAFETY.

If the monitor is dropped, have it checked by qualified service personnel before taking it back into use.

WARNING

PATIENT SAFETY.

To avoid risks to patient safety, never modify or alter the connectors on product or accessories in any way. Alterations or modifications may affect patient safety, performance, and accuracy.

Site requirement warnings

WARNING

BEFORE INSTALLATION.

Compatibility is critical to safe and effective use of this device. Verify the compatibility of all system components and device interfaces, including hardware and software versions, prior to installation and use.

System caution safety messages

The following caution safety messages apply to this monitoring system.

Indications for use cautions

CAUTION

PRESCRIPTION DEVICE.

U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION

SUPERVISED USE.

This equipment is intended for use under the direct supervision of a licensed healthcare practitioner.

Loss of data

CAUTION

LOSS OF DATA.

Should the monitor at any time temporarily lose patient data, the potential exists that active monitoring is not being done. Close patient observation or alternate monitoring devices should be used until monitor function is restored. If the monitor does not automatically resume operation within 60 seconds, power cycle the monitor using the On/Off button. Once monitoring is restored, you should verify correct monitoring state and alarm function.

Electrical caution

CAUTION

POWER REQUIREMENTS.

Before connecting the device to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the device's label. If this is not the case, do not connect the system to the power line until you adjust the device to match the power source. In U.S.A., if the installation of this equipment will use 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit. This equipment is suitable for connection to public mains as defined in CISPR 11.

EMC cautions

CAUTION

DEGRADED PERFORMANCE.

Use of known RF sources, such as cell/portable phones, RFID, electronic article surveillance (EAS) systems, diathermy, or other radio frequency (RF) emitting equipment near the system may cause unexpected or adverse operation of this device/system. Consult qualified personnel regarding device/system configuration.

Site requirement cautions

CAUTION

LOSS OF MONITORING.

Leave space for circulation of air to prevent the device from overheating. The manufacturer is not responsible for damage to device caused by improperly vented cabinets, improper or faulty power, or insufficient wall strength to support device mounted on such walls.

Disposal cautions

CAUTION

DISPOSAL.

At the end of its service life, the product described in this manual, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of each product. If you have any questions concerning disposal of a product, please contact GE HealthCare or its representatives.

CAUTION

PACKAGING DISPOSAL.

Dispose of the packaging material, observing the applicable waste control regulations.

Notice safety messages

The following notice safety message applies to this monitoring system:

NOTICE

The warranty does not cover damages resulting from the use of accessories and consumables from other manufacturers.

ESD safety precautions

- To avoid electrostatic charges building up, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or greater.
- To prevent applying a possible electrostatic charge to the ESD-sensitive parts of the equipment, touch the metallic frame of the component or a large metal object located close to the equipment. When working with the equipment and specifically when the ESD-sensitive parts of the equipment may be touched, a grounded wrist strap intended for use with ESD-sensitive equipment should be worn. See the documentation provided with the wrist straps for details of proper use. Floors should be covered by ESD-dissipative carpets or similar. Non-synthetic clothing should be used when working with the component.

Indications for use

The Portrait VSM vital signs monitor is intended to monitor a single patient's vital signs at the site of care or during intra-hospital transport.

The noninvasive oscillometric blood pressure parameter is intended for measurement of systolic, diastolic, and mean arterial blood pressure, as well as pulse rate, for adult, pediatric and neonatal patients.

The optional GE TruSignal pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO_2) and pulse rate, including monitoring during conditions of clinical patient motion or low perfusion, with adult, pediatric and neonatal patients.

The optional Masimo SET® pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO_2) and pulse rate, during both no motion and motion conditions, and for patients who are well or poorly perfused (low perfusion) for adult, pediatric and neonatal patients.

The optional Nellcor™ pulse oximetry and accessories are indicated for the continuous noninvasive monitoring of functional Oxygen Saturation (SpO_2) and pulse rate of adult, pediatric, and neonatal patients during both motion and non-motion conditions, and for patients who are well or poorly perfused.

The optional Welch Allyn® SureTemp® Plus electronic thermometer is intended to measure one of oral, axillary, and rectal temperature of adult and pediatric patients.

The optional Exergen TemporalScanner thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

The optional HeTaiDa electronic infrared non-touch thermometer is intended for the intermittent measurement of human body temperature of patients of all ages.

A wireless network connection is provided to transmit clinical data into various hospital information systems. An optional remote alarm cable connection is intended to complement visual and audible alarms and not replace the need for the presence of a caregiver.

The portable device is designed for use in hospitals and hospital-type facilities. The Portrait VSM vital signs monitor can also be used in satellite areas or alternate care settings.

The Portrait VSM vital signs monitor is intended for use under the direct supervision of a licensed health care practitioner.

The Portrait VSM vital signs monitor is not intended for use during MRI.

"Portable" refers to the ability of the Portrait VSM vital signs monitor to be easily moved by the caregiver, such as on a roll stand.

Clinical benefits

- The device enables acquisition and transmission of the patient's data during patient care.
- Real time physiological parameters monitoring benefits the patient and helps the clinical professional evaluate the patient's condition and aid in timely patient care decisions when needed.
- Secure and accurate transmission of a patient's data between a patient monitor and clinical information systems benefits the patient through reliable patient data management.

Intended users

The device is intended to be used in healthcare facilities by clinical professionals or under their guidance.

The device is intended to be serviced by qualified biomedical engineers or other qualified service engineers.

Contraindication

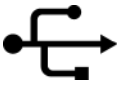
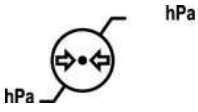
The Portrait VSM is not indicated for use during MRI.

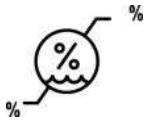
Equipment symbols

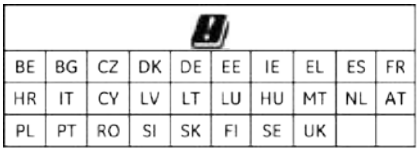
For user interface keys and symbols, please refer to "Monitoring basics" chapter.

For a list of product-related symbols with their standard references, see the Symbols glossary on page 253 at the end of this manual.

	General warning sign.
	Caution. Highlights the fact that there are specific warnings or precautions associated with the device.
	Warning. Electric shock hazard. This equipment must be serviced by qualified service personnel only. ISO 7010. This symbol is identified by a yellow background, black triangular band, and a black symbol.
	Follow instructions for use.
 eIFU indicator	Consult electronic instructions for use.
	Electrostatic sensitive device. Connections should not be made to this device unless ESD precautionary procedures are followed.
	Non-ionizing electromagnetic radiation. Interference may occur in the vicinity of this device.
	Type BF (IEC 60601-1) defibrillator-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, excluding direct cardiac application.
	Type CF (IEC 60601-1) defibrillator-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application.
	Protective earth ground. Connectors grounded to the AC power source.
	Power On/ Standby key.

	On the front cover: power indicator. On the back cover: alternating current.
	On the front cover: battery indicator.
	Equipotentiality. Connect device to a potential equalization conductor.
X1	Recorder connector.
X4	Nurse call connector.
	USB connector.
	Ethernet connector.
HDMI	HDMI connector.
IP22	Degree of ingress protection (on monitor).
	Date of manufacture, and Country of manufacture. The first four digits identify the year, the following two digits identify the month, and the last two digits identify the day. The alpha-3 characters in the center identify the country code.
	Manufacturer name and address.
REF	Catalog or orderable part number.
SN	Device serial number.
#	Device model number or type number.
UDI	Every device has a unique marking for identification. The UDI marking appears on the device label.
	Atmospheric pressure limitations.
	Temperature limitations.

	Humidity limitations.
	Keep dry. Protect from rain.
	Fragile. Handle with care.
	This way up.
	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment. The separate collection symbol is affixed to a battery, or its packaging, to advise you that the battery must be recycled or disposed of in accordance with local or country laws. To minimize potential effects on the environment and human health, it is important that all marked batteries that you remove from the product are properly recycled or disposed of. For information on how the battery may be safely removed from the device, please consult the service manual or equipment instructions.
	Recycled materials or may be recycled.
	Recyclable lithium-ion.
	European authorized representative.
	Swiss authorized representative.
	European Union Declaration of Conformity.
Rx Only U.S.	Prescriptive Device. USA only. For sale by or on the order of a Physician.
	The National Recognized Testing Laboratory (NRTL) mark. Indicates that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.

ANATEL	Brazil only. Approved under ANATEL (Agência Nacional de Telecomunicações) requirements.
CMIIT ID	China only. China Ministry of Industry and Information Technology identification number for Radio Transmission Equipment Type Approval.
	Australia and New Zealand only. Regulatory Compliance Mark (RCM). Indicates compliance with electrical safety, EMC, electromagnetic energy, and telecommunications requirements applicable to each product.
	This product is restricted to indoor use. Restricted Member States as below: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE) and United Kingdom (UK).
	Korea only. Approved under KCC (Korea Communications Commission) requirements. This device has been evaluated to use in a business environment, and there is a risk of radio interference if used in a home environment.
	Philippines only. The product complies with the NTC (National Telecommunications Commission) requirements.
	Malaysia only. Malaysian Communication and Multimedia Commission (MCMC) certification mark.
	South Africa only. Approved under ICASA (Independent Communications Authority of South Africa) requirements.
	Brazil only. INMETRO certificate.
	MR Unsafe. Indicates that the device is not intended for use in an MR environment.
	This product is a medical device.
	Indicates medical USB.
	Indicates NIBP connector.
	Indicates SpO_2 connector.

Temp	Indicates temperature connector.

Unique Device Identifier (UDI)

	Unique Device Identifier. (UDI) Every medical device has a unique marking for identification. The UDI marking appears on the device labeling. Note that this is only an example of a UDI marking. The device may have a DataMatrix code as in this example, or a linear bar-code, or only alphanumeric identifiers with no barcode. Identifi-ers also vary per product.

The characters used in the UDI marking represent specific identifiers. In the example above:

Device identifier:

- (01) = GS1 global trade item number (GTIN) of the device.
- 01234567123456 = Global trade item number.

Production identifiers:

- (21) = GS1 application identifier for the serial number of the device.
- XYZ12345678XY = Serial number.
- (11) = GS1 application identifier for the manufacturing date of the device.
- 180718 = Manufacturing date: year-month-day (YYMMDD).

Note that for some product types, the production identifier can have other elements instead of the ones listed above:

- (10) = GS1 application identifier for the batch or lot number, followed by the batch or lot number.
- (17) = GS1 application identifier for the expiration date of the device, followed by the expiration date.

Country of origin

Country of origin: refer to the device label.

Serious incident reporting

Any serious incident related to the use of this GE HealthCare device, should be reported to both the manufacturer and the health authority/competent authority where the device is installed.

To report to GE HealthCare:

- Either contact your local service representative
- Or report to: In-box.complaints@ge.com

Please provide the following information:

- The catalogue number or the model designation of the device as stated on its identification plate affixed on the device
- The System ID/serial number/lot number of the device

- Date of incident
- Description of incident, including any patient or user impact/injury
- Your contact information (facility, address, contact name, title, and telephone number)

Training requirements

No product-specific training is required for the use of this device.

Residual risks

There are no specific residual risks for this device. The risk mitigations such as instructions, warnings, and cautions provided within the product manuals have disclosed the risks properly and allow for safe and effective use of the device.

System introduction

System safety precautions

System warnings

WARNING

PATIENT SAFETY.

Never install the equipment above the patient to avoid the risk of any part of the equipment falling on the patient.

WARNING

INACCURATE RESULTS.

Do not use or store the equipment outside the specified temperature, humidity, or altitude ranges, or outside the specified performance range. Using or storing the equipment outside the specified operating environment or outside the specified performance range may cause inaccurate results.

WARNING

PHYSICAL INJURY.

Take care when mounting devices to an IV pole. If a device is mounted too high, the IV pole may become unbalanced and tip over.

WARNING

EXCESSIVE LEAKAGE CURRENT.

A display or printer that is a non-medical grade device and is used within the patient environment, must always be powered from an additional transformer providing at least basic isolation (isolating or separating transformer). Using without an isolating transformer could result in unacceptable enclosure leakage currents.

WARNING

ELECTRIC SHOCK.

Do not touch the electrical connector located within the module housing or frame to avoid the risk of electric shock.

WARNING

ELECTRIC SHOCK.

Always unplug the grounded data cables when not in use. Leaving them connected could result in an electric shock from the ground contact in the other end.

WARNING

EXPLOSION OR FIRE.

Using non-recommended batteries could result in injury/burns to the patients or users. Only use batteries recommended or manufactured by GE HealthCare. The warranty can be voided if non-recommended batteries are used.

WARNING

EXPLOSION HAZARD.

Do not incinerate a battery or store at high temperatures. Serious injury or death could result.

WARNING

MISSED ALARMS.

Do not connect a single-color display to the monitor. Visual alarm indicators may not appear properly.

WARNING

EQUIPMENT DAMAGE.

To prevent liquids from entering the monitor, do not tilt the monitor more than +/-15 degrees.

WARNING

MISSED ALARMS.

Secondary displays will not sound the audible alarms. Keep the patient under close surveillance.

System caution

CAUTION

RF EXPOSURE.

To comply with the FCC RF exposure requirements, the monitor with the wireless network (WLAN) option must be operated with a separation distance of 20 cm or more from a person’s body.

Short description of the equipment

The device is equipped with a 10-inch wide-screen LCD touch display that measures the most commonly used patient vital signs: Non-invasive Blood Pressure (NIBP), Pulse Rate (PR), Temperature (Temp), and Pulse Oxygen Saturation (SpO_2). At the same time, the device also supports early warning score calculation and manually entering clinical observations.

The device supports two kinds of clinical mode: **Spot Check** mode and **Monitoring** mode.

The device supports sending measured or manually entered patient data to Electronic Medical Record (EMR) systems by interfacing with Hospital Information Systems (HIS) over a wired or wireless network.

Product configurations

The following table shows all the optional product configurations and whether they need a license or not.

√: License is required.

Configuration	License
GE TruSignal SpO_2	√
Masimo SpO_2	√
Nellcor SpO_2	√
Welch Allyn Temperature	License is not needed.
Exergen Temperature	
HeTaida Temperature	
Wi-Fi	√
Early Warning Score	√
PDQ Patient Query	√
PCD-01 Outbound	√
LDAP Caregiver Validation	√
Cerner iBus/Cloud	√
Round Advisor	√

NOTE
The device must be pre-configured with one of three selectable SpO_2 technologies before leaving the factory.

System overview

The system can be used within the patient environment as long as an additional transformer providing at least basic isolation is used with non-medical grade secondary displays and printers.

NOTE
It is not recommended that the system be connected to other non-isolated monitoring equipment or communication networks. In such cases, it is the end user's responsibility to ensure compliance with IEC60601-1 or other IEC standards.

Front view

1.	Alarm light	3.	Power LED
2.	On/Off key	4.	Battery LED

Left side view

1.	Transportation handle	3.	SpO_2 connector
2.	Two medical USB connectors (reserved for future use)	4.	NIBP connector

Right side view

1.	USB connector	4.	**X1** recorder connector
2.	HDMI connector	5.	Welch Allyn temperature module (optional)
3.	Ethernet connector	6.	Welch Allyn temperature holder (optional)

NOTE
If necessary, you can use the optional Welch Allyn temperature holder for cable management.

Back view

1.	Receptacle for power cord	3.	**X4** nurse call connector
2.	Equipotential connector	4.	Two USB connectors

Monitor battery

The device is designed to operate on battery power when used in transport or whenever AC power is interrupted. The lithium-ion battery is a rechargeable battery containing lithium-ion cells.

The LED indicators on the monitor's front panel indicate whether the monitor is being used on battery or mains power, and also whether the battery is charging, full or missing:

Front panel indicator	Meaning
Power LED	Monitor is operating on mains power.
Battery LED	Green lit. Monitor is operating on battery power.
	Orange flashing. Battery failure.
	Orange lit. Battery is charging. The indicator goes off when the battery is fully charged.

Checking the battery charge with monitor software

You can check the monitor battery status using the monitor software:

1. Select the battery charge symbol. See Monitor battery charge symbols on screen on page 42.
2. Check the battery status that appears. You can find the **Remaining time**, battery **Quality**, **Maximum capacity (%)** and current **Capacity percent (%)** in this menu.

Monitor battery charge symbols on screen

You can check the battery charge level from the monitor battery symbol on the right upper corner of the display.

Screen symbol	Meaning
	Battery capacity is between 87.5% ~ 100%.
	Battery capacity is between 62.5% ~ 87.5%.
	Battery capacity is between 37.5% ~ 62.5%.
	Battery capacity is between 12.5% ~ 37.5%.
	Battery capacity is between 0% ~ 12.5%.
	Monitor battery is missing.
	Monitory battery failure.
	Monitor battery is charging and current battery capacity is between 0% ~ 12.5%.
	Monitor battery is charging and current battery capacity is between 12.5% ~ 37.5%.

Screen symbol	Meaning
	Monitor battery is charging and current battery capacity is between 37.5% ~ 62.5%.
	Monitor battery is charging and current battery capacity is between 62.5% ~ 87.5%.
	Monitor battery is charging and current battery capacity is between 87.5% ~ 100%.

Compatible devices

Compatibility

Devices and versions not specifically stated have not been verified and validated as comprising a conforming system with the monitor.

In the following section, compatible devices refer to devices that have been verified to be compliant with the standard IEC 60601-1. Supported devices refer to devices that are compatible with the system, but have not been verified to meet the recent standard requirements.

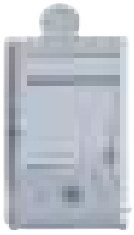
Devices and versions listed as supported only: refer to their original user and technical documentation.

For the list of monitor-compatible supplies and accessories, refer to the Supplies and Accessories.

Input-output device

The following graphics are used for illustration purpose.

Device	Graphic	Description
Display device (Supported device)		External display The monitor has an HDMI port for a commercial display, whose resolution should be 1280*800.
Data collection device (Supported device)		USB storage device (file system: FAT32) To save and load logs and settings.
Input device (Supported device)		USB barcode reader Used to scan information from barcodes when you admit patient, login caregiver, or load parameters data from the Hub.

Device	Graphic	Description
Input device (Compatible device)		Portrait™ HUBXB hardware with Portrait™ HSWXB software The monitor can capture patient information and parameter values displayed on Hub through QR code scanning when they are used on the same patient. For more information, see Scanning QR code from the Hub in the Portrait™ Mobile Monitoring Solution on page 70.
Printing device (Compatible device)		B1X5-REC recorder in local

Network compatibility

The monitor is capable of Hospital Information System (HIS) connectivity over a wired or wireless network.

The following connectivity options are available for using the monitor with an HIS.

Item	Version	Description
PDQ (Patient Demographics Query)	HL7 v2.5	The device queries patient demographics from server using the HL7 v2.5.
PCD-01	HL7 v2.6	The device sends patient data to server using the HL7 v2.6.
EMR Gateway Pro	V2	The device achieves the PDQ inbound and PCD-01 outbound using the EMR Gateway Pro.
LDAP (Lightweight Directory Access Protocol)	V3	The device validates caregiver identity from HIS using the LDAP.
Cerner iBus (traditional)	V6.5.3 and above	The device integrates with Cerner server using the Cerner iBus (traditional or cloud): • patient demographics query • caregiver authentication • outbound patient measurement data
Cerner iBus Cloud	No regulation	

Monitoring basics

Operation safety precautions

Operation warnings

WARNING

PATIENT SAFETY.

After transferring or reinstalling the device, always check that it is properly connected and all parts are securely attached. Otherwise, there may be a risk of equipment falling on the patient and causing injury.

WARNING

ACCURACY.

If the accuracy of any value displayed on the monitor, or printed on a graph strip is questionable, determine the patient's vital signs by alternative means. Verify that all equipment is working properly.

WARNING

PATIENT SAFETY.

If you accidentally drop any of the system parts, have them checked by qualified service personnel prior to clinical use. Using damaged equipment may lead to risks of erroneous readings, missed alarms, or misinterpretation of monitoring data, and therefore result in compromised patient safety.

WARNING

PATIENT SAFETY.

Do not use the monitor without manufacturer approved mounting attached. Otherwise, there may be a risk of the monitor falling on the patient and causing injury, or falling on the floor and getting damaged.

WARNING

INACCURATE RESULTS.

After transport or storage of the device outside the specified operating temperature range, always allow the device to stabilize back to operating temperature range before applying power to it. Using the device outside the specified operating environment may result in inaccurate results.

Monitor installation points to note

- To avoid electrostatic charges building up, it is recommended to store, maintain and use the equipment at a relative humidity of 30% or greater. Floors should be covered by ESD-dissipative carpets or similar ESC-dissipative products. Non-synthetic clothing should be used when working with the component.
- Choose a location that offers an unobstructed view of the display and easy access to the operating controls, including power cord or connectors at the monitor. Position the equipment so that access to disconnection via appliance coupler or mains plug is easy and unobstructed.
- Set up the monitor in a location that affords sufficient ventilation. The ventilation openings of the device must not be obstructed (by equipment, walls, or blankets, for example).
- The environmental operating conditions specified in the technical specifications must be ensured at all times.
- The system is designed to comply with the requirements of IEC 60601-1.
- Using the power cord supplied with the device, connect it to the power line. Use only the original cord.
- We recommend connecting the system to the potential equalization system (IEC 60601-1) to ensure equal potential levels between the devices in the system. Use the green and yellow potential equalization cable and connect it to the pin labeled with the equipotential symbol: ⏚.
- For instructions regarding unpacking and how to proceed if the packaging has been damaged, unintentionally opened, or exposed to environmental conditions outside those specified, see the Technical Manual.

Connecting and removing parts

Connecting the B1X5-REC recorder

1. Using the recorder connector line, connect the recorder connector to **X1** on the right side of monitor.
2. When the monitor is powered on, make sure the power indicator on recorder is lit.

Inserting the B1X5-REC recorder

NOTE
It's recommended to mount the recorder on a roll stand, or a wall mount bracket through their insertion guides.

1. Align the recorder to the insertion guides.
2. Push down the recorder until it clicks.

Removing the recorder

NOTE
If the recorder is mounted on the roll stand, remove the top basket first, refer to the roll stand's instructions.

1. Disconnect the recorder connector line.
2. If necessary, pull the recorder upwards by the tab. Make sure not to drop it when it comes out.

Connecting to the mains power

1. Connect power cords to a wall outlet and to the mains power supply inlet on all system components that require AC mains power input.
2. Secure all power cords by routing through the retaining clips, as applicable.

NOTE
Before taking the monitor into use for the first time, the battery should be fully charged. Keep the monitor connected to the mains until the battery charge symbol disappears.

Connecting the RFID beacon

The RFID beacon is a small, coin cell beacons which to be affixed to the device for asset tracking. It has ultra-low RF transmit powers for increased locate accuracy and improved performance in high density deployments.

See the Supplies and accessories for part number to re-order.

1. Take off the adhesive sticker at the back of the RFID beacon.
2. Attach the RFID beacon to the back side of monitor.

User interface keys

Various functions of the monitor can be accessed through the monitor's soft keys on screen.

	**Home** • Close all menus displayed on the monitor and return to the normal screen.
	**Patients & Records** Open **Patients & Records** menu to: • View and manage (send or print) historical data of multiple patients • View numerical trends of single patient • View alarm history of single patient • View and manage (send or print) reports • Edit patient demographics.
	**Configurations** Open **Configurations** menu to: • Access **Parameter Setup** menu for parameter settings. • Access **Monitor Setup** menu to set up monitor settings. • Access **Advanced** menu (password protected) to set up clinical and service advanced settings. • Access **E-Manual** menu to view the electronic manuals.

	**Alarm Setup** Open **Alarm Setup** menu to: • Set up alarm limits and status (On/Off) • Adjust alarm volume • Audio pause, audio off or reactivate alarms • Set up alarm priorities
	**Round Advisor** (Spot Check mode only) Open **Round Advisor** menu to: • Start a ward round spot check • Set up ward round patient group
	**Next** (Spot Check mode only): • Move to the **Report** menu.
	**Send** (Spot Check mode only): • Send patient information and measurement data to EMR when the device has the PCD-01 or Cerner iBus/Cloud license. Or **Save** (Spot Check mode only): • Save patient information and measurement data to local device when there is no PCD-01 or Cerner iBus/Cloud license.
	On the system status area, open secondary menu to: • Audio pause active alarms. • Reactivate alarms. In Observations window, open the **Observations** full window to: • View all the observations in use. • Set up related observation items.
	**Audio pause** • Audio pause active alarms.
	Acknowledge • Acknowledge active alarms.
	Mode Switch • Shift between Spot Check mode and Monitoring mode.
	**Login** Open **Login** menu, you can: • Enter caregiver information manually to log in a caregiver.
	**Log out** Select the key to log out the current caregiver.
	Lock • Select the key to lock the screen.
	Battery icon with 87.5% ~ 100% capacity (for example). The battery icon varies with different capacities and on different statuses (charging, failure or missing). Refer to the Monitor battery charge symbols on screen on page 42 for the full list of battery icons. • Check battery status, including current capacity percent, remaining time, quality and maximum capacity.

	Select the icon to show the detailed information.
	**Admit New** Open **Admit New** menu, you can: • Enter / load patient information, to admit a patient.
	**Discharge** • Discharge current patient.
	**Edit** • Edit patient information. Or: • Edit start time and **Reminding interval when overdue**. (**Round Advisor** menu only)
	Calendar • Open the calendar menu to select a date.
	**Start** or **Cancel** (Spot Check mode only) Or **Start manual** or **Cancel** (Monitoring mode only) • Start or stop a single NIBP measurement.
	**Start cycling** or **Stop cycling** (Monitoring mode only) • Start or stop an auto NIBP measurement.
	**Cycling settings** (Monitoring mode only) • Set up the cycle interval.
	Password Show • Show the password when entered. Or Vital Signs Show • Show details of vital signs data.
	Password Hide • Hide the password when entered. Or Vital Signs Hide • Hide detail of vital signs data.
	Close • Exit the current menu.
	Sort • Sort the data in ascending or descending order.
	Ascending • Present the data in ascending order.
	Descending • Present the data in descending order.

	Filter • Filter the data by pre-configured options.
	Filtered • Change the filter previously set.
	Report View the report of one single record.
	**Print** • Print the report or selected record(s).
	**To current caregiver** • Associate the selected record(s) with current caregiver.
	**Trends** • View numerical trends of a single patient.
	**Stop printing** • Stop the current printing process.
	Snail icon • Switch to the Monitor-mode temperature measurement when the predictive measurement is complete with Welch Allyn temperature technology.
	Back • Return to the previous menu.
	Zoom in (in E-manual view) • Adjust the display scale
	Zoom out (in E-manual view) • Adjust the display scale
	Collapse bookmark (in E-manual view) • Collapse the bookmark of the current manual
	Expand bookmark (in E-manual view) • Expand the bookmark of the current manual
	Next checking time function is turned on. • View the **Next checking time** details and **Adjust checking time** if necessary.
	**Adjust checking time** • Adjust checking time for the next ward round spot check.
	Next checking time is overdue. Open the menu to: • View **Checking time** • Select **Remind me later** • Select **Start new round**

	**Remove all from my patients** • Remove all the patients from **My patients** group.
	Delete (on-screen keyboard)
	Return (on-screen keyboard)
	Collapse (on-screen keyboard)
	Shift (on-screen keyboard)
	Caps Lock (on-screen keyboard)
	Language (on-screen keyboard)

User interface symbols

The following symbols appear in the software user interface.	
	Audio alarms off indicator. Displays on the system status area when all audio alarms are turned off.
	Alarm off indicator. Displays in the parameter window in Spot Check mode to indicate no physiological alarms are supported, or in Monitoring mode when physiological alarms are turned off.
	Audio alarms acknowledge indicator. Displays in the message field and indicates that alarms are acknowledged.
	Audio alarms pause indicator. Displays on the system status area and indicates that alarms are audio paused.
	Alarm volume indicator. Displays beside the alarm volume setup option.
	Sound volume indicator. Displays in the Monitor Setup menu and indicates that the sound volume is turned off.
	Sound volume indicator. Displays in the Monitor Setup menu and indicates that the sound volume is low.
	Sound volume indicator. Displays in the Monitor Setup menu and indicates that the sound volume is medium.
	Sound volume indicator. Displays in the Monitor Setup menu and indicates that the sound volume is high.

The following symbols appear in the software user interface.	
	General warning sign. Displays in the caregiver login menu.
	General error sign. Displays in the caregiver and patient login menu.
	Indicates adult or pediatric patient has been admitted.
	Indicates neonatal patient has been admitted.
	Caregiver information indicator.
	Information point sign. Identifies a place where information may be found.
	Search box indicator.
	Screen brightness indicator.
	Locked indicator. Indicates the screen has been locked.
	Unlocked indicator. Indicates the screen is unlocked.
	WLAN signal strength. The number of colored segments corresponds to the signal strength: four segments indicate strong signal, one segment weak signal.
	Ethernet connected indicator.
	No network connected indicator.
	Patient sit indicator. Displays in the selection list of **Position** for NIBP measurement.
	Patient stand indicator. Displays in the selection list of **Position** for NIBP measurement.
	Patient prone indicator. Displays in the selection list of **Position** for NIBP measurement.
	Patient supine indicator. Displays in the selection list of **Position** for NIBP measurement.

The following symbols appear in the software user interface.	
●●●	Other options indicator. Displays in the selection list of **Position** for NIBP measurement.
	Adult or pediatric patient indicator. Displays in the selection list of **Site** for NIBP measurement.
	Neonatal patient indicator. Displays in the selection list of **Site** for NIBP measurement.
	Left side of patient. Displays at the left side of the patient image.
	Right side of patient. Displays at the right side of the patient image.
	Finger indicator. Displays in the selection list of **Site** for SpO_2 measurement.
	Toe indicator. Displays in the selection list of **Site** for SpO_2 measurement.
	Nose indicator. Displays in the selection list of **Site** for SpO_2 measurement.
	Earlobe indicator. Displays in the selection list of **Site** for SpO_2 measurement.
	Oral indicator. Displays in the selection list of **Site** for Welch Allyn temperature measurement.
	Axillary indicator. Displays in the selection list of **Site** for Welch Allyn temperature measurement.
	Rectal indicator. Displays in the selection list of **Site** for Welch Allyn temperature measurement.
	Notification success indicator. Displays in the message field and indicates that the data has been sent successfully to EMR.
	Filtered indicator. Displays in the **Patients & Records** menu and indicates that the displayed records have been filtered.
	Sent success indicator. Displays in the **Patients & Records** menu and indicates that the patient record has been sent successfully.
	Sent failure indicator. Displays in the **Patients & Records** menu and indicates that the patient record has been failed to send.

The following symbols appear in the software user interface.	
	Sending indicator. Displays in the **Patients & Records** menu and indicates that the patient record is being sent.
	NIBP progress bar. Indicates the amount of time remaining until the next automatic measurement.
	Multiple selection indicator.
	High priority alarm indicator.
	Medium priority alarm indicator.
	Low priority alarm indicator.

Main screen layout

This manual uses the following illustration as an example of main screen layout. The layout varies depending on the EWS license and settings for Observations.

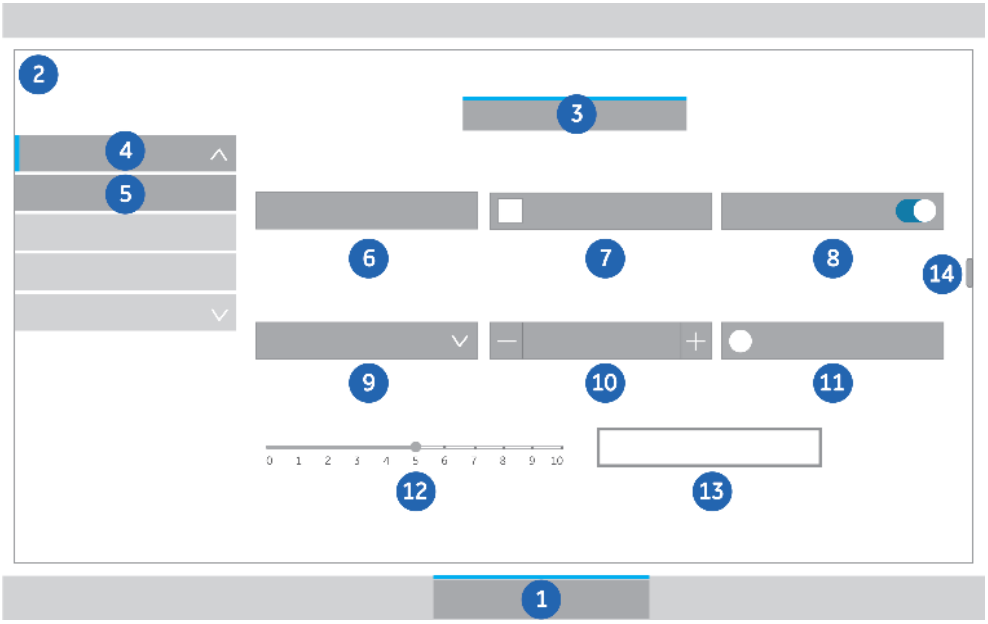
1.	Clinical mode area	Indicate the current clinical mode: **Spot Check** mode or **Monitoring** mode. Select this area to change clinical modes. See Changing clinical mode on page 65 for more information.
2.	Message field	Display alarms and system messages. The physiological alarms are active only in Monitoring mode.
3.	Caregiver information area	Display login information of caregiver. Select this area to log the caregiver in or out.
4.	System status area	Select the keys to audio pause / reactivate alarms, lock the screen, view the battery status, network status, current system time, and check next checking time if the function is enabled in Round Advisor.
5.	Patient information area	Display patient information, including patient ID, **Location**, **Visit number**, **Gender**, **Type**, **Age** and **Date of birth**. **NOTE** The patient ID can be configured in the **Advanced** menu (password protected). The choices are **Patient ID**, **MRN**, **SSN**, **Account number**, **Health card**. Select **Admit New** to admit a new patient manually or from HIS. Select **Edit** to edit the patient information. Select **Discharge** to discharge the current patient manually.
6.	Parameter window(s)	Display parameter measurement information, such as parameter values and waveform. Allow user to enter temperature and RR values manually with the on-screen keyboard. In NIBP parameter window, you can also start or stop NIBP measurement.
7.	Observations window	Select the custom defined fields to manually enter clinical observations.

8.	Early Warning Score (EWS) window	Display current EWS protocol type (for example, NEWS2) and the score based on the data gathered. EWS is an optional, license-based feature.
9.	Main menu area	Provide tabs to navigate within the user interface. Selecting the tab can trigger related functions. The **Round Advisor** tab is available only when the monitor has a Round Advisor license.
10.	Send / Save / Next key	The key is only displayed in Spot Check mode. This key changes according to the PCD-01/Cerner iBus license and settings in the **Advanced** menu (password protected).

Menu layout

NOTE
Not all menus have these same components.

The following is an example of a menu illustrating some of the components and how they are referred to in this manual:



1.	Main menu tab: to navigate within the user interface.
2.	Menu title (for example, **Configurations**)
3.	First-level horizontal tab (for example, **Advanced**)
4.	Second-level vertical tab (for example, **Clinical**)
5.	Third-level vertical tab (for example, **Alarm Settings**)
6.	Button: to initiate an actionable function.
7.	Check box: to select or deselect a feature.
8.	Toggle: to enable or disable a feature.
9.	Selection list: when selecting the arrow, a list of options appears.
10.	Plus / Minus spinner: to increase or decrease a value.
11.	Radio button: to select one of the available features.
12.	Sliding scale: to increase or decrease a value.
13.	Edit box: to enter or edit the text.
14.	Vertical scroll bar: to present contents on more than one page.

Menu options

Select the following main menu tabs to open the related menu.

- **Home**: close all menus displayed on the monitor and return to the normal screen.
- **Patients & Records**: view and manage the historical data.
- **Configurations**: access the menus of **Parameter Setup**, **Monitor Setup**, **Advanced** and view **E-Manual**.
- **Alarm Setup**: view and adjust alarm limits, audio and priorities.

- **Round Advisor**: start a ward round spot check. The tab is available only when the monitor has a Round Advisor license.

Selecting menu options with a touchscreen

NOTE
Do not use pencils, pens, or other sharp objects to activate the touchscreen. The touchscreen will not function properly if tape, paper, or liquid is stuck to the display surface.

1. Touch the menu option with your finger.
2. Lift your finger off the screen, and the selected function is performed (e.g., a list opens).

Entering data

When data entry is required, the monitor automatically displays an on-screen keyboard for you to use.

1. Select the desired data field.
2. Enter data:
   - Select the characters with the touchscreen.

Locking the screen

You can turn the touchscreen feature off when you need to clean the screen.

1. Select on the system status area.
2. Swipe **Lock touchscreen** to to enable this feature.
3. To unlock the screen: touch and hold the **Unlock** button for 3 seconds.

Turning the monitor on/off

The monitor is preset at the factory for a specific AC voltage. Before applying power, be sure that the power requirements match your power supply. Refer to the label on the device for voltage and current requirements.

1. Ensure all cables are properly connected.
2. Turn on the power:

   Press the `On/Off` button (more than 3 seconds).

   The welcome screen will appear.
3. Turn off the power:

   Press the `On/Off` button (more than 3 seconds).

   The message "**Monitor is shutting down...**" will appear on the screen.

Automatically turn off the monitor

When the monitor is not connected to the mains AC power, and the battery remaining time is less than 3 minutes, the monitor will automatically turn off.

NOTE
There is technical alarm when monitor battery is low or empty.

Setting up password at first time to use

When first time turn on the monitor, the password setup wizard will be displayed on the screen. You need to set up all the monitor's passwords.

There are 2 ways to set up password: from USB disk to import setting file, or set up manually.

Please consult qualified and trained technical users to set up. For more information about password management, refer to the Technical Manual.

Performance check

After turning on the monitor, and during operation, the monitor runs automatic self-tests. If a malfunction is detected, the monitor displays a message or an alarm, depending on the severity of the malfunction.

Mains supply interruption

If the mains supply to the equipment is interrupted, the monitor keeps the patient data and the latest user-made settings. If not, contact authorized service personnel.

Setting up the monitor before use

About configurations

The monitor configurations have two levels of access:

- General settings by any user.
- Advanced settings by qualified and trained technical users only (including biomedical engineers, service personnel and IT professionals). These settings are for advanced configuration, calibration and maintenance of the monitor. To access these settings, select the **Configurations** > **Advanced** (password protected) > **clinical** or **service** vertical tab.

  Instructions for the advanced settings are provided in the Technical Manual.

About the user default settings

The monitor provides different factory default settings to accommodate the varying patient types. You can change some settings and then save the changed settings as user default settings.

The user default settings control the following configurations:

- **Alarm Setup**
- **Parameter Setup**
- **Monitor Setup**: only alarm volume, **Completed NIBP volume** and **Completed Temp volume**.

The monitor can save the user default settings to the patient types: **Adult / Pediatric** or **Neonatal**. Each patient type can have unique settings. When you admit a patient, make sure you select the correct patient type. The default patient type is **Adult / Pediatric**. The monitor will reload the user default settings if patient is discharged or patient type is changed.

For information regarding how to set up the user default settings and change the default patient type, consult qualified and trained technical users. For more information, refer to the Technical Manual.

Normal screen

Whenever the home icon is selected, the system will return to the normal screen.

Changes in the **Configurations** settings and a different clinical mode will affect the screen display.

Adjusting sound volumes

You can adjust various sound volumes according to your care environment needs. While you are adjusting the volume, you will hear a corresponding sound that will guide you in determining a suitable level.

NOTE
Alarm volume cannot be set to 0.

1. Select the **Configurations** > **Monitor Setup** > **Sound & Brightness** vertical tab.
2. Adjust following sound volumes with the sliding scale.
   - **High, medium & low priority alarm volume**: display only when **Common for all** is selected in the **Advanced** menu (password protected)
   - **High & medium priority alarm volume** and **Low priority alarm volume**: display only when **Separate for low** is selected in the **Advanced** menu (password protected)
   - **Completed NIBP volume**
   - **Completed Temp volume** (display only when Welch Allyn temperature technology is used)
   - **Round Advisor reminding volume** (display only when the device has Round Advisor license)
   - **RR reminding volume** (a reminder beep when the RR timer reaches 15 s or 30 s)

Adjusting the display brightness

You can set the display brightness level according to your needs.

1. Select the **Configurations** > **Monitor Setup** > **Sound & Brightness** vertical tab.
2. Select the **Screen brightness type**.
3. When the **Screen brightness type** is set to **Manual**, adjust the **Screen brightness** with the sliding scale.
4. When **Screen brightness type** is set to **Auto**, the display adjusts screen brightness automatically according to the ambient light.

Setting parameters

1. Select the **Configurations** > **Parameter Setup**.
2. Select each parameter to adjust the settings.

The device also has some quick settings in the related parameter window. For details about these settings, refer to the parameter's chapter.

Advanced setup changes

The following are advanced clinical settings that are password protected.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

- Workflow settings
- Alarm settings
- Parameter settings (Units and Colors)
- Observations settings
- EWS settings (Early Warning Score protocols)
- Date and time
- Print settings

Starting and ending monitoring

Starting and ending safety precautions

Starting and ending warnings

WARNING

MISSED ALARMS.

There are no physiological alarms in Spot Check mode. When you use Spot Check mode to monitor a patient, there is a risk of missed alarms.

WARNING

DELAYED SPOT CHECK.

When using Round Advisor, do not soley rely on the **Next checking time**, as there is a risk of delayed spot check.

WARNING

MISSED ALARMS.

When starting to monitor a patient, always make sure that you select the correct patient type. The patient type will affect the user default settings for **Alarm Setup**. If you select a wrong patient type to admit, there is a risk of missed alarms.

Starting and ending caution

CAUTION

PATIENT DISCHARGE.

When you take measurements for a new patient, ensure the previous patient has been discharged.

About clinical modes

The monitor has two clinical modes: **Spot Check** mode and **Monitoring** mode.

The Spot Check mode is intended for intermittent examinations, while the Monitoring mode is intended for continuous monitoring. Physiological alarms are only active in the Monitoring mode. For details about how to change the clinical mode, see Changing clinical mode on page 65.

The factory default clinical mode is the Spot Check mode.

Spot Check measurement workflow

The following is an overview of Spot Check measurement workflow for use with the monitor. The list of steps below is a representation of procedures covered in the different sections. Read the manual to get familiar with everything necessary for effective and safe use of the device.

It is not mandatory to follow these steps in sequence. Always consider your professional healthcare facility guidelines as well.

1. Turn on the device.
2. Prepare for monitoring, see Pre-monitoring checklist on page 65.
3. Ensure the device is in **Spot Check** mode.
4. Log in the caregiver.
5. Admit a new patient. Or you can use the Round Advisor feature for patient admittance, see About Round Advisor on page 71.
6. Take measurements.
7. Enter observations manually and read EWS score (if configured).
8. Send or save the data.
9. Review and manage the historical data.
10. Move to the next patient and repeat from Step 5.

NOTE
If you need to confirm report before sending or saving the data in Spot Check mode, consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

NOTE
In Spot Check measurement, you can change the clinical mode to **Monitoring** mode whenever close surveillance is required. For how to change the clinical mode, see Changing clinical mode on page 65.

Monitoring measurement workflow

The following is an overview of Monitoring measurement workflow for use with the monitor. The list of steps below is a representation of procedures covered in the different sections. Read the manual to get familiar with everything necessary for effective and safe use of the device.

It is not mandatory to follow these steps in sequence. Always consider your professional healthcare facility guidelines as well.

1. Turn on the device.
2. Prepare for monitoring, see Pre-monitoring checklist on page 65.
3. Ensure the device is in **Monitoring** mode.
4. Log in the caregiver.
5. Admit a new patient.
6. Take measurements.

7. Enter observations manually and read EWS score (if configured).
8. Review and manage the historical data.
9. Discharge the patient or turn off the device.

NOTE
In Monitoring mode, if no patient is admitted, the device will automatically admit a patient when any of the following conditions occurs:

- The SpO_2 measurement has been kept for at least 60 seconds.
- NIBP cycling measurement starts.
- Temperature measurement is complete and the value is valid.

NOTE
The monitor supports the following user-defined settings for **Patient data auto saving in Monitoring mode** in the **Advanced** menu (password protected):

- set **Interval**
- enable or disable **On NIBP completion**
- enable or disable **On Temp completion**
- enable or disable **Auto send saved monitoring data to EMR**

Pre-monitoring checklist

Before you start any measurements, check the following:

- The battery capacity is enough or the device is connected to the mains power.
- Physiological alarms are in active state. (Monitoring mode only)
- Check alarm limits and adjust if necessary. (Monitoring mode only)
- Accessories are intact and properly connected.
- No messages are displayed indicating the monitor is not functioning.
- Appropriate parameters and observation items are selected.
- Alarm signals are working and can be seen and heard in your care environment.
- Required parameter calibrations are completed.

Changing clinical mode

1. Select the clinical mode area accompanying with .
2. Choose **Spot Check** or **Monitoring** as necessary.

NOTE
If a patient has been admitted, when you change the clinical mode, a **Confirm same patient** menu will appear on the screen. Select either of the below options to enter the changed clinical mode.

- **Keep same patient**: keep the curret patient with previous setting
- **Admit new patient**: discharge previous patient and the monitor reverts to user default setting

About caregiver login

The following sections explain how to enter caregiver information with barcode reader or manually, and how to use the monitor without caregiver login for emergency cases.

Alternatively, you can skip the caregiver login step if not mandatory.

The monitor can log out current caregiver automatically after a configured period of time through the settings in the **Advanced** menu (password protected).

Entering caregiver information with barcode reader

You can scan caregiver information in a barcode if the function is activated during monitor configuration.

1. Plug an approved barcode reader into one of USB connectors on the monitor.
2. Scan the identification badge.
3. Select the **Caregiver** in the pop-up **Scan type** window, or select **Cancel** to cancel the selection and exit.
4. The caregiver login menu pops up. Verify that the data content in the barcode is correctly populated into the related fields.
5. If required, edit the scanned contents manually.
6. Enter the **Password** if required.
7. Select **Login** to validate the login credentials or select **Cancel** to cancel the entry and exit.
8. If the caregiver identification was validated, the system will return to the main screen, and `caregiver name` will be displayed.

   NOTE
   The caregiver name or ID can be hidden with *** using the settings in the **Advanced** menu (password protected).
9. If the caregiver identification was not validated and this is required by the hospital policy, repeat the above steps.
10. If you need to change the caregiver or log out current cargiver, select the caregiver information area and choose **Log out** from the selection list.

Entering caregiver information manually

1. Select the **Login** on the caregiver information area.

2. Edit or enter the **User ID**, **Username** or **Password** if required. You can select or to hide or show the password when you enter it.
3. Select **Login** to validate the login credentials or select **Cancel** to cancel entry and exit.
4. If the caregiver identification was validated, the system will return to the main screen, and `caregiver name` will be displayed.

   NOTE
   The caregiver name or ID can be hidden with *** using the settings in the **Advanced** menu (password protected).
5. If the caregiver identification was not validated and this is required by the hospital policy, repeat the above steps.
6. If you need to change the caregiver or log out current cargiver, select the caregiver information area and choose **Log out** from the selection list.

Using the monitor without caregiver information

For emergency cases, you can use the monitor directly without entering any caregiver information.

If you have opened the caregiver login menu by selecting the **Login**, then select **Cancel** key to exit.

Entering patient data

Patient data privacy protection

Patient data and patient information are invisible in the clinical logs or the setting file you downloaded. The patient trend cannot be downloaded.

Entering patient information with barcode reader

You can scan patient information in a barcode if the function is activated during monitor configuration.

1. Plug an approved barcode reader into one of USB connectors on the monitor.
2. Scan the identification badge.
3. Select the **Patient** in the pop-up **Scan type** window, or select **Cancel** to cancel the selection and exit.
4. The **Admit New** menu pops up. Verify that the data content is correct in the related fields.
5. If required, edit the scanned contents manually.
6. Select the check box for **Add to my patients** if you want this new patient to be added in Round Advisor as patient card. For more information, see Managing my patients on page 74.

7. Select **Admit** to admit the patient or **Cancel** to exit.

   NOTE
   If the same unique ID has already existed in the system, but other patient information is inconsistent with the previous data, a **Confirm patient information** menu will appear on the screen. Choose the **New** or **Existing** patient information and then select **Confirm**.

   If you select **New** in the **Confirm patient information** menu, all the historical data under this unique ID will be removed from the device.

8. If the patient was admitted, all the related patient information will be displayed in the patient information area on main screen.

   NOTE
   Patient name can be hidden with *** using the settings in the **Advanced** menu (password protected).

9. Select the **Edit** to edit the patient information if required.

Loading patient information from the HIS

When the network and PDQ / Cerner iBus are configured correctly by service, you can search for the patient in the HIS.

1. Select the **Admit New** on the patient information area.
2. Select **Admit from List** tab.
3. Enter the unique ID in the **Search PID** box to look for the patient.

   Alternatively, you can scan the patient's barcode directly.

   NOTE
   The unique ID can be configured in the **Advanced** menu (password protected). The choices are **Patient ID**, **MRN**, **SSN**, **Account number**, **Health card**.

4. Check the patient information.

   NOTE
   If the search returns a list, choose the correct patient after checking patient information.

5. Select the check box for **Add to my patients** if you want this new patient to be added in Round Advisor as patient card. For more information, see Managing my patients on page 74.
6. Select **Admit** to admit the patient or **Cancel** to exit.

   NOTE
   If the same unique ID has already existed in the system, but other patient information is inconsistent with the previous data, a **Confirm patient information** menu will appear on the screen. Choose the **New** or **Existing** patient information and then select **Confirm**.

   If you select **New** in the **Confirm patient information** menu, all the historical data under this unique ID will be removed from the device.

7. If the patient was admitted, all the related patient information will be displayed in the patient information area on main screen.

NOTE
Patient name can be hidden with *** using the settings in the **Advanced** menu (password protected).

8. Select the **Edit** to edit the patient information if required.

Entering patient information manually

1. Select the **Admit New** on the patient information area.
2. Edit or enter the **First name**, **Last name**, **Patient ID**, and **Visit number** by selecting the areas you can edit.

NOTE
Whether the **Patient ID** is mandatory for patient admittance depends on the **PID 1 required** settings in the **Advanced** menu (password protected). If the **PID 1 required** is disabled, then **Patient ID** is not mandatory and the device will create an automatic **Patient ID** for the measured data.

NOTE
Patient ID and **Visit number** can be replaced by other ID names depending on settings in the **Advanced** menu (password protected).

3. Select values for the following patient information:
   - **Gender**: **Female**, **Male**, **Other**
   - **Age**, Age unit options
   - **Date of birth**

NOTE
Date of birth is related to **Age**, which **Age** is automatically calculated from **Date of birth**.

4. Enter the **Location**.

NOTE
When the location **Fixed** is enabled in the **Advanced** menu (password protected), the **Location** is fixed and can not be edited.

5. Select the **Type** for the patient. The choices are:
   - **Adult / Pediatric**
   - **Neonatal**

NOTE
Selecting correct patient type is important as it is associated with user default setting.

6. Select the check box for **Add to my patients** if you want this new patient to be added in Round Advisor as patient card. For more information, see Managing my patients on page 74.

7. Select **Admit** to admit the patient or **Cancel** to exit.

   NOTE
   If the same unique ID has already existed in the system, but other patient information is inconsistent with the previous data, a **Confirm patient information** menu will appear on the screen. Choose the **New** or **Existing** patient information and then select **Confirm**.

   If you select **New** in the **Confirm patient information** menu, all the historical data under this unique ID will be removed from the device.

8. If the patient was admitted, all the related patient information will be displayed in the patient information area on main screen.

   NOTE
   Patient name can be hidden with *** using the settings in the **Advanced** menu (password protected).

9. Select the **Edit** to edit the patient information if required.

Scanning QR code from the Hub in the Portrait™ Mobile Monitoring Solution

The Hub collects and displays real-time monitoring data for pulse oximetry, pulse rate and respiration rate measurements.

The monitor (Portrait™ VSM Vital Signs Monitor) can capture patient information and parameter values from Hub through QR code scanning when they are used on the same patient.

NOTE
The feature is only available in Spot Check mode.

Follow this procedure on the monitor:

1. Plug an approved barcode reader into one of the USB connectors on the monitor.
2. Generate a QR code on the Hub through **Capture vital signs**.
3. Scan the QR code with the barcode reader.
4. A pop-up window appears on the screen. Check the **Data from QR code**. Then select **Confirm** to import the scanned data, or select **Cancel** to exit.
5. When the scanned patient is admitted, all the related patient information will be displayed in the patient information area on main screen.

   NOTE
   Patient name can be hidden with *** using the settings in the **Advanced** menu (password protected).

6. When the parameter values are imported to the monitor, the **Source: Manual** appears in the related parameter window.

   NOTE
   The imported parameter values can not trigger any alarms on the monitor.

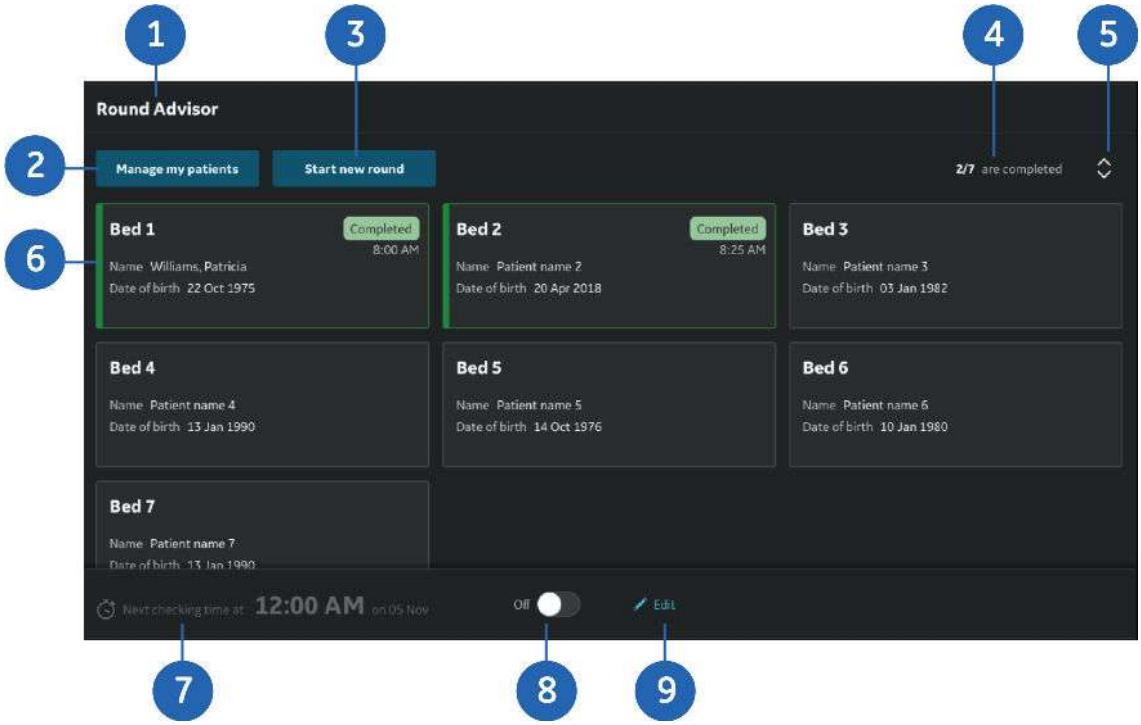
NOTE
For the imported parameter values, their valid display time can be set in the **Advanced** menu (password protected). When the setup expiration time is reached, the system will clear these values from main screen.

7. Select the **Edit** to edit the patient information if required.
8. Start the measurement for the patient using the monitor.

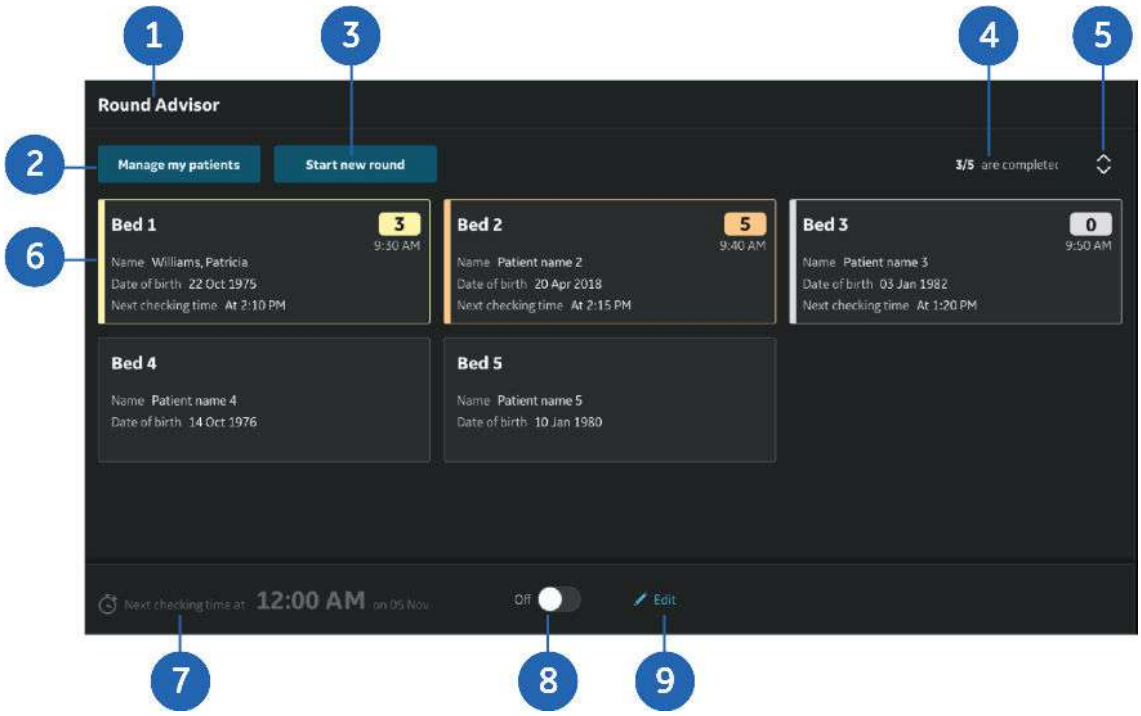
About Round Advisor

Round Advisor™ is an optional, license-based feature which makes the workflow more efficient and easier when you need to do spot checks for multiple patients assigned to you in sequence. You can view and manage the assigned patients in the **Round Advisor** menu and start spot checks one by one. You can also set a reminder for the next checking time on the monitor.

Round Advisor menu without EWS license:



Round Advisor menu with EWS license:



1.	Round Advisor (**Round Advisor**)	Menu title
2.	Manage my patients (**Manage my patients**)	Select the tab to access **Manage my patients** menu.
3.	Start new round (**Start new round**)	Select the tab to reset all patient cards and start a new round of measurements.
4.	X/X are completed (**X/X are completed**)	Indicates the completion progress of this round of Spot Check measurements.
5.	⇕	Select the key to sort the patient cards in the following options: • **Sort by location** in ascending order • For patient cards without EWS: ◦ **Checked patient on top** ◦ **Unchecked patient on top** • For patient cards with EWS: ◦ **Sort by total score**, from highest to lowest ◦ **Sort by next checking time**, from latest to farthest
6.	Patient card (without EWS license)	The patient card consists of the patient's **Location**, **Name** and **Date of birth**. After the patient is measured and the data has been saved or sent, the patient card will display a **Completed** label and the measurement time.
	Patient card (with EWS license)	The patient card consists of the patient's **Location**, **Name**, **Date of birth** and **Next checking time**. After the patient is measured and the data has been saved or sent, the patient card will display the calculated EWS score, the measurement time and the **Next checking time**. The **Next checking time** is automatically calculated from recommended monitoring frequency based on the measurement complete time and EWS value.

7.	Next checking time at (**Next checking time at**)	Reminder of next spot check time.
8.	Off (**Off**)	Indicates that the next checking time function is turned off (default setting). To turn on this function, move the toggle to **On** .
9.	Edit (**Edit**)	Select the key to edit the start time and **Reminding interval when overdue** for the next checking.

Using Round Advisor

NOTE
The device will retain the patient group which was set up by the last user. Make sure you check and manage your own patient group using the **Manage my patients** settings before starting any vital sign measurements.

1. Ensure the device is in Spot Check mode.
2. Select the **Round Advisor** tab to open the **Round Advisor** menu.
3. Select **Manage my patients** tab to set up your own patient group. See Managing my patients on page 74. When your patients are confirmed, their patient cards will appear in the **Round Advisor** menu, and each patient's **Location**, **Name** and **Date of birth** are synchronized to the related patient card.
4. Select the desired patient card and confirm the patient information to start vital signs. The device returns to the main screen and the selected patient is auto admitted.
5. Complete vital sign measurements and enter observations for the patient. Follow Steps 6 ~ 10 in Spot Check measurement workflow on page 64.
6. Re-open the **Round Advisor** menu by repeating Step 2.

   The patient card has a different appearance depending on whether it is with or without EWS. See About Round Advisor on page 71.
7. Select the next patient card and repeat from Step 4. Follow this procedure until you complete the measurements for all the required patients.
8. Select the key to sort the patient cards if required.
9. Set the toggle to **On** to turn on the next checking time function. If you want to edit the start time or **Reminding interval when overdue** for the next checking, select **Edit**.

   After the function is turned on, the symbol appears on the system status area. By selecting the , you can view the **Next checking time** details. **Adjust checking time** is also available.

   When it's time to start a new round, a drop-down menu pops up and a reminder beep tone sounds. You can then choose **Remind me later** or **Start new round** in this menu. After you confirm the new round, the device opens the **Round Advisor** menu and all previous measurement data in patient cards are reset.

   When the checking time is overdue, the key changes its image to , and the device will have visual and audible reminders at **Reminding interval when overdue**.

10. Select the **Start new round** tab whenever you want to start a new round of spot check measurements.

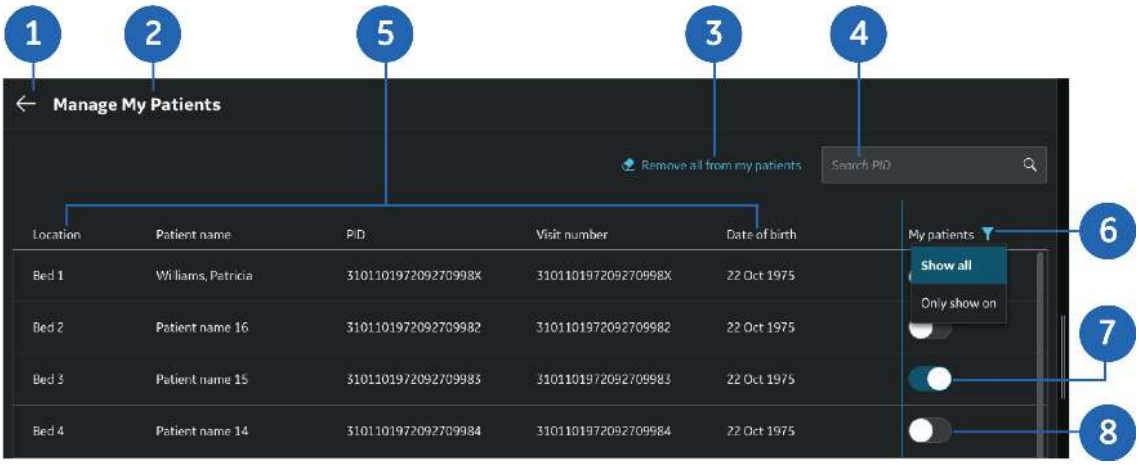
> **NOTE**
> The **Start new round** tab is enabled only after you complete the measurement for at least one patient.

Managing my patients

> **NOTE**
> The **Manage my patients** settings are intended for single device use which cannot be synchronized to EMR or transferred to other monitors.

The **Manage my patients** function helps clinicians set up their own patient group for the ward round spot check. To use this function, select the **Manage my patients** tab in the **Round Advisor** menu. See About Round Advisor on page 71.

The **Manage my patients** menu is shown as follows:



1.	←	Return to the **Round Advisor** menu.
2.	Manage my patients (**Manage my patients**)	Menu title
3.	Remove all from my patients (**Remove all from my patients**)	Remove all the patients from **My patients** group. All the toggles will turn to .
4.	Search PID (**Search PID**)	Search the unique ID of patient depending on setting in the **Advanced** menu (password protected). This text appears in the search box when there are no entries. When you enter the unique ID, the device starts the search automatically.
5.	Patient information	Patient information consists of **Location**, **Patient name**, **Patient ID**, **Visit number** and **Date of birth** . **NOTE** Displaying **Patient ID** or **Visit number** depends on settings in the **Advanced** menu (password protected). **NOTE** Patients will be automatically added to the **Manage my patients** menu after they are admitted in the device.
6.	My patients (**My patients**)	Select the key and a drop-down list will pop up. You can filter the patient information by two options: **Show all** or **Only show on**.
7.		Indicates that the patient has been added to the **My patients** group, and the patient's card appears in the **Round Advisor** menu.
8.		Indicates that the patient is removed from **My patients** group.

1. If required, select **Remove all from my patients** to remove all the patients from **My patients** group.
2. Enter the unique ID of patient in the search box to start the search automatically.
3. If required, add a new patient to the **Manage my patients** menu by admitting the patient first.
4. Select the **My patients** key to filter the patient information by **Show all** or **Only show on**.

5. Select or to add or remove the patient from **My patients** group.

NOTE
Patients can be automatically added to the **My patients** group if the **Add to my patients** check box is selected in the **Admit New** menu. See Entering patient information manually on page 69 or Loading patient information from the HIS on page 68.

Entering RR and Temp values manually

The device allows users to manually enter RR and temperature values in parameter windows with the numeric keyboard.

NOTE
To improve the accuracy of estimated RR value, the device also provides a timer next to the numeric keyboard. For more information about the timer, see Setting the RR timer on page 138.

NOTE
For Welch Allyn temperature, you can manually enter a temperature value only when the temperature probe is in the probe well or after 10 minutes in Monitor mode. For more information about the Monitor mode, see Taking a Monitor-mode temperature measurement on page 131.

NOTE
The manual input temperature value will be replaced by measured data when you take any new measurements.

NOTE
For all the manually entered values, their valid display time can be set in the **Advanced** menu (password protected). When the setup expiration time is reached, the system will clear these values and the accompanying messages from main screen.

Range (**Range**)	Range for the selected parameter value. The range value will differ according to the selected parameter.
	Use the delete key to clear the entry.
	Use the return key to confirm the entry.
	Use the keyboard key to collapse the keyboard.

1. Select the parameter's numeric value to open the numeric keyboard.
2. Enter a new value.

   NOTE
   The value should be within the required range. Otherwise, the value cannot be entered.

3. If the wrong value is entered, select the ⌫ key to clear the entry and start again.
4. Select the ↵ key to confirm the value. Then **Source: Manual** appears in the related parameter window.

About standby

The monitor has an automatic standby feature in order to conserve battery life. If the monitor has been inactive for a configured period of time without any ongoing measurements, notifications or alarms, the device will automatically switch to standby mode. Within the first five minutes of the configured time, the screen will get dark automatically.

When the monitor is running on battery and **Next checking time at** (reminder of next spot check time) is turned off, it will automatically shut down after 30 minutes of standby.

When the charger is connected, the monitor will not automatically shut down.

Starting standby manually

1. Press the `On/Off` button briefly to put the monitor into a standby state.

   NOTE
   This is possible only when there are no ongoing measurements.

   NOTE
   Entering standby mode will not discharge the patient, but log off the caregiver.

2. The screen will go blank.

End of standby

The monitor ends the standby state automatically when any of the following conditions occurs:

- The touchscreen is pressed.
- The `On/Off` button is pressed briefly.
- An ongoing SpO_2 or temperature measurement is detected.
- Round Advisor reminding time is reached.
- The barcode reader is operated.
- The monitor is connected to or disconnected from AC power.

If a patient has been admitted before the monitor enters standby mode, a **Confirm same patient** menu will open. You can choose to **Admit new patient** or **Keep same patient**.

Discharging a patient

The discharging process is affected by the **Advanced** > location **Fixed** settings (password protected).

In Spot Check mode:

- When the location **Fixed** is enabled, you should discharge the patient manually. After the patient is discharged, the patient data will be removed from monitor.
- When the location **Fixed** is disabled, the patient will be discharged automatically after you select the **Send** or the **Save** to end the current measurement. The discharging process will not remove the patient data from monitor. You can find all the historical data in the **Patients & Records** menu.

NOTE

Before you select the **Send** or the **Save** key, you can also discharge the patient manually. Then the device will clear all the data from main screen and no records will be saved.

In Monitoring mode, you should discharge the patient manually.

- When the location **Fixed** is enabled, discharging a patient will delete the patient data in monitor.
- When the location **Fixed** is disabled, the discharging process will not remove the patient data from monitor. You can find all the historical data in the **Patients & Records** menu.

To discharge a patient manually:

1. Disconnect patient sensors.
2. Select the **Discharge** > **Confirm**.

The monitor will revert to user default settings when a patient is discharged.

NOTE

After you discharge a patient, the monitor will keep current clinical mode.

Alarms

Alarm safety precautions

Alarm warnings

WARNING

PATIENT SAFETY.

When the alarms are off or while alarm audio is paused either temporarily or indefinitely, observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS.

Always make sure that the audio alarm volume level is adequate in your care environment to avoid missing alarms or not recognizing them due to too low a volume. Audio levels that are less than ambient levels may lead to unrecognized or missed alarms.

WARNING

MISSED ALARMS.

Always make sure that the alarm light brightness is adequate in your care environment to avoid missing any alarms.

WARNING

PATIENT SAFETY.

Always make sure that necessary alarm limits are active and set according to the patient's clinical condition when you start monitoring a patient in Monitoring mode to avoid any risks to the patient safety caused by erroneous or no alarms.

WARNING

PATIENT SAFETY.

Verify that the alarm processing is active and check the patient to ensure no arrhythmias occurred during a power interruption. Otherwise, there is a risk of compromised patient safety.

WARNING

MISSED ALARMS.

Always check the alarm status after a prolonged power interruption to avoid missing any alarms.

WARNING

PATIENT SAFETY.

Alarms do not sound, alarm histories are not stored, and alarms are not sent to the network when the alarms are turned off. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS.

Alarms do not sound during Audio Pause. As this may lead to missed alarms, observe the patient frequently.

WARNING

MISSED ALARMS.

The peripheral device’s alarms must not be turned off or the volume reduced in any way to diminish the importance of the peripheral device as the primary alarm source for parameters monitored by the peripheral device.

WARNING

PATIENT SAFETY.

There are no alarm indications until parameter-specific alarm prerequisites have been met. Keep the patient under close surveillance when starting the monitoring.

WARNING

PATIENT SAFETY.

Alarm messages may not be visible on the alarm display area when more than one alarm are active. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

MISSED ALARMS.

Equipment malfunctions, network disconnection, and alarm volume settings may result in missed alarms. Always keep the patient under close surveillance.

WARNING

PATIENT SAFETY.

Latched alarms are not retained through a monitor reset if the alarm condition has been removed. Observe the patient frequently to avoid the risk of not identifying important changes in the patient status that might lead to compromised patient safety.

WARNING

PATIENT SAFETY.

The secondary alarm system shall not be relied upon for receipt of alarm signals.

WARNING

MIXED ENVIRONMENT.

A hazard can exist when the same type of monitors in the same care area are using different clinical modes and default configuration settings.

WARNING

MISSING CRITICAL EVENTS.

Reducing the physiological alarms' priority levels lower than the default level can lead to missed detection of critical or serious events and therefore to adverse patient outcome. If you adjust the priority levels for the alarms lower than the default value, keep the patient under close surveillance.

WARNING

MISSED ALARMS.

Do not connect a single-color display to the monitor. Visual alarm indicators may not appear properly.

WARNING

MISSED ALARMS.

Reducing the technical alarms' priority levels lower than the default level can lead to missed detection of critical events and therefore to adverse patient outcome. If you adjust the priority level for SpO2 probe off alarm lower than the default value, keep the patient under close surveillance.

Alarm overview

Alarm types

There are two types of alarm settings, system and patient-specific. System alarm settings are set globally across an entire care environment. They are configured at the time of installation and are password protected. Examples of system alarm settings are:

- Minimum alarm volume
- Audio off allowed
- Alarm tones

Patient-specific alarm settings are individualized, based on a patient's current condition. Examples of patient-specific alarm settings are:

- Parameter alarm limits
- Alarm priority settings

Alarm conditions

- Physiological alarm conditions are triggered by a patient measurement that is outside the parameter limits in Monitoring mode only.
- Technical alarm conditions are triggered by an electrical, mechanical, or other failure of the equipment, or by failure of a sensor or component. Technical alarm conditions may also be caused when an algorithm cannot classify or interpret the available data. The visual manifestation of a technical alarm is active as long as the reason for that alarm exists.

Checking alarm function

1. Select the Monitoring mode.
2. Set a parameter alarm limit outside of the current measured patient values. For example, connect the SpO_2 sensor and adjust the SpO_2 high limit under measured SpO_2 values.
3. Confirm that the following alarm notifications occur:
   - The audible alarm sounds the correct priority tone.
   - The alarm light illuminates.
   - The alarm message displays in the message field.
   - The SpO_2 numeric value flashes in the parameter window with the correct priority color when the **SpO2 high** alarm priority is set to High, Medium or Escalating.
4. Acknowledge or audio pause the alarms and confirm that the audible alarms are paused.
5. Return the parameter alarm limit to the original value.

Visual alarm indications

Alarm icons on the screen

For more information for the on screen alarm icons, see User interface symbols on page 52.

Description of alarm and information messages

Alarm and information messages can be displayed in two areas:

- The message field

- The parameter window

In the message field, only the newest highest priority alarm or information message is displayed with an accompanying number. The number indicates the total amount of active alarms or information messages. You can select the ⌄ key to open the list of all active alarms or information messages, from the newest highest priority to the oldest lowest priority.

In the parameter window, the alarm or information message is displayed with the ⓘ symbol.

If a patient is admitted and the alarm priority is low, medium or high priority, the alarm messages will be stored in the **Alarm history**. You can access them through the **Records** menu. See Reviewing the historical data for a single patient on page 147. The alarm messages stored in the **Alarm history** include:

- Time of occurrence
- Alarm message text
- Alarm message priority
- Parameter value and unit if a limit alarm

Visual alarm signals and priority levels

Alarm signals indicate that an alarm condition is present. The alarm priority levels are indicated by visual and audible signals. The visual and audible alarm signals assume that the patient monitor and the operator are within the patient environment (1.5 meters).

The following table lists alarm signals for different alarm priority levels:

Signal	Priority level			
	High	**Medium**	**Low**	**Informational**
Message field	White text inside a red box.	Black text inside a yellow box.	Black text inside a cyan (blue) box.	Black text inside a gray box.
Parameter window physiological data values	White text flashes inside a red box.	Black text flashes inside a yellow box.	Not applicable.	Not applicable.
Parameter window messages	Text	Text	Text	Text
Alarm light indicator	Flashes red Frequency: 1.667 Hz ±10%	Flashes yellow Frequency: 0.625 Hz ±10%	Solid cyan Constantly on	No effect

Audible alarm indications

Audible alarm signals

When more than one alarm occurs at the same time, the monitor will sound an alarm tone for the highest priority alarm. Any lower priority audible alarm tones are suppressed by the higher priority alarm tone.

In Monitoring mode, physiological alarms always take precedence over technical alarms.

Alarm tones

The alarm tones can be configured to sound in one of four different tone patterns: **General**, **IEC**, **ISO**, or **ISO2**.

The low priority alarm tone can be configured to **Single** or **Repeat** sound.

For more information, refer to the Technical Manual.

NOTE
To avoid user confusion with alarm tones, configure all related monitors to the same type of audible alarm tones used in your clinical environment.

Adjusting the alarm volume

1. Select the **Alarm Setup**.
2. Select the **Audio** tab.
3. Adjust the value (the menu differs according to **Alarm volume control** settings in the **Advanced** menu):
   - **High, medium & low priority alarm volume**: adjust volume for all alarms. Or:
   - **High & medium priority alarm volume** and **Low priority alarm volume**: separately adjust volume for High & medium priority alarms, and Low priority alarms.

   The lower the number, the quieter the alarm volume.

Auditory information signals

The monitor performs a self-diagnostic procedure at startup and generates an auditory test signal. There are also other auditory information signals indicating the status of some parameter measurements.

- Start-up sound
- Completed NIBP volume
- Completed Temp volume
- Round Advisor reminding volume
- RR reminding volume
- Reminder beep (For more information, see Turning audible alarms on/off on page 86.)

Parameter alarms

Setting parameter alarm limits

NOTE
The alarm limit settings apply to Monitoring mode only.

Parameter alarm limits are set in **Alarm Setup** menu. Alarm limits should not be set beyond reasonable physiological boundaries in order to maintain patient safety. Parameter settings outside of reasonable boundaries will cause the alarms to be ineffective.

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Adjust the parameter alarm limits with the plus / minus spinner.
3. Select alarms **ON** or **OFF** from the **Alarm On/Off** list.

   In Monitoring mode, when a parameter alarm is set to **OFF**, the symbol will appear in the related parameter window.

Alarm priorities and escalation

Alarm priority levels

Physiological and technical alarms are categorized by priority level:

- High priority alarms require an immediate response.
- Medium priority alarms require a prompt response.
- Low priority alarms require you to be aware of this condition.
- Informational priority messages provide information you should know.

Alarm priority escalation

An escalating alarm starts at a designated priority level (low or medium) and will escalate to the next higher priority level (after a set number of seconds) if the alarm condition has not been resolved. It is important to note that the alarms escalate up to the next level but will not reset until the condition has been resolved.

NOTE
Alarm priority escalation affects the currently ongoing alarm condition, not any future alarms of the same type. Any new alarms will alarm at their designated priority level, not at the escalated level.

For more information, see the Alarm specifications chapter.

Selecting parameter alarm priority levels

Parameter alarm priorities can be selected. The alarm priority is based on clinical considerations.

The allowed priorities for different alarms are defined in the **Advanced** menu and they are password protected.

For more information, refer to the Technical Manual.

1. Select the **Alarm Setup** > **Priorities** tab.
2. Find the parameter alarm and select the alarm priority from the list.

If the selected alarm priority deviates from the recommended levels of alarm safety standards, the symbol ⚠ will display following the priority label.

When you select the ⚠, the screen pops up with the following warning text:

"**This alarm priority setting deviates from the recommendations of international alarm safety standards.**"

Pausing and silencing alarms

Audible alarms off behavior

Depending on the **Audio off allowed** default settings configured during installation, you can turn audible alarms on or off.

For more information, refer to the Technical Manual.

When audible alarms are turned off, the audio off bell icon displays on the system status area.

Turning audible alarms on/off

You can turn the audible physiological alarm tones on/off for all alarms.

1. Select the **Alarm Setup** > **Audio** tab.
2. Select the **Silence all** to turn off all audible alarms.
3. To turn on all audible alarms again, select **Reactivate alarms**.

NOTE
The **Reactivate alarms** key is also available when you select the ••• on the system status area.

NOTE
If all alarms are set to off and an alarm occurs, a beep tone will sound every 2 minutes as a reminder that audible alarms are turned off. The **Reminder volume** can be adjusted in the **Advanced** menu (password protected).

NOTE
France only: The **Reminder volume** setting is not available. A reminder beep tone sounds every 2 minutes when audible alarms are turned off.

Acknowledge and audio pause

Selection	Result	Indicator
Select the (Acknowledge)	• Start a 2 minute alarm silence for all current active alarms. • Remove all latched alarms (including message and light). • Does not silence any new alarms. • Cease the audio pause state, if available.	• Alarm light: Yes • Alarm message: Yes and display the acknowledge symbol in the message block with countdown timer • Alarm audio: No
Select the (on the system status area) > **Audio pause**[*1] once	• Start a 2 minute audio pause state for all alarms. • Remove all latched alarms[*2] (including message and light).	• Alarm light: Yes • Alarm message: Yes and display the audio pause countdown icon • Alarm audio: No
Second selection of **Audio pause** during the 2 minute pause	• Cease the audio pause state.[*3] • Deactivate some alarms in list below.	• Alarm light: Yes • Alarm message: Yes • Alarm audio: Yes

[*1] You can also select the **Alarm Setup** > **Audio** > **Audio pause**.

[*2] For details about latched alarms, refer to “Latched alarms” paragraph below.

[*3] To stop the audio pause state within 2 minutes, you can also select **Reactivate alarms**.

Deactivating alarms with the audio pause key

You can deactivate the following alarms by second selection of **Audio pause** during the 2 minute pause. For more information, see Acknowledge and audio pause on page 86.

- Physiological alarms:
  - **NIBP DIA high/NIBP SYS high/NIBP MAP high/NIBP PR high**
  - **NIBP DIA low/NIBP SYS low/NIBP MAP low/NIBP PR low**
- Technical alarms:
  - **No SpO2 probe**
  - **SpO2 probe off**
  - **Check SpO2 probe**
  - **No SpO2 pulse**
  - **NIBP cuff loose**
  - **NIBP cuff occlusion**
  - **Check NIBP**
  - **Weak pulsation**
  - **Long measurement time**
  - **NIBP manual**
  - **NIBP cuff overpressure**
  - **NIBP call service error**
  - **NIBP measurement removed**
  - **SpO2 measurement removed**

- **STP measurements removed**
- **Recorder: cover open**
- **Recorder: input voltage high**
- **Recorder: input voltage low**
- **Recorder: out of paper**
- **Recorder: system error**
- **Recorder: thermal array overheat**
- **Printing**
- **Condition battery**
- **No battery backup**
- **Replace battery**
- **Temp measurement removed**
- **Temp probe too hot**
- **Temp probe error**
- **Temp module error**
- **Check Temp probe**
- **Temp no determination**
- **Temp not available**
- **Certificate close to expiration**
- **Certificate expired**

Latched alarms

Alarms can be configured to latch or not. The **Latching alarms** setting is configured in the **Advanced** menu and it is password protected. When alarms are latched, the visual message and alarm light remain after the alarm condition no longer exists. You will also hear a reminder beep every 10 seconds.

For more information, refer to the Technical Manual.

To clear the visual indication and beep for no longer active alarm messages:

- Select the (Acknowledge), or:
- Select the > **Audio pause**, or select the **Alarm Setup** > **Audio** > **Audio pause**.

Nurse call

The nurse call settings are defined in the **Advanced** menu and they are password protected. You can select whether nurse call can be turned on according to the nurse call system electrical level in the hospital.

- **Normal open**: high electrical level is exported from the nurse call connector when there is medium or high priority alarm.

- **Normal close**: low electrical level is exported from the nurse call connector when there is medium or high priority alarm.

For more information, refer to the Technical Manual.

Alarm settings after a power loss

If the monitor loses power, the alarm settings that were in effect before the power loss are restored automatically.

Stored alarm data during a power cycle or power loss

If the monitor goes through a power cycle or loss power, the stored alarm data in the Alarm log will not be affected. The alarm data remains stored in the Alarm log until the monitor automatically clears the oldest stored data to allow new data to be stored.

NOTE
The Alarm log is a service level function and it is password protected.

Non-invasive blood pressure

NIBP safety precautions

NIBP warnings

WARNING

PATIENT SAFETY.

The NIBP parameter will not measure blood pressure effectively on patients who are experiencing seizures or tremors.

WARNING

PATIENT SAFETY.

Arrhythmias will increase the time required by the NIBP parameter to determine a blood pressure and may extend the time beyond the capabilities of the parameter.

WARNING

ERRONEOUS READINGS.

Do not apply external pressure against the cuff while monitoring. Doing so may cause inaccurate blood pressure values. Use care when placing the cuff on an extremity used to monitor other patient parameters.

WARNING

ERRONEOUS READINGS.

NIBP cuff inflation/deflation may lead to inaccurate values from other monitored patient parameters that are measured distally from the NIBP measurement site at the same extremity.

WARNING

PATIENT SAFETY.

Ensure that the connection tubing is not kinked. Kinked tubing may cause continuous cuff pressure, which can interfere with the blood flow and cause injury to the patient.

WARNING

PATIENT SAFETY.

Do not place the cuff on the arm on the side of a mastectomy as this may lead to injury or swelling of the arm due to cuff pressurization. To avoid this risk, use another limb if possible.

WARNING

PATIENT SAFETY.

Do not place the cuff over a wound as this may cause further injury.

WARNING

ERRONEOUS READINGS.

GE HealthCare NIBP devices are designed for use with dual-hose cuffs and tubing. The use of single-hose cuffs with dual hose tubing can result in unreliable and inaccurate NIBP data.

WARNING

PATIENT SAFETY.

To prevent injury to the patient, do not place the cuff on a limb being used for A-V fistulas, intravenous infusion or on any area where circulation is compromised or has the potential to be compromised. To avoid this risk, use another limb if possible.

WARNING

ERRONEOUS READINGS.

Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper size cuff.

WARNING

NIBP READINGS MAY TIME OUT WHEN USING IABP.

An IABP creates non-physiological arterial waveforms. These waveforms create an oscillometric signal that may not be interpreted by the NIBP algorithm, causing NIBP to time out. The patient blood pressure can be monitored from the balloon pump device.

WARNING

PATIENT SAFETY.

The NIBP cuff size must be correctly selected in the NIBP Setup window to obtain reliable NIBP data and to prevent excessive cuff pressure during infant (neonate) or child (pediatric) use.

WARNING

PATIENT SAFETY.

Always ensure that you are using NIBP neonatal settings when monitoring neonatal patients. Using other settings may lead to risks to the patient due to wrong alarm limits or cuff pressure, for example.

WARNING

ERRONEOUS READINGS.

If a patient's beat-to-beat pulse amplitude varies significantly (e.g., because of pulsus alternans, atrial fibrillation, or the use of a rapid-cycling artificial ventilator), blood pressure and pulse rate readings can be erratic, and an alternate measuring method should be used for confirmation.

WARNING

INACCURATE READINGS.

Effectiveness of the NIBP measurement has not been established in pregnant (including pre-eclamptic) patients.

WARNING

BURNS.

When using an electrosurgery unit, note that the measurement cables do not incorporate means to protect against burns in case of a defective ESU return electrode. To avoid burns at the monitor measurement sites, ensure the following:

Proper contact of the ESU return electrode to the patient.

ESU return electrode near the operating area.

Measurement probes far from the surgical site and the ESU return electrode.

WARNING

PATIENT SAFETY.

Devices that exert pressure on tissue have been associated with purpura, skin avulsion, compartmental syndrome, ischemia, and/or neuropathy. To minimize these potential problems, especially when monitoring at frequent intervals or over extended periods of time, make sure the cuff is applied appropriately and examine the cuff site and the limb distal to the cuff regularly for signs of impeded blood flow. Periodically check patient limb circulation distal to the cuff. Check frequently when using auto NIBP in 1 and 2 minute intervals. The 1 and 2 minute intervals are not recommended for extended periods of time.

NIBP cautions

CAUTION

PATIENT SAFETY.

The device sets the inflation pressure automatically according to the previous measurement. Discharge patient to reset the inflation limits before measuring NIBP on a new patient.

NIBP measurement limitations

- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease heart rate.
- Although automated NIBP is generally safe and accurate, it has some limitations. It may be difficult to obtain reliable readings under the following circumstances:
  - Shock accompanied by low blood pressure and pulse.
  - Variations in blood pressure and pulse rate.
  - In patients with anatomic abnormalities, such as calcified (hardened) arteries or subclavian compression.
  - Compression of the cuff caused by shivering, seizures, arm movement, or bumping against the cuff.
- Proper sizing and position of the cuff are essential for obtaining reliable readings:
  - Too large a cuff is better than too small a cuff, which may yield falsely high readings.
  - The cuff should also fit properly over the brachial artery (or whatever artery is being used) so that the cuff is sufficiently sensitive to vibrations in the artery.

NIBP points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF Surgical Equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Blood pressure measurements determined with this device are equivalent to those obtained by an intra-arterial blood pressure measurement device, within the limits prescribed by the standard.
- Use the appropriate size NIBP cuff for the patient (adult, pediatric, or neonatal).
- Operator position: Make sure you do not lean on the cuff or hoses, and do not disturb the patient in any way during measurement. Position yourself accordingly.
- The measurement site, patient’s position (standing, sitting, lying down), exercise, or physiological condition can affect the NIBP readings.
- With mobile patients and when taking routine resting blood pressure, ensure that:
  - The patient is comfortably seated, with their legs uncrossed and feet flat on the floor.
  - The patient’s arms and back are supported.
  - The middle of the cuff is at the level of the right atrium of the patient’s heart.
- Also consider the following recommendations:
  - Allow 5 minutes to pass before taking the first measurement.
  - Ensure that the patient is relaxed and does not talk during the measurement.

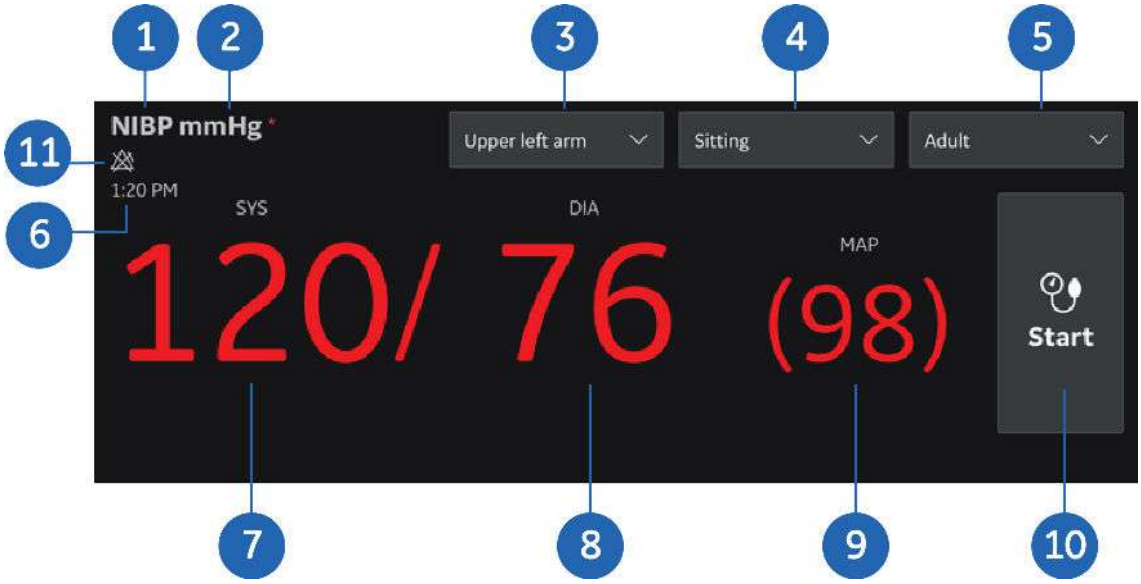
NIBP instruction

Non-invasive blood pressure (NIBP) monitoring is an indirect measurement that reflects the force exerted by circulating blood on the walls of blood vessels.

NIBP measurement displayed on the monitor screen

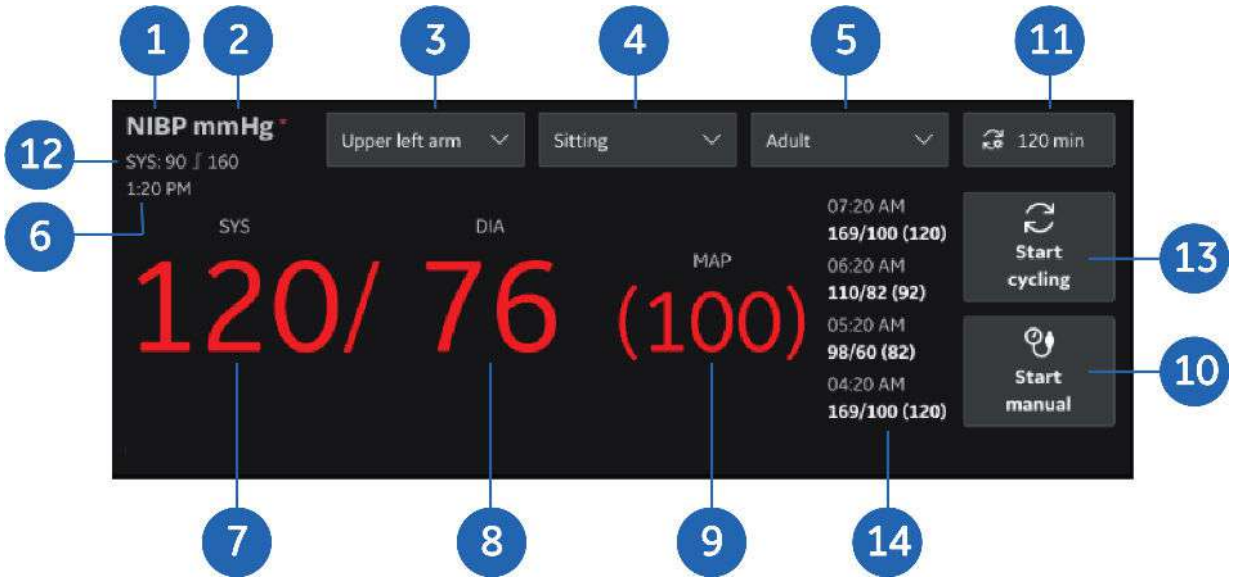
The NIBP parameter window view varies depending on which clinical mode is used, Spot Check or Monitoring mode.

In **Spot Check** mode:



1.	NIBP (**NIBP**): parameter label
2.	mmHg (**mmHg**): unit
3.	Upper left arm (**Upper left arm**): **Site** for measurement
4.	Sitting (**Sitting**): patient position
5.	Adult (**Adult**): cuff size
6.	Time: when the displayed values were taken
7.	SYS (**SYS**): Systolic pressure
8.	DIA (**DIA**): Diastolic pressure
9.	MAP (**MAP**): Mean pressure
10.	Start (**Start**): the button to start a single NIBP measurement After selecting this button, the text will change to **Cancel** and it's used to stop a single measurement.
11.	: indicates no physiological alarms in Spot Check mode

In **Monitoring** mode:



1.	NIBP (**NIBP**): parameter label
2.	mmHg (**mmHg**): unit
3.	Upper left arm (**Upper left arm**): **Site** for measurement
4.	Sitting (**Sitting**): patient position
5.	Adult (**Adult**): cuff size
6.	Time: when the displayed values were taken
7.	SYS (**SYS**): Systolic pressure
8.	DIA (**DIA**): Diastolic pressure
9.	MAP (**MAP**): Mean pressure
10.	Start manual (**Start manual**): the button to start a single NIBP measurement After selecting this button, the text will change to **Cancel** and it's used to stop a single measurement, or the STAT NIBP measurement if required.
11.	120 min (**120 min**): cycle interval selected in the **Cycling settings** list
12.	**SYS** alarm limits: low limit and high limit of one enabled alarm When **NIBP SYS**, **NIBP DIA**, **NIBP MAP** are all set to **ON** in the **Alarm Setup** > **Alarm Limits** menu, the monitor displays SYS alarm limits with the highest priority, then DIA alarm limits with medium priority, and MAP alarm limits with the lowest priority. The alarm limits will be replaced by the symbol when all NIBP alarms are set to **OFF**.
13.	Start cycling (**Start cycling**): the button to start an auto cycle NIBP measurement After selecting this button, the text will change to **Stop cycling** and it's used to end the auto cycle NIBP measurement.
14.	The history records of previous measurements: time and NIBP value (SYS, DIA, MAP) The history records are placed in a display queue from the latest measurement (at the top) to the oldest measurement. The history records will be removed after being generated 24 hours ago, or when patient is discharged or device is turned off.

There are other displays in different situations, see below instructions for more details.

- **Start cycling** (Monitoring mode only):

During cycling measurement, a time progress bar displays in the NIBP parameter window and indicates the selected cycling interval.

- **Start STAT** (**Continuous NIBP for 5 min**) (Monitoring mode only):

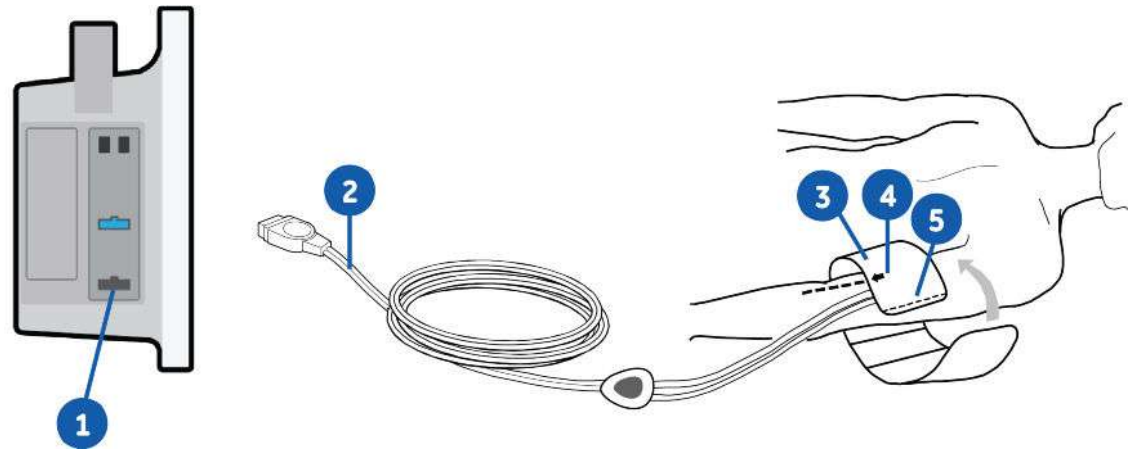
  During STAT measurement, a five-minute progress bar with the text **STAT** displays in the NIBP parameter window.

During cuff inflation and deflation phases, the real-time pressure against the cuff will be labeled as **Cuff** to display in the parameter window.

For all the periodically measured values (NIBP or Temp), their valid display time can be set in the **Advanced** menu (password protected). When the setup expiration time is reached, the system will clear these values and the accompanying messages from main screen.

NIBP measurement setup

NIBP equipment to patient connection



1.	NIBP connector	4.	Brachial artery arrow (printed on cuff)
2.	Cuff hose	5.	Cuff index line (printed on cuff)
3.	Cuff of correct size		

Preparing the NIBP patient connection

1. Select an appropriate NIBP cuff size for the patient.
2. Connect the NIBP cuff hose to the NIBP connector.
3. Position the NIBP cuff on the patient:
   - Place the cuff arrow over the brachial artery (or whatever artery is being used).
   - Make sure that the cuff index line falls within the range markings on the cuff.
   - Wrap the cuff around the limb.
4. Make sure that the NIBP cuff tubes are not kinked, compressed, or stretched.

5. Select the correct clinical mode.

   NOTE
   Manual NIBP measurements are available in both Spot Check and Monitoring mode. Automatic and STAT NIBP measurements are only available in Monitoring mode.

6. If required, select the site and patient position in NIBP parameter window or NIBP setup menu. To access NIBP setup menu, select the **Configurations** > **Parameter Setup** > **NIBP** vertical tab.

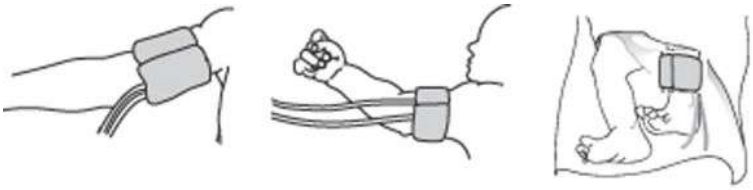
   You can show or hide the **Site** or/and **Patient position** list from NIBP parameter window by selecting the respective option from **Show on main screen** list in the NIBP setup menu.

7. Verify or select the correct cuff size in the NIBP parameter window or NIBP setup menu.

NIBP cuffs

NIBP cuff selection and placement

Always choose the appropriate blood pressure measurement site. In adult and pediatric patients, the upper arm is preferred for convenience and because normative values are generally based on this site. When factors prohibit use of the upper arm, the clinician must plan patient care accordingly, taking into account the patient's cardiovascular status and the effect of an alternative site on blood pressure values, proper cuff size, and comfort.



Always measure the patient's limb and select appropriately sized cuff according to size marked on cuff or cuff packaging. When cuff sizes overlap for a specified circumference, choose the larger size cuff.

If patient is standing, sitting, or inclined, ensure that cuffed limb is supported to maintain the cuff at level of patient's heart. If the cuff is not at heart level, the difference in the measured pressure values due to hydrostatic effect must be considered.

Selecting NIBP cuff size

You must select the NIBP cuff size before starting an NIBP measurement for the next patient.

1. Select **Adult**, **Pediatric** or **Neonatal** from the **Cuff size** list in the NIBP parameter window or NIBP setup menu.

   NOTE
   When the patient type is **Neonatal**, only **Neonatal** cuff can be selected.

Initial NIBP cuff inflation pressure

The default value for initial NIBP cuff inflation pressure corresponds to **Cuff size** selected. You can adjust the inflation pressure, if you do not wish to use the default value.

Table 1 Default inflation pressure

Cuff size	Inflation pressure
Adult or **Pediatric**	135 mmHg (18 kPa)
Neonatal	100 mmHg (13.3 kPa)

Using the default NIBP cuff inflation pressure

The system can determine the default inflation pressure according to the selected **Cuff size**.

1. Access NIBP setup menu.
2. Select **Use default inflation pressure**.

Setting the target NIBP inflation pressure

You can manually change the target inflation pressure for the NIBP measurement.

1. Access NIBP setup menu.
2. Check that **Use default inflation pressure** is not selected.
3. Set the value for **Inflation pressure** (**mmHg**) or **Inflation pressure** (**kPa**) with plus / minus spinner depending on your settings for the blood pressure unit.

Manual NIBP measurements

Starting or stopping a single NIBP measurement

1. Start the measurement by selecting any of the following buttons:
   - **Start** or **Start manual** in NIBP parameter window, depending on your selection of clincal mode (Spot Check or Monitoring mode)
   - **Start manual** in NIBP setup menu
2. Stop the measurement by selecting the **Cancel** in NIBP parameter window or NIBP setup menu.

Automatic NIBP measurements

NIBP Auto mode

NOTE
NIBP Auto mode is only available in Monitoring mode.

The NIBP Auto mode initiates repeated measurements for the selected cycle interval. There will be at least a 30 seconds' delay between two consecutive NIBP measurements during auto cycling.

Setting the custom series for NIBP measurement

You can set a custom series for NIBP automatic measurement. NIBP has user-defined 1 to 4 series measurement modes. The measurement interval of each series is adjustable from 1 to 120 minutes. The repeat number of measurements is adjustable from continuous, and from 1 to 25 times.

1. Access NIBP setup menu.
2. Set up time interval from the **Custom series** > **x BP Series** (**1st BP series**, **2nd BP series**, **3rd BP series**, **4th BP series**) > **Interval** list. Set up repeat times from the **Repeat** list.
3. Set the **Cycling settings** to **Custom** in the NIBP setup menu or NIBP parameter window.

Starting or stopping an Auto NIBP measurement

1. Ensure the device is in **Monitoring** mode.
2. Select the cycle interval from the **Cycling settings** list in the NIBP parameter window or NIBP setup menu.
3. Select the **Start cycling** button in the NIBP parameter window or NIBP setup menu.
4. Stop the measurement by selecting the **Stop cycling** button in the NIBP parameter window or NIBP setup menu.

NOTE

You can also stop a single cycle only by selecting the **Cancel** button nearby.

NIBP STAT mode

NOTE

NIBP STAT mode is only available in Monitoring mode.

The **STAT** mode initiates a continuous cycle of measurements for five minutes. A new NIBP measurement starts after the previous measurement completes. After five minutes, the monitor automatically returns to the previously selected cycling interval or manual mode.

STAT NIBP measurement is deactivated when **Cuff size** is set to **Neonatal** or a neonatal patient is admitted.

Starting or stopping a STAT NIBP measurement

1. Ensure the device is in **Monitoring** mode.
2. Select **Start STAT** (**Continuous NIBP for 5 min**) in NIBP setup menu.
3. Stop the measurement by selecting the **Cancel** button in the NIBP parameter window, or **Stop STAT** in NIBP setup menu.

NIBP volume and display settings

Adjusting the NIBP measurement completion tone volume

1. Access NIBP setup menu. Or select the **Configurations** > **Monitor Setup** > **Sound & Brightness** vertical tab.
2. Set the **Completed NIBP volume** with the sliding scale.

Selecting the NIBP unit

The NIBP unit settings require a password.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

Selecting the NIBP color

The NIBP color settings require a password.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

NIBP alarms

Setting the NIBP alarm limits

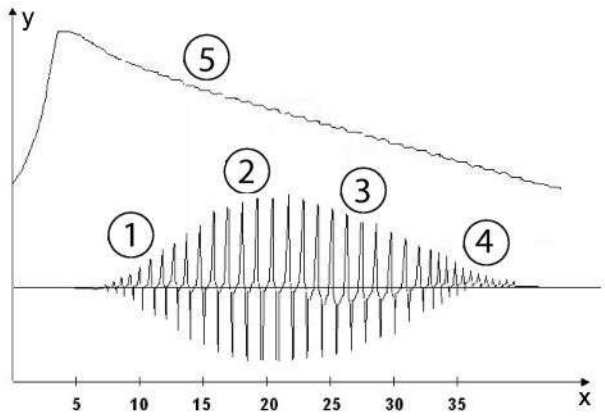
1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Set the **NIBP SYS**, **NIBP DIA**, or **NIBP MAP** alarm limits (**Low limit** and **High limit**) with plus / minus spinners.
3. Check that the related NIBP alarm is turned on.

NOTE
If you want to turn off the alarm, select **OFF** from the **Alarm On/Off** list.

NIBP measurement description

NIBP is acquired using oscillometric technology. Oscillometry is the most commonly used means of indirect blood pressure measurement in automated devices. It is based on the principle that pulsatile blood flow through an artery creates oscillations of the arterial wall.

Oscillometric devices use a blood pressure cuff to sense these oscillations, which appear as tiny pulsations in cuff pressure. By measuring and analyzing at various cuff pressures, the amplitude (which changes based on the pressure within the cuff) and the frequency of these pulsations (which is dependent on the patient’s heart rate), oscillometric devices can non-invasively determine blood pressure.



x = Time(s)

y = Pressures

1.	Systolic	4.	Extracted pulse wave
2.	Mean	5.	Cuff pressure
3.	Diastolic		

DINAMAP SuperSTAT NIBP technology

DINAMAP SuperSTAT technology estimates the systolic, mean arterial, and diastolic values by evaluating all cuff pressure data gathered during an NIBP determination.

The first determination initially pumps up to a default target cuff pressure of about 135 mmHg for adults/children, or 100 mmHg for neonatal patients. To allow for rapid setting of cuff pressure, the monitor will momentarily inflate to a higher pressure, then immediately deflate to the target pressure.

As a determination is taken, the pattern of the patient's oscillation size is stored as a function of pressure. In any subsequent determination, as few as four pressure steps may be necessary to complete the process. When employing fewer pressure steps, the system uses the stored information from the previous blood pressure determination to decide the best pressure steps to take. The consistency of pulse sizes is measured to ascertain if the oscillations taken at a step are correct and if more steps are needed.

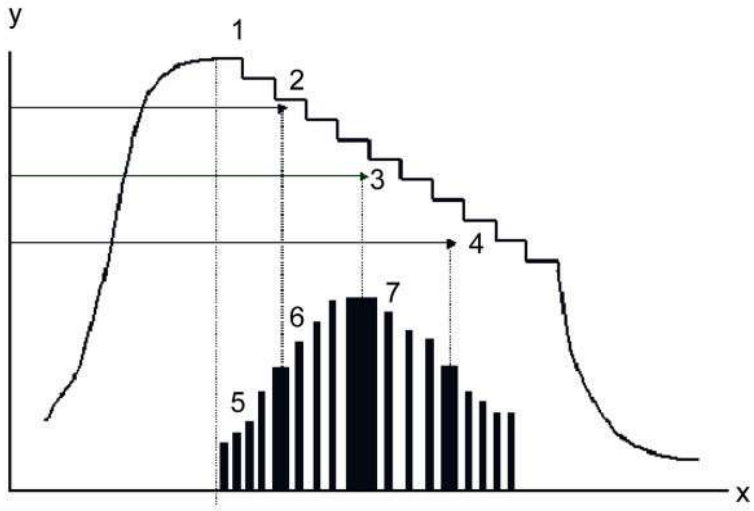
If the current blood pressure reading is similar to the previous reading, some information from the previous blood pressure may be used in the current determination. The data is constantly evaluated during a measurement to try to perform a blood pressure determination in the shortest possible time, providing greater comfort to the patient.

If it has been 16 minutes or less since the last determination and the current blood pressure is similar to the previous reading, the monitor will try to make an accelerated determination of blood pressure.

DINAMAP Step Deflation technology

DINAMAP SuperSTAT technology includes DINAMAP Step Deflation technology. During the deflation process, the monitor measures two consecutive pulsations in cuff pressure. If their amplitude differs by an acceptably small amount and the time interval between the pulsations matches the previous time intervals, the pulsations are averaged and stored along with the corresponding cuff pressure. The cuff is then deflated to the next step (in steps of 5-10 mmHg). As the deflation occurs, oscillation waves are assessed for strength and amplitude until the maximum oscillation amplitude or MAP is obtained.

If either of the above criteria is not met, the cuff pressure is maintained until two consecutive pulsations are detected that meet the criteria. Eventually, if the cuff is maintained at one pressure step for longer than one minute or the determination time exceeds 85 seconds (neonatal cuffs) or two minutes (adult and child cuffs), the monitor will time out and display an error.



x = Cuff pulsation waveform

y = Cuff pressure

1.	Cuff deflation	5.	Cuff pulsations (each pulsation represents one heart beat)
2.	Systolic pressure (ratio of maximum amplitude)	6.	Amplitude (changes based on cuff pressure)
3.	Mean arterial pressure (maximum pulsation amplitude)	7.	Resulting waveform
4.	Diastolic pressure (ratio of maximum amplitude)		

Systolic and diastolic determinations are based on a mathematical calculation within the algorithm. The deflation mode is heart-rate dependent: it is typically longer with heart rates that are slow and/or irregular.

This patented process of finding two matched pulsations of relatively equal amplitude and frequency at each step rejects artifact due to patient movement or other deviations from ideal conditions (e.g., cuff disturbances) and greatly enhances the overall accuracy of the measurement.

NOTE

NIBP values are based on the oscillometric method of non-invasive blood pressure measurement taken with a cuff on the arm of adult and child patients, and a cuff on the calf of infants. The values correspond to comparisons with intra-arterial values within IEC-specific standards for accuracy (a mean difference of ± 5 mmHg, and a standard deviation of < 8 mmHg).

Pulse oximetry

SpO_2 safety precautions

SpO_2 warnings

WARNING

DEFIBRILLATOR PRECAUTIONS.

Patient signal inputs labeled with the CF and BF symbols with paddles are protected against damage resulting from defibrillation voltages. To ensure proper defibrillator protection, use only the recommended cable and sensor. Using other cable or sensor may result in damage to the equipment and compromise patient and user safety.

WARNING

PATIENT SAFETY.

The operator is responsible for checking the compatibility of the pulse oximetry device, sensor, and patient cable prior to use. Incompatible components can result in degraded performance and/or device malfunction and compromised patient safety.

WARNING

PATIENT SAFETY.

If the accuracy of any measurement does not seem reasonable, first check the patient's vital signs, then check for conditions that may cause inaccurate SpO_2 readings. If the problem is still not resolved, check the monitor and the cable, or sensor for proper functioning.

WARNING

PATIENT SAFETY.

A pulse oximeter should not be used as an apnea monitor. A pulse oximeter should be considered an early warning device. As a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory CO-oximeter to completely understand the patient's condition.

WARNING

PATIENT SAFETY.

Check that the pulse oximetry waveform is physiological in shape to ensure waveform quality and minimize noise spikes caused by motion conditions. (Not applicable when monitoring SpO_2 with Masimo SET technology.) Otherwise, there is a risk of compromised patient safety.

WARNING

PATIENT SAFETY.

To prevent erroneous readings, do not use physically damaged sensors, cables or modules. Discard a damaged sensor or cable immediately. Never repair a damaged sensor or cable; never use a sensor or cable repaired by others. A damaged sensor or a sensor soaked in liquid may cause burns during electrosurgery.

WARNING

PATIENT SAFETY.

Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis. Otherwise, there is a risk of compromised patient safety.

WARNING

PATIENT SAFETY.

Cable/sensor after care:

Do not immerse sensors or patient cables in water, solvents or cleaning solutions.

Do not reuse sensors intended for single patient use.

Do not sterilize sensors or patient cables by irradiation, steam, or ethylene oxide.

Clean the surface of the probe before and after each patient use.

Allow sensor and cable to dry completely after cleaning. Moisture and dirt on the connector can affect the measurement accuracy.

If a probe is damaged in any way, discontinue use immediately.

Inaccurate SpO_2 data can result if a sensor is past its useful life. Therefore, re-evaluate the measurement periodically by performing additional assessment of the patient and equipment, including consideration of use of alternate monitoring methods such as direct measurement of arterial oxyhemoglobin saturation (SaO_2).

A damaged sensor may cause burns during electrosurgery.

WARNING

PATIENT SAFETY.

Oximetry performance may be impaired when patient perfusion is low or signal attenuation is high. Always keep the patient under close observation.

WARNING

INACCURATE RESULTS.

The display of inaccurate pulse oximetry (SpO_2) values has been linked to the presence of poor signal strength or artifact due to patient motion during signal analysis. This condition is most likely to be encountered when the monitor is used on neonates or infants. These same conditions in adults do not impact the SpO_2 values to the same extent.

We recommend the application of the following criteria when using the pulse oximetry function on neonates and infants:

The peripheral pulse rate (PPR) as determined by the SpO_2 function must be within 10% of the heart rate, and

The SpO_2 signal strength should be adequate. This is indicated by the display of two or three asterisks or the absence of the **Low signal quality** message.

Procedures or devices previously applied in your facility for SpO_2 monitoring should be used in the event the SpO_2 value from the monitor cannot be validated by the above criteria.

WARNING

ERRONEOUS READINGS.

Many factors may cause inaccurate readings and alarms, decreased perfusion, and or low signal strength:

Interfering substances:

Carboxyhemoglobin may erroneously increase SpO_2 reading.

Methemoglobin (MetHb) usually represents less than 1% of the total Hb, but in the case of methemoglobinemia that can be congenital or induced by some IV dyes, antibiotics (such as sulphas), inhaled gases, etc., this level increases sharply and thus can cause inaccuracies in the SpO_2 reading.

Intravascular dyes (such as indocyanine green, methylene blue, etc.)

Physiological characteristics:

Cardiac arrest

Hypotension

Shock

Severe vasoconstriction

Severe anemia

Hypothermia

Venous pulsations

Darkly pigmented skin

Ventricular septal defects (VSDs)

Nail polish or artificial nails at the measurement site

Environmental conditions:

Electromagnetic interference

Excessive ambient light

Electrical interference

Electrosurgery

Defibrillation - may cause inaccurate reading for a short amount of time.

Excessive patient/sensor motion. Artifact can simulate an SpO_2 reading, so that the device fails to sound an alarm. In order to ensure reliable patient monitoring, the proper application of the probe and the signal quality must be checked at regular intervals.

Sensor placement:

Incorrect sensor placement - prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently for poor perfusion or for neonates). Refer to the instructions supplied with the sensor.

Sensor placement on the same extremity as a blood pressure cuff, arterial catheter or intravascular line; or arterial occlusion proximal to the sensor.

Poor sensor fit or sensor applied too tightly.

Do not allow tape to block the sensor light emitter and detector.

Improper connection to the monitor or interconnect cable.

Contamination of lenses inside the sensor.

WARNING

FAILURE TO DETECT LETHAL ARRHYTHMIA.

The SpO_2 parameter pulsatile heart rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximetry parameter should not be used as a replacement or substitute for ECG based arrhythmia analysis.

WARNING

PATIENT SAFETY.

Using the **Maximum** sensitivity setting can reduce the **SpO2 probe off** detection alarm. It is recommended to use the **Maximum** sensitivity setting in care areas where the application site is inspected frequently to ensure patient safety. (Available when monitoring SpO_2 with Masimo SET technology.)

WARNING

PATIENT SAFETY.

With deactivated **SpO2 probe off** alarm, keep the patient under close surveillance.

WARNING

MISSED ALARM.

Check the SpO_2 measurement when switching the SpO_2 measurement sources to avoid missed SpO_2 alarms.

WARNING

SKIN IRRITATION.

Prolonged monitoring or incorrect sensor application can cause skin irritation or impaired circulation. It is recommended that you check the probe site every four hours (more frequently in case of poor perfusion or neonatal patients). Refer to the instructions supplied with the sensor.

SpO_2 cautions

CAUTION

BURNS.

A damaged sensor or a sensor soaked in liquid may cause burns during electrosurgery. To avoid this risk, always ensure that the sensor is undamaged and dry.

Masimo warnings

WARNING

As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

WARNING

Do not place the pulse oximetry device or accessories in any position that might cause it to fall on the patient.

WARNING

Do not start or operate the pulse oximetry device unless the setup was verified to be correct.

WARNING

Do not use the pulse oximetry device during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING

Do not use the pulse oximetry device if it appears or is suspected to be damaged.

WARNING

EXPLOSION HAZARD.

Do not use the pulse oximetry device in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING

To ensure safety, avoid stacking multiple devices or placing anything on the instrument during operation.

WARNING

To protect against injury, follow the directions below:

Avoid placing the device on surfaces with visible liquid spills.

Do not soak or immerse the device in liquids.

Do not attempt to sterilize the device.

Use cleaning solutions only as instructed in operator's manual.

Do not attempt to clean the device while monitoring a patient.

WARNING

To protect from electric shock, always remove the sensor and completely disconnect the pulse oximetry device before bathing the patient.

WARNING

If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximetry device for proper functioning.

WARNING

Inaccurate SpO_2 readings may be caused by:

Improper sensor application.

Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-oximetry) of a blood sample should be performed.

Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.

Elevated levels of bilirubin.

Severe anemia.

Low arterial perfusion.

Motion artifact.

WARNING

INTERFERING SUBSTANCES.

Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.

WARNING

The pulse oximetry device should not be used as the sole basis for medical decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING

The pulse oximetry device is not an apnea monitor.

WARNING

The pulse oximetry device may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING

The pulse oximetry device may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING

The pulse oximetry device should not be used for arrhythmia analysis.

WARNING

SpO_2 is empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING

Do not adjust, repair, open, disassemble, or modify the pulse oximetry device or accessories. Injury to personnel or equipment damage could occur. Return the pulse oximetry device for servicing if necessary.

Masimo cautions

CAUTION

Do not place the pulse oximetry device where the controls can be changed by the patient.

CAUTION

Electrical shock and flammability hazard: Before cleaning, always turn off the instrument and disconnect from any power source.

CAUTION

When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION

Do not place the pulse oximetry device on electrical equipment that may affect the instrument, preventing it from working properly.

CAUTION

If the SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

CAUTION

If the Low Perfusion message is frequently displayed, find a better perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

CAUTION

Change the application site or replace the sensor and/or patient cable when a persistent poor signal quality message is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

CAUTION

If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the instrument might read zero for the duration of the active irradiation period.

CAUTION

To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse oximetry device is used.

CAUTION

Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory instruments prior to clinical decision making to completely understand the patient's condition.

CAUTION

Do not submerge the pulse oximetry device in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse oximetry device.

CAUTION

ELECTRICAL SHOCK HAZARD.

Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1 and UL60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

CAUTION

DISPOSAL OF PRODUCT.

Comply with local laws in the disposal of the instrument and/or its accessories.

CAUTION

To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse oximetry device.

CAUTION

Replace the cable or sensor when a replace sensor or when Low signal quality is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

SpO_2 measurement limitations

- The pulse oximeter cannot distinguish between oxyhemoglobin and dyshemoglobins.
- Poor perfusion may affect the accuracy of measurement, especially when using an ear sensor.
- To avoid erroneous measurements, do not use a blood pressure cuff on the same limb as the SpO_2 sensor.
- There are several factors that may cause inaccurate readings and alarms. Familiarize yourself with the SpO_2 safety precautions so that you are aware of these factors and can take them into consideration.

SpO_2 points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Disturbances from HF Surgical Equipment.
- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- For more detailed information regarding sensor accuracies, refer to the supplemental analysis graphs provided.
- Use dry and clean sensors only.

- Do not use damaged sensors.
- Check that you are not re-using a disposable sensor or other disposable accessories.
- Refer to the sensor instructions for use for the recommended maximum application times for different sensor types.
- Always check the patient and the sensor site if the accuracy of the SpO_2 values is questionable.
- Depending on the SpO_2 technology used, not all SpO_2 measurements and settings are available to view or change.
- There are three supported pulse oximetry technologies:
  - Masimo SET
  - Nellcor OxiMax
  - GE TruSignal
- With Nellcor™ sensors with OxiMax™ technology and Masimo SET technology, the pulse oximetry waveform is a normalized waveform. It is not normalized with GE TruSignal technology. GE TruSignal technology provides the actual IrMod% values.

Masimo points to note

- A functional tester cannot be used to assess the accuracy of the pulse oximetry device.
- High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor may not allow the pulse oximetry device to obtain vital sign readings.
- When using the Maximum Sensitivity setting, performance of Sensor Off detection may be compromised. If the instrument is on this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental “noise” such as light, vibration, and excessive air movement.
- Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
- Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
- Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of the patient monitoring time.

SpO_2 measurement guidelines

GE TruSignal technology and sensor measurement guidelines

The following measurement guidelines apply to GE TruSignal SpO_2 technology:

- The time period for acquiring a measurement average is adjustable.
- The SpO_2 waveform corresponds to (but is not proportional to) the arterial pressure waveform.
- Only TruSignal sensors are supported.

- Use the following guidelines when using TruSignal sensors and cables:
  - Read the sensor instructions for use of the SpO_2 sensor before using it.
  - Periodically inspect extension cables and sensors for damage.
  - Do not use damaged sensors.
  - Refer to the cleaning instructions in the instructions for use of reusable TruSignal sensors.
  - Do not use NIBP or constricting instruments on the same appendage as the SpO_2 sensor.

Masimo SET technology and sensor measurement guidelines

With motion, the plethysmographic waveform (or SpO_2 waveform) is often distorted and may be obscured by the artifact. With Masimo SET technology, the plethysmographic waveform is not an indication of signal quality or validity. Even with a waveform obscured by artifact, Masimo SET technology is able to read through the noise and locate the arterial pulsation.

Although Masimo SET technology processes SpO_2 measurements differently than other SpO_2 technologies, the function and appearance is essentially the same as other technologies. The following measurement guidelines apply to Masimo SET technology only:

- The time period for acquiring a measurement average is adjustable.
- Only Masimo RD SET and LNCS sensors are supported. Masimo RD SET or LNCS sensors non-invasively measure pulse rate and the amount of oxygenated hemoglobin. Use the following guidelines when using Masimo RD SET or LNCS sensors:
  - Read the sensor directions before use.
  - Only use sensors with Masimo SET technology.
  - Do not use damaged sensors.
  - Do not use a sensor with exposed optical components.
  - Refer to the cleaning instructions in the directions for use for reusable Masimo RD SET or LNCS sensors.

Additional information for Masimo technology

NO IMPLIED LICENSE: Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device. Sensors that are designated for single use are licensed for use on a single patient only, and are not sold. There is no license, implied or otherwise, that would allow use of single-use Masimo sensors beyond their intended single use. After use of single-use Masimo sensors, the license is exhausted, there is no further license granted by Masimo, and they must be discarded.

This device is covered under one or more patents as set forth at https://www.masimo.com/company/masimo/patents/.

We recommend the use of Masimo SET sensors for use with Masimo technology.

Nellcor OxiMax technology and sensor measurement guidelines

The following measurement guidelines apply to Nellcor OxiMax:

- The SpO_2 waveform corresponds to (but is not proportional to) the arterial pressure waveform.

- Only Nellcor OxiMax sensors are supported. Use the following guidelines when using OxiMax SpO_2 accessories and sensors:
  - Periodically inspect extension cables and sensors for damage and discontinue use if damage is found.
  - Do not immerse sensors.
  - Do not use NIBP or constricting instruments on the same appendage as the SpO_2 sensor.

Additional information for Covidien technology

NOTICE: Purchase of this instrument confers no express or implied license under any Covidien patent to use this instrument with any oximetry, level of consciousness, regional oxygen saturation and respiration rate, as an applicable Sensor that is not manufactured or licensed by Covidien.

SpO_2 measurement description

Pulse oximetry (SpO_2) is a non-invasive method used for monitoring tissue oxygenation. The measurement method is based on the absorption of red and infrared light in pulsating arterial blood. The ratio of oxygen carrying hemoglobin (HbO_2) to the total amount of hemoglobin capable of transporting oxygen (HbO_2 + Hb) is called functional oxygen saturation of arterial blood (SaO_2). GE HealthCare pulse oximetry is calibrated to display functional oxygen saturation.

The actual measurement of arterial oxygen saturation is performed by spectrophotometry, a technique that quantifies the amount of transmitted light. A beam of light is passed through a monitored site of pulsating arterial blood. A pulse oximeter emits red and infrared light through its LEDs and measures the relative absorbtion of red and infrared light. Because HbO_2 and Hb absorb different amounts of light at each of these wavelengths, the oximeter can compare the ratio of each absorbance and convert it into an SpO_2 value.

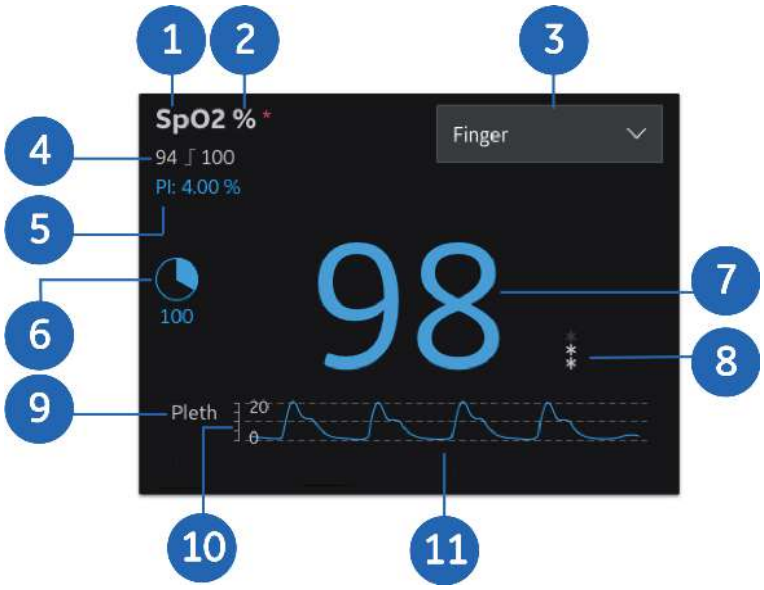
Plethysmographic pulse waveform is derived from the infrared signal. It reflects the blood pulsation at the measuring site, and the amplitude of the waveform represents perfusion. Peak detection of the plethysmographic pulse wave is used for calculating pulse rate.

There are 3 supported pulse oximetry technologies:

- GE TruSignal
- Masimo SET
- Nellcor OxiMax

SpO_2 measurement displayed on the monitor screen

The SpO_2 parameter window varies depending on your settings in the **Configurations** > **Parameter Setup** > **SpO2** vertical tab > **Show on main screen** list. You can show or hide **Site**, **Waveform** or **PI** in the SpO_2 parameter window.

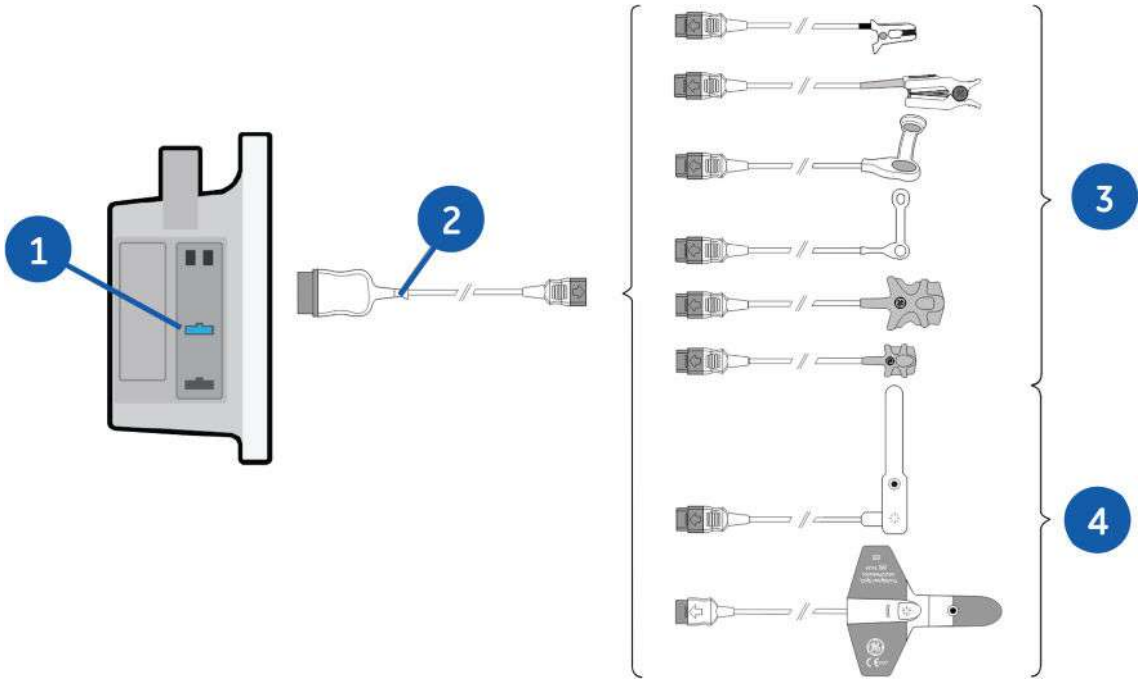


1.	SpO_2 (**SpO2**): parameter label	7.	SpO_2 value Displays "– – –" when no data is acquired from the connected SpO_2 sensor.
2.	SpO_2 unit	8.	Masimo SpO_2 only. SpO_2 signal strength indicator.
3.	Finger (**Finger**): **Site** for measurement	9.	Pleth (**Pleth**): waveform label
4.	SpO_2 alarm limits (appear in Monitoring mode only) The alarm limits will be replaced by the symbol when the SpO_2 alarm is set to **OFF** or in Spot Check mode.	10.	Pleth waveform scale: the displayed numbers represent the current **Pleth scale**.
5.	PI (**PI**): Perfusion Index value (for GE TruSignal and Masimo technology and sensors only).	11.	Pleth **Waveform**
6.	Nellcor OxiMax SatSeconds™ alarm management indicator (appear in Monitoring mode only) Indicates the amount of time the SpO_2 saturation is outside the limits before alarms are generated. The number indicates the current threshold setting. For how to set the threshold, see Setting the SatSeconds™ alarm management threshold on page 121.		

When the SpO_2 value is imported from the Hub, the text **Source: Manual** will display in the SpO_2 parameter window. For more information, see Scanning QR code from the Hub in the Portrait™ Mobile Monitoring Solution on page 70.

SpO_2 measurement setup

SpO_2 equipment to patient connection



1.	SpO_2 connector	3.	Reusable sensors
2.	Interconnect cable	4.	Disposable sensors

Preparing the SpO_2 connection

1. Connect the adapter cable to the SpO_2 connector.
2. Clean the surface of reusable sensors.
3. Prepare the application site.
4. Remove nail polish and earrings.
5. Follow the sensor manufacturer's instructions to position the sensor.
6. Attach the sensor to the patient.
7. Stabilize the sensor cable to minimize sensor movement.

Checking the SpO_2 measurement

1. Check that the red light is lit on the sensor.
2. Check that the waveforms and parameter values are displayed when the sensor is connected to the patient.

SpO_2 functional testers

You can verify the functionality of the pulse oximeter sensor and monitor with a SpO_2 functional tester but you cannot evaluate their accuracy with such a device. For more information, refer to the standard ISO 80601-2-61 Annex FF (Simulators, calibrators and functional testers for pulse oximeter equipment).

Using the SpO_2 measurement

Selecting the SpO_2 measurement site

1. If required, select the measurement site in SpO_2 parameter window or SpO_2 setup menu. The options are **Finger**, **Nose**, **Toe**, **Earlobe** or **Other**.

   To access SpO_2 setup menu, select the **Configurations** > **Parameter Setup** > **SpO2** vertical tab.

Changing the SpO_2 waveform scale

1. Access SpO_2 setup menu.
2. Select the scale from the **Pleth scale** list:
   - For GE TruSignal technology and sensors, the options are:
     - **Auto**: The scale is automatically selected according to the IrMod % (infrared modulation percentage) received from the measurement source.
     - Other scale options are **2**, **5**, **10**, **20**, or **50**.
   - For Masimo or Nellcor technology and sensor, the options are: **1x**, **2x**, **4x**, or **8x**.

Selecting the GE TruSignal SpO_2 response averaging time

NOTE
GE TruSignal technology and sensors only.

You can have an average of the SpO_2 measurement on screen instead of the beat-to-beat values. You can select the average time for response.

1. Access SpO_2 setup menu.
2. Select the average time from the **SpO2 response** list. The choices are:
   - **Normal**: 12 seconds
   - **Fast**: 3 seconds

Selecting the Masimo SpO_2 averaging time

NOTE
Masimo technology and Masimo sensors only.

You can have an average of the SpO_2 measurement on screen instead of the beat to beat values, and you can select how many seconds are used for this averaging: **2s**, **4s**, **8s**, **10s**, **12s**, **14s**, or **16s**.

1. Access SpO_2 setup menu.
2. Select the number of seconds from the **Averaging** list.

Selecting the Masimo SpO_2 sensor sensitivity level

NOTE
Masimo technology and Masimo sensors only.

1. Access SpO_2 setup menu.
2. Select the appropriate option from the **Sensitivity** list:
   - Use the **Normal** sensitivity setting for normal patient monitoring purposes.
   - Use the **Maximum** sensitivity setting for improved poor perfusion performance and for faster tracking of rapid SpO_2 saturation changes.

     Using the **Maximum** sensitivity setting delays the **Probe off** detection alarm.
   - Use the **APOD** (Adaptive Probe Off Detection) sensitivity settings for better probe off detection.

Setting the SpO_2 to show PI

NOTE
For GE TruSignal technology and sensors, and for Masimo technology and Masimo sensors only.

PI (Perfusion Index) is a relative assessment of the pulse strength at the monitoring site.

PI clinical practicalities:

- During sensor placement, use PI to quickly evaluate the appropriateness of an application site, looking for the site with the highest PI number.
- Placing the sensor at the site with the strongest pulse amplitude (highest PI number) improves performance during motion. Monitor the trend of the PI for changes in physiological conditions.
- Changes in sympathetic nervous tone affect smooth muscle tone, thereby altering levels of perfusion.

1. Access SpO_2 setup menu.
2. Select **PI** from the **Show on main screen** list.

The larger the PI value, the greater the strength.

Nellcor OxiMax SatSeconds™ alarm management

Nellcor OxiMax technology uses SatSeconds alarm management to decrease the likelihood of false SpO_2 saturation alarms caused by motion artifact. It does not apply to pulse rate.

With both traditional and SatSeconds pulse oximetry alarm management, upper and lower saturation alarm limits are set. With traditional alarm management, as soon as a limit is reached or violated, an alarm is generated. With SatSeconds alarm management, a cumulative limit violation index

is calculated, and when this index reaches the SatSeconds alarm management limit, an alarm is generated. The cumulative limit violation index is simply the sum of violation magnitudes calculated each second the limit is being violated.

For example, suppose that the SpO_2 low alarm limit is 90%, meaning that 91% is the lowest value not producing an alarm in the traditional case. Now suppose the following consecutive values are recorded each second: 92%, 89%, 87%, 87%, 80%. The corresponding violation magnitudes are 0, 2, 4, 4, 11, and the cumulative limit violation index is correspondingly 0, 2, 6, 10, 21. If the Saturation Seconds limit setting was 20, an alarm would be annunciated at this point, or after four seconds. When the SpO_2 saturation value is no longer in violation, the alarm notification clears and the cumulative limit violation index decrements in the same manner in which it increments.

With some patients, saturation levels may frequently drop below the limit, but not staying below the limit long enough for the SatSeconds alarm management time setting to be reached. In such situations, that is, when three or more limit violations occur within 60 seconds, an alarm sounds even if the cumulative limit violation index has not reached the SatSeconds alarm management time setting value.

SatSeconds™ calculation

This method of calculation is as follows: The number of percentage points that the SpO_2 saturation falls outside the alarm limit is multiplied by the number of seconds that it remains outside the limit.

This can be stated as the equation "points x seconds = SatSeconds", where points equals SpO_2 percentage points at or outside the limit, and seconds equals the number of seconds SpO_2 remains at that point outside the limit.

The table below demonstrates the alarm response time with a SatSeconds limit set at 30 and a lower SpO_2 limit of 80%. In this example, the SpO_2 level drops to 79% (2 points) and remains there for 2 seconds. Then it drops to 76% (5 points) for 3 seconds, and then to 75% (6 points) for 2 seconds. The resulting SatSeconds are as follows:

Table 2 SatSeconds Calculation

SpO_2 Saturation	Clock Seconds	SatSeconds
2 x	2 =	4
5 x	3 =	15
6 x	2 =	12
	Total SatSeconds	31

SatSeconds™ alarm management response example

Saturation levels may fluctuate above and below an alarm limit, re-entering the acceptable range (non-alarm range) several times. During such fluctuation, the SpO_2 device integrates the number of SpO_2 saturation points, both positive and negative, until either the SatSeconds alarm management limit is reached or the saturation level returns to within the normal range and remains there.

When an SpO_2 saturation value exceeds an alarm limit, a pie chart (circular graph) in the SpO_2 parameter menu begins to fill in a clockwise direction. As seconds pass and the value is compared against the alarm limits and the SatSeconds alarm management setting, the chart fills proportionately. When the pie chart is completely filled, indicating that the SatSeconds alarm management limit has been reached, an alarm sounds. When the SpO_2 value is within the set limits, the SatSeconds alarm management pie chart empties in a counterclockwise direction.

Showing SatSeconds™ alarm management in the SpO_2 parameter window

NOTE
Nellcor technology and Nellcor sensors only.

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Select a threshold from **SatSeconds** list.
3. Select **ON** from the **Alarm On/Off** list and set the SpO_2 alarm limits.

Setting the SatSeconds™ alarm management threshold

NOTE
Nellcor technology and Nellcor sensors only.

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Select the threshold from **SatSeconds** list. The choices are: **10**, **25**, **50**, **100**.

Setting the SpO_2 alarm limits

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Set the **SpO2** alarm limits (**Low limit** and **High limit**) with plus / minus spinner.
3. Check that the **SpO2** alarm is turned on.

NOTE
If you want to turn off the alarm, select **OFF** from the **Alarm On/Off** list.

Setting the Masimo SpO_2 alarm delay

NOTE
Masimo technology and Masimo sensors only.

The alarm delay time for **SpO2 low** alarm can be selected. But if the SpO_2 value drops below the alarm limit by more than 5%, the **SpO2 low** alarm will be triggered immediately, regardless of the alarm delay setting.

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Select the seconds from the **Alarm delay** list. The choices are: **0s**, **5s**, **10s**, or **15s**.

Stopping the SpO_2 measurement

1. Remove the SpO_2 sensor from the patient.
2. Disconnect the sensor from the sensor cable.
3. If required, disconnect the sensor cable from the host.

4. Select to acknowledge the **SpO2 probe off** alarm.
5. Discard single-use sensors.
   - Always disconnect the sensor from the cable before repositioning the sensor. Reconnect the cable to the sensor after the sensor has been repositioned.

How to interpret the SpO_2 values

SpO_2 signal strength

- For Masimo technology.

  The Signal strength is indicated with asterisks in the SpO_2 parameter window. The signal strength indicator refers to Masimo's proprietary measurement, Signal Identification and Quality (Signal IQ) indicator. The Signal IQ provides an indicator of the assessment of the confidence in the displayed SpO_2 value.

- For GE TruSignal technology.

  The signal strength indicator is displayed as the PI value in the SpO_2 parameter window.

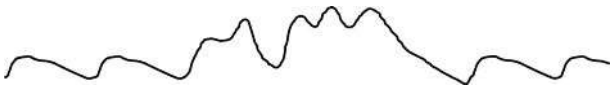
SpO_2 waveform quality

NOTE
Not for Masimo SET technology.

Under normal conditions, the SpO_2 waveform corresponds to (but is not proportional to) the arterial pressure waveform. The typical SpO_2 waveform can help the user find a sensor location with the fewest noise spikes.

Normal waveform

If noise (artifact) is seen on the waveform because of poor sensor placement, the photodetector may not be flush with the tissue. Check that the sensor is secured and the tissue sample is not too thick. Pulse rate is determined from the SpO_2 waveform, which can be disrupted by hemodynamic pressure disturbances. Motion at the sensor site is indicated by noise spikes in the normal waveform.



Abnormal waveform

SpO_2 waveform stability

The stability of the displayed SpO_2 values can also be used as an indication of signal validity. To aid you in successful SpO_2 monitoring, messages are provided in the SpO_2 parameter window. For details about the messages, see Messages related to SpO_2 measurement on page 161.

Temperature

Temperature safety precautions

Welch Allyn warnings

WARNING

PATIENT SAFETY.

To ensure patient safety and accurate Welch Allyn temperature measurement, use only GE HealthCare approved Welch Allyn accessories and supplies.

WARNING

PATIENT SAFETY.

Do not take a patient's temperature without using a Welch Allyn disposable probe cover. Doing so can cause patient discomfort, patient cross-contamination, and erroneous temperature readings. Use only Welch Allyn temperature probe covers.

WARNING

PATIENT SAFETY.

Long-term continuous monitoring beyond five minutes is not recommended for Welch Allyn temperature measurements.

WARNING

ERRONEOUS READINGS.

Do not take an axillary temperature through patient's clothing. Direct probe cover to skin contact is required.

WARNING

PATIENT SAFETY.

Do not reuse, or sterilize and reuse protective covers. Apply a new cover before each use.

WARNING

PATIENT SAFETY.

Visually inspect the probe covers for contaminants or damage prior to use.

WARNING

PATIENT SAFETY.

Oral/axillary probes (blue ejection button at the top of the probe) and blue oral/axillary removable probe wells are used for taking oral and axillary temperatures only. Rectal probes (red ejection button) and red rectal removable probe wells are used for taking rectal temperatures only. Use of the incorrect removable probe well could result in patient cross-contamination.

WARNING

ERRONEOUS READINGS.

To ensure optimal accuracy, always confirm that the correct mode and site are selected.

WARNING

DISPOSAL.

Always dispose of probe covers properly to prevent potential injury due to choking or slip-and-fall hazards. Ensure that probe covers are disposed of according to facility requirements or local regulations.

WARNING

PATIENT INJURY.

If the tip is inserted too far, patient tissue damage may occur and the probe tip may not have good contact with tissue. Use of a lubricant on the probe cover is optional.

WARNING

PATIENT SAFETY.

Before performing rectal temperature measurement on neonates and children, check hospital policy whether it is allowed and with what conditions.

Welch Allyn cautions

CAUTION

EQUIPMENT DAMAGE.

Be careful not to overextend the coiled cord of the temperature probe. Overextension can damage the probe coil connector interfaces.

CAUTION

EQUIPMENT DAMAGE.

Keep the temperature probe secured in the probe well when not in use.

CAUTION

EQUIPMENT DAMAGE.

Biting the probe tip while taking a temperature may result in damage to the probe.

CAUTION

EQUIPMENT DAMAGE.

Do not use any Welch Allyn probe or probe cover to select items on the touch screen:

The tip is sensitive and misusing it may damage the probe.

Using the probe or the probe cover as selection tool may scratch or damage the screen.

Using a used probe cover may increase the risk of cross-contamination via the touch screen.

CAUTION

PATIENT SAFETY.

The Sure Temp Plus feature operates only when the probe well is correctly installed.

CAUTION

PATIENT INJURY.

Injury may occur as a result of patient movement during the procedure.

CAUTION

PATIENT SAFETY.

Do not insert the probe cover into the probe well.

CAUTION

DISPOSAL.

To prevent cross-contamination, properly dispose of the probe cover when the measurement is complete.

Temperature points to note

- For information on materials used in accessories and their biocompatibility, refer to the instructions for use in the accessory package.
- Use only GE HealthCare approved temperature accessories.
- For more detailed information regarding the temperature probes, refer to their own instructions for use.

Welch Allyn points to note

- The thermometer case, connectors, and probe are not waterproof. Do not immerse or drip fluids on these items. Should this occur, dry the device with warm air. Check all operating functions for proper operation.
- The Welch Allyn SureTemp® Plus thermometer consists of high-quality precision parts. Protect it from severe impact and shock. If the thermometer has been dropped or if you notice any signs of damage to the probe or instrument, do not use the thermometer. Contact service personnel to ensure proper operation to further use.
- Cross-contamination or nosocomial infection risk. Thorough handwashing before and after the measurement greatly reduces the risk of cross-contamination and nosocomial infection.

Temperature measurement description

The monitor supports only one temperature site for a single measurement. Temperature monitoring provides numeric values only. No waveform is generated or displayed.

The monitor can measure temperature with any one of the following temperature probes:

- Welch Allyn SureTemp® Plus temperature probe
- Exergen TemporalScanner™ thermometer
- HeTaida thermometer

Exergen and HeTaida thermometers are medical devices from the OEM manufacturers, always refer to their own instructions for use.

NOTE
Temperature monitoring is disabled when two or more temperature probes are connected to the monitor simultaneously. Disconnect the extra probe(s) and the only one left will return to work immediately.

You can also manually input a temperature value on the device. For more information, see Entering RR and Temp values manually on page 76.

Temperature measurement displayed on the monitor screen

1.	Temp (**Temp**): parameter label
2.	Temperature unit
3.	Oral (**Oral**): **Site** for measurement The choices of **Site** settings are: • **Adult axillary** or **Pediatric axillary** for Welch Allyn axillary temperature measurement • **Oral** for Welch Allyn oral temperature measurement • **Rectal** for Welch Allyn rectal temperature measurement • **Temporal** for Exergen temperature measurement • **Forehead** for HeTaida temperature measurement The **Site** for measurement will disappear from the Temp parameter window if you enter a temperature value manually.
4.	Indicates there are no physiological alarms for temperature measurement.
5.	Time: when the displayed value was taken
6.	Temperature value Displays "**– – –**" when no data is acquired from the connecting temperature probe or when the temperature value times out. The "**– – –**" will be animated when you start to take a predictive temperature measurement, refer to Step 6 in Taking a predictive temperature measurement on page 130.

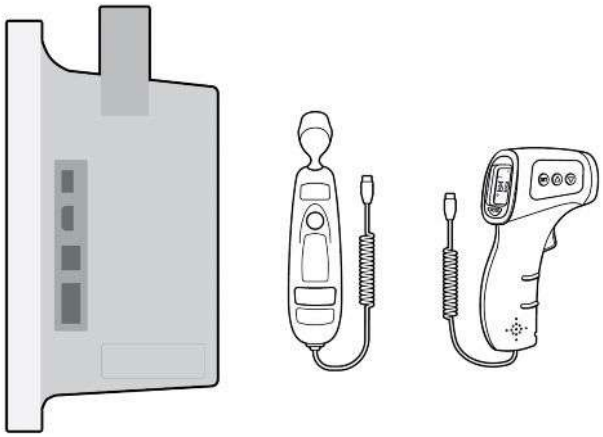
For all the periodically measured values (NIBP or Temp), their valid display time can be set in the **Advanced** menu (password protected). When the setup expiration time is reached, the system will clear these values and the accompanying messages from main screen.

When the temperature value is entered by the user manually, the text **Source: Manual** displays in the Temp parameter window. For more information, see Entering RR and Temp values manually on page 76.

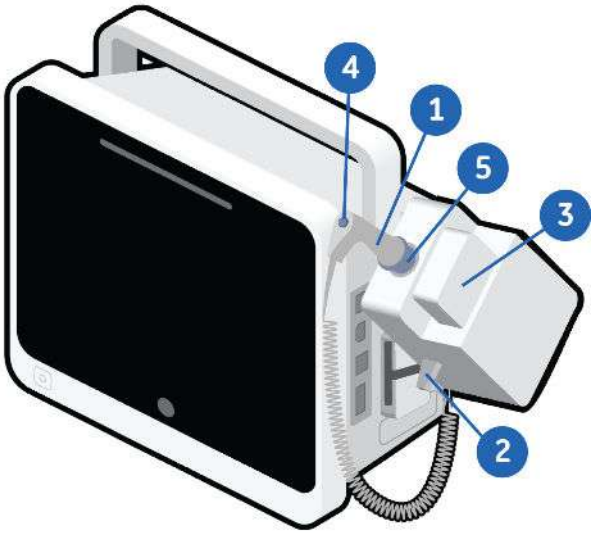
Temperature measurement setup

Temperature equipment to patient connection

For Exergen and HeTaida temperature measurement, connect the thermometer cable to one of the USB connectors on the monitor. The graphic below only shows the USB connector on the right side of the monitor. For an overview of all the three USB connectors, see Right side view on page 41 and Back view on page 41.



For Welch Allyn temperature measurement, connect the latching probe connector (2) to the Welch Allyn temperature module and insert the probe (1) into the probe well (5). Place the box of disposable probe covers (3) into the temperature module.



1.	Temperature probe	4.	Ejection button
2.	Probe connector	5.	Probe well
3.	Disposable probe covers		

NOTE
A probe for oral and axillary measurement has a blue ejection button (4) that pairs with a blue probe well (5). A probe for rectal measurement has a red ejection button that pairs with a red probe well. Although the detection mechanism at the probe well allows the Welch Allyn device to recognize the used probe, always ensure that the probe and the probe well colors match.

For information on the patient-applied measurement site, refer to each temperature probe's details section.

Preparing the patient for temperature measurement

1. Follow the manufacturer's instructions for thermometer or probe application.

Adjusting the temperature measurement completion tone volume

You can adjust the **Completed Temp volume** only when Welch Allyn temperature technology is used.

1. Select the **Configurations** > **Parameter Setup** > **Temp** vertical tab.

   Alternatively, select the **Configurations** > **Monitor Setup** > **Sound & Brightness** vertical tab.
2. Set **Completed Temp volume** with the sliding scale.

Selecting the temperature unit

The temperature unit settings require a password.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

Using a Welch Allyn temperature probe

The Welch Allyn temperature measurement is suitable for use on adult (18 years and older) and pediatric (17 years and younger) patients. You can measure oral, axillary or rectal temperature with the Welch Allyn temperature probe. When the tip of the probe is brought in contact with surrounding tissue, the electrical resistance is measured, the algorithm calculates and displays the patient's temperature. The probe requires a disposable probe cover and should never be used without one.

Selecting temperature probes

The temperature probes are color-coded to indicate which probes are used for oral/axillary or rectal measurement sites.

Color of the probe ejection button	Measurement site
Blue	Oral or axillary
Red	Rectal

The blue oral/axillary probe should only be used with blue probe well, while the red rectal probe should only be used with red well.

Be sure to select correct probe according to the measurement site.

For temperature probe and probe cover reorder part numbers, see the Supplies and Accessories.

About measurement methods

The device supprots two measurement methods using the Welch Allyn temperature probe.

- Predictive temperature measurement: Thermometers that render a temperature reading before steady state is achieved are classified as Predictive Thermometers. Predictive Thermometers reduce the time required for measurement by using algorithms to predict what the temperature would be if the probe were left in place until steady state is achieved.
- Monitor-mode temperature measurement: A function or mode of an electronic thermometer used to continuously monitor temperature until it reaches the thermal steady state (unchanging). The thermal steady state is achieved through an oral or rectal measurement in approximately 3 minutes and through an axillary measurement in approximately 5 minutes.

Taking a predictive temperature measurement

1. Check that the probe and probe well colors match, see Selecting temperature probes on page 129. Ensure they are connected to the device and the probe is in the probe well.
2. Select the required measurement site from **Site** list in the Temp parameter window or Temp setup menu. To access Temp setup menu, select the **Configurations** > **Parameter Setup** > **Temp** vertical tab. The options are **Oral**, **Pediatric axillary**, and **Adult axillary**.

   NOTE
   For rectal temperature measurement, the default **Site** is **Rectal**.

   NOTE
   To prevent erroneous readings, make sure you select the correct **Site** before measuring.
3. Remove the probe from the probe well. Insert the probe shaft into a probe cover and firmly press down until retaining rings of the probe cover seat securely over the retaining ring barb of the probe shaft.
4. Verify that the probe cover fits snugly.

   NOTE
   Failure to firmly install the probe cover may result in the probe cover becoming loose or disengaged during use. Unintended probe cover ejection can lead to patient injury.

   NOTE
   Do not allow the probe tip to come into contact with the patient until the probe is placed at the measurement site. Before this, any contact between the probe tip and the tissue or other material may cause inaccurate readings.
5. The temperature probe starts to warm up when the probe is taken out. When the warm-up is complete, the monitor will sound one beep.
6. Place the probe at the measurement site (> 34°C or 93.2°F), the predictive measurement will start automatically. The previous temperature value is cleared and the monitor starts the animation of "– – –" in the Temp parameter window.
   - When taking an oral temperature, apply the probe under the patient's tongue from either side of the mouth. Verify that the probe reaches the rear sublingual pocket. Have the patient close

his/her lips to hold the probe. Hold the probe in place. Make sure that the probe contacts with the patient's oral tissue throughout the measurement.

- When taking an axillary temperature, lift the patient's arm to expose the entire armpit. Apply the probe as high as possible in the armpit. Check that the probe tip is completely surrounded by the axillary tissue. Lower the patient's arm so that it is tightly placed at the patient side. Keep the patient's arm and the probe in place throughout the measurement.
- When taking a rectal temperature, separate patient's buttocks with one hand, and the probe 1.5 cm (0.6 inches) inside the rectum with the other hand. For a pediatric patient, the depth of insertion will be less. Tilt the probe so that it always contacts with patient's tissue. Lubricant can be used in rectal mode.

7. Always hold the probe in place, maintaining tissue contact until temperature measurement is complete. Do not allow the patient to reposition the probe.
8. When predictive measurement is complete, the monitor will beep three times. The temperature reading appears in the Temp parameter window.
9. Withdraw the probe. Firmly press the ejection button on the top of the probe to eject the probe cover. Place the probe into the probe well.

The predictive temperature measurement ends when one of the following occurs:

- A final value is determined.
- The probe is inserted into the probe well.
- The predictive measurement is not successful, and the measurement method automatically changes to Monitor-mode temperature measurement.

Taking a Monitor-mode temperature measurement

When the predictive measurement is complete, a snail icon appears in the Temp parameter window. Select the snail icon to switch to the Monitor-mode temperature measurement, which measures the temperature continuously. When the Monitor mode is selected, the snail icon will be animated during the measurement.

NOTE
If the predictive measurement failed, the measurement method automatically changes to Monitor-mode temperature measurement.

1. Enter the Monitor mode.
2. Place the probe at measurement site and then start measuring. Refer to Step 6 in Taking a predictive temperature measurement on page 130. The continuously measured temperature reading appears in the Temp parameter window.
3. Hold the probe in place for approximately 3 minutes (for oral and rectal) or 5 minutes (for axillary) to ensure that the probe tip has warmed up to the temperature of the surrounding tissues, giving a valid reading.
4. After the Monitor-mode temperature measurement ends, withdraw the probe. Firmly press the ejection button on the top of the probe to eject the probe cover. Place the probe into the probe well.
5. The monitor screen displays the following contents:
   - The temperature value and time of previous predictive measurement.

- Or "– – –" if the previous predictive measurement was expired or not successful.

The Monitor mode is not intended for long-term monitoring of a patient's temperature; rather, it is intended to produce a spot-check of the patient's temperature in cases where the predictive algorithm is unable to produce a result.

NOTE
Long-term continuous monitoring is not recommended for Welch Allyn temperature measurements. The Monitor-mode temperature measurement is automatically terminated after 10 minutes of monitoring.

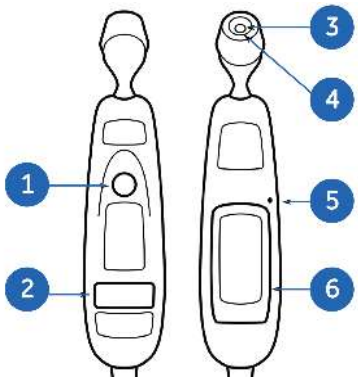
Using an Exergen thermometer

The Exergen TemporalScanner is a handheld infrared thermometer used by medical professionals for the intermittent measurement of human body temperature of people of all ages by scanning the forehead skin over the temporal artery. The monitor can use Exergen TemporalScanner technology when the thermometer is connected to the monitor's USB port.

For more information regarding clinical use, especially safety precautions and cleaning procedures, refer to the manufacturer's instructions available at http://www.exergen.com/s.

NOTE
The link to http://www.exergen.com/s appears on the front label of the thermometer as a scannable "QR" symbol for easy linking to the site.

Overview of an Exergen thermometer



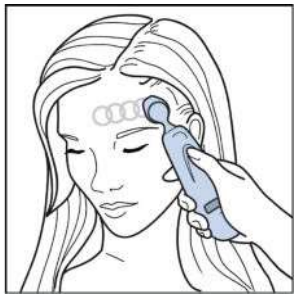
1.	ON button	4.	Probe cone
2.	LED display	5.	Pinhole
3.	Sensor lens	6.	Compartment door

Taking a temperature with an Exergen thermometer

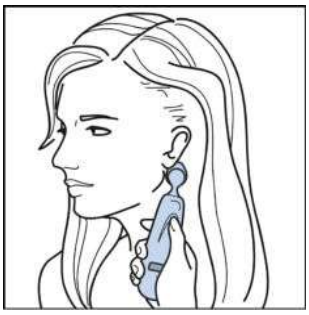
Below is an introduction for taking a temperature with an Exergen thermometer. For information regarding how to improve the accuracy of temperature measurements, refer to the manufacturer's instructions available at http://www.exergen.com/c.

1. Check that the thermometer is connected to the monitor, refer to Temperature equipment to patient connection on page 128.

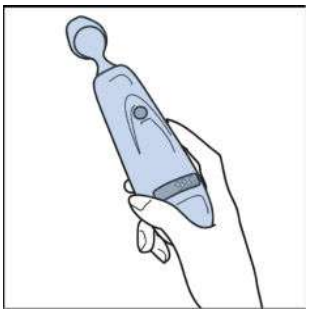
2. Check if the Exergen display screen displays a low battery message. If it does, replace the Exergen battery. To replace, insert the end of a bent paper clip into the pinhole on the side of the unit to release the battery compartment door. Disconnect the old battery and replace with a new one in the same location. Replace the cover.
3. If needed, place a disposable cap over the probe head or a protective sheath over the entire thermometer. Be sure to inspect the protective cover or sheath before each use to make sure the cover or sheath is defect free, contamination free, and installed properly with a snug fit. When using a protective disposable cap or sheath, always use a new protective cover or sheath when taking a measurement on a different patient.
4. Brush patient's hair aside if covering the temporal artery area or the ear area.
5. Slide across forehead. Place probe flush on center of forehead and depress button. Keeping button depressed, slowly slide probe mid-line across forehead to the hair line.

6. For adult temperature measurement only. Slide behind ear. Keeping button depressed, lift probe from forehead, touch behind ear halfway down the mastoid process and slide down to the soft depression behind the earlobe.



7. Release button, remove from head and read.



8. Read the temperature. When the determination is complete, an audible double tone sounds and the temperature displays on the Exergen display screen and on the monitor.

   The reading will remain on the Exergen display screen for 30 seconds after the **ON** button is released. And the reading will remain on the monitor's display for a valid period.

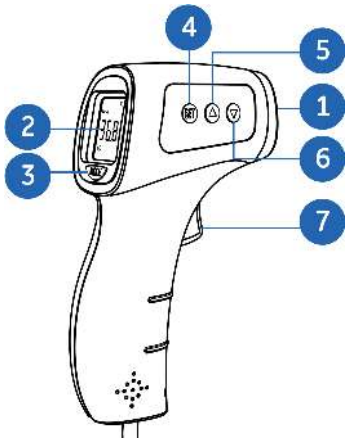
9. If you placed a protective disposable cap or scanner sheath on the thermometer, dispose of the protective disposable cap or sheath according to the applicable waste control regulations of your facility.
10. Clean the Exergen thermometer according to the manufacturer's instructions.

Using a HeTaida thermometer

The HeTaida thermometer is a non-contact infrared thermometer that measures human body temperature via the skin temperature on the forehead. It is applicable for adult, pediatric and neonatal patients. The monitor can use HeTaida temperature technology when the thermometer is connected to the monitor's USB port.

This manual provides an overview of HeTaida thermometer operation. For more information regarding clinical use, especially safety precautions and cleaning procedures, refer to the instructions provided by the manufacturer.

Overview of a HeTaida thermometer



1.	IR sensor	5.	Up Arrow button
2.	Liquid crystal display (LCD)	6.	Down Arrow button
3.	MODE button	7.	ON/measure button
4.	Set button		

Taking a temperature with a HeTaida thermometer

1. Check that the thermometer is connected to the monitor, refer to Temperature equipment to patient connection on page 128.
2. Turn on the thermometer by pressing the **`ON/measure`** button. The thermometer will perform a self-test with all segments displayed for two seconds.
3. Align the thermometer to the middle of forehead and keep a distance of 0.1-15 cm (0.04 - 5.9 inch).
4. Press the **`ON/measure`** button to start the measurement, then read the data on the monitor or HeTaida LCD screen.

Pulse rate

PR points to note

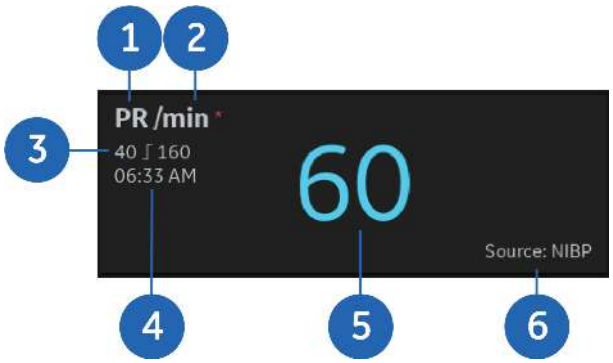
- If Masimo rainbow SET® is the data source, the pulse rate values are filtered by an averaging technique that determines how quickly the reported values respond to changes in the patient's saturation. Changing the averaging time affects time to alarm for SpO_2 saturation and pulse rate limits.
- As the various sources use different algorithms to measure the heartbeat, values in the PR window may differ when the monitor changes from one source to another.
- A patient's vital signs may vary dramatically during the use of cardiovascular agents such as those that raise or lower blood pressure or those that increase or decrease heart rate.

PR measurement description

The pulse numeric counts the arterial pulsations that result from the mechanical activity of the heart. The pulse rate (PR) value can be from SpO_2 or NIBP. The SpO_2 parameter is always the primary data source for pulse rate, whereas NIBP is the secondary source.

When the SpO_2 or NIBP measurement is complete, a value is displayed in the PR parameter window. The data source is also displayed underneath the PR value.

PR measurement displayed on the monitor screen



1.	PR (**PR**): parameter label
2.	/min (**/min**): unit
3.	PR alarm limits (appear in Monitoring mode only) The alarm limits will be replaced by the symbol when the PR alarm is set to **OFF** or in Spot Check mode.
4.	Time: when the displayed value was taken When the source is SpO_2, the displayed PR value is a calculated real-time value, so the measurement time is not displayed.
5.	PR value Displays "**– – –**" if the PR value is invalid or expired. The PR value displays in the similar lighter color as the source parameter (SpO_2 or NIBP).
6.	Source: NIBP (**Source: NIBP**): PR source Other available PR sources are **Source: SpO2** and **Source: Manual**. The text **Source: Manual** appears in the PR parameter window only when the PR value is imported from the Hub. For more information, see Scanning QR code from the Hub in the Portrait™ Mobile Monitoring Solution on page 70.

PR measurement setup

The PR parameter receives data from the SpO_2 or NIBP parameter. For information on SpO_2 or NIBP measurement setup, see the related parameter's chapter.

Using the PR measurement

Setting the PR alarm limits

1. Select the **Alarm Setup** > **Alarm Limits** tab.
2. Set **PR** alarm limits (**Low limit** and **High limit**) with the spinners.

3. Check that the **PR** alarm is turned on.

NOTE
If you want to turn off the alarm, select **OFF** from the **Alarm On/Off** list.

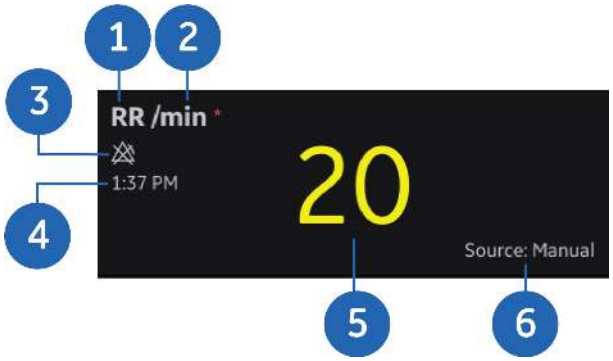
Respiration rate

RR measurement description

The monitor allows users to enter a respiration rate (RR) value per minute manually. Like the temperature parameter, you can enter the RR value with the numeric keyboard. See Entering RR and Temp values manually on page 76.

To improve the accuracy of the estimated value, the device also provides a timer next to the numeric keyboard. For more information about the timer, see Setting the RR timer on page 138.

RR measurement displayed on the monitor screen



1.	RR (**RR**): parameter label
2.	/min (**/min**): unit
3.	Indicates there are no alarms for RR measurement.
4.	Time: When the displayed value was manually entered
5.	RR value Displays "**– – –**" when the manual input RR value is invalid or expired.
6.	Source: Manual (**Source: Manual**): RR source The text appears in the RR parameter window when a valid RR value is manually entered or imported from the Hub. For more information, see Entering RR and Temp values manually on page 76 and Scanning QR code from the Hub in the Portrait™ Mobile Monitoring Solution on page 70.

Using the RR measurement

Setting the RR timer

The device provides a 60-second timer for users to calculate the RR value for the patient.

1.	Timer (**Timer**)	Menu title
2.	Circle progress bar	A full circle represents 60 seconds. When the timer starts, the circle color turns from gray to blue as a progress bar to indicate the time progress. There are two dots in the circle, indicating 15 s and 30 s. When the dot time is passed, the dot color changes from gray to white.
3.	Restart (**Restart**)	Restart key to reset and start the timer again.

1. Select the RR numeric value to open the **Timer** menu and the numeric keyboard. The timer starts when the menu is displayed.
2. Calculate the RR with the timer. The monitor will give a beep when the time reaches 15 s or 30 s. During the calculation, you can also select **Restart** key at any time to restart the timer.
3. Enter a new RR value with the numeric keyboard. See Entering RR and Temp values manually on page 76.

Adjusting the RR reminding volume

A reminder beep tone sounds when the RR timer reaches 15 s or 30 s.

1. Select the **Configurations** > **Monitor Setup** > **Sound & Brightness** vertical tab.
2. Set **RR reminding volume** with the sliding scale.

Selecting the RR color

The RR color settings require a password.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

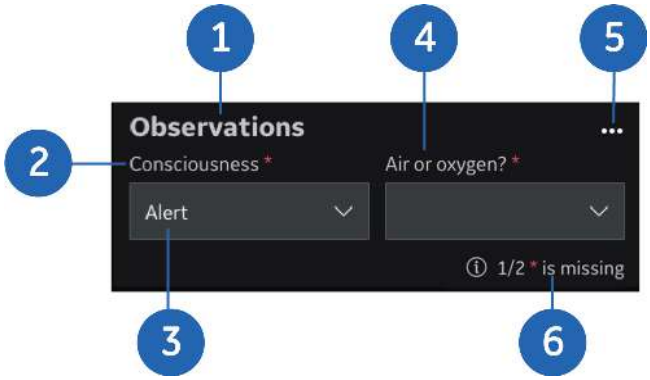
Observations

Observations description

The monitor allows users to enter physiological observations of a patient manually for clinical evaluation and record. The observations can be saved for reviewing, printing, or sending to EMR.

Observations displayed on the monitor screen

The observations have three different layouts on the screen: a selection list, a box for numbers only, or a box for free text. The layout depends on the observation type and affects the way that users input the value. The graphic below only shows one of the layouts.



1.	Observations (**Observations**): Observations window label
2.	Consciousness (**Consciousness**): Title of one available observation
3.	Alert (**Alert**): the selected observation status. The input method for this observation value is selection list. Users can select an appropriate option from the pre-configured list.
4.	Air or oxygen? (**Air or oxygen?**): Title of one available observation
5.	Select the ••• key to open the **Observations** full window. **NOTE** You can view all the observations in use and set up related observation items in the **Observations** full window.
6.	1/2 * is missing (1/2 * **is missing**): a message that indicates how many EWS scoring required observations are missing.

NOTE
The Observations window display will differ when EWS is enabled or disabled.

Using the observations

The following is an example of a procedure setting up Observations window for NEWS2. NEWS2 is one EWS protocol type. For more information, see Early Warning Score on page 142.

NOTE
The device supports up to 10 observations to be used. To change the options, consult authorized service personnel. For more information, refer to Technical Manual.

1. Select an appropriate option from the **Consciousness** list. The full options are **Alert**, **Confusion**, **Voice**, **Pain** and **Unresponsive**.
2. Select **Air** or **Oxygen** from the **Air or oxygen?** list.
3. If required, select the ••• key to open the **Observations** full window and set up other observations. The following are all the pre-configured observation options:
   - **Consciousness**
   - **CRT**
   - **Mucous color**
   - **GMFCS**
   - **Muscle strength**
   - **Feeding type**
   - **Hourly urine**
   - **Air or oxygen?**
   - **Bedside glucose**
   - **Pain score**
   - **Fluid inputs**
   - **Fluid outputs**
   - **Height**
   - **Weight**
   - **Airway**
   - **Breathing**
   - **Edema**
   - **Drainage**
   - **Wound**
   - **Nutrition**

   Select the ✕ key to save all the settings in the **Observations** full window and exit.

Early Warning Score (EWS)

EWS safety precautions

EWS warning

WARNING

PATIENT SAFETY.

Consider EWS as a secondary source for deterioration of vitals. Early Warning Score and Clinical Response Message serve as guide to protocols at your facility. In Monitoring mode, do not replace patient physiological alarms with EWS. Appropriate alarm settings must be set and maintained to ensure patient safety.

WARNING

PATIENT SAFETY.

NEWS2 and MEWS are not applicable to patients younger than 16 years or pregnant patients. Make sure the patient meets the indication before using NEWS2 or MEWS.

Early Warning Score

Early Warning score (EWS) is an optional, license-based feature that helps to recognize the early signs of deterioration in medical patients.

EWS is a simple scoring system in which a score is allocated to physiological parameters measured in clinical practice. Some parameters for EWS may be entered manually.

EWS feature can help clinician to recognize the early signs of deterioration in medical patients, follow prompt and effective action, and minimize the occurrence of adverse events.

The device supports the following scores' protocol type:

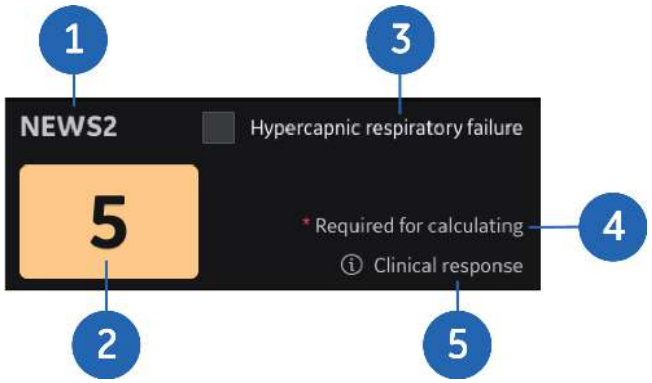
- NEWS2 (National Early Warning Score 2) (default)

  GE HealthCare provides the National Early Warning Score reference from the Royal College of Physicians to enable caregivers to track patient conditions. National Early Warning Score (NEWS)2: Standardizing the assessment of acute-illness severity in the NHS. Updated report of a working party. London: RCP, 2017.

- MEWS (Modified Early Warning Score)
- Customized EWS

EWS displayed on the monitor screen

The following is an example of one EWS protocol type.



1.	NEWS2 (**NEWS2**): EWS protocol label
2.	Total EWS score: displays only when all the required parameter and observations are obtained The background color changes when the total score is different. **NOTE** The score interval and background color may differ when using different EWS protocols.
3.	Hypercapnic respiratory failure (**Hypercapnic respiratory failure**): For NEWS2 only. Select the check box to use the SpO_2 scale that is dedicated for patients with hypercapnic respiratory failure for EWS scoring.
4.	Required for calculating (**Required for calculating**): The parameters or observations with the * mark are required for EWS calculation.
5.	Clinical response (**Clinical response**): select the ⓘ key to view the clinical response of the total EWS score.

Using the EWS

Setting up customized EWS protocols

The monitor supports customized EWS protocols based on your hospital-specific EWS scoring rules. If this is necessary, consult authorized service personnel.

For more information, refer to the Technical Manual.

Selecting the EWS type

The device is configured with the NEWS2 protocol as default. To change the EWS protocol type, consult qualified and trained technical users.

For more information, refer to the Technical Manual.

Calculating EWS

EWS scoring is performed automatically. When all parameters and observations required for EWS scoring are obtained, the monitor will calculate the total score automatically.

If any of the parameter or observation values change, the subscore and total score are recalculated accordingly.

1. For NEWS2, check if **Hypercapnic respiratory failure** needs to be selected depending on the patient's status.
2. Measure or manually enter all required parameters and observations. A message will appear in the EWS window to indicate how many EWS scoring required parameters or observations are missing.
3. After all parameters and observations required for EWS scoring (with the * mark) are obtained, the total score appears in the EWS window automatically. You can select the ⓘ key to view the clinical response of the total score.

NOTE
If any of the parameter or observation values become invalid, the total score disappears from the main screen.

Viewing EWS history

1. Select the **Patients & Records** tab to view the total scores of historical measurements.
2. Select a key to open the **Report** menu for a single measurement. You can then view the detailed EWS history for this measurement, including the EWS protocol type, subscore of each parameter and observation, total score and clinical response.

Historical data

Historical data safety precautions

Historical data warning

WARNING

PATIENT DATA.

You can only review the patient data which are saved by this monitor.

Historical data description

Historical data refers to the patient information, vital signs data, observations and EWS (optional) for all historical measurements.

The monitor allows users to review and manage historical data in the **Patients & Records** menu.

NOTE
The historical data will be automatically removed from the device after seven days.

Historical data displayed on the monitor screen

Historical data is displayed in the **Patients & Records** menu. Select the **Patients & Records** tab to open this menu.

1.	Patients & Records (**Patients & Records**): menu title
2.	Period (**Period**): a list of time periods that you can select for how long ago the historical data to be displayed on the screen
3.	Last 12 hours (**Last 12 hours**): one time period option
4.	Show vital signs (**Show vital signs**): Shows detailed vital signs data. After selecting the key, it changes to Hide vital signs (**Hide vital signs**) and the vital signs data are hidden.
5.	Search PID (**Search PID**): search the unique ID of patient depending on setting in the **Advanced** menu (password protected). This text appears in the search box when there are no entries. When you enter the unique ID, the device starts the search automatically.
6.	Time (**Time**): complete time for each measurement Select the key, it changes to the key and the records are displayed in descending order of complete time. The most recent record displays first. Select the key, it changes to the key and the records are displayed in ascending order of complete time. Select the **EWS** key, it changes to the key and the records are displayed in descending order of EWS score.
7.	Patient name/PID (**Patient name/PID**): patient name and unique ID for each measurement
8.	Labels and units of vital signs parameters
9.	EWS (**EWS**): EWS protocol label The records are displayed in descending order of EWS score. The record with the highest score displays first. Select the key again, it changes to the key and the records are displayed in ascending order of EWS score. Select the **Time** key, it changes to the key and the records are displayed in descending order of complete time.

10.	Status (**Status**): label of data-sending status. Select the key and a drop-down list pops up. You can filter the records by three options: **Sent**, **Failed** or **Unsent**. The key supports both single and multiple choices. After the data is filtered, the key changes to . Different symbols are displayed on the screen to indicate different statuses: for send success, for send failure, for being sent.
11.	Report (**Report**): report for each record. Select a key to review the **Report** for the selected measurement.
12.	Check all box: used for selecting all stored records
13.	Check single box: used for selecting a single record

NOTE
The **EWS** column appears on the screen only when the device has EWS license.

NOTE
The **Status** column may disappear from the **Patients & Records** menu depending on settings in the **Advanced** menu (password protected).

Reviewing the historical data for multiple patients

You can review all the historical data in the **Patients & Records** menu.

The steps listed below is guidance to finding the required data for multiple patients. You do not need to follow the steps in sequence. Always consider your professional healthcare facility guidelines as well.

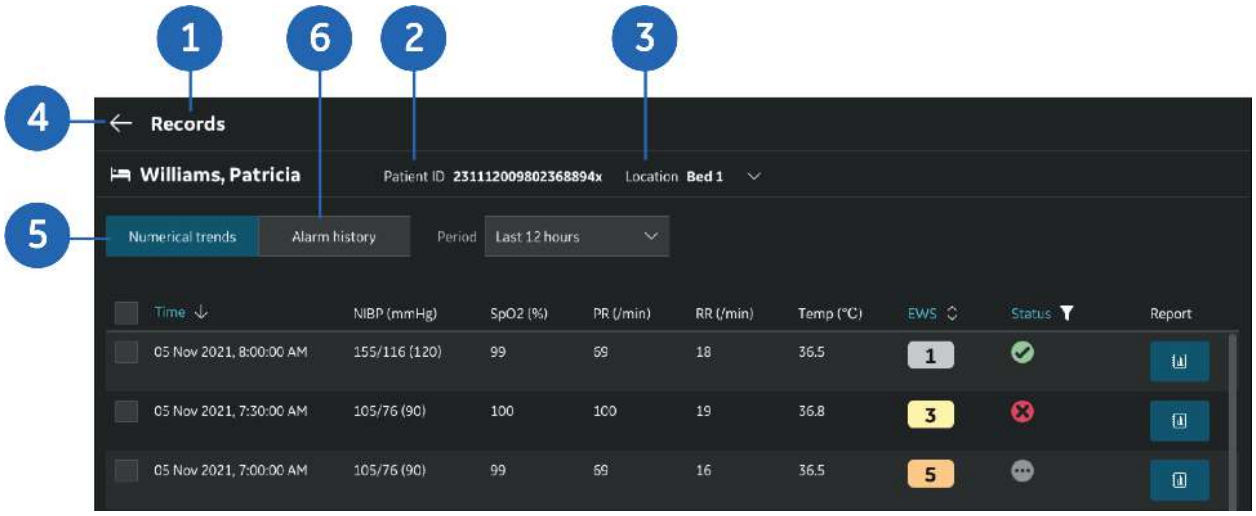
For more details about the following keys, see Historical data displayed on the monitor screen on page 145.

1. Select the required time period from the **Period** list.
2. Select the key or the key to show or hide the vital signs data on the screen.
3. Enter the unique ID of patient in the search box to start the search automatically.
4. Select the key or the key (or the key) to change the display order of records.
5. Select the key to filter the records by the pre-configured options.
6. Select a key to review the **Report** for the selected record.

Reviewing the historical data for a single patient

You can review the historical data for a single patient by selecting the patient's name in the **Patients & Records** menu or selecting the **Trends** key. For how to access the **Trends** key, see Managing historical data on page 149.

After that the **Records** menu appears. The layout is similar to the **Patients & Records** menu, so the following graphic only illustrates the major differences.



1.	Records (**Records**): menu title
2.	Patient ID (**Patient ID**): unique ID of patient The unique ID can be set in the **Advanced** menu (password protected).
3.	Location (**Location**): location of the patient
4.	Select the ← key to return to the **Patients & Records** menu.
5.	Numerical trends (**Numerical trends**): select the tab to view the numerical trends for the patient
6.	Alarm history (**Alarm history**): select the tab to view the alarm history for the patient

The steps listed below is guidance to finding the required data for a single patient. You do not need to follow the steps in sequence. Always consider your professional healthcare facility guidelines as well.

1. Select the required time period from the **Period** list.
2. Select the ↓ key or the ↑ key (or the ⇕ key) to change the display order of records.
3. Select the ▼ key to filter the records by the pre-configured options.
4. Select a key to review the **Report** for the selected record.
5. If required, select the **Alarm history** tab to review each historical alarm's occurrence time, description, priority, value and unit.

Reviewing the report

The report is detailed view of a record. You can review the report by selecting a key in the **Patients & Records** menu or the **Records** menu. For details about the two menus, see Historical data displayed on the monitor screen on page 145 and Reviewing the historical data for a single patient on page 147.

In the **Report** menu, you can review the following data of the selected record:

- Sending status (display or hide depending on settings in the **Advanced** menu)
- Caregiver name
- Complete time of the report
- Patient information

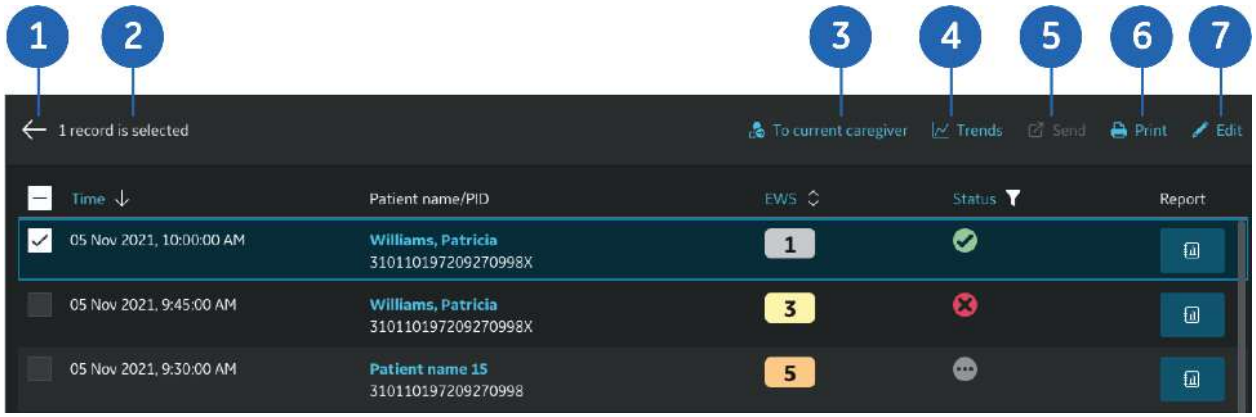
- Vital signs
- Observations
- EWS history: EWS protocol type, subscore of each parameter and observation, total score and clinical response (depending on license)

Managing historical data

The monitor allows users to manage the historical records.

In the **Report** menu, you can send or print the specific record, or edit the patient demographics.

In the **Patients & Records** menu or the **Records** menu, you can manage the historical data by selecting the check single box(es) or the check all box. For details about the two menus, see Historical data displayed on the monitor screen on page 145 and Reviewing the historical data for a single patient on page 147. Afterward, a bar appears on the screen.



1.	←	Cancel the selection of check box(es) and the bar disappears.
2.	1 record is selected (**1 record is selected**)	Display how many records are selected by the user.
3.	To current caregiver (**To current caregiver**)	Associate the selected record(s) with the current caregiver.
4.	Trends (**Trends**)	The key only appears in the **Patients & Records** menu. Open the **Records** menu to view the numerical trends for the patient.
5.	Send (**Send**)	Send the selected record(s) to EMR.
6.	Print (**Print**)	Print the selected record(s).
7.	Edit (**Edit**)	Open the **Edit** menu to edit the patient demographics.

You can use the above keys to manage historical data. But some keys will be disabled and dimmed in the following conditions:

- **To current caregiver**: when no caregiver is logged in or the selected records have been linked to caregiver
- **Trends**: when two or more records of different patients are selected

- **Send**: when a sent record is selected
- **Edit**: when more than one record is selected

NOTE

The **Send** key may disappear from the bar depending on settings in the **Advanced** menu (password protected).

Printing

Printing description

The data can be printed to a recorder connected directly to the monitor.

NOTE
Before you start printing, check that the recorder is operational, and make sure the recorder door is closed.

NOTE
Recordings on thermal paper may be destroyed when exposed to light, heat, alcohol, etc. Take a photocopy for your archives.

Setting the printer

Setting automatic printing

The monitor provides an automatic printing function. After setting this function, when you select the **Send** or **Save** key in Spot Check mode, printing will start automatically.

The related setting requires a password.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

Printing historical data

You can print historical record(s) in the **Report**, the **Patients & Records** or the **Records** menu. For more information, see Managing historical data on page 149.

In the **Report** menu, select the **Print** key to start printing. In the **Patients & Records** or the **Records** menu, follow the procedure below:

1. Select the required record(s) and press the **Print** key.

   When you select multiple records to print, the printing sequence follows the display sequence of the records list.

2. The system returns to the previously unselected status and a print progress indicator displays on the screen. If you want to stop the printing before it is complete, select the .

NOTE
When the monitor is in the process of printing, the **Print** key is disabled.

Printing format

Recorder print header

The recorder print header can include:

- Title
- Date and time of the printout
- Caregiver information
- Patient name
- Patient ID or Patient visit number (or other ID names depending on settings in the **Advanced** menu)
- Date and time of the medical record
- EWS score (if EWS is enabled and calculated)
- Values and units of vital signs: SYS, DIA, MAP, SpO_2, PR, RR, Temp (PR label shall contain the source of PR measurement)
- Values and units of observations (supports free text as well)

NOTE
You can print or hide caregiver information or patient name using the **Print Settings** in the **Advanced** menu.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

Inserting recorder paper

1. Press the door latch to open the recorder door.
2. Remove the paper core.
3. Place a new paper roll between the tabs of the paper holder. Make sure the paper unrolls from underneath the paper roll.

4. Pull out 3 to 4 cm of paper, then close the door.
5. Select the **Print** key to print out a strip. See Printing historical data on page 151.

Periodic Maintenance

Maintenance safety precautions

Care warnings

WARNING

EQUIPMENT FAILURE.

Regular preventive maintenance should be carried out every 24 months. Failure to implement the recommended maintenance schedule may cause equipment failure and possible health hazards.

WARNING

SAFETY HAZARD.

To avoid risks to personnel and patient, or damage to the equipment, only perform maintenance procedures described in this manual. Unauthorized modifications can lead to safety hazards.

WARNING

ENVIRONMENTAL HAZARD.

Cleanup and disposal of broken displays must be in compliance with the safety and waste control guidelines regulating this product.

WARNING

ELECTRIC SHOCK.

Non-medical equipment does not provide the same level of protection against electrical shock. Do not touch the patient and any part of non-medical equipment at the same time. An example of non-medical equipment is external display.

Before any planned maintenance or regular checks

Make sure that the patient is not being monitored during maintenance or regular check procedures.

Planned maintenance for the monitor

Service personnel should perform the following checkout procedures every 24 months after installation. Refer to the technical manuals for planned maintenance procedures.

- Visual inspection

- Electrical safety tests
- Functional check

Recommended check schedules

Daily checks

- Check that the accessories, cables, cable connectors, monitor and display parts are clean and intact.
- Check the charge of the monitor battery.

Check every 24 months

- Check the calibration of temperature and NIBP.
- Planned maintenance check

NOTE
Discharge patient before doing calibration and maintenance.

Regular calibration checks

NIBP and Temperature calibration check

The calibration check interval for NIBP and Tempeature is at least once every two years.

For calibration instructions, please refer to the Technical Manual of the monitor.

About battery care

Monitor battery

The monitor has one rechargeable lithium-ion battery to supply device operation without AC power.

- Condition battery: Connect device to the AC mains to charge battery. If the message **Condition battery** still persists, contact authorized service personnel to replace battery.
- Check battery status and performance: see Checking the battery charge with monitor software on page 42.
- Recycle battery: When the battery fails, or its runtime is significantly less than the specification, it should be replaced. A **Replace battery** message may appear. Please contact authorized service personnel to replace the old battery, and properly dispose of the battery according to your local recycling guidelines.

Internal RTC battery

The monitor has one button cell to retain the correct time and date for the device.

If the device time is reset to the factory default setting, please contact qualified service personnel to replace this battery.

How to store devices

- Store the device in a clean and dry, well-ventilated area.
- Hang the device using a holder, if available.
- If cables are attached, they should hang straight. Do not coil cables tightly around the device.

NOTE
If the device will enter long-term storage after usage, fully charge the monitor battery beforehand.

Disposal instructions

The product described in this manual, as well as its accessories and packaging, must be disposed of according to local environmental and waste disposal regulations. Always consider your hospital guidelines as well.

For detailed information regarding the substances contained in the product and their treatment, please request WEEE Selective Treatment Passports from GE HealthCare or its representatives.

This product contains lithium-ion batteries. At the end of their service life, batteries in this product must be recycled or disposed of in accordance with local or national regulations. Do not dispose of batteries as trash or unsorted municipal waste. Requirements and services for recycling of batteries vary between countries.

Troubleshooting

NIBP troubleshooting

Problem	Solution
NIBP measurement does not work or the values seem unstable.	• Check that the cuff tubing is not bent, stretched, compressed, or loose. • Check the cuff position and cuff tube connection. • Prevent motion artifact. • Use NIBP cuffs of correct size.
Why does the mean value display while the associated systolic and diastolic values display as - - -?	Assess the patient and perform a visual inspection of the equipment to ensure system integrity. The following conditions may cause the mean value to display in the NIBP digit field while the associated systolic and diastolic values display as - - -: • Very low systolic and diastolic amplitude fluctuations (e.g., patient in shock). • Very small difference between the mean and systolic pressure or the mean and diastolic pressure. • Loss of system integrity (e.g., loose connections or worn parts)
Why is the monitor re-inflating the cuff automatically?	The cuff target pressure must be higher than the patient's systolic pressure to obtain an accurate systolic and diastolic measurement. If a systolic blood pressure cannot be found, a systolic reading is searched for by re-inflating the cuff to a higher pressure. During a systolic search, the maximum cuff inflation pressure will not exceed the normal pressure range of the cuff. For more information, refer to the technical specifications.

SpO_2 troubleshooting

Problem	Solution
SpO_2 signal is poor	• Check the sensor and sensor position. • Make sure the patient is not shivering, moving, or does not have tremors. • The patient's pulse may be too low to measure.
Why does the pulse oximeter sometimes read differently to a blood gas analyzer?	Blood gas analyzers calculate the O_2 saturation based on normal values for pH, $PaCO_2$, Hb, temperature, etc. (i.e., a normal oxyhemoglobin dissociation curve). Depending on the patient's physiological and metabolic status, this curve and all values may be shifted away from normal. Thus the oximeter, which measures O_2 saturation, may not agree with the blood gas.
What effect can ambient light have on pulse oximetry monitoring?	Light sources such as surgical lamps, bilirubin lamps, fluorescent lights, infrared heating lamps, and sunlight can cause poor waveform quality and inaccurate readings. Error messages are possible. Shielding the sensor with opaque tape, a Posey wrap, or other dark or opaque material can increase oximetry accuracy, verified by good waveform and signal strength.

Problem	Solution
What does electrosurgical interference look like and how can it be minimized?	Electrosurgical interference is most obvious on the displayed waveform. It is a very spiky, erratic looking waveform caused by the electrosurgical unit's overwhelming interference. It can result in grossly inaccurate pulse oximeter results. Electrosurgical interference can be minimized by: • Making sure the pulse oximeter sensor is as far away from the return pad and operating site as possible. • Making sure the sensor is not between the return pad and operating site. • Keeping the power cord and sensor cable away from the power cord of the electrosurgical unit. • Plugging the electrosurgery unit into a separate set of outlets from the monitor.
What does motion artifact look like, what problems can it cause, and how can it be corrected?	For the device using Nellcor OxiMax technology, the main problem motion artifact can cause is erroneous SpO_2 readings. Motion artifact occurs with excessive motion of the sensor, the cable leading to the sensor, or the cable/sensor junction. In other words, anything that causes any of these things to move, like the patient moving his hands, or the cable lying across the ventilator tubing and being moved with every cycle, can cause motion artifact. A non-arterial, often erratic looking waveform and a pulse rate that does not coincide with the heart rate on the ECG will result. Motion artifact can be reduced, if not eliminated, by selecting a "quieter" site on the patient. An ear sensor if the hands do not remain still, an adhesive sensor on the toe, or an adhesive sensor on the little finger for an adult or on the sole of the foot in a newborn can help greatly. Cable movement can be reduced by applying the sensor with the cable leading toward the patient, then taping the cable to the side of the hand or foot. The cable and sensor can also be stabilized with a stress loop near the sensor. Tape the stress loop to the patient (excluding children). In the case of the butterfly sensor, the tape was designed to secure the cable to the finger. It has been noted that letting the patient view the SpO_2 waveform enables the patient to assist in reducing motion artifact.
Why is no SpO_2 data displayed on the monitor after connecting the SpO_2 interface cable and sensor?	No SpO_2 data is displayed due to a hardware failure or an unrecognized or defective sensor. • Make sure the accessories are compatible with the monitor. • Make sure the sensor is attached to the interface cable and the cable is connected to the monitor. • Change the sensor. • Change the cable. If the problem persists, contact authorized service personnel.

Temperature troubleshooting

Problem	Solution
Temperature measurement fails	• Check that the probe is properly connected to the monitor. • Check that you are using the correct probe for the site being monitored. • Use a probe that is compatible with your system. • Try using a known good probe in case the sensor is damaged. • Check the patient connection. • Check that there are not two or more temperature probes connecting to the monitor simultaneously. • If the problem persists, contact authorized service personnel.

Welch Allyn troubleshooting

Problem	Cause	Solution
Temperature readings are lower than expected or reading is not obtained.	• The measurement may be affected by external influences. • The probe may not be in consistent tissue contact. • The probe may be incorrectly positioned. • Incorrect probe covers are used. • The axillary position of the probe may be too low to obtain a predictive measurement or the probe tip may be exposed to air through the back of the axilla.	• Eliminate external influences caused by ambient air temperature or the intake of any liquids or physical matter by mouth before taking a measurement. • Verify the temperature probe is correctly positioned for the site being measured: ◦ Oral measurement: Place the thermometer tip in either the right or left sublingual pocket (heat pocket) at the base of the tongue. Have the patient close his or her lips over the probe. Continue to hold the probe in place, as motionless as possible, until the final reading is obtained. ◦ Axillary measurement: Insert the probe in the patient's axilla, making sure the tip of the probe is in contact with the skin and positioned as close as possible to the axillary artery with the patient's arm held close to his or her side. ◦ Rectal measurement: Insert the probe, using current hospital technique for penetration. • Use Welch Allyn oral/axillary or rectal probe covers on the Welch Allyn temperature probe. Refer to the Supplies and Accessories for reorder part numbers.
	• The temperature probe is worn out.	• Change the temperature probe.
Repeated error messages appear when taking a rectal temperature.	• The lubricant applied to the probe cover is too thick, reducing the heat transfer from the patient to the probe. • The lubricant is too cool. • The probe may not be in consistent tissue contact.	• Do not over-apply lubricant to the probe. • Allow the lubricant to warm to room temperature before application to the probe cover. • To take an accurate rectal temperature reading, insert the probe tip according to hospital protocol - but no further than 1.5 cm (0.6 inches) for adults, less for pediatric patients. If the tip is inserted too far, damage may occur and the probe tip may not have good contact with tissue.

Problem	Cause	Solution
Temperature readings do not register on hypothermic patients.	Wait until the predictive measurement is complete. Then switch manually to Monitor mode. Allow the temperature values to stabilize before recording the temperature. It will continue to monitor the patient's temperature until the probe is removed from the patient (the temperature reading will change as soon as the probe is removed from the patient; record the temperature displayed at the prescribed time before removing the probe from the patient.	The monitor does not beep to indicate a final reading. Leave the probe in place for the same length of time as required by standard hospital procedure for taking a continuous (monitor) temperature measurement.

Messages

Messages related to NIBP measurement

For information regarding alarm priorities and escalation times, see the alarm specifications section.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- PW = parameter window

NOTE
There are no physiological alarms in Spot Check mode.

Message	Location	Possible causes	Suggested actions
• **Call service: Error x** where x = 0 - 18	• PW	Technical fault.	• Restart the monitor. • Contact authorized service personnel.
• **NIBP call service error**	• MF		
• **Check NIBP**	• MF	Systolic and/or diastolic results missing.	• Check patient status. • Check NIBP cuff and hoses. • Repeat the measurement.
• **Cuff loose**	• PW	Loose cuff or cuff hose.	• Check the cuff and cuff hose.
• **Cuff occlusion**	• PW	Occlusion during measurement or overpressured cuff.	• Check the cuff.
• **Cuff overpressure**	• PW	NIBP cuff has exceeded the maximum cuff pressure during an NIBP measurement.	• Check NIBP cuff and hoses.
• **NIBP cuff overpressure**	• MF		
• **Long measurement time**	• PW	The measurement time is long. The triggering values vary according to the module and inflation limits in use: • >2 min for adult/child, 75 s to 80 s for infant	• Check patient status. • Check the cuff and hose connections. • Restart the measurement.
• **NIBP long measurement time**	• MF		
• **NIBP manual**	• MF	During auto cycling • Loose cuff or cuff hose. • Long measurement time	• Check the cuff and cuff hose whether loose.
• **NIBP cuff loose**	• MF	Loose cuff or cuff hose.	• Check the cuff and cuff hose whether loose.
• **NIBP cuff occlusion**	• MF	Occlusion during measurement or overpressured cuff.	• Check the cuff.

Message	Location	Possible causes	Suggested actions
• **NIBP DIA high** • **NIBP DIA low** • **NIBP MAP high** • **NIBP MAP low** • **NIBP SYS high** • **NIBP SYS low**	• MF (only Monitoring mode)	Measurement values are equal to or outside the set alarm limits.	• Check patient status. • Adjust alarm limits if necessary.
• **NIBP measurement removed**	• MF	Lost NIBP measurement.	• If the problem persists, contact authorized service personnel.
• **Unstable zero pressure**	• PW	Pressure is unstable at start of the NIBP measurement.	• Check patient status. • Check hose and cuff position. • Repeat the measurement. • If the problem persists, contact authorized service personnel.
• **Weak pulsation**	• PW	Weak or unstable oscillation signal.	• Check patient status. • Reposition the cuff. • Repeat the measurement.
• **NIBP weak pulsation**	• MF		

Messages related to SpO_2 measurement

For information regarding alarm priorities and escalation times, see the alarm specifications section.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- PW = parameter window

NOTE
There are no physiological alarms in Spot Check mode.

Message	Location	Possible causes	Suggested actions
• **Check device**	• PW	Only for Masimo type. Module malfunction.	• If the problem persists, contact authorized service personnel.
• **Check SpO2 probe**	• MF	There is no detectable SpO_2 signal, the sensor is faulty or is detached from the patient.	• Check the sensor and connections.
• **Check probe**	• PW		
• **Faulty probe**	• PW	The sensor has failed, or not compatible.	• Replace the sensor.
• **Incompatible probe**	• PW	Only for GE TruSignal or Masimo type. The sensor is not compatible.	• Replace the sensor.
• **Incompatible SpO2 probe**	• MF		
• **Interference**	• PW	Only for Nellcor or Masimo type. The measurement is disturbed.	• Check the sensor.

Message	Location	Possible causes	Suggested actions
• **Low perfusion**	• PW	Only for Masimo type. Low perfusion at the measurement point.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• **Low signal quality**	• PW	Only for Masimo type. The quality of the signal is questionable.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• **No SpO2 probe**	• MF	Sensor is not connected to the monitor. Sensor is not compatible.	• Check connection between the sensor and the monitor. • Replace the sensor.
• **No probe**	• PW		
• **No SpO2 pulse**	• MF (only Monitoring mode)	Only for GE TruSignal type. No pulses detected.	• Try another measuing site.
• **No pulse**	• PW		
• **Poor signal**	• PW	Only for GE TruSignal type. When low perfusion is detected.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• **Pulse search**	• PW	Defective or damaged sensor or cable. Sensor is off of the patient. Detection of a repeatable pulse has stopped.	• Check the sensor and cable. • Reposition or replace sensor.
• **Faulty SpO2 probe**	• MF	The sensor has failed, or is not compatible.	• Replace the sensor.
• **SpO2 high** • **SpO2 low**	• MF (only Monitoring mode)	Measurement values are equal to or outside the set alarm limits.	• Check patient status. • Adjust alarm limits if necessary.
• **SpO2 measurement removed**	• MF	Only for Nellcor or Masimo type. Lost SpO_2 measurement.	• If the problem persists, contact authorized service personnel.
• **STP measurements removed**	• MF	Only for GE TruSignal type. Lost SpO_2 measurement.	• If the problem persists, contact authorized service personnel.
• **SpO2 module error**	• MF	Only for Nellcor or Masimo type. SpO_2 module detects a communication problem.	• If the problem persists, contact authorized service personnel.
• **STP module error**	• MF	Only for GE TruSignal type. SpO_2 module detects a communication problem.	• If the problem persists, contact authorized service personnel.

Message	Location	Possible causes	Suggested actions
• **Incompatible Masimo**	• MF	The Masimo version is not compatible.	• Replace the sensor.
• **SpO2 probe off**	• MF	The finger or earlobe may be too thin or the sensor is off the patient.	• Check patient status. • Reposition the SpO_2 sensor. • Replace the SpO_2 sensor.
• **Probe off**	• PW		

Messages related to temperature measurement

For information regarding alarm priorities and escalation times, see the alarm specifications section.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- PW = parameter window

NOTE
There are no physiological alarms in Spot Check mode.

Message	Location	Possible causes	Suggested actions
• **Duplicate Temp modules**	• MF	Two or more temperature probes are connected to the same monitor.	• Remove the extra temperature probes.
• **Temp measurement removed**	• MF	Lost temperature measurement.	• Check connections of temperature probe or module. • Replace the temperature probe. • If the problem persists, contact authorized service personnel.
• **Temp probe too hot**	• MF	Only for Welch Allyn type. Probe temperature is too high.	• Wait unitil the probe temperature is stable.
• **Temp probe error**	• MF	Only for Welch Allyn type. Probe malfunction.	• Replace the temperature probe.
• **Temp module error**	• MF	Only for Welch Allyn type. Module malfunction.	• Restart the monitor. • If the problem persists, contact authorized service personnel.
• **Check Temp probe**	• MF	Only for Welch Allyn type. The temperature probe is disconnected.	• Attach the probe again.
• **Temp no determination**	• MF	Only for Welch Allyn type. The predictive measurement is not successful.	• Insert the probe to probe well and perform a new temperature measurement. • Select the snail icon to start Monitor mode and to display realtime measurement data.

Message	Location	Possible causes	Suggested actions
• **Temp not available**	• MF	Only for Welch Allyn type. Probe temperature is too low. It takes too long for a predictive temperature measurement.	• Insert the probe to probe well and perform a new temperature measurement. • If the problem persists, replace the temperature probe.
• **Ambient Temp low**	• PW	Ambient temprature is low.	• Move the patient to a warmer place and take temperature measurement again if necessary.
• **Ambient Temp high**	• PW	Ambient temperature is high.	• Move the patient to a cooler place and take temperature measurement again if necessary.
• **Measurement too low**	• PW	Body temperature is too low.	• Check patient status.
• **Measurement too high**	• PW	Body temperature is too high.	• Check patient status.
• **No Temp measurement**	• PW	No temperature probe or module is connected to the monitor.	• Connect one temperature probe to the monitor. • If the problem persists, contact authorized service personnel.
• **Interference detected**	• PW	Only for Welch Allyn type. Measurement is above or below the allowable patient or environmental temperature. Temperature module malfunction.	• Check patient temperature manually. • If the problem persists, contact authorized service personnel.
• **Probe too hot**	• PW	Only for Welch Allyn type. Probe temperature is too high.	• Wait unitil the probe temperature is stable.
• **Tissue contact lost**	• PW	Only for Welch Allyn type. The temperature probe is not in consistent tissue contact.	• Position the temprature probe correctly for the site being measured.
• **Probe well missing**	• PW	Only for Welch Allyn type. Probe well is missing or not installed properly.	• Verify the probe well is installed correctly. • If the problem persists, contact authorized service personnel.
• **Probe error**	• PW	Only for Welch Allyn type. Probe malfunction.	• Replace the temperature probe.
• **Module error**	• PW	Only for Welch Allyn type. Module malfunction.	• If the problem persists, contact authorized service personnel.
• **No probe**	• PW	Only for Welch Allyn type. The probe is not connected to the monitor.	• Attach the probe again.
• **No determination**	• PW	Only for Welch Allyn type. The predictive measurement is not successful.	• Insert the probe to probe well and perform a new temperature measurement. • Select the snail icon to start Monitor mode and to display realtime measurement data.

Message	Location	Possible causes	Suggested actions
• **Not available**	• PW	Only for Welch Allyn type. Probe temperature is too low. It takes too long for a predictive temperature measurement.	• Insert the probe to probe well and perform a new temperature measurement. • If the problem persists, replace the temperature probe.
• **Battery low**	• PW	Only for Exergen type. The thermometer battery is low.	• Replace the battery.
• **Battery empty**	• PW	Only for Exergen type. The thermometer has no battery inside.	• Install a new battery.
• **Internal error**	• PW	Only for Exergen type. The thermometer has internal error.	• Replace the temperature probe.

Messages related to PR measurement

For information regarding alarm priorities and escalation times, see the alarm specifications section.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- PW = parameter window

NOTE
There are no physiological alarms in Spot Check mode.

Message	Location	Possible causes	Suggested actions
• **PR high** • **PR low** • **NIBP PR high** • **NIBP PR low**	• MF (only Monitoring mode)	Measurement values are equal to or outside the set alarm limits.	• Check patient status. • Adjust alarm limits if necessary.

Messages related to various situations

For information regarding alarm priorities and escalation times, see the alarm specifications section.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- PW = parameter window

NOTE
There are no physiological alarms in Spot Check mode.

Message	Location	Possible causes	Suggested actions
• **Patient admitted**	• MF	The current patient has been admitted.	• No action required.

Message	Location	Possible causes	Suggested actions
• **Patient discharged**	• MF	The patient has been discharged.	• No action required.
• **Printing**	• MF	Printing is in progress.	• Wait for the printing to finish.
• **Recorder: out of paper**	• MF	The recorder is out of paper.	• Replace recorder paper.
• **Recorder: cover open**	• MF	The recorder cover is open.	• Close the recorder cover.
• **Recorder: input voltage high** • **Recorder: input voltage low**	• MF	There are problems with the recorder input voltage.	• Contact authorized service personnel.
• **Recorder: system error**	• MF	The local recorder is not working.	• Disconnect and reconnect the recorder cable. • If the problem persists, contact authorized service personnel.
• **Recorder: thermal array overheat**	• MF	There are problems with the recorder temperature. Printing for a long time.	• Try stopping the recording. • If the problem persists, contact authorized service personnel.
• **Recorder module removed**	• MF	Recorder module has been removed.	• Reconnect the recorder module if necessary.
• **Battery empty**	• MF	The monitor is battery powered and less than 5 min of monitoring time is available with battery.	• Charge the battery by using the monitor on mains power.
• **Battery low**	• MF	The monitor is battery powered and less than 20 min of monitoring time is available with battery.	• Charge the battery by using the monitor on mains power.
• **Battery temperature high**	• MF	The battery's temperature is too high.	• If the problem persists, contact authorized service personnel.
• **Certificate close to expiration**	• MF	The CA and client certificate in system time is 0-14 days before expire time.	• Contact authorized service personnel to install another CA certificate.
• **Certificate expired**	• MF	CA and client certificate is expired.	• Contact authorized service personnel to install another CA certificate.
• **Condition battery**	• MF	Battery is not working properly.	• Connect AC main to condition battery. • If the problem persists, contact authorized service personnel.
• **E-Manual lost**	• MF	E-manual is not available.	• Contact authorized service personnel.
• **Identical IP address noticed**	• MF	Two or more monitors on the network have the same IP address.	• Contact authorized service personnel.
• **License invalid**	• MF	License is invalid during start up.	• Contact authorized service personnel.
• **No battery backup**	• MF	Battery missing from the battery compartments.	• Contact authorized service personnel.
• **Replace battery**	• MF	Battery is not working properly.	• Replace the battery.
• **Restart needed**	• MF	The monitor should be restarted.	• Restart the monitor.

Message	Location	Possible causes	Suggested actions
• **Frame temperature high**	• MF	The temperature inside the frame is over 70°C/158 °F.	• Turn off the monitor, wait for it cool down. • Make sure there is sufficient ventilation. • Check and clean monitor ventilation holes.
• **Audio fail**	• MF	The system can't communicate with audio clip hardware.	• Check the patient status. • If the problem persists, contact authorized service personnel.

Cleaning and disinfection

About these instructions

The following cleaning and disinfection information applies to the devices and device components listed in this instruction and manufactured by GE HealthCare. Follow these instructions to clean and disinfect the devices and parts that are not in direct contact with the patient, referred to as non-applied parts, unless there are separate part-specific instructions.

For details about cleaning, disinfecting and sterilizing accessories, see the instructions for use in the accessory package.

Always consider your professional healthcare facility guidelines as well.

For cleaning, disinfection, and care information for devices, device components, supplies, and accessories made by manufacturers other than GE HealthCare, see the applicable instructions for use provided by the manufacturer. The information provided in this supplement does not supersede any instructions for use provided by the manufacturer or provided with a device, device component, supply, or accessory.

- Cleaning is physical removal of soil and contaminants.
- Disinfection reduces the number of viable microorganisms on a product to a level previously specified as appropriate for its use.

About cleaning and disinfection

Cleaning warnings

WARNING

EQUIPMENT DAMAGE.

Avoid using other chemicals than the ones described in this manual as they may damage device surfaces, labels, or cause equipment failures.

WARNING

EQUIPMENT DAMAGE.

To prevent liquids from entering the monitor, do not tilt the monitor more than +/-15 degrees. Any liquids entering the device may damage it.

WARNING

EQUIPMENT DAMAGE.

If liquid has accidentally entered the system or its parts, disconnect the power cord from the power supply and have the equipment serviced by qualified service personnel.

WARNING

EQUIPMENT DAMAGE.

Never immerse any part of the device or cables in liquids or allow liquid to enter the interior of the device.

WARNING

EQUIPMENT DAMAGE.

Do not autoclave any part of the system with steam (including cables) or sterilize with ethylene oxide.

WARNING

EQUIPMENT DAMAGE.

To avoid the risk of damaging the devices, do not use any automated cleaning procedures. Always clean manually according to the instructions provided.

WARNING

EQUIPMENT DAMAGE.

Do not pour or spray any liquid directly on the device or cables, or permit fluid to seep into connections or openings.

WARNING

EQUIPMENT DAMAGE.

Never use conductive solutions, oxidizing compounds, wax, or wax compounds to clean the device.

Cleaning cautions

CAUTION

EQUIPMENT DAMAGE.

Do not apply pressurized air or gas to any outlet or tubing connected to the monitor. Pressure may destroy sensitive elements.

Cleaning points to note

Observe these guidelines while cleaning the device.

- Your professional healthcare facility guidelines permitting, all cleaning activities can be carried out at the bedside.
- Be especially careful when cleaning the displays. They are more sensitive to rough cleaning methods than, for example, the monitor housing.
- Avoid contact with open vents, plugs, or connectors during the cleaning procedures.
- Always dilute cleaning agents according to their manufacturer’s instructions.

- Always consider your professional healthcare facility guidelines as well.
- Prolonged contact of cleaning solutions with metal parts may cause corrosion.
- Do not clean any part of the system using automated cleaning.
- Do not use excessive drying techniques, such as oven, forced heat, or sun drying.
- Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.
- The warranty does not cover any damage caused by using any substances and methods other than those approved by GE HealthCare.

Disinfection points to note

- Your professional healthcare facility guidelines permitting, all disinfection activities can be carried out at the bedside.
- Always clean before disinfecting.
- Always dilute disinfectant agents according to their manufacturer’s instructions.
- Always consider your professional healthcare facility guidelines as well.
- Use only the permitted substances.
- Prolonged contact of disinfecting solutions with metal parts may cause corrosion.
- Do not disinfect any part of the system with automated disinfection techniques.

Visual inspection before cleaning and disinfection

Carefully inspect devices visually to verify proper function. Do not use improperly functioning, damaged, or excessively worn devices, or devices with unrecognizable markings or missing or worn device labeling or marking. Evidence of damage and wear on a device may include but is not limited to discoloration, excessive scratches, melting, dulling, distortion, wear, and cracks. If a device is extremely soiled and cannot be cleaned using the normal procedure, replace it. Contact qualified service personnel and follow your professional healthcare facility procedures.

If you discover any signs of deterioration or damage in the device, discontinue its use.

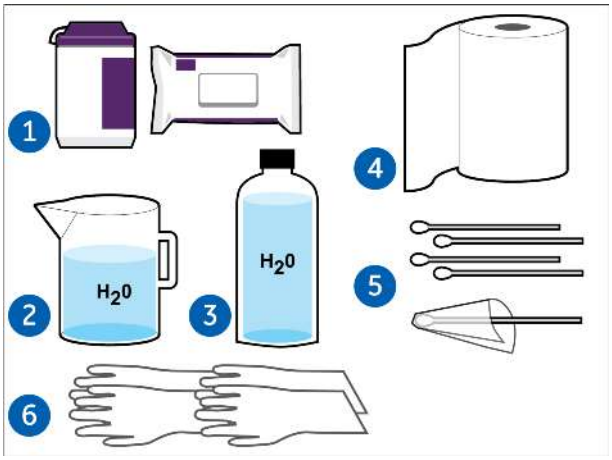
Cleaning and disinfection frequency

The following table indicates the frequency of visual inspection, cleaning, and disinfection procedures.

Device	Visual inspection	Cleaning	Disinfection
Monitor 	• Before and after cleaning or disinfection	• Between patients, or when in use and visible soil is present.	• Perform disinfection after cleaning, not before • Between patients, or when in use and visible soil is present.

Device	Visual inspection	Cleaning	Disinfection
B1X5-REC Recorder 	• Before and after cleaning or disinfection	• Weekly • When in use and visible soil is present.	• Perform disinfection after cleaning, not before • Weekly

Supplies needed for cleaning and disinfection



1. Cleaning/disinfection wipes (commercial) or detergent/disinfectant.
2. Cleaning: water, if required for rinsing off the detergent
   - Tap (utility) water is water that has not been processed. You can use tap water if it is not contaminated.
3. Disinfection: critical water, if required for rinsing off the disinfectant
   - Critical water (sterile water, water that is extensively treated to ensure microorganisms, inorganic, and organic materials are removed).
4. Non-linting cloths
5. Cotton swabs
6. Disposable gloves and any other Personal Protective Equipment (PPE) recommended by your professional healthcare facility guidelines

Replace soiled or dry wipes or non-linting cloths as needed.

- Do not use sharp tools to clean the device.
- Do not damage or bend connector pins when cleaning or disinfecting.
- Do not use a dripping cloth on surfaces.

Permitted cleaning and disinfection agents

GE HealthCare used Super Sani-Cloth wipes during cleaning and disinfection efficacy validation. This cleaning agent is not listed in preference to other available cleaning agents, which may also perform satisfactorily.

The following products are compatible with the devices and may be used for cleaning and disinfection. It should be noted that the generic agents have not been validated.

All third party trademarks are property of their respective owners.

Trademark names and product availability may vary in different countries. Consult the column that lists ingredients to determine if an equivalent disinfectant is available in your country.

When using other than validated cleaning or disinfection agents, note the following:

- Use only soft, non-linting cloths.
- Prepare and use the agent according to the manufacturer instructions.
- Let the disinfectant remain on the device surface according to the manufacturer instructions.

Product	Manufacturer	Type of Disinfectant	Active Ingredients*
70-96%Ethanol	Generic	Alcohol	Ethanol (CAS 64-17-5)
Clinell wipes Universal - Green	GAMA Healthcare	Quaternary ammonium	• 2-Phenoxyethanol (CAS 122-99-6) ≤0.6% • Benzalkonium chloride (CAS 68424-85-1) ≤0.6% • Didecyldimethyl ammonium chloride (CAS 7173-51-5) ≤0.6% • Biphenyl-2-ol (CAS 90-43-7) ≤0.1%
Terralin liquid	Shülke & Mayr GmbH	Alcohol	• Propan-1-ol (CAS 71-23-8) 35% • Ethanol (CAS 64-17-5) 25%
Oxivir TB wipes	Diversey	Hydrogen peroxide	• Benzyl alcohol (CAS 100-51-6) 1-5% • Hydrogen peroxide (CAS 7722-84-1) >0.1 - <1%
Incidine oxy wipes	Ecolab	Hydrogen peroxide	Hydrogen peroxide (CAS 7722-84-1) >= 1 - < 2.5
Mikrozid universal wipes	Shülke & Mayr GmbH	Alcohol	• Ethanol (CAS 64-17-5) 12.6% • Propan-2-ol (CAS 67-63-0) 17.4%
Super Sani-Cloth® Germicidal Disposable Wipe (Purple)	PDI	Quaternary ammonium and alcohol	• Isopropyl alcohol (CAS 67-63-0) 55.5% • Quaternary ammonium compounds, C12-18-alkyl [(ethylphenyl) methyl] dimethyl, chlorides (CAS 68956-79-6) 0.25% • n-Alkyl Dimethyl Benzyl Ammonium Chloride (CAS 68391-01-5) 0.25%
Clorox hydrogen peroxide wipes	Clorox	Hydrogen peroxide	• Hydrogen peroxide (CAS 7722-84-1) 0.5-2% • Benzyl alcohol (CAS 100-51-6) 1-5%

Product	Manufacturer	Type of Disinfectant	Active Ingredients*
Reynard premier detergent and disinfectant wipes	Reynard	Quaternary ammonium	• Didecyldimethyl ammonium chloride (CAS 7173-51-5) <5% • C12/16 Alkyl dimethyl benzyl ammonium chloride (CAS 68424-85-1) <5% • C12/14 Alkyl dimethylethyl benzyl ammonium chloride (CAS 854090-23-0) <5%
Rely+on Virkon	LANXESS	Organic salts and organic acids	Concentrate is dissolved to a 1% solution. Concentrate contains: • Pentapotassium bis(peroxymonosulphate bis(sulphate) (CAS 70693-62-8) >30 - <50% • Malic acid (CAS 6915-15-7) >20 - <30% • Sulphamidic acid (CAS 5329-14-6) >5 - <10% • Sodium dodecylbenzenesulfonate (CAS 25155-30-0) >1 - <5% • Potassium hydrogensulphate (CAS 7646-93-7) >1 - <5% • Dipotassium peroxodisulphate (CAS 7727-21-1) 1 - <5% • Dipotassium disulphate (CAS 7790-62-7) 1 - <5%
Bleach max. 5.25% by volume mixed with water in the ratio of 1:10	Generic	Chlorine	Sodium hypochlorite (CAS 7681-52-9) 0.525 %
70% IPA	Generic	Alcohol	Isopropyl alcohol (CAS 67-63-0)
Sani-Cloth Bleach Germicidal Disposable Wipes	PDI	Chlorine	Sodium hypochlorite (CAS 7681-52-9) 0.63%
PDI Easy Screen Cleaning Wipes	PDI	Alcohol	Isopropyl alcohol (CAS 67-63-0) 70%
Getinge Clean*1	Getinge	Enzymatic or neutral pH detergents	Enzymatic or neutral pH detergents
* Ingredients, if applicable. Listed as indicated in the disinfectant package or Material Safety Data sheet at the time of publishing this manual. All generic agents: check the minimum disinfection times as per your healthcare facility guidelines.			
*1 The agent can only be used for cleaning.			

Do NOT use any of the following to clean the device because they may damage its surfaces:

- Organic solvents
- Abrasive cleaners or solvents of any kind
- Acetone
- Ketone
- Betadine
- Sodium salts

How to clean and disinfect

Cleaning and disinfecting the monitor

NOTE
Before you start, remove the AC power supply. You can also decide to do the following according to your needs:

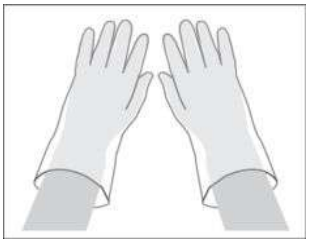
- Turn off the monitor.
- Lock the screen (e.g., when the monitor is in use and visible soil is present). For details about how to lock the screen, see Locking the screen on page 59.
- Discharge patient, and disconnect cables or devices if necessary.

NOTE
Clean the devices thoroughly prior to disinfection. For the agents list, see Permitted cleaning and disinfection agents on page 172.

NOTE
The monitor in the illustration graphics is configured with one of the optional temperature accessories. It may differ from the monitor you are using.

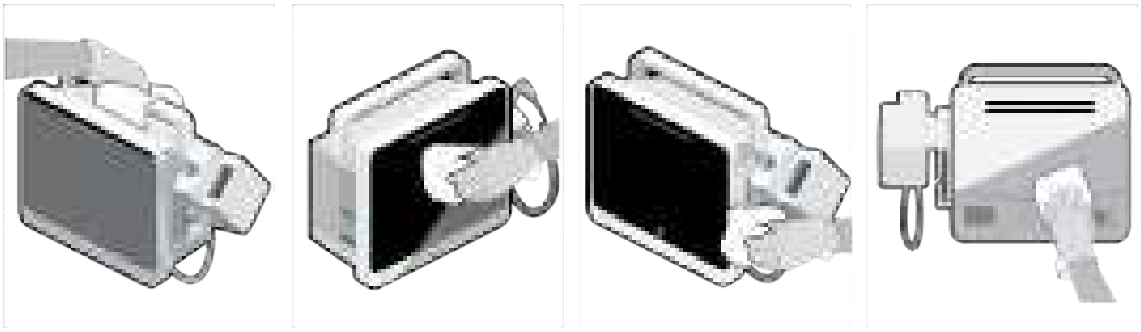
NOTE
For cleaning and disinfection of accessories, see the instructions for use provided by the manufacturer.

1. Put on new disposable gloves and any other Personal Protective Equipment (PPE) recommended by your professional healthcare facility guidelines.

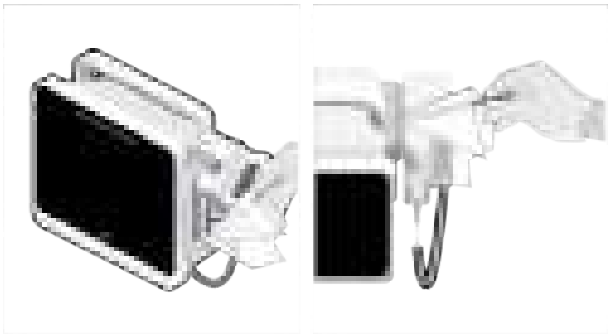


2. Get a new wipe or dampen a soft non-linting cloth with one of the permitted detergents.

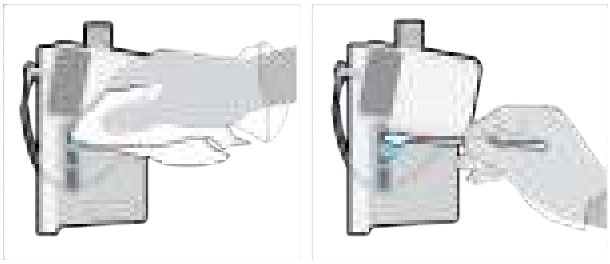
3. Wipe the device's exterior surface. Remove any soil by wiping the device until soil and organic matter have been visibly removed.



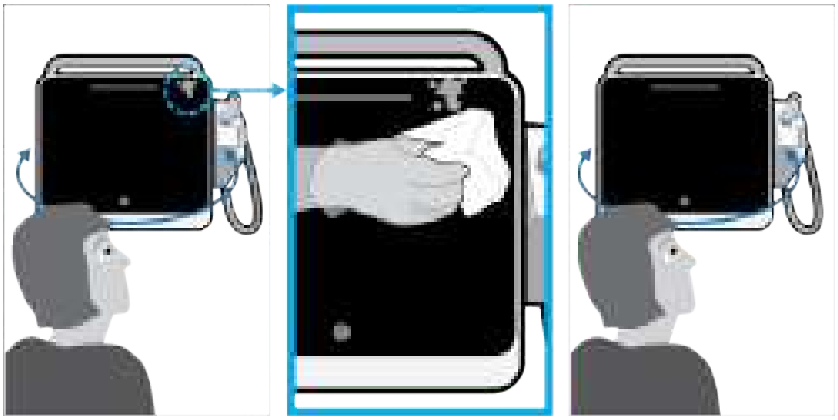
Pay special attention to hard-to-clean areas like grooves and crevices. Scrub these areas with a cotton swab inside a wipe.



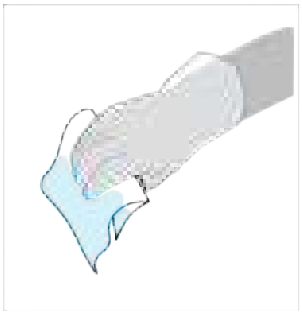
4. Ensure there is no liquid pooling around connection pins. If this happens, blot dry with a cotton swab or soft non-linting cloth.



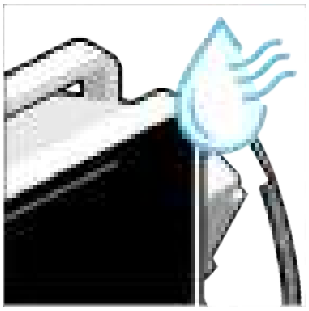
5. Inspect the device to ensure the complete removal of soil from surfaces, cavities, and movable parts. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.



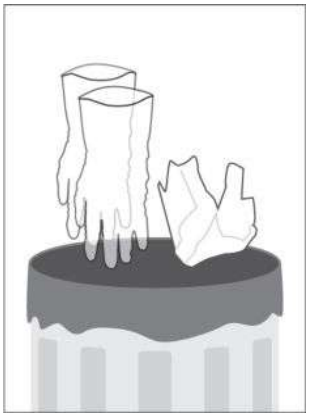
6. If required, manually rinse the device by wiping it for 30 seconds using a sterile, soft, non-linting cloth saturated with lukewarm water (temperature range 27 to 44°C, 81 to 111°F).



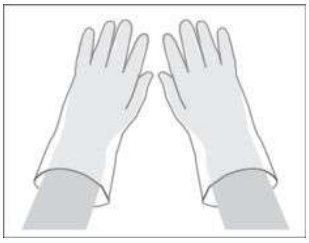

7. Allow the device to air dry until it is visibly dry. Drying times may vary based on the environmental conditions.



8. Discard disposable wipes, gloves and other PPE according to your professional healthcare facility guidelines. Do not reuse wipes, gloves, or other PPE.

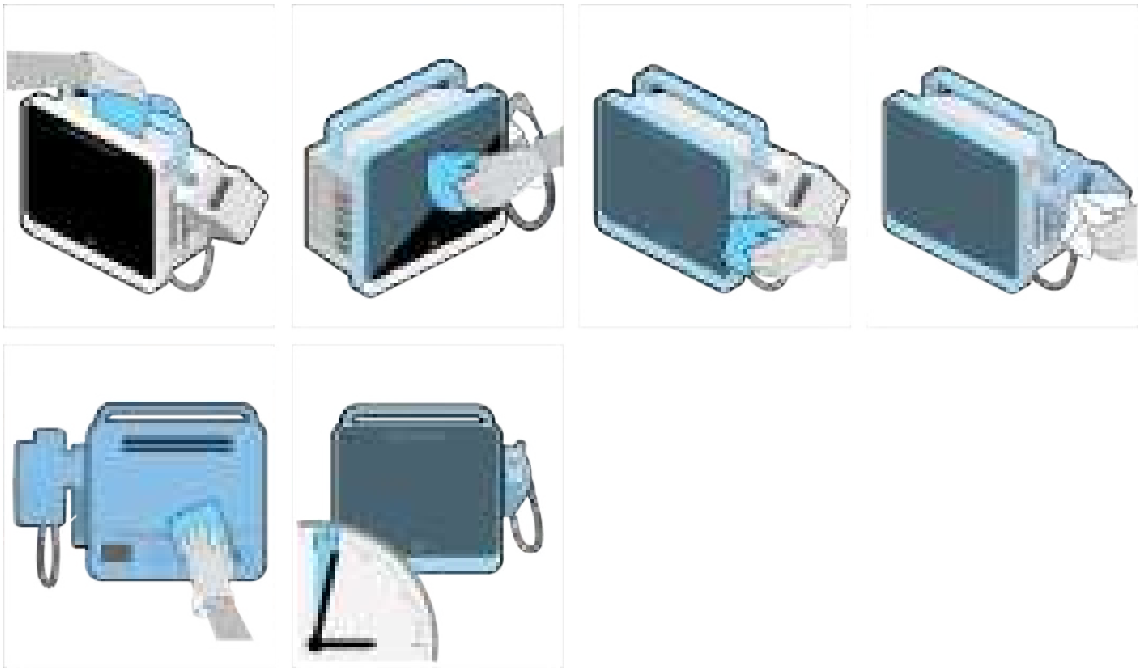


9. Start disinfection by putting on new disposable gloves and any other PPE recommended by your professional healthcare facility guidelines.

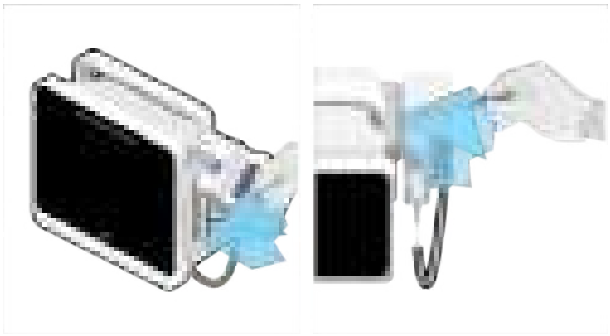


10. Get a new wipe or dampen a soft non-linting cloth with one of the permitted detergents.

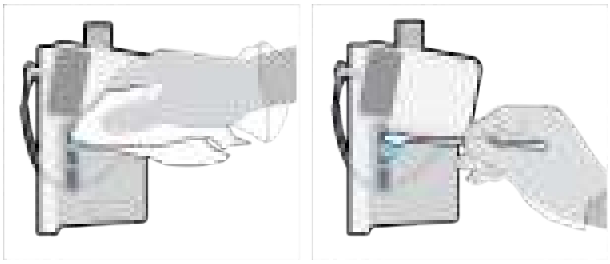
11. Wipe the device surface. Make sure all surfaces are uniformly wiped. Treated surfaces must remain visibly wet for a minimum of two minutes (Super Sani-Cloth) or according to the disinfectant manufacturer's instructions. To ensure this, use additional disinfectant wipes as necessary.



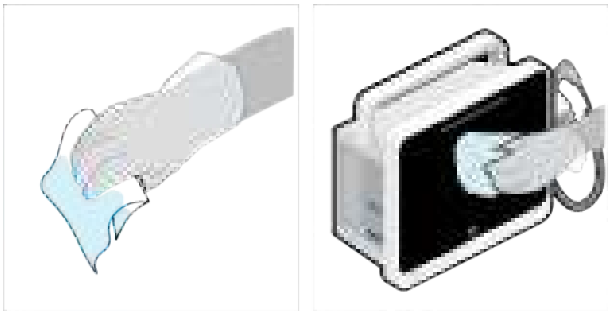
Pay special attention to hard-to-clean areas, like grooves and crevices. Scrub these areas using a cotton swab inside the wipe.



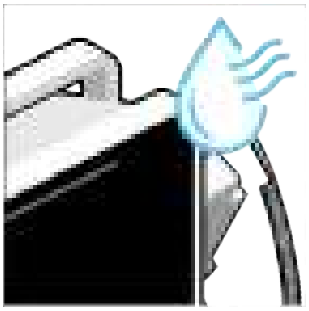
12. Ensure there is no liquid pooling around the pins. If this happens, blot dry with a cotton swab or soft non-linting cloth.



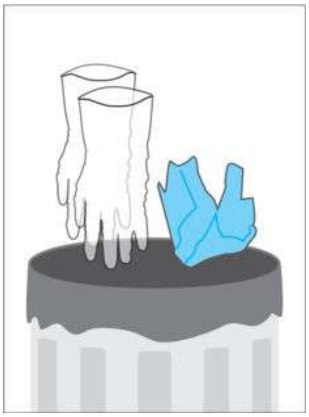
13. If required, manually rinse the device by wiping it for 30 seconds using a sterile, soft, non-linting cloth saturated with critical water (sterile water, temperature range 27 to 44°C, 81 to 111°F).



14. Allow the device to air dry until it is visibly dry. Drying times may vary based on the environmental conditions.



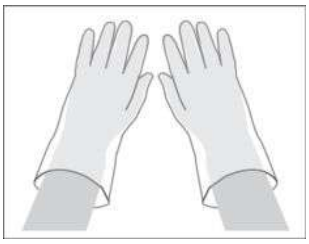
15. Discard disposable wipes, gloves, and other PPE according to your professional healthcare facility guidelines. Do not reuse wipes, gloves, or other PPE.



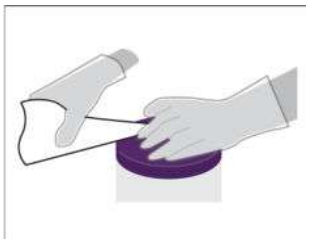
Cleaning and disinfecting the B1X5-REC recorder

NOTE
Before you start, please remove the recorder from the monitor. See Removing the recorder on page 47.

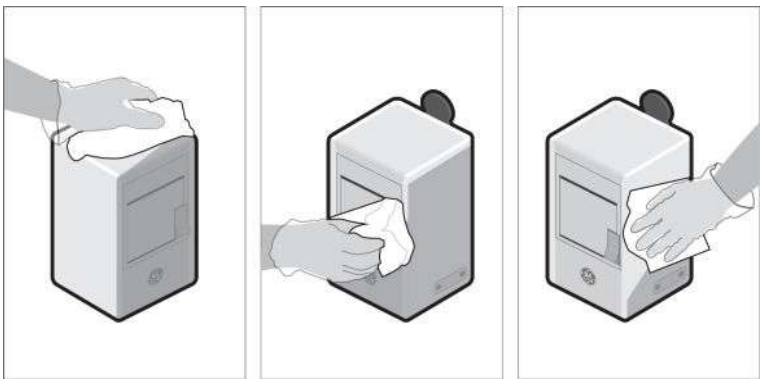
1. Put on new disposable gloves and any other Personal Protective Equipment (PPE) recommended by your professional healthcare facility guidelines.



2. Get a new wipe or dampen a soft non-linting cloth with one of the permitted detergents.

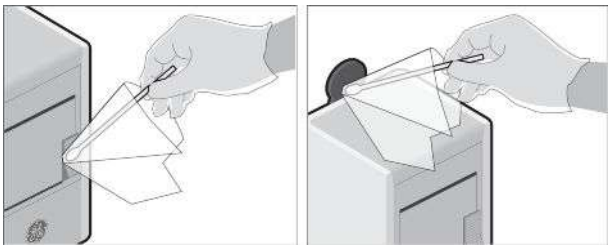


3. Wipe the device's exterior surface. Remove any soil by wiping the device until soil and organic matter have been visibly removed.

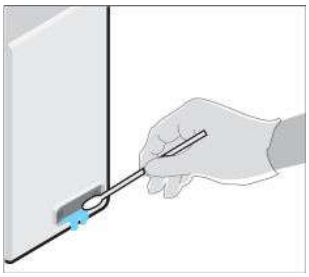


NOTE
Do not clean inside the paper compartment. If the paper compartment is soiled or contaminated, do not use the device and contact qualified service personnel for maintenance.

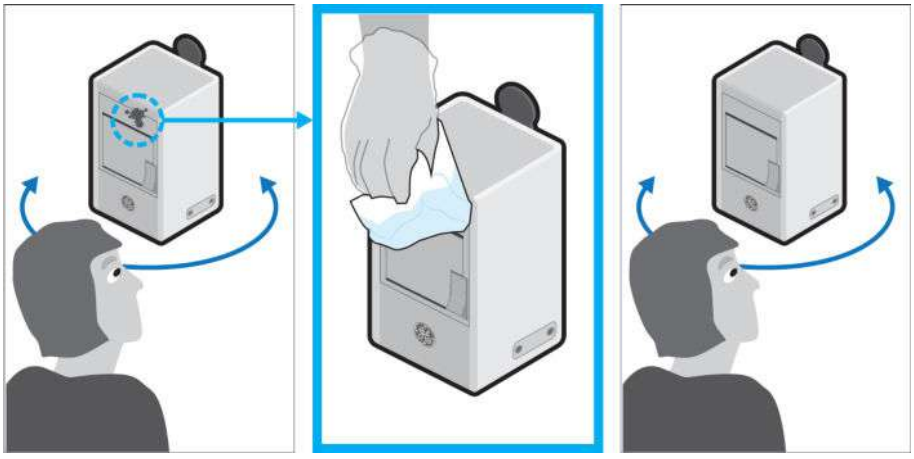
Pay special attention to hard-to-clean areas like grooves and crevices. Scrub these areas with a cotton swab inside a wipe.



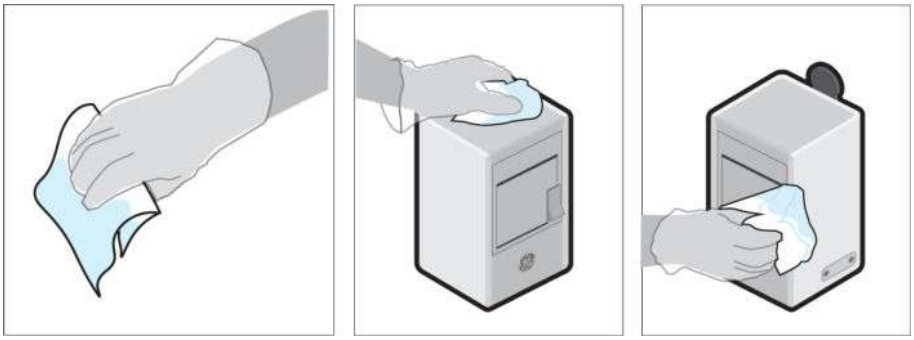
4. Ensure there is no liquid pooling around connection pins. If this happens, blot dry with a cotton swab or soft non-linting cloth.



5. Inspect the device to ensure the complete removal of soil from surfaces, cavities, and movable parts. If visible soil remains, repeat cleaning procedure until the device is thoroughly clean.

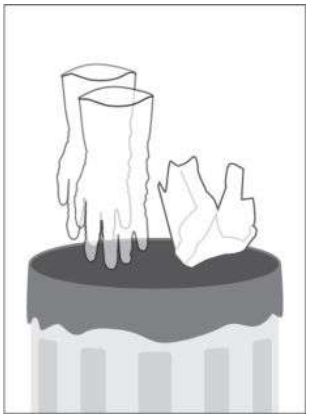


6. If required, manually rinse the device by wiping it for 30 seconds using a sterile, soft, non-linting cloth saturated with lukewarm water (temperature range 27 to 44 °C, 81 to 111 °F).

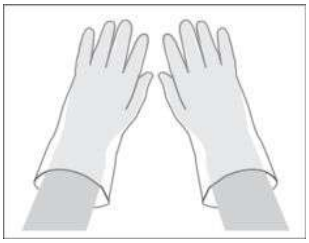


7. Allow the device to air dry until it is visibly dry. Drying times may vary based on the environmental conditions.

8. Discard disposable wipes, gloves and other PPE according to your professional healthcare facility guidelines. Do not reuse wipes, gloves, or other PPE.

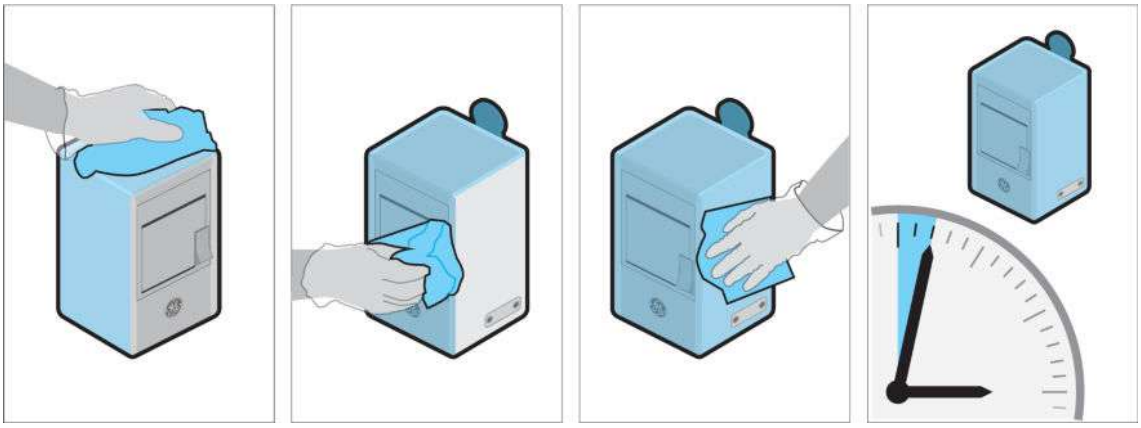


9. Start disinfection by putting on new disposable gloves and any other PPE recommended by your professional healthcare facility guidelines.



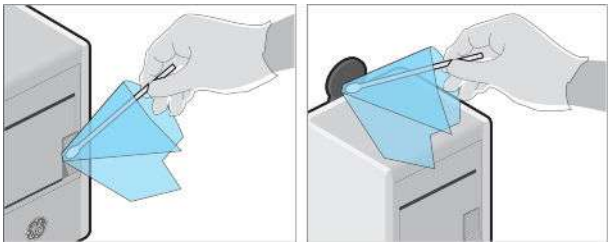
10. Get a new wipe or dampen a soft non-linting cloth with one of the permitted detergents.

11. Wipe the device surface. Make sure all surfaces are uniformly wiped. Treated surfaces must remain visibly wet for a minimum of two minutes. To ensure this, use additional disinfectant wipes as necessary. Also refer to the instructions provided by disinfectant manufacturer.

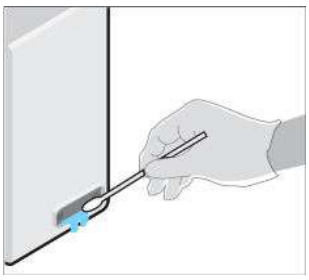


NOTE
Do not disinfect inside the paper compartment. If the paper compartment is soiled or contaminated, do not use the device and contact qualified service personnel for maintenance.

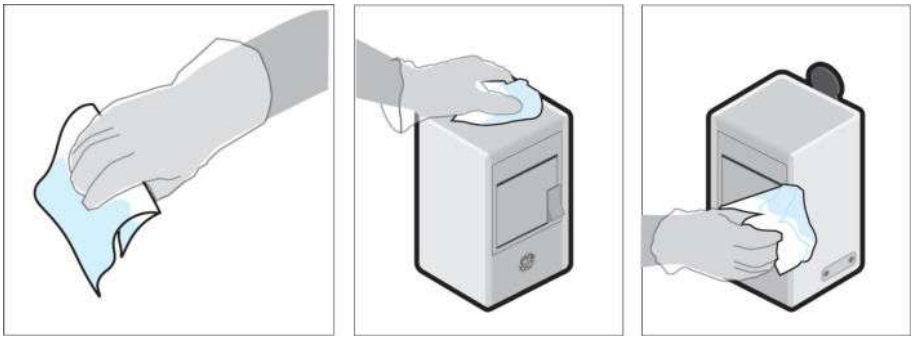
Pay special attention to hard-to-clean areas, like grooves and crevices. Scrub these areas using a cotton swab inside the wipe.



12. Ensure there is no liquid pooling around the pins. If this happens, blot dry with a cotton swab or soft non-linting cloth.

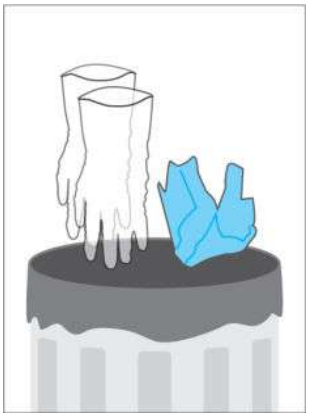


13. If required, manually rinse the device by wiping it for 30 seconds using a sterile, soft, non-linting cloth saturated with critical water (sterile water, temperature range 27 to 44°C, 81 to 111°F).



14. Allow the device to air dry until it is visibly dry. Drying times may vary based on the environmental conditions.

15. Discard disposable wipes, gloves, and other PPE according to your professional healthcare facility guidelines. Do not reuse wipes, gloves, or other PPE.



Additional information

- The cleaning and disinfection information is provided in accordance with ANSI/AAMIST81, ISO 17664. The instructions have been validated as capable of preparing non-sterile medical devices. It remains the responsibility of the professional healthcare facility to ensure that the cleaning and disinfection are performed according to these instructions, using appropriate equipment, materials, and personnel, so that the desired result is achieved. This requires validation and routine monitoring of the process.
- All users should be qualified personnel with documented expertise, competency, and training. Users should be trained on their professional healthcare facility policies and procedures along with current applicable guidelines and standards.

- Personnel should wear appropriate Personal Protective Equipment (PPE) when cleaning and disinfecting devices in accordance with their local blood-borne pathogen guidelines.

Technical specifications

Design, environmental, and physical specifications

Operating/storage and transport altitude: The system will meet specifications when subjected to altitudes corresponding to pressure readings from 700 hPa to 1060 hPa.

NOTE
An average pressure reading of 700 hPa corresponds to an altitude of 3000 m (10,000 ft) and 1060 hPa corresponds to an altitude of –400 m (–1000 ft).

NOTE
Operation of the monitor outside the environmental specifications may cause inaccurate results.

Monitor specifications

Size (H x W x D) Without recorder and temperature module	275 mm x 265 mm x 175 mm
Weight With battery, without recorder and temperature module	≤ 3.8 kg
Monitor operating temperature range	5 to 40°C (41 to 104°F)
Battery charging temperature range	5 to 35°C (41 to 95°F)
Storage and transport temperature range	-20 to 60°C (-4 to 140°F)
Operating humidity range	15 to 90% RH non-condensing
Storage and transport humidity range	10 to 90% RH non-condensing
Operating altitude range	700 to 1060 hPa (525 to 795 mmHg)
Storage and transport altitude range	700 to 1060 hPa (525 to 795 mmHg)
Degree of protection against harmful ingress of water	IP22
Power supply	Internal battery or AC power
Power requirements line voltage	100-240 VAC ±10%, 50/60 Hz
Power consumption	≤ 150 VA
Touchscreen	Capacitive
Alarm light	Illuminates red, yellow and cyan
Display size	10.1 in
Resolution	1280*800
Video connector	One HDMI connector for slave display

Ethernet port connector	One ethernet interface (RJ45)
USB 2.0 port connector	Universal Serial Bus (USB type A connectors) compatible with the USB 2.0 standard 3 USB connectors
Recorder connector	One external thermal recorder interface
Nurse call connector	One nurse call connector
Medical USB connector	Two medical USB connectors (reserved for future use)
Service life	10 years

Battery specifications

	High capacity battery
Battery type	Lithium-ion
Battery model	FLEX-3S2P
Battery voltage	10.8V±10%
Operation time	> 5.5 hours with full capacity new battery under certain conditions*
Charging time	< 4 hours to 90% capacity
*Conditions: The new battery has been fully charged and discharged for three cycles. The device is under usage scenario of NIBP determinations every 10 minutes, SpO_2 sensor, temperature sensor and barcode scanner connected, display brightness set to factory default, WLAN on.	

WLAN specifications

Type	VSM-WLAN-01
Bands	2.4 GHz: Note the available channels for 802.11 b/g operation in the US are Channels 1 to 11. The range of channels is limited by firmware. 5.0 GHZ: The use in the UNII (Unlicensed National Information Infrastructure) band 1 5150-5250 MHz band is restricted to indoor use only to reduce potential for harmful interference to co-channel mobile satellite systems. Any other use will make the operation of this device illegal.
Protocols	Radio support 802.11 abgn
RF output power	**2.4 GHz EIRP**: up to +16.97dBm **5 GHz EIRP**: up to +12.06dBm NOTE: May be further restricted on some channels according to regulatory domain.
Data speed	Up to MCS15 (144 Mbps)
Radio RF standards	• USA: FCC Part 15.247, 15.401-15.407 • European Union: EN300328, EN301893 • Australia: AS/NZS 4268 • Canada: RSS-247
Minimum RSSI value and data rate, which must be maintained in the coverage area to support application performance	RSSI Value: -65dBm Data rate: 5Mbps

Maximum packet delay value before degradation of application quality	1 s
Maximum packet loss value before degradation of application quality	5%

Parameter specifications

NIBP performance specifications

NIBP measurement technique	Oscillometric
NIBP measurement supported modes	Manual, Auto, and Stat
NIBP measurement time	Adult/child inflate duration time: less than 120 s Neonate inflate duration time: less than 85 s
NIBP measurement range	• Systolic: ◦ Adult/Pediatric: 30 to 290 mmHg ◦ Neonate: 30 to 140 mmHg • MAP: ◦ Adult/Pediatric: 20 to 260 mmHg ◦ Neonate: 20 to 125 mmHg • Diastolic: ◦ Adult/Pediatric: 10 to 220 mmHg ◦ Neonate: 10 to 110 mmHg
NIBP measurement accuracy	No more than 8 mmHg (1.1 kPa) standard deviation
NIBP pulse rate measurement range	30 to 250 bpm
NIBP pulse rate measurement accuracy	±5% or ±5 bpm, whichever is greater
NIBP measurement default initial inflation pressure	• Adult/Pediatric: 135 ±15 mmHg • Neonate: 100 ±15 mmHg
Maximum cuff measurement pressure (overpressure limit) allowed by independent safety controller	• Adult/Pediatric: 300 ±6 to 330 mmHg • Neonate: 150 ±3 to 165 mmHg
NIBP measurement available automatic cycle intervals	Custom, 1 min, 2 min, 3 min, 4 min, 5 min, 10 min, 15 min, 20 min, 30 min, 1 h, 1.5 h, and 2 h

SpO_2 displayed saturation values

GE TruSignal, Masimo SET and Nellcor OxiMax pulse oximetry are calibrated to display functional saturation.

NOTE

You can verify the functionality of pulse oximeter sensor and monitor with a functional SpO_2 tester but you cannot evaluate their accuracy with such a device. For more information, refer to the standard ISO 80601-2-61 Annex FF (Simulators, calibrators and functional testers for pulse oximeter equipment).

SpO_2 summary of clinical studies used to establish accuracy claims (Nellcor, Masimo)

Accuracy of Nellcor Oximax technology with Oximax sensors

The Nellcor Oximax Technology with Oximax sensors have been validated for no motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. Subjects used to validate SpO_2 measurement accuracies were healthy and recruited from the local population. Subjects comprised both adult men and women and spanned a range of skin pigmentations. Because scatter and bias of pulse oximeter SpO_2 and blood SaO_2 comparisons commonly increase as the saturation decreases, and accuracy specifications are calculated from data spanning the stated range, different accuracy values may result when describing partially overlapping ranges. When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ± 1 digit, as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.

Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter.

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 61 observations made spanning a range of 77% to 98% SaO2.

Accuracy of Masimo SET technology with Masimo sensors

Masimo SET Technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

For detailed information, refer to the supplemental analysis graphs in the appendix (Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582).

SpO_2 test methods used to establish accuracy claims during motion (Nellcor, Masimo)

Nellcor^{TM} sensors' accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range.

Nellcor sensors' motion performance was validated during a controlled hypoxia blood study over an SaO_2 span of 70% to 98.9% and a convenience-sample heart range of 41-105 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent range was validated using

synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

Masimo SET Technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in the range of 70% to 100% SpO_2 compared against a laboratory CO-oximeter and ECG monitor. The variation equals ±1 standard deviation, which encompasses 68% of the population.

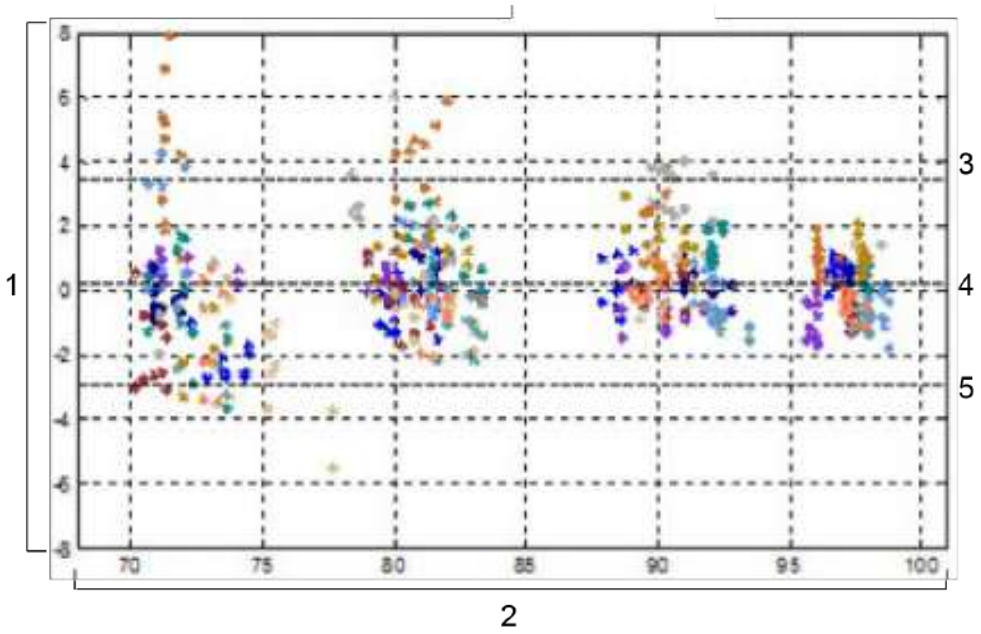
NOTE
Accuracy during motion has not been specified for Masimo SET sensors TC-I, TF-I, DBI, Blue, and E-1.

Additional accuracy information for Nellcor™ sensors

The table information provides supplemental data analysis for Nellcor sensors' measurement accuracy. The tables are provided by Covidien.

The following modified Bland-Altman plots show SpO_2 data by sensor type. Each individual subject is represented by a unique marker on the plots. Subject identification numbers are indicated in the legend with each plot.

Figure 1 Modified Bland-Altman for SpO_2 - DS-100A Sensor: SaO_2 vs. (SpO_2 - SaO_2)

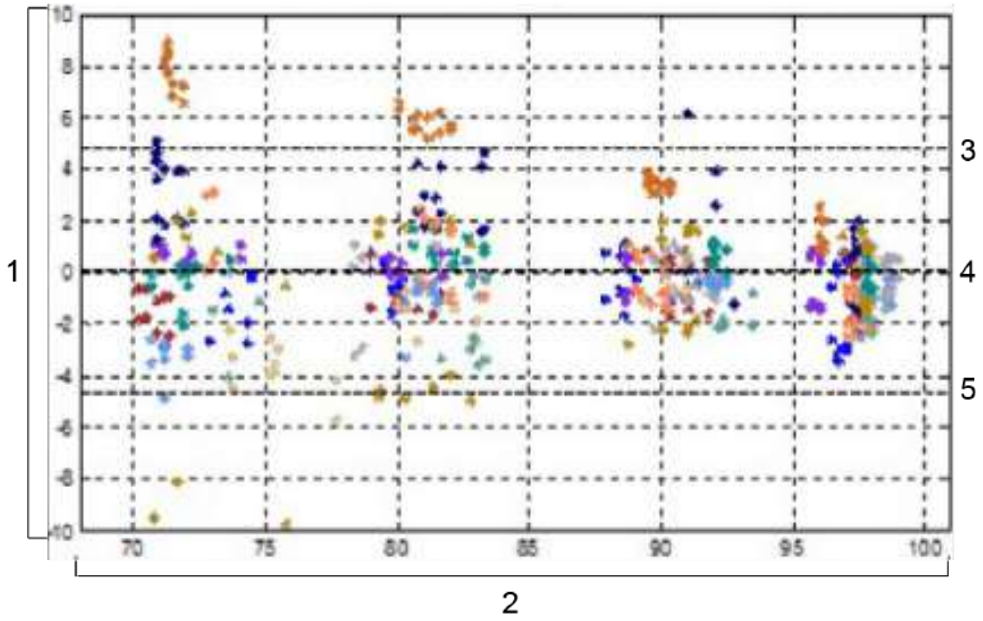


1.	SpO_2 - SaO_2 (%)	4.	Bias
2.	SaO_2 (%)	5.	Bias - (1.96 x σ (errs))
3.	Bias + (1.96 x σ (errs))		

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.16%

Measured A_{RMS} values	
Range	**A_{RMS}**
80-90%	1.67%
70-80%	2.25%

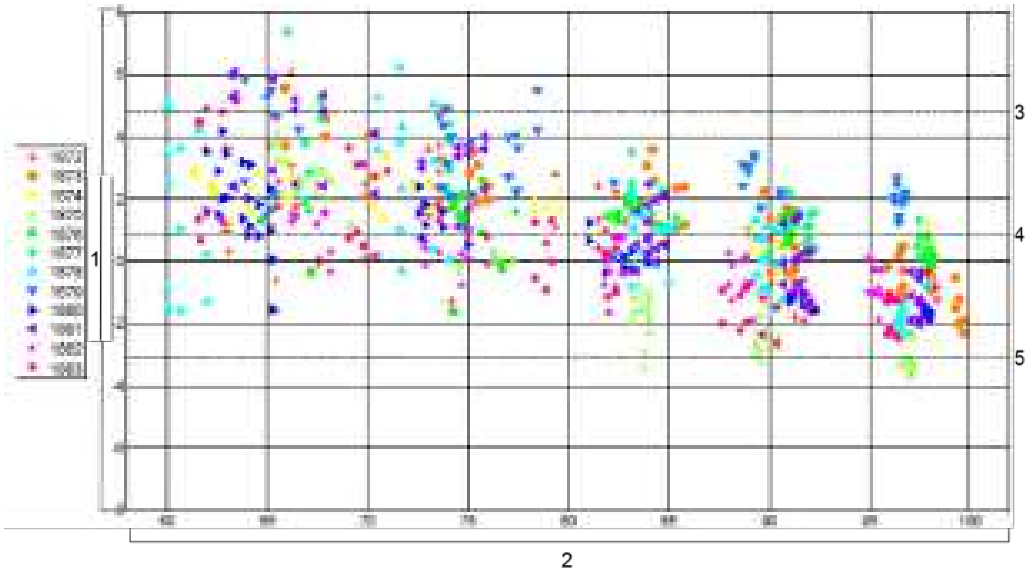
Figure 2 Modified Bland-Altman for SpO_2 - D-YS, D-YSE, D-YSPD, OXI-A/N, OXI-P/I Sensors: SaO_2 vs. (SpO_2 - SaO_2)



1.	SpO_2 - SaO_2 (%)	4.	Bias
2.	SaO_2 (%)	5.	Bias - (1.96 x σ (errs))
3.	Bias + (1.96 x σ (errs))		

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.38%
80-90%	2.5%
70-80%	3.6%

Figure 3 Modified Bland-Altman for SpO_2 - MAX-A, MAX-AL, MAX-N, MAX-I, MAX-P, MAX-R Sensor: SaO_2 vs. (SpO_2 - SaO_2)



1.	SpO_2 - SaO_2 (%)	4.	Mean Bias
2.	SaO_2 (%)	5.	Lower 95%
3.	Bias + (1.96 x σ (errs))		

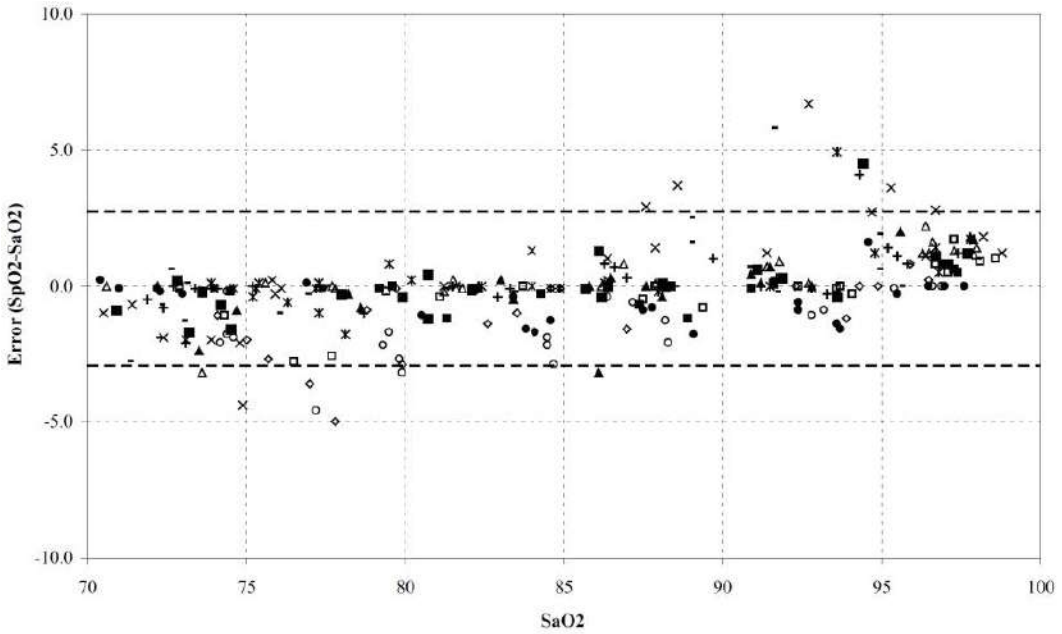
Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.49%
80-90%	1.57%
70-80%	2.5%

Additional accuracy information for Masimo sensors

The table information provides supplemental data analysis for Masimo sensors' measurement accuracy. The tables are provided by Masimo.

The table information for the plots below show A_{RMS} values measured with Masimo SET Oximetry Technology in a clinical study.

Figure 4 Adtx/Pdtx

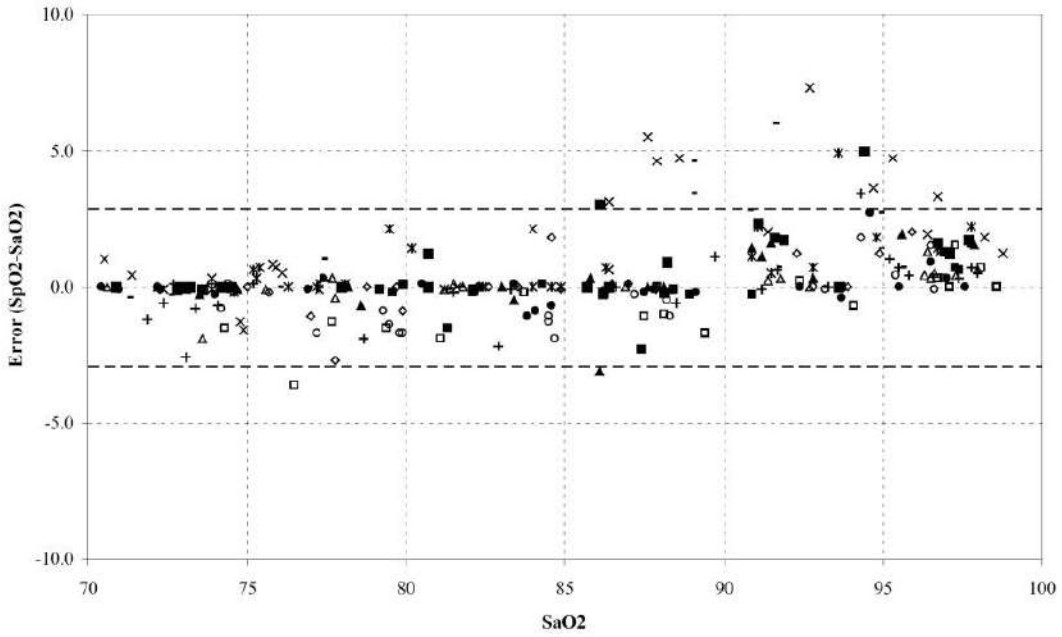


The Adtx/Pdtx are single-patient-use sensors. They are not provided sterile.

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.64%
80-90%	1.07%
70-80%	1.55%

Overall claimed accuracy value	
Range	**A_{RMS}**
70-100%	± 2%

Figure 5 Inf/Neo/NeoPt

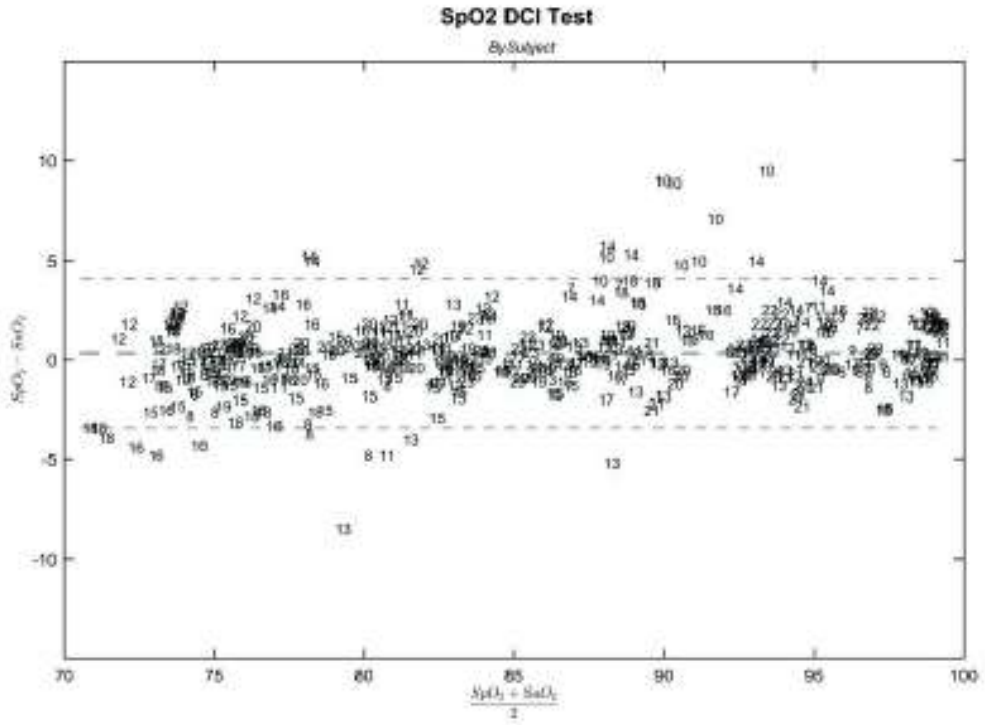


The Inf/Neo/NeoPt sensors are single-patient-use sensors. They are not provided sterile.

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.85%
80-90%	1.44%
70-80%	0.89%

Overall claimed accuracy value			
Range	**A_{RMS}**		
	Inf	**Neo***	**Neo Pt***
70-100%	± 2%	± 2% Adult ± 3% Neonatal	± 3%
* The saturation accuracy of the Neonate and Preterm sensors was validated on adult volunteers and 1% was added to account for the properties of fetal hemoglobin.			

Figure 6 DCI/DCIP

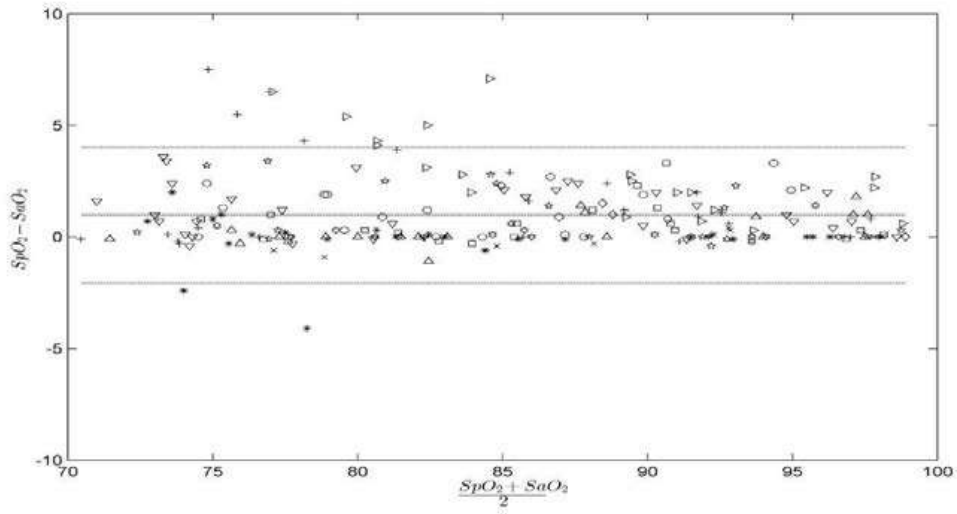


The DCI/DCIP sensors are reusable sensors. They are not provided sterile.

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.44%
80-90%	2.30%
70-80%	1.84%

Overall claimed accuracy value	
Range	**A_{RMS}**
70-100%	1.90%

Figure 7 TCI



The TCI sensor is a reusable sensor. It is not provided sterile.

Measured A_{RMS} values	
Range	**A_{RMS}**
90-100%	1.05%
80-90%	1.67%
70-80%	2.43%

Overall claimed accuracy value	
Range	**A_{RMS}**
70-100%	3.5%

SpO_2 summary of clinical studies used to establish accuracy claims (GE TruSignal)

Accuracy of GE technology with TruSignal sensors

GE Technology with TruSignal sensors has been validated for no motion accuracy in controlled hypoxia studies with total 25 healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by a laboratory co-oximeter. Subjects comprised both healthy adult men (11) and women (14) and spanned a range of ages (20-46 years old) and skin pigmentations (Fitzpatric 1-5). Five subjects had dark skin (Fitzpatric 5 or 6).

For the actual measured accuracy and modified Bland-Altman plots of the hypoxia study, see Additional accuracy information for GE TruSignal sensors on page 196 (Bland and Altman. Agreement between methods of measurement with multiple observations per individual. Journal of Biopharmaceutical Statistics (2007) vol. 17 pp. 571-582).

Neonatal clincial performance of GE TruSignal technology with TruSignal sensors

As suggested in “Pulse Oximeters – Premarket Notification Submissions [510(k)s], Guidance for Industry and Food and Drug Administration Staff, March 4, 2013” convenience samples were collected in neonatal patients to demonstrate clinical performance.

For GE TruSignal technology with TruSignal AllFit (TS-AF-10, TS-AF-25) sensors, a clinical study was conducted using 38 patients, including 17 females and 21 males. Test subjects ranged in age from 1 day to 19 days, and ranged in weight from 0.7 kg to 4.4 kg. The skin tone of the test subjects included in the study ranged from light to dark. An observed Arms of 2.57% was obtained from 52 observations spanning a range of 79.2% to 100.7% SaO_2.

For GE TruSignal technology with TruSignal Sensitive Skin (TS-SE-3) sensors, a clinical study was conducted using 40 patients, including 19 females and 21 males. Test subjects ranged in age from 1 day to 19 days, and ranged in weight from 0.7 kg to 4.4 kg. The skin tone of the test subjects included in the study ranged from light to dark. An observed Arms of 2.57% was obtained from 52 observations spanning a range of 86.8% to 100.2% SaO_2.

SpO_2 test methods used to establish accuracy claims during motion (GE TruSignal)

GE Technology with TS-AF, TS-AP, and TS-AAW sensors has been validated for motion accuracy in controlled hypoxia studies with (13) healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). The following motion types were used: mechanically induced 3 Hz tapping motion at an amplitude of 1-2 cm, patient induced non-repetitive rubbing motion, and patient induced nonrepetitive hand motion in supine position. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by CO-oximetry.

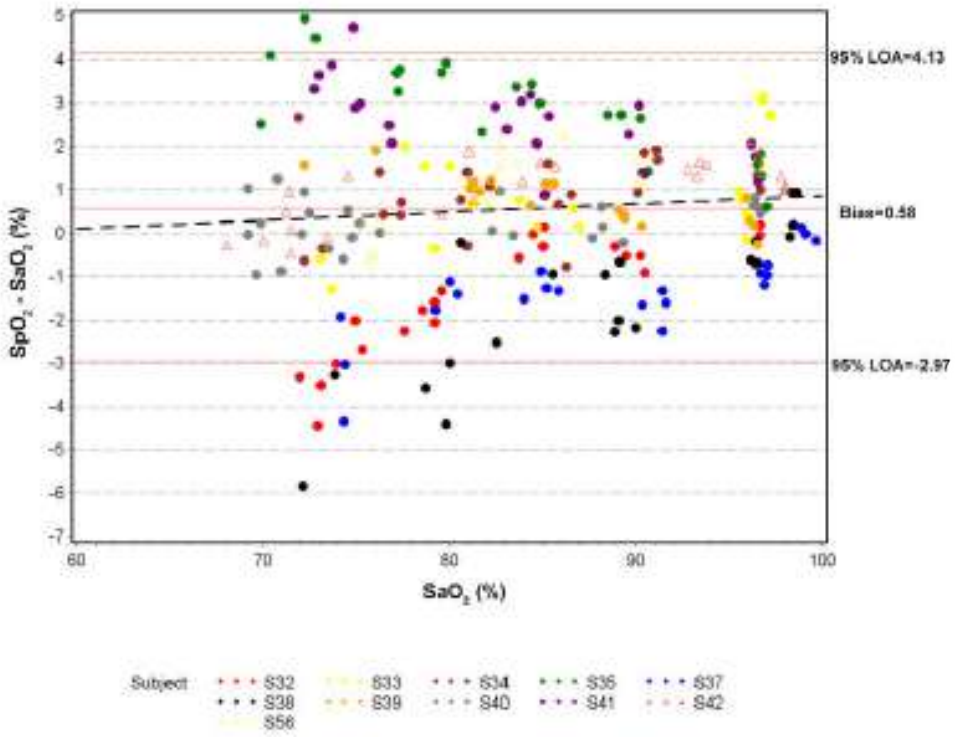
Subjects comprised both healthy adult men (6) and women (7) and spanned a range of ages (22-46 years old) and skin pigmentations (from light to dark). 3 subjects had dark skin (Fitzpatric 5 or 6).

Additional accuracy information for GE TruSignal sensors

The table information provides supplemental data analysis for GE TruSignal sensors’ measurement accuracy.

The following modified Bland-Altman plots show SpO_2 data by sensor type.

Figure 8 Modified Bland-Altman plot for SpO_2 - TS-W-D sensor, non-motion



The TS-W-D sensor is a reusable sensor. It is not provided sterile.

Table 3 Overall results, non-motion

Sensor: TS-W-D **Motion condition: No** **Subject group: All** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	242	73	83	80
Bias	0.58	0.25	0.71	0.74
Arms	1.85	2.5	1.55	1.41
LOA (95%)	(-2.97, 4.13)	(-4.66, 5.17)	(-2.01, 3.44)	(-1.62, 3.10)

Table 4 Male subjects, non-motion

Sensor: TS-W-D **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	85	22	36	27
Bias	1.34	1.61	1.18	1.35

Table 4 Male subjects, non-motion (Table continued)

Sensor: TS-W-D **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
Arms	1.77	2.28	1.48	1.63
LOA (95%)	(-0.92, 3.60)	(-1.63, 4.85)	(-0.60, 2.96)	(-0.49, 3.18)

Table 5 Female subjects, non-motion

Sensor: TS-W-D **Motion condition: No** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	157	51	47	53
Bias	0.16	-0.33	0.36	0.43
Arms	1.89	2.59	1.61	1.28
LOA (95%)	(-3.54, 3.86)	(-5.42, 4.76)	(-2.75, 3.47)	(-1.95, 2.81)

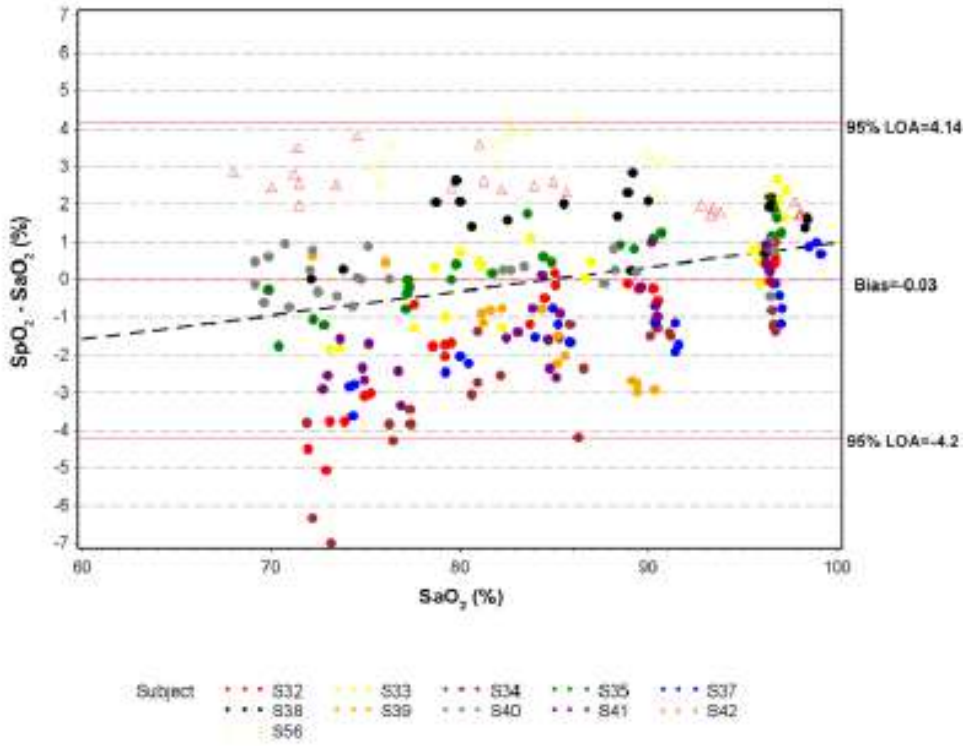
Table 6 Light-pigmented subjects, non-motion

Sensor: TS-W-D **Motion condition: No** **Subject group: Light** **Number of subjects in group: 9**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	204	67	64	67
Bias	0.49	0.23	0.6	0.65
Arms	1.93	2.59	1.64	1.39
LOA (95%)	(-3.18, 4.16)	(-4.87, 5.33)	(-2.42, 3.62)	(-1.77, 3.07)

Table 7 Dark-pigmented subjects, non-motion

Sensor: TS-W-D **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	38	6	19	13
Bias	1.04	0.49	1.11	1.2
Arms	1.31	1.07	1.22	1.51
LOA (95%)	(-0.53, 2.61)	(-1.55, 2.52)	(-0.07, 2.14)	(-0.68, 3.08)

Figure 9 Modified Bland-Altman plot for SpO_2 - TS-SE-3 sensor, non-motion



The TS-SE-3 sensor is a reusable sensor. It is not provided sterile.

Table 8 Overall results, non-motion

Sensor: TS-SE-3 **Motion condition: No** **Subject group: All** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	236	73	83	74
Bias	-0.03	-0.89	0.08	0.66
Arms	2.06	2.59	2	1.52
LOA (95%)	(-4.20, 4.14)	(-5.68, 3.91)	(-3.86, 4.01)	(-2.05, 3.36)

Table 9 Male subjects, non-motion

Sensor: TS-SE-3 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	82	22	36	24
Bias	-1.31	-2.58	-1.36	-0.08

Table 9 Male subjects, non-motion (Table continued)

Sensor: TS-SE-3 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
Arms	2.18	3.19	1.82	1.41
LOA (95%)	(-4.75, 2.13)	(-6.34, 1.19)	(-3.76, 1.05)	(-2.89, 2.73)

Table 10 Female subjects, non-motion

Sensor: TS-SE-3 **Motion condition: No** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	154	51	47	50
Bias	0.65	-0.16	1.18	1.01
Arms	1.99	2.28	2.12	1.57
LOA (95%)	(-3.04, 4.35)	(-4.66, 4.34)	(-2.32, 4.68)	(-1.37, 3.40)

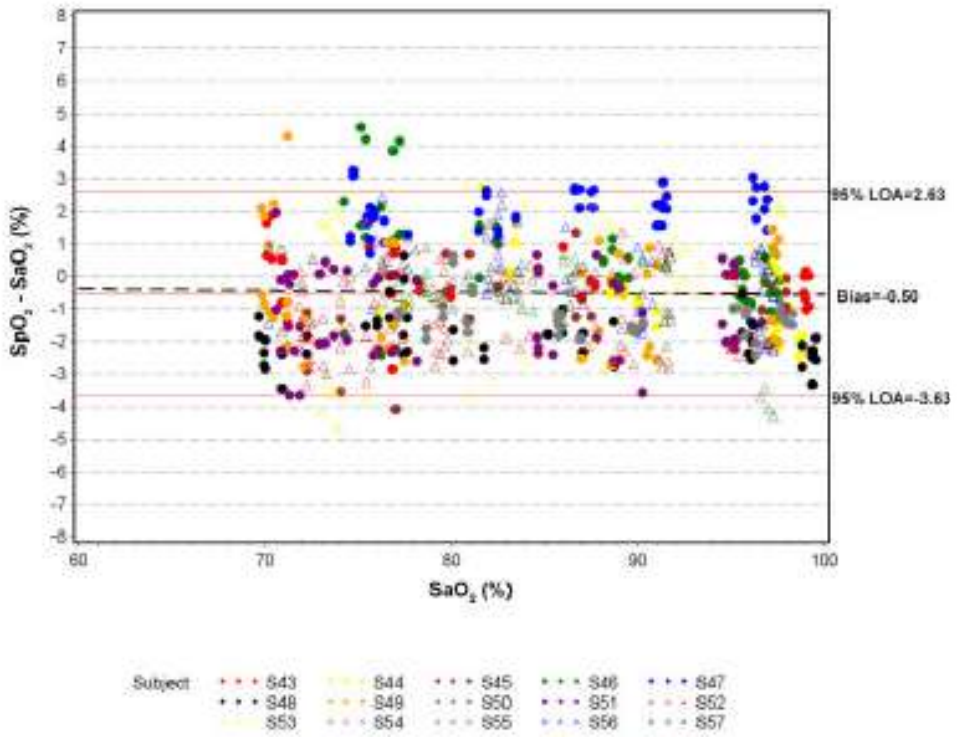
Table 11 Light-pigmented subjects, non-motion

Sensor: TS-SE-3 **Motion condition: No** **Subject group: Light** **Number of subjects in group: 9**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	203	67	64	66
Bias	-0.23	-1.17	-0.08	0.52
Arms	1.93	2.59	1.66	1.34
LOA (95%)	(-3.99, 3.53)	(-5.73, 3.40)	(-3.36, 3.20)	(-1.92, 2.96)

Table 12 Dark-pigmented subjects, non-motion

Sensor: TS-SE-3 **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	33	6	19	8
Bias	1.19	2.23	0.61	1.78
Arms	2.73	2.55	2.85	2.55
LOA (95%)	(-3.70, 6.08)	(-0.45, 4.90)	(-5.00, 6.22)	(-2.05, 5.62)

Figure 10 Modified Bland-Altman plot for SpO_2 - TS-E-D, TS-E2-GE, TS-E4-GE sensors, non-motion



The TS-E-D, TS-E2-GE, TS-E4-GE sensors are reusable sensors. They are not provided sterile.

Table 13 Overall results, non-motion

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: All** **Number of subjects in group: 15**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	663	236	200	219
Bias	-0.5	-0.57	-0.26	-0.63
Arms	1.65	1.83	1.5	1.57
LOA (95%)	(-3.63, 2.63)	(-3.99, 2.84)	(-3.16, 2.65)	(-3.45, 2.20)

Table 14 Male subjects, non-motion

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	301	118	94	89
Bias	-0.06	-0.18	0.17	-0.14

Table 14 Male subjects, non-motion (Table continued)

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
Arms	1.54	1.73	1.27	1.53
LOA (95%)	(-3.08, 2.96)	(-3.57, 3.21)	(-2.31, 2.64)	(-3.14, 2.87)

Table 15 Female subjects, non-motion

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: Female** **Number of subjects in group: 8**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	362	118	106	130
Bias	-0.86	-0.97	-0.63	-0.96
Arms	1.74	1.93	1.68	1.59
LOA (95%)	(-3.83, 2.10)	(-4.24, 2.31)	(-3.71, 2.44)	(-3.46, 1.54)

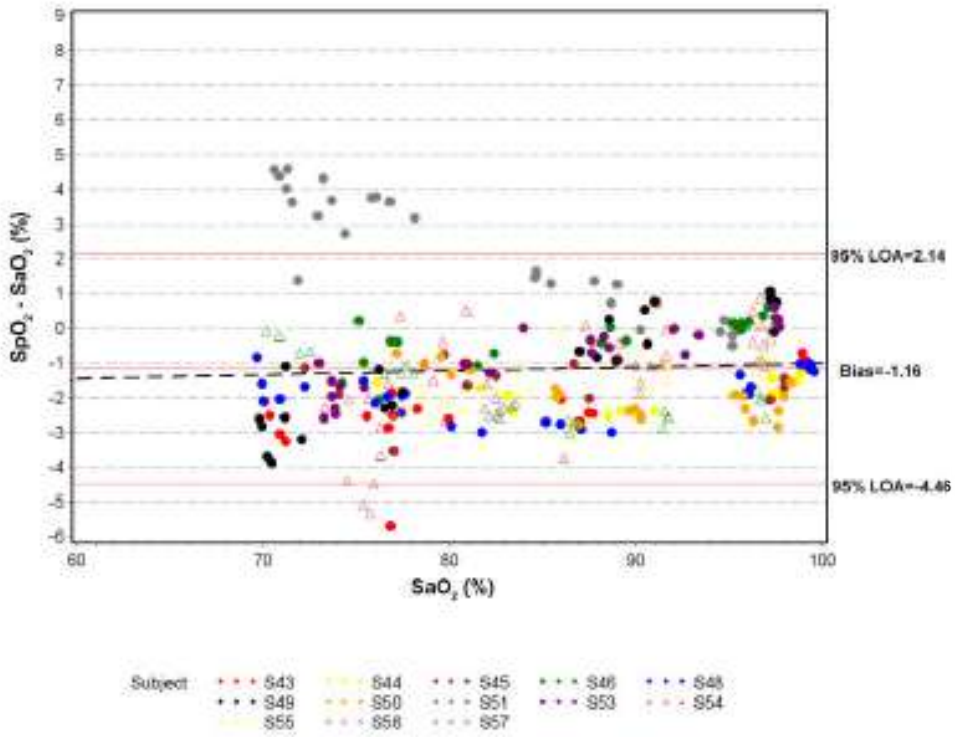
Table 16 Light-pigmented subjects, non-motion

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: Light** **Number of subjects in group: 12**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	527	200	156	163
Bias	-0.86	-0.95	-0.69	-0.91
Arms	1.63	1.78	1.47	1.59
LOA (95%)	(-3.59, 1.87)	(-3.90, 2.00)	(-3.23, 1.85)	(-3.48, 1.66)

Table 17 Dark-pigmented subjects, non-motion

Sensor: TS-E-D, TS-E2-GE, TS-E4-GE **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 3**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	136	36	44	56
Bias	0.9	1.52	1.28	0.21
Arms	1.72	2.11	1.62	1.49
LOA (95%)	(-1.97, 3.77)	(-1.40, 4.44)	(-0.72, 3.27)	(-2.71, 3.12)

Figure 11 Modified Bland-Altman plot for SpO_2 - TS-F-D, TS-F2-GE, TS-F4-GE sensors, non-motion



The TS-F-D, TS-F2-GE, TS-F4-GE sensors are reusable sensors. They are not provided sterile.

Table 18 Overall results, non-motion

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: All** **Number of subjects in group: 13**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	280	94	84	98
Bias	-1.16	-1.17	-1.42	-0.91
Arms	2.01	2.59	1.89	1.38
LOA (95%)	(-4.46, 2.14)	(-5.72, 3.38)	(-3.89, 1.04)	(-2.95, 1.13)

Table 19 Male subjects, non-motion

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: Male** **Number of subjects in group: 5**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	99	35	31	33
Bias	-1.55	-1.81	-1.81	-1.04

Table 19 Male subjects, non-motion (Table continued)

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: Male** **Number of subjects in group: 5**				
Arms	1.89	2.15	2.01	1.45
LOA (95%)	(-3.69, 0.58)	(-4.11, 0.49)	(-3.54, -0.08)	(-3.03, 0.94)

Table 20 Female subjects, non-motion

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: Female** **Number of subjects in group: 8**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	181	59	53	65
Bias	-0.95	-0.79	-1.2	-0.84
Arms	2.07	2.82	1.83	1.34
LOA (95%)	(-4.57, 2.67)	(-6.13, 4.56)	(-3.93, 1.53)	(-2.90, 1.23)

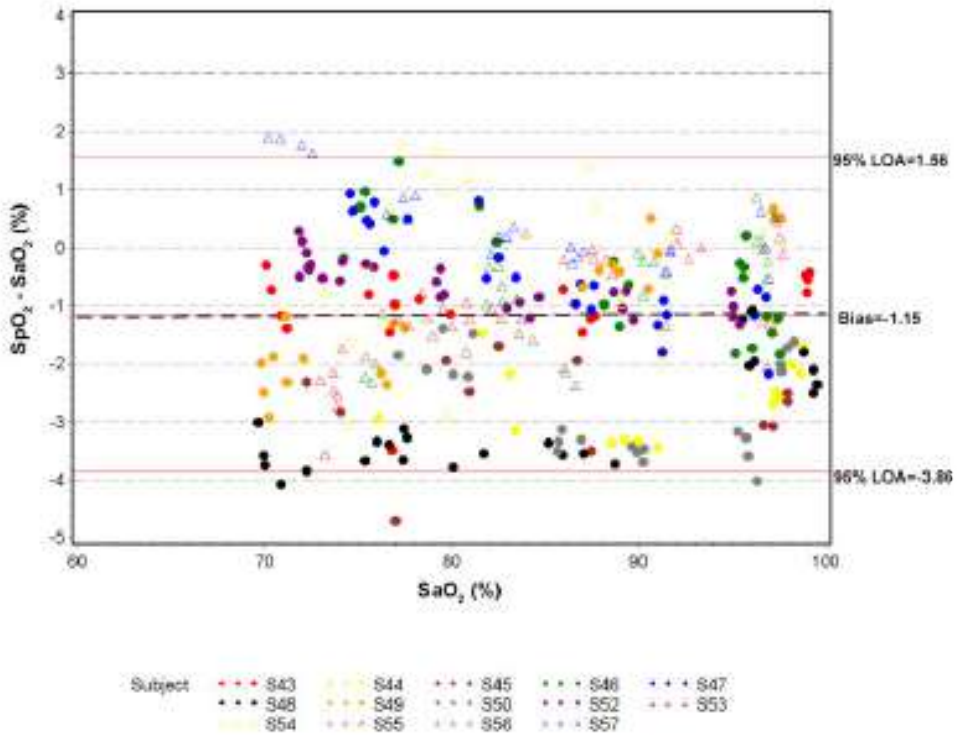
Table 21 Light-pigmented subjects, non-motion

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: Light** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	236	84	70	78
Bias	-1.17	-1.03	-1.41	-1.06
Arms	2.04	2.52	1.91	1.5
LOA (95%)	(-4.45, 2.12)	(-5.57, 3.51)	(-3.95, 1.14)	(-3.14, 1.01)

Table 22 Dark-pigmented subjects, non-motion

Sensor: TS-F-D, TS-F2-GE, TS-F4-GE **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	44	10	14	20
Bias	-1.16	-2.36	-1.51	-0.3
Arms	1.86	3.09	1.82	0.74
LOA (95%)	(-4.05, 1.74)	(-6.47, 1.74)	(-3.58, 0.55)	(-1.67, 1.06)

Figure 12 Modified Bland-Altman plot for SpO_2 - TS-SA-D, TS-SA4-GE, and TS-SP-D sensors, non-motion



The TS-SA-D, TS-SA4-GE, and TS-SP-D sensors are reusable sensors. They are not provided sterile.

Table 23 Overall results, non-motion

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: All** **Number of subjects in group: 14**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	304	104	93	103
Bias	-1.15	-1.06	-1.25	-1.08
Arms	1.77	1.87	1.78	1.6
LOA (95%)	(-3.86, 1.56)	(-4.11, 1.99)	(-3.75, 1.25)	(-3.39, 1.23)

Table 24 Male subjects, non-motion

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	149	59	47	43
Bias	-0.73	-0.37	-0.88	-1.07

Table 24 Male subjects, non-motion (Table continued)

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
Arms	1.29	1.3	1.21	1.36
LOA (95%)	(-2.83, 1.36)	(-2.84, 2.09)	(-2.54, 0.78)	(-2.74, 0.59)

Table 25 Female subjects, non-motion

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	155	45	46	60
Bias	-1.54	-1.96	-1.63	-1.09
Arms	2.13	2.43	2.21	1.75
LOA (95%)	(-4.44, 1.35)	(-4.81, 0.90)	(-4.60, 1.35)	(-3.78, 1.61)

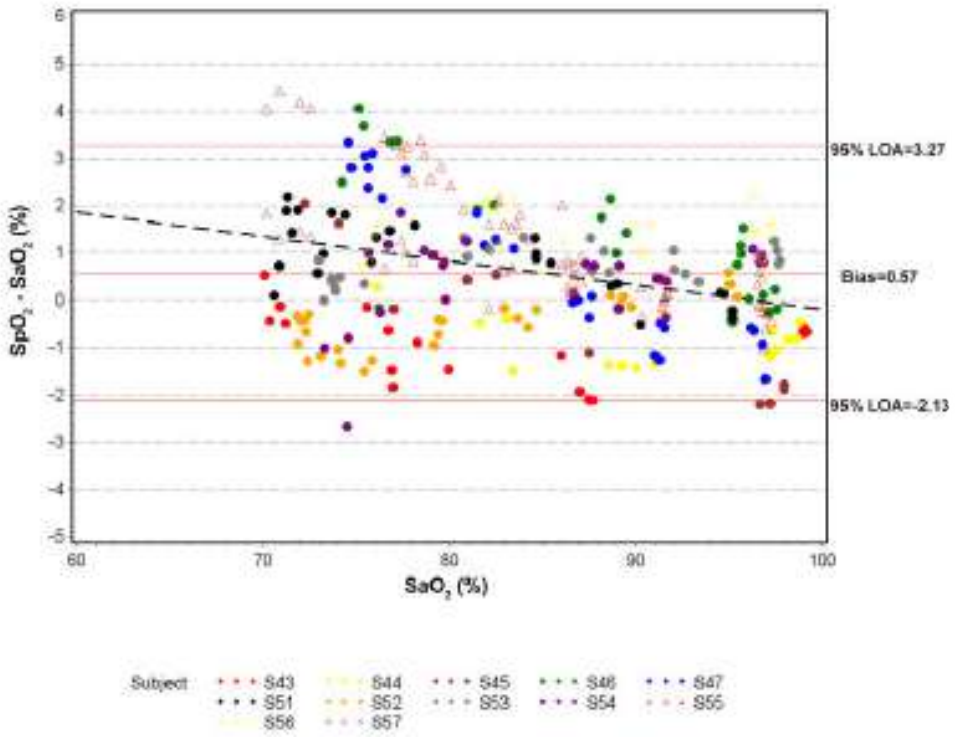
Table 26 Light-pigmented subjects, non-motion

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: Light** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	236	86	71	75
Bias	-1.33	-1.25	-1.46	-1.22
Arms	1.93	1.98	1.98	1.75
LOA (95%)	(-4.08, 1.42)	(-4.29, 1.78)	(-4.11, 1.19)	(-3.71, 1.27)

Table 27 Dark-pigmented subjects, non-motion

Sensor: TS-SA-D, TS-SA4-GE, TS-SP-D **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 3**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	68	18	22	28
Bias	-0.51	-0.12	-0.56	-0.72
Arms	1.05	1.22	0.84	1.07
LOA (95%)	(-2.31, 1.29)	(-2.57, 2.32)	(-1.83, 0.70)	(-2.30, 0.86)

Figure 13 Modified Bland-Altman plot for SpO_2 - TS-AF-10, TS-AF-25 sensors, non-motion



The TS-AF-10, TS-AF-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 28 Overall results, non-motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: All** **Number of subjects in group: 12**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	288	105	89	94
Bias	0.57	0.98	0.65	0.03
Arms	1.47	1.97	1.23	0.9
LOA (95%)	(-2.13, 3.27)	(-2.38, 4.35)	(-1.41, 2.71)	(-1.74, 1.79)

Table 29 Male subjects, non-motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	176	67	55	54
Bias	0.54	1.11	0.6	-0.24

Table 29 Male subjects, non-motion (Table continued)

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 7**				
Arms	1.64	2.3	1.22	0.82
LOA (95%)	(-2.50, 3.58)	(-2.86, 5.08)	(-1.50, 2.70)	(-1.79, 1.30)

Table 30 Female subjects, non-motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: Female** **Number of subjects in group: 5**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	112	38	34	40
Bias	0.61	0.75	0.73	0.39
Arms	1.14	1.2	1.24	0.99
LOA (95%)	(-1.28, 2.51)	(-1.09, 2.60)	(-1.28, 2.73)	(-1.43, 2.21)

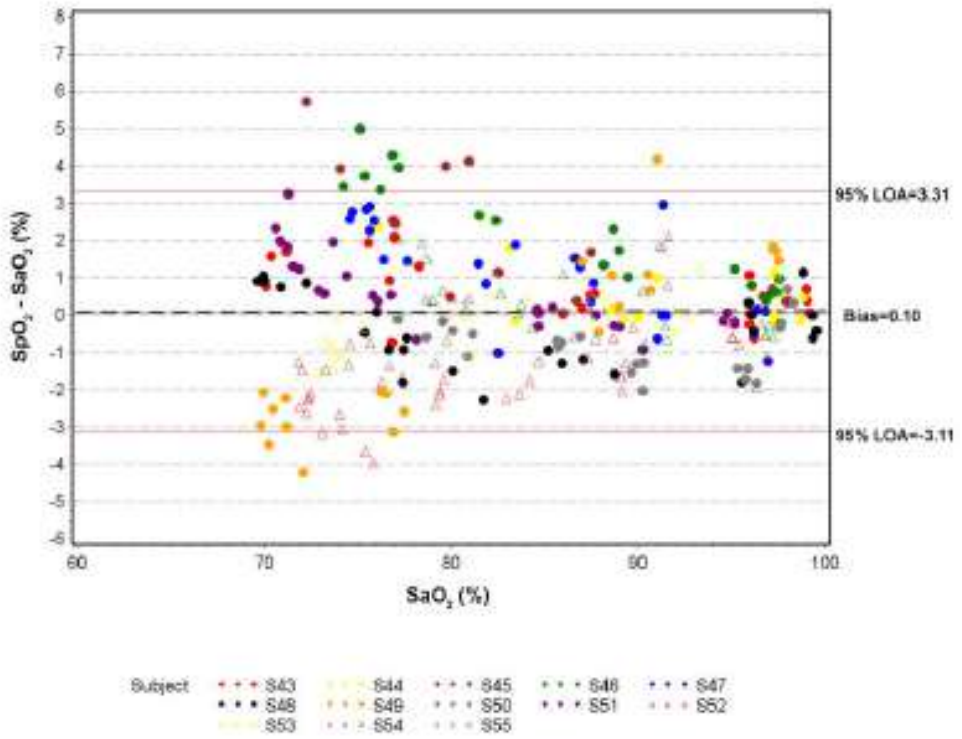
Table 31 Light-pigmented subjects, non-motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: Light** **Number of subjects in group: 9**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	220	87	67	66
Bias	0.36	0.68	0.42	-0.12
Arms	1.35	1.79	1.1	0.8
LOA (95%)	(-2.20, 2.92)	(-2.59, 3.95)	(-1.60, 2.43)	(-1.67, 1.43)

Table 32 Dark-pigmented subjects, non-motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 3**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	68	18	22	28
Bias	1.23	2.43	1.35	0.36
Arms	1,78	2.67	1.55	1.1
LOA (95%)	(-1.31, 3.77)	(0.21, 4.65)	(-0.19, 2.89)	(-1.71, 2.44)

Figure 14 Modified Bland-Altman plot for SpO_2 - TS-AF-10, TS-AF-25 sensors, motion



The TS-AF-10, TS-AF-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 33 Overall results, motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: All** **Number of subjects in group: 13**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	287	106	84	93
Bias	0.1	0.15	0.04	0.15
Arms	1.61	2.17	1.23	1.04
LOA (95%)	(-3.11, 3.31)	(-4.12, 4.42)	(-2.38, 2.46)	(-1.87, 2.17)

Table 34 Male subjects, motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	128	51	39	38
Bias	0.5	0.83	0.45	0.11

Table 34 Male subjects, motion (Table continued)

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
Arms	1.9	2.65	1.44	0.76
LOA (95%)	(-3.10, 4.10)	(-4.15, 5.80)	(-2.27, 3.17)	(-1.38, 1.61)

Table 35 Female subjects, motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	159	55	45	55
Bias	-0.22	-0.48	-0.32	0.17
Arms	1.33	1.62	1	1.19
LOA (95%)	(-2.80, 2.37)	(-3.54, 2.58)	(-2.20, 1.56)	(-2.16, 2.50)

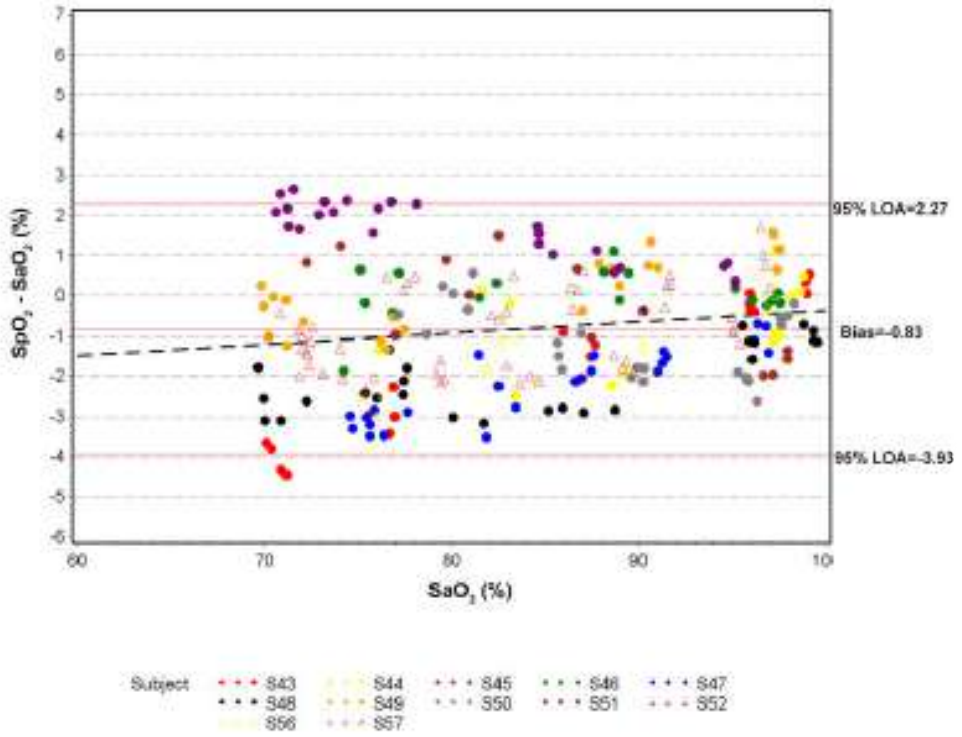
Table 36 Light-pigmented subjects, motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: Light** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	245	92	70	79
Bias	-0.15	-0.29	-0.22	0.11
Arms	1.5	1.98	1.13	1.04
LOA (95%)	(-3.07, 2.77)	(-4.14, 3.56)	(-2.41, 1.97)	(-1.93, 2.14)

Table 37 Dark-pigmented subjects, motion

Sensor: TS-AF-10, TS-AF-25 **Motion condition: Yes** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	42	14	14	14
Bias	1.59	3.04	1.34	0.38
Arms	2.15	3.19	1.62	1.03
LOA (95%)	(-1.29, 4.46)	(1.07, 5.01)	(-0.51, 3.20)	(-1.56, 2.33)

Figure 15 Modified Bland-Altman plot for SpO_2 - TS-AP-10 and TS-AP-25 sensors, non-motion



The TS-AP-10 and TS-AP-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 38 Overall results, non-motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: All** **Number of subjects in group: 12**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	260	91	78	87
Bias	-0.83	-1.18	-0.87	-0.41
Arms	1.75	2.34	1.57	1.06
LOA (95%)	(-3.93, 2.27)	(-5.17, 2.81)	(-3.45, 1.71)	(-2.33, 1.51)

Table 39 Male subjects, non-motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 6**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	127	51	38	38
Bias	-1.15	-1.86	-0.91	-0.42

Table 39 Male subjects, non-motion (Table continued)

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 6**				
Arms	1.9	2.56	1.5	0.98
LOA (95%)	(-4.12, 1.82)	(-5.35, 1.62)	(-3.27, 1.45)	(-2.17, 1.32)

Table 40 Female subjects, non-motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: Female** **Number of subjects in group: 6**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	133	40	40	49
Bias	-0.52	-0.31	-0.84	-0.4
Arms	1.61	2.03	1.64	1.12
LOA (95%)	(-3.51, 2.46)	(-4.29, 3.67)	(-3.64, 1.96)	(-2.46, 1.67)

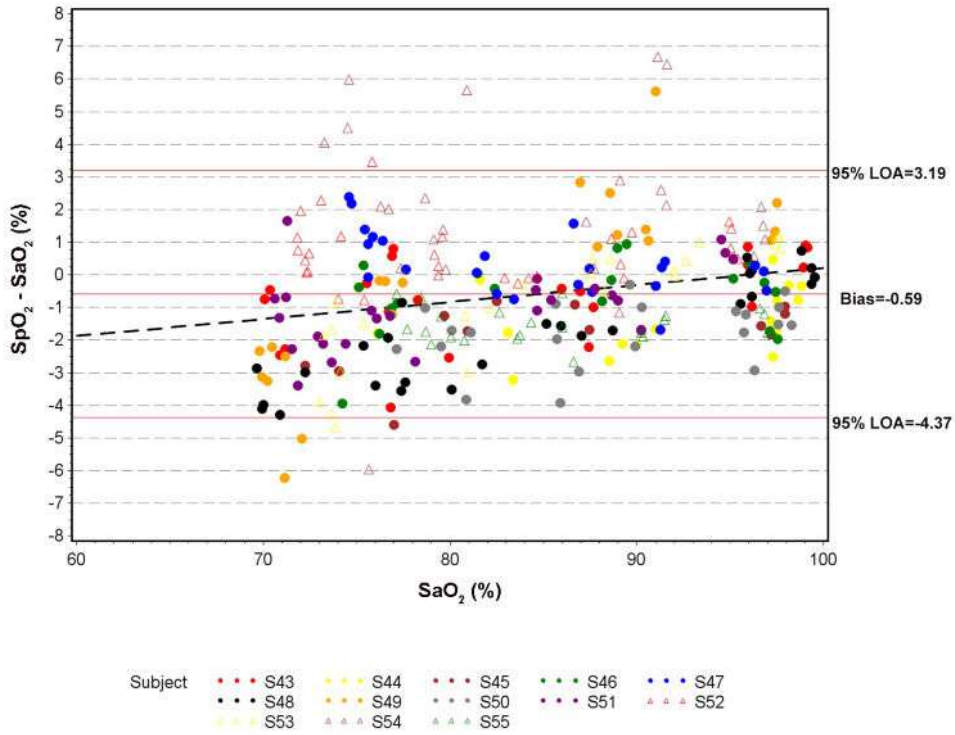
Table 41 Light-pigmented subjects, non-motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: Light** **Number of subjects in group: 9**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	196	73	56	63
Bias	-0.69	-0.86	-0.81	-0.36
Arms	1.69	2.14	1.57	1.12
LOA (95%)	(-3.73, 2.35)	(-4.73, 3.02)	(-3.48, 1.86)	(-2.45, 1.73)

Table 42 Dark-pigmented subjects, non-motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 3**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	64	18	22	24
Bias	-1.26	-2.49	-1.04	-0.54
Arms	1.93	3.02	1.57	0.89
LOA (95%)	(-4.14, 1.62)	(-5.94, 0.97)	(-3.40, 1.32)	(-1.95, 0.87)

Figure 16 Modified Bland-Altman plot for SpO_2 - TS-AP-10 and TS-AP-25 sensors, motion



The TS-AP-10 and TS-AP-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 43 Overall results, motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: All** **Number of subjects in group: 13**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	285	106	84	91
Bias	-0.59	-0.94	-0.7	0.02
Arms	1.99	2.37	1.7	1.65
LOA (95%)	(-4.37, 3.19)	(-5.22, 3.35)	(-3.76, 2.36)	(-3.23, 3.28)

Table 44 Male subjects, motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	127	51	39	37
Bias	-0.45	-0.37	-0.55	-0.45

Table 44 Male subjects, motion (Table continued)

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
Arms	1.41	1.74	1.15	1.13
LOA (95%)	(-3.08, 2.18)	(-3.74, 2.99)	(-2.56, 1.45)	(-2.51, 1.62)

Table 45 Female subjects, motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	158	55	45	54
Bias	-0.71	-1.46	-0.83	0.35
Arms	2.35	2.83	2.06	1.93
LOA (95%)	(-5.12, 3.71)	(-6.26, 3.33)	(-4.58, 2.92)	(-3.41, 4.10)

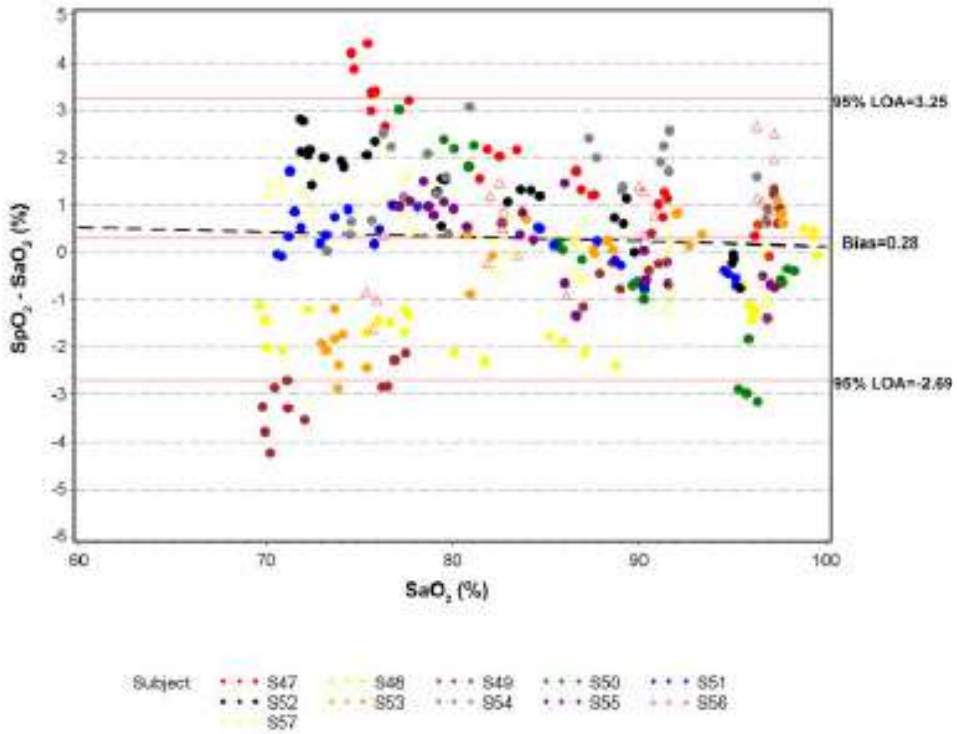
Table 46 Light-pigmented subjects, motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: Light** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	243	92	70	77
Bias	-0.68	-1.1	-0.85	0.1
Arms	2.1	2.46	1.84	1.75
LOA (95%)	(-4.58, 3.23)	(-5.45, 3.25)	(-4.07, 2.37)	(-3.36, 3.56)

Table 47 Dark-pigmented subjects, motion

Sensor: TS-AP-10, TS-AP-25 **Motion condition: Yes** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	42	14	14	14
Bias	-0.08	0.1	0.05	-0.4
Arms	1.13	1.62	0.68	0.88
LOA (95%)	(-2.33, 2.16)	(-3.18, 3.39)	(-1.34, 1.44)	(-1.99, 1.19)

Figure 17 Modified Bland-Altman plot for SpO_2 - TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensors, non-motion



The TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 48 Overall results, non-motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: All** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	288	104	88	92
Bias	0.28	0.51	0.36	0.07
Arms	1.51	1.95	1.16	1.12
LOA (95%)	(-2.69, 3.25)	(-3.19, 4.21)	(-1.80, 2.53)	(-2.13, 2.27)

Table 49 Male subjects, non-motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	123	46	41	36

Table 49 Male subjects, non-motion (Table continued)

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: Male** **Number of subjects in group: 4**				
Bias	0.83	1.85	0.63	-0.22
Arms	1.45	2.08	1.01	0.73
LOA (95%)	(-1.51, 3.18)	(-0.06, 3.75)	(-0.95, 2.20)	(-1.61, 1.17)

Table 50 Female subjects, non-motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	165	58	47	56
Bias	-0.13	-0.55	0.14	0.26
Arms	1.54	1.83	1.27	1.31
LOA (95%)	(-3.15, 2.90)	(-4.00, 2.91)	(-2.36, 2.63)	(-2.28, 2.79)

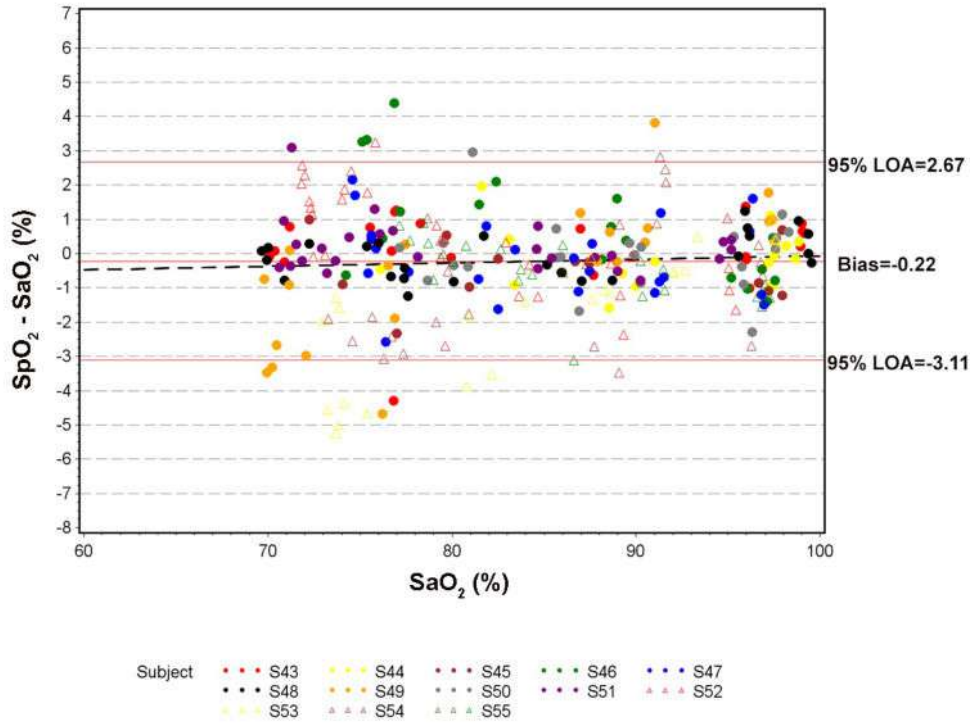
Table 51 Light-pigmented subjects, non-motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: Light** **Number of subjects in group: 9**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	242	92	72	74
Bias	0.08	0.31	0.2	-0.17
Arms	1.42	1.77	1.1	1.08
LOA (95%)	(-2.70, 2.87)	(-3.13, 3.74)	(-1.93, 2.33)	(-2.27, 1.93)

Table 52 Dark-pigmented subjects, non-motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: No** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	46	12	16	18
Bias	1.34	2.08	1.1	1.05
Arms	1.89	2.96	1.39	1.26
LOA (95%)	(-1.32, 3.99)	(-2.23, 6.40)	(-0.62, 2.82)	(-0.34, 2.44)

Figure 18 Modified Bland-Altman plot for SpO_2 - TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensors, motion



The TS-AAW-10, TS-AAW-25, TS-PAW-10, and TS-PAW-25 sensors are single-patient-use sensors. They are not provided sterile.

Table 53 Overall results, motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: All** **Number of subjects in group: 13**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	287	106	84	93
Bias	-0.22	-0.24	-0.41	0
Arms	1.48	1.9	1.23	1.06
LOA (95%)	(-3.11, 2.67)	(-3.95, 3.48)	(-2.69, 1.87)	(-2.09, 2.09)

Table 54 Male subjects, motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	128	51	39	38

Table 54 Male subjects, motion (Table continued)

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: Male** **Number of subjects in group: 6**				
Bias	0.06	0.67	-0.27	-0.42
Arms	1.28	1.62	1.01	1
LOA (95%)	(-2.46, 2.58)	(-2.24, 3.59)	(-2.20, 1.65)	(-2.22, 1.38)

Table 55 Female subjects, motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: Female** **Number of subjects in group: 7**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	159	55	45	55
Bias	-0.45	-1.08	-0.53	0.29
Arms	1.62	2.13	1.39	1.1
LOA (95%)	(-3.50, 2.60)	(-4.71, 2.55)	(-3.08, 2.03)	(-1.81, 2.39)

Table 56 Light-pigmented subjects, motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: Light** **Number of subjects in group: 11**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	245	92	70	79
Bias	-0.3	-0.42	-0.54	0.07
Arms	1.48	1.88	1.26	1.06
LOA (95%)	(-3.15, 2.55)	(-4.03, 3.19)	(-2.79, 1.71)	(-2.02, 2.17)

Table 57 Dark-pigmented subjects, motion

Sensor: TS-AAW-10, TS-AAW-25, TS-PAW-10, TS-PAW-25 **Motion condition: Yes** **Subject group: Dark** **Number of subjects in group: 2**				
SaO_2 range (%)	68-100 (Overall)	70-80	80-90	90-100
# of data pairs	42	14	14	14
Bias	0.25	0.95	0.23	-0.42
Arms	1.45	2.04	1.04	1.04
LOA (95%)	(-2.58, 3.09)	(-2.73, 4.62)	(-1.84, 2.30)	(-2.34, 1.51)

SpO_2 test methods used to establish accuracy claims during low perfusion

Low perfusion accuracy of Nellcor Oximax technology with Oximax sensors

Nellcor Oximax technology with Oximax sensors has been validated for SpO_2 low perfusion accuracy in bench top testing using Nellcor's PS II simulator with signal strength setting of 0.03% modulation and oxygen saturation levels of 70 to 100% at a pulse rate of 90 BPM. Nellcor Oximax Technology with Oximax sensors has been validated for low perfusion pulse rate accuracy in bench top testing using Nellcor's PS II simulator at a simulated low perfusion level of 0.10% modulation in the pulse rate range of 40 to 250 beats per minute (BPM) at an SpO_2 of 95%.

Low perfusion accuracy of Masimo SET technology

Masimo SET technology has been validated for low perfusion accuracy in bench top testing against Biotek Index 2^{TM} Simulator and Masimo's simulator with signal strength setting of greater than 0.02% and transmission of greater than 5% for saturation ranging from 70 to 100%. This variation equals ±1 standard deviation. ±1 standard deviation encompasses 68% of the population.

Low perfusion accuracy of GE TruSignal technology with TruSignal sensors

GE TruSignal technology with TruSignal sensors has been validated for low perfusion accuracy in a simulator test for saturation ranging from 70% to 100%. The test was conducted using a Fluke ProSim 8 simulator using 0.03% pulse amplitude and the Thin Finger transmission setting.

SpO_2 test methods used to establish pulse rate accuracy

Pulse rate accuracy of Nellcor Oximax technology with Oximax sensors

Accuracy specifications were validated using measurements of healthy non-smoking adult volunteers during controlled hypoxia studies spanning the specified saturation ranges. Subjects were recruited from the local population and comprised both men and women ranging in age from 18-50 years old, and spanned a range of skin pigmentations. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as ±1 SD. Because pulse oximeter equipment measurements are statistically distributed, about two-thirds of the measurements can be expected to fall in this accuracy (A_{RMS}) range.

Adult specifications are shown for OxiMax MAXA and MAXN sensors with the pulse oximeter.

Neonate specifications are shown for OxiMax MAXN sensors with the pulse oximeter.

Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO_2 accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750 to 4,100 grams, and 61 observations made spanning a range of 77% to 98% SaO_2.

The specification applies to monitoring cable performance. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03% - 1.5%) was validated using signals supplied

by a patient simulator. SpO_2 and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

Nellcor^{TM} sensors' motion performance was validated during a controlled hypoxia blood study over an SaO_2 span of 70% to 98.9% and a convenience-sample heart range of 41-105 bpm. Subjects performed rubbing and tapping movements 1-2 cm in amplitude with aperiodic intervals (randomly changing) with a random variation in frequency between 1-4 Hz. The average percent range was validated using synthetic signals from a patient simulator that comprised representative cardiac and signal artifact components. Applicability: OxiMax MAXA, MAXAL, MAXP, MAXI, and MAXN sensors.

Pulse rate accuracy of Masimo SET technology with Masimo sensors

Masimo SET Technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2 simulator. The variation equals plus or minus one standard deviation, which encompasses 68% of the population.

Pulse rate accuracy of GE TruSignal technology with TruSignal sensors

GE TruSignal technology with TruSignal sensors has been validated for pulse rate accuracy over the specified range in bench top testing against a patient simulator.

SpO_2 performance specifications

The following specifications apply to all compatible modules unless otherwise indicated.

Pulse oximetry saturation measurement value and display range	0 to 100%
Pulse oximetry saturation measurement value accuracy	The specified accuracy for each module is the root-mean-square (RMS) difference between the measured values and the reference values. Because pulse oximetry equipment measurements are statistically distributed, only about two-thirds of the pulse oximetry equipment measurements can be expected to fall within the ±1 A_{rms} of the value measured by a CO-oximeter. Actual accuracy depends on sensor. Please refer to the sensor instructions for use for more detailed information. GE TruSignal: • Adult/Pediatric (70 to 100%): ◦ Without motion: ±2 ◦ With motion: ±3 ◦ Low perfusion: ±3 • Neonatal (70 to 100%): ◦ Without/with motion: ±3 • SpO_2 (< 70%): Unspecified Nellcor: • Adult/Pediatric (70 to 100%): ±2 • Neonatal (70 to 100%): ±3 • Low perfusion: ±2 • SpO_2 (<70%): Unspecified

	Masimo: • Without motion: ◦ Adult/Pediatric (70 to 100%): ±2 ◦ Neonatal (70 to 100%): ±3 • With motion: Adult/Pediatric/Neonatal (70 to 100%): ±3 • Low perfusion: ±2 • SpO_2 (<70%): Unspecified
Pulse oximetry saturation display resolution	1 digit (% of SpO_2)
Pulse oximetry peripheral pulse rate range	GE TruSignal: 30 to 250 bpm Nellcor: 20 to 250 bpm Masimo: 25 to 240 bpm
Pulse oximetry peripheral pulse rate accuracy	The specified accuracy for each module is the root-mean-square (RMS) difference between the measured values and the reference values. Actual accuracy depends on sensor. Please refer to the sensor instructions for use for more detailed information. GE TruSignal: • Without motion: ±2 bpm • With motion: ±3 bpm • Low perfusion: ±5 bpm Nellcor: • ±3 bpm Masimo: • Without motion: ±3 bpm • With motion: ±5 bpm
Pulse oximetry peripheral pulse rate display resolution	1 bpm
Pulse oximetry saturation and pulse rate averaging time	The GE TruSignal configuration provides averaging time options of 3, and 12 seconds. When using the default averaging time, the overall alarm generation delay of SpO_2 is typically less than 28 seconds from the actual SpO_2 value for the patient. This delay is due to the SpO_2 averaging, signal processing and data transmission delays. The delay consists of the alarm condition and alarm generation delay, being typically <10 seconds and <18 seconds, respectively. For pulse rate, the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO_2 and Pulse Rate data is updated every second.

	The Nellcor OXIMAX algorithm used in the device automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measurement conditions. There are various matrices within the saturation pulse rate detection algorithm. Some of these are used to assess the severity of conditions presented to the measuring of SpO_2 and pulse rate on a patient. These individual matrices or combinations of these matrices are used to determine the quality of the received SpO_2 signal. The advanced signal processing in the algorithms automatically extends the amount of data required for measuring SpO_2 and pulse rate depending on the measuring conditions. During normal measurement conditions, the averaging time is approximately three seconds. The overall alarm generation delay of SpO_2 is typically less than 28 seconds from the actual SpO_2 value in the patient. This delay is due to SpO_2 averaging, signal processing and data transmission delays. The delay consists of the alarm condition and alarm generation delay, which are typically <10 seconds and <18 seconds, respectively. For pulse rate, the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO_2 and Pulse Rate data is updated every second. The Masimo configuration provides averaging time options of 2, 4, 8, 10, 12, 14, and 16 seconds. When using the default averaging time, the overall alarm generation delay of SpO_2 is typically less than 28 seconds from the actual SpO_2 value in the patient. This delay is due to SpO_2 averaging, signal processing and data transmission delays. The delay consists of the alarm condition and alarm generation delay, which are typically <10 seconds and <18 seconds, respectively. For pulse rate, the alarm generation delay is typically less than 11 seconds, in which the alarm signal delay is less than a second. The SpO_2 and Pulse Rate data is updated every second.
Pulse oximetry waveform scale options	GE TruSignal: 2, 5, 10, 20, and 50 mod%, and auto Nellcor: 1x, 2x, 4x, and 8x Masmio: 1x, 2x, 4x, and 8x
Wavelength of SpO_2 probe LEDs	Information on the peak wavelengths and maximum output power can be especially useful to clinicians performing photodynamic therapy. GE TruSignal: • Infrared LED: 940 nm • Red: 660 nm Nellcor: • Infrared LED: 900 nm • Red: 660 nm Masimo: • Infrared LED: 905 nm • Red: 660 nm

Maximum energy of SpO_2 probe LEDs	Information on the peak wavelengths and maximum output power can be especially useful to clinicians performing photodynamic therapy. GE TruSignal: • Infrared: 42 µJ/pulse • Red: 62 µJ/pulse Nellcor: • ≤ 15 mW Masimo: • Infrared: ≤ 22.5 mW • Red: ≤ 27.5 mW

Monitor temperature performance specifications

Temperature measurement range	Welch Allyn: 80 to 110°F (26.7 to 43.3°C) Exergen: 61 to 110°F (16.0 to 43.0°C) HeTaida: 93.2 to 109.4°F (34 to 43°C)
Temperature measurement display resolution	0.1°F or 0.1°C

Welch Allyn temperature performance specifications

Temperature measurement range	26.7 to 43.3°C (80 to 110°F)
Clinical accuracy of Monitor-mode temperature measurement	±0.1°C (±0.2°F) (when tested in a calibrated liquid bath in Monitor mode or with a blackbody calibration tester); meets ISO 80601-2-56 and ASTM E1112, Table 1, in range specified. **NOTE** If large changes occur in the ambient temperature, the temperature system can be recalibrated by cycling the monitor's power using the On/Off button.
Clinical accuracy of predictive temperature measurement	Refer to the below table of clinical accuracy results.
Temperature measurement display resolution	0.1°C or 0.1°F
Temperature measurement units	°C or °F
Operating mode	• Test mode: when taking a Monitor-mode temperature measurement • Adjusted mode: when taking a predictive temperature measurement
Operating temperature range	10 to 40°C (50 to 104°F)
Operating humidity range	15 to 95% RH non-condensing
Storage and transport temperature range	-20 to 50°C (-4 to 122°F)
Storage and transport humidity range	15 to 95% RH non-condensing

Measurement site	• Adult axillary or Pediatric axillary for Welch Allyn axillary temperature measurement • Oral for Welch Allyn oral temperature measurement • Rectal for Welch Allyn rectal temperature measurement
Reference body site (predictive mode only)	Axillary, Oral or Rectal (depending on the Measurement site)

Results of clinical accuracy validation according to ISO 80601-2-56:

Mode	Clinical Bias (°C)	Limit of Agreement	Clinical Repeatability
Oral	0.01	0.63	0.14
Rectal	-0.12	0.59	0.29
Pediatric Axillary	-0.03	0.56	0.14
Adult Axillary	0.13	0.43	0.14

Temperature measurement time:

Mode	Time
Oral	Approx. 4 to 6 s
Adult axillary (18 years and older)	Approx. 12 to 15 s
Pediatric axillary (17 years and younger)	Approx. 10 to 13 s
Rectal	Approx. 10 to 13 s

Exergen temperature performance specifications

Temperature measurement range	16.0 to 43.0°C (61 to 110°F)
Temperature measurement accuracy	±0.1°C (±0.2°F)
Operating environment (ambient)	16.0 to 40.0°C (61 to 104°F)
Arterial head balance range for body temperature[*1]	34.5 to 43.0°C (94 to 110°F)
Temperature measurement display resolution	0.1°C or 0.1°F
Temperature measurement units	°C or °F
Operating mode	Adjusted mode
Temperature measurement time	Approximately 0.04 seconds, typical
Storage conditions	-20.0 to 50.0°C (-4.0 to 122°F)
Measurement site	Temporal
Reference body site	Arterial or Oral (depending on the probe type)
[*1] Automatically applied when temperature is within normal body temperature range, otherwise reads surface temperature.	

HeTaida temperature performance specifications

Temperature measurement range	34 to 43°C (93.2 to 109.4°F)
Temperature measurement accuracy	• 34.0 to 34.9°C : ±0.3°C / 93.2 to 94.8°F: ±0.5°F • 35.0 to 42.0°C : ±0.2°C / 95.0 to 107.6°F: ±0.4°F • 42.1 to 43.0°C : ±0.3°C / 107.8 to 109.4°F: ±0.5°F
Temperature measurement display resolution	0.1°C or 0.1°F
Temperature measurement units	°C or °F
Operating mode	Adjusted mode
Temperature measurement time	≤ 2 s
Operating condition	
Operating temperature	15 to 40°C (59.2 to 104°F)
Relative humidity	≤ 85%
Atmospheric pressure	70 to 106 Kpa
Storage and transport condition	
Storage temperature	-20 to 55°C (-4 to 131°F)
Relative humidity	≤ 93%
Atmospheric pressure	70 to 106 Kpa
Measurement site	Forehead
Reference body site	Axillary

Pulse rate performance specifications

Pulse rate measurement range	For the following sources: • GE TruSignal: 30 to 250 bpm • Nellcor: 20 to 250 bpm • Masimo: 25 to 240 bpm • NIBP: 30 to 250 bpm
Pulse rate measurement accuracy	For the following sources: • GE TruSignal: ±2 bpm without motion, ±3 bpm with motion and ±5 bpm for low perfusion • Nellcor: ±3 bpm • Masimo: ±3 bpm without motion and ±5 bpm with motion • NIBP: ±5 % or ±5 bpm, whichever is greater
Pulse rate display resolution	1 bpm

Alarm specifications

Alarm standards compliance

The system complies with IEC 60601-1-8.

Auditory alarm volume

Tested in accordance with IEC 60601-1-8 subclause 6.3.3.2 with alarm volume control set to maximum.

Alarm volume can be adjusted from 45 to 85 dB.

Alarm volume setting	Sound pressure level
10	High priority: 72.0 dB average Medium priority: 64.9 dB average Low priority: 54.5 dB average
1	High priority: 57.9 dB average Medium priority: 51.6 dB average Low priority: 40.6 dB average

Audio alarm sound tolerances

General alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep (500 ms) Silence (500 ms) Frequency: 815 Hz
Medium	• Beep (500 ms) Silence (500 ms) • Beep (500 ms) Silence (5 s) Frequency: 815 Hz
Low	• Beep (500 ms) Silence (30 s) Frequency: 815 Hz

IEC alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep “C” (373 Hz/80 ms) Silence (120 ms) • Beep “F” (498 Hz/80 ms) Silence (120 ms) • Beep “G” (560 Hz/80 ms) Silence (320 ms) • Beep “A” (628 Hz/80 ms) Silence (120 ms) • Beep “B” (705 Hz/80 ms) Silence (1020 ms) • Beep “C” (373 Hz/80 ms) Silence (120 ms) • Beep “F” (498 Hz/80 ms) Silence (120 ms) • Beep “G” (560 Hz/80 ms) Silence (320 ms) • Beep “A” (628 Hz/80 ms) Silence (120 ms) • Beep “B” (705 Hz/80 ms) Silence (5 s)
Medium	• Beep “C” (373 Hz/150 ms) Silence (250 ms) • Beep “G” (560 Hz/150 ms) Silence (250 ms) • Beep “B” (705 Hz/150 ms) Silence (19 s)
Low	• Beep “C” (373 Hz/150 ms) Silence (30 s)

ISO alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (200 ms) • Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (1 s) • Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (200 ms) • Beep (100 ms) Silence (100 ms) • Beep (100 ms) Silence (5 s) Frequency: 815 Hz
Medium	• Beep (200 ms) Silence (200 ms) • Beep (200 ms) Silence (200 ms) • Beep (200 ms) Silence (19 s) Frequency: 815 Hz
Low	• Beep (500 ms) Silence (30 s) Frequency: 815 Hz

ISO2 alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep “C” (523 Hz/80 ms) Silence (120 ms) • Beep “F” (698 Hz/80 ms) Silence (120 ms) • Beep “G” (784 Hz/80 ms) Silence (220 ms) • Beep “A” (880 Hz/80 ms) Silence (120 ms) • Beep “B” (988 Hz/80 ms) Silence (1020 ms) • Beep “C” (523 Hz/80 ms) Silence (120 ms) • Beep “F” (698 Hz/80 ms) Silence (120 ms) • Beep “G” (784 Hz/80 ms) Silence (220 ms) • Beep “A” (880 Hz/80 ms) Silence (120 ms) • Beep “B” (988 Hz/80 ms) Silence (5 s)
Medium	• Beep “C” (523 Hz/115 ms) Silence (185 ms) • Beep “G” (784 Hz/115 ms) Silence (185 ms) • Beep “B” 988 Hz/115 ms) Silence (19.5 s)
Low	• Beep “C” (523 Hz/380 ms) Silence (30 s)

Auditory information signal characteristics

Measurement and start-up related information signals		
Signal	**Frequency (Hz)**	**Duration (ms)**
Start-up sound	523	1000
Completed NIBP volume	250	500
Completed Temp volume	250	50
Round Advisor reminding volume	250	200
Reminder tone	523	125

Visual information signals

For information regarding visual information signals, see the Alarms chapter.

Physiological alarm limits specifications

Alarm limits specifications for NIBP alarms

The following table lists the alarm limits for physiological alarms related to the non-invasive blood pressure measurement.

Alarm	Limit range	Limit increment
NIBP SYS high **NIBP SYS low**	A/P: 30 to 290 mmHg NEO: 30 to 140 mmHg	5 mmHg
NIBP DIA high **NIBP DIA low**	A/P: 10 to 220 mmHg NEO: 10 to 110 mmHg	5 mmHg
NIBP MAP high **NIBP MAP low**	A/P: 20 to 260 mmHg NEO: 20 to 125 mmHg	5 mmHg

Alarm limits specifications for SpO_2 alarms

The following table lists the alarm limits for physiological alarms related to the SpO_2 measurement.

Alarm	Limit range	Limit increment
No pulse **No SpO2 pulse**	NA	NA
SpO2 high	51 to 100%	1%
SpO2 low	50 to 100%	1%

Alarm limits specifications for PR alarms

The following table lists the alarm limits for physiological alarms related to the PR measurement.

Alarm	Limit range	Limit increment
PR high **NIBP PR high**	25 to 300 bpm	5 bpm
PR low **NIBP PR low**	20 to 295 bpm	5 bpm

Alarm delay specifications

The alarm system delay consists of two components:

- Alarm signal detection delay: <3 s
- Fixed delay of the algorithm and monitor software: see following list for alarm priorities and escalations

Possible interferences and poor quality signals in a clinical environment may extend the disclosed alarm system delays.

Local alarm condition delay to output port: <5 s

Alarm priorities and escalations

Alarm priorities and escalation times for NIBP

The following table shows related messages with their priorities and escalation times. In the table, the message location is indicated by the following: MF = message field; PW = parameter window. For more information on alarm messages, refer to the messages chapter.

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Call service: Error x where x = 0 - 18	PW		0 s			
Check NIBP	MF				If measurement finished, but value is missing: 0 s If measurement interrupted: 15 s	
Cuff loose	PW		< 30 s			
Cuff occlusion	PW		0 s			
Cuff overpressure displays for 10 s	PW		0 s			
NIBP cuff overpressure	MF				0 s	
Long measurement time displays for 10 s	PW		0 s			
NIBP long measurement time	MF				0 s	
NIBP call service error	MF				0 s	
NIBP cuff loose	MF				< 30 s	
NIBP cuff occlusion	MF				0 s	
NIBP manual	MF				0 s	
NIBP SYS high / **NIBP SYS low** **NIBP MAP high** / **NIBP MAP low** **NIBP DIA high** / **NIBP DIA low**	MF	High, Medium, Low		0 s, according to priority setting		
NIBP measurement removed	MF		5 s (if no patient is admitted)		5 s (if patient is admitted)	

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Unstable zero pressure displays for 10 s	PW		0 s			
Weak pulsation	PW		0 s			
NIBP weak pulsation	MF				0 s	

Alarm priorities and escalation times for SpO_2

The following table shows related messages with their priorities and escalation times. In the table, the message location is indicated by the following: MF = message field; PW = parameter window. For more information on alarm messages, refer to the messages chapter.

During NIBP measurement, the new **SpO2 high**, **SpO2 low** alarms will de-escalate to the low priority.

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Check device	PW		0 s			
Check probe	PW		0 s			
Check SpO2 probe	MF			5 s	30 s	
Faulty probe	PW		0 s			
Incompatible probe	PW		0 s			
Incompatible SpO2 probe	MF			5 s	30 s	
Interference	PW		0 s			
Low perfusion	PW		0 s			
Low signal quality	PW		0 s			
No probe	PW		0 s			
No SpO2 probe	MF			5 s	30 s	
No pulse	PW		0 s			
No SpO2 pulse	MF			10 s	15 s, escalates to Medium only if PR source is pleth	
Poor signal	PW		0 s			
Probe off	PW	High, Medium, Low		0 s, according to priority setting		
		Escalating	0 s			
Pulse search	PW		0 s			
Faulty SpO2 probe	MF			5 s	30 s	

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
SpO2 high **SpO2 low** (SatSeconds is on)	MF	High, Medium, Low		0 s, according to priority setting		
		Escalating		0 s, de-escalate to low when NIBP cuff pressure is over 30 mmHg	0 s	32 s
SpO2 high	MF	High, Medium, Low		10 s, according to priority setting		
		Escalating		10 s, de-escalate to low when NIBP cuff pressure is over 30 mmHg	10 s	42 s
SpO2 low	MF	High, Medium, Low		10 s, according to priority setting For Masimo: Alarm delay time, or 0 s when SpO_2 value below low limit more than 5%		
		Escalating		10 s, de-escalate to low when NIBP cuff pressure is over 30 mmHg	10 s For Masimo: Alarm delay time, or 0 s when SpO_2 value below low limit more than 5%	42 s For Masimo: Alarm delay time + 32 s, or 32 s when SpO_2 value below low limit more than 5%
SpO2 measurement removed	MF		5 s (patient discharged)		5 s (patient admitted)	
STP measurements removed	MF		5 s (patient discharged)		5 s (patient admitted)	
SpO2 module error	MF				0 s	
STP module error	MF				0 s	
Incompatible Masimo	MF					0 s
SpO2 probe off	MF	High, Medium, Low		5 s, according to priority setting		
		Escalating		5 s	30 s	

Alarm priorities and escalation times for temperature

The following table shows related messages with their priorities and escalation times. In the table, the message location is indicated by the following: MF = message field; PW = parameter window. For more information on alarm messages, refer to the messages chapter.

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
Duplicate Temp modules	MF	Medium			0 s	
Temp measurement removed	MF		0 s			
Temp probe too hot	MF	Low		0 s		
Temp probe error	MF	Low		0 s		
Temp module error	MF	Low		0 s		
Check Temp probe	MF	Low		0 s		
Temp no determination	MF	Low		0 s		
Temp not available	MF	Low		0 s		
Ambient Temp low	PW		0 s			
Ambient Temp high	PW		0 s			
Measurement too low	PW		0 s			
Measurement too high	PW		0 s			
No Temp measurement	PW		0 s			
Interference detected	PW		0 s			
Probe too hot	PW		0 s			
Tissue contact lost	PW		0 s			
Probe well missing	PW		0 s			
Probe error	PW		0 s			
Module error	PW		0 s			
No probe	PW		0 s			
No determination	PW		0 s			
Not available	PW		0 s			
Battery low	PW		0 s			
Battery empty	PW		0 s			
Internal error	PW		0 s			

Alarm priorities and escalation times for PR

The following table shows related messages with their priorities and escalation times. In the table, the message location is indicated by the following: MF = message field; PW = parameter window. For more information on alarm messages, refer to the messages chapter.

MESSAGE	LOCATION	ALARM PRIORITY SETTING	PRIORITIES AND ESCALATION TIMES			
			info	low	medium	high
PR high **PR low** **NIBP PR high** **NIBP PR low**	MF	High, Medium, Low		0 s, according to priority setting		
		Escalating			0 s	69 s

Alarm priorities and escalation times for various situations

The following table shows related messages with their priorities and escalation times. In the table, the message location is indicated by the following: MF = message field; PW = parameter window. For more information on alarm messages, refer to the messages chapter.

MESSAGE	LOCATION	PRIORITIES AND ESCALATION TIMES			
		info	low	medium	high
Battery empty	MF			0 s	
Battery low	MF		0 s		
Battery temperature high	MF			0 s	
Certificate close to expiration	MF		0 s		
Certificate expired	MF		0 s		
Condition battery	MF			0 s	
E-Manual lost	MF				0 s
Identical IP address noticed	MF			max. 40 s	
License invalid	MF	0 s			
No battery backup	MF			0 s	
Patient admitted	MF	0 s			
Patient discharged	MF	0 s			
Printing	MF	3 s			
Recorder: cover open	MF	0 s			
Recorder: input voltage high **Recorder: input voltage low**	MF	0 s			
Recorder: out of paper	MF	0 s			
Recorder module removed	MF	5 s		5 s (if patient case is started)	
Recorder: system error	MF	0 s			
Recorder: thermal array overheat	MF	0 s			
Replace battery	MF			0 s	

MESSAGE	LOCATION	PRIORITIES AND ESCALATION TIMES			
		info	low	medium	high
Restart needed	MF				0 s
Frame temperature high	MF			0 s	
Audio fail	MF			0 s	

Default settings

Understanding your monitor configuration

The monitor's configuration is dependent on the equipment used, the software license, and the settings that define how the software application behaves.

Basic default settings

Admit/Edit settings

On the patient information area, you can adjust the admit/edit patient settings.

Setting	Default value
Select the **Admit New** key. Or select the **Edit** key.	
First name	NA
Last name	NA
PID 1 (unique ID of patient)	NA (the default type is **Patient ID**)
PID 2	NA
Gender	NA
Location	NA
Type	**Adult / Pediatric** or **Neonatal** depending on **Default patient type** (password protected)
Age	NA
Age Unit	**Years** Neonatal patient: **Days**
Date of birth	NA

Historical data settings

Open the **Patients & Records** menu, **Records** menu or **Report** menu to view and manage the historical data.

For how to access these menus, see the Historical data chapter.

Setting	Default value
Include EWS in report	Selected

Sound & Brightness settings

Select the **Configurations**> **Monitor Setup** > **Sound & Brightness** vertical tab to adjust the sound volume and display brightness.

Setting	Default value
High, medium & low priority alarm volume	**5**
High & medium priority alarm volume	**5**
Low priority alarm volume	**5**
Completed NIBP volume	**3**
Completed Temp volume	**3**
RR reminding volume	**0**
Round Advisor reminding volume	**0**
Screen brightness type	**Manual**
Screen brightness	**4**

Alarm setup settings

Select the **Alarm Setup** tab to set up alarm settings.

Setting	Description	Default value
Select **Alarm Limits** tab. **NOTE** The alarm limit settings apply to Monitoring mode only.		
NIBP SYS alarm limits	Select the high/low alarm limits.	Adult/Pediatric patient: **150/70** mmHg Neonatal patient: **100/40** mmHg
NIBP MAP alarm limits	Select the high/low alarm limits.	Adult/Pediatric patient: **100/40** mmHg Neonatal patient: **70/30** mmHg
NIBP DIA alarm limits	Select the high/low alarm limits.	Adult/Pediatric patient: **90/30** mmHg Neonatal patient: **60/20** mmHg
SpO2 alarm limits	Select the high/low alarm limits.	High limit: OFF Low limit: **90** for Adult/Pediatric patient, **88** for Neonatal patient
PR alarm limits	Select the high/low alarm limits.	**160/40** Neonatal patient: **200/90**
Alarm On/Off	Select to turn the alarm on/off .	**ON**
Alarm delay (Masimo SpO_2 only.)	Select the alarm delay.	**5s**
SatSeconds (Nellcor SpO_2 only.)	Select the threshold.	**OFF**

Setting	Description	Default value
Select **Audio** tab.		
High, medium & low priority alarm volume	Select the volume for High, medium & low priority alarms.	**5**
High & medium priority alarm volume	Select the volume for High & Medium priority alarms.	**5**
Low priority alarm volume	Select the volume for Low priority alarms.	**5**
Reactivate alarms	Activate all audio off alarms.	NA
Silence all	Audio off all alarms except the break-through alarms.	Disabled
Audio pause	Audio pause all alarms except the breakthrough alarms.	NA

Select **Priorities** tab to adjust the alarm priority settings.

Setting	Default value
NIBP high/low	**Medium**
SpO2 high	**Escalating**
SpO2 low	**Escalating**
SpO2 probe off	**Escalating**
PR high	**Medium**
PR low	**Medium** Neonatal patient: **High**

Round Advisor settings

Select the **Round Advisor** tab to adjust the related settings.

Setting	Default value
Next checking time at	**00:00 on 1 Jan 2023** and disabled
Reminding interval when overdue	**30min**

Installation default settings

The **Advanced** menu includes the advanced configuration settings which need password to enter.

Please consult qualified and trained technical users to set up. For more information, refer to the Technical Manual.

To access and customize the installation settings:

1. Select the **Configurations** > **Advanced** tab.
2. Select **Username** and enter **Password**.
3. Select **Login**.

NOTE
Username and password are case sensitive.

Alarm settings

Select the **Configurations** > **Advanced** > **Clinical** > **Alarm Settings**.

Setting	Description	Default value
Minimum alarm volume settings		
Alarm volume control	Select the policy for alarm volume control. • Common for all: the same volume for high, medium and low priorities alarms • Separate for low: a separate volume for low priority alarms	**Common for all**
High, medium & low priority alarm volume	Display when you select "Common for all". Select the minimum audible alarm volume for high, medium and low priorities alarms.	**5**
High & medium priority alarm volume	Display when you select "Separate for low". Select the minimum audible alarm volume for high & medium priorities alarms.	**5**
Low priority alarm volume	Display when you select "Separate for low". Select the minimum audible alarm volume for low priority alarms.	**5**
Other alarm audio settings		
Audio off allowed	Select whether to allow silence all alarms function.	Disabled
Reminder volume	Select the reminder audible volume.	**5**
Alarm tones	Select the alarm tone patterns. The choices are IEC, ISO, General and ISO2.	**ISO2**
Low priority alarm tone	Select the audible alarm tone sound (Single / Repeat) for low priority alarms.	**Single**
Allowed alarm priorities settings		
NIBP high/low	Select the allowed priorities settings for this alarm.	**High, medium**
SpO2 low		**Escalating, high, medium**
SpO2 probe off		**Escalating, high**
PR high		**Escalating, high, medium**
PR low		**Escalating, high, medium**
Other settings		
Latching alarms	Enable or disable to keep the below alarm indicators even if initial alarm condition goes away. • alarm messages on MF (message field) of the screen • alarm light • A alarm reminder beep shall be sounded every 10 seconds.	Disabled

Setting	Description	Default value
Nurse call	Select the nurse call system electrical level in the hospital. The choices are: • Normal open: high electrical level export from the nurse call connector when there is medium or high priority alarm. • Normal close: low electrical level export from the nurse call connector when there is medium or high priority alarm.	**Normal open**

Parameter default settings

NIBP default settings

Select the **Configurations** > **Parameter Setup** > **NIBP** vertical tab.

Setting	Description	Default value
Start manual	Start/stop a single NIBP measurement.	NA
Start cycling	Start/stop auto NIBP measurement.	NA
Start STAT	Start/stop five-minute continuous NIBP measurement.	NA
Site	Select the measuring site.	NA
Patient position	Select the patient position.	NA
Cuff size	Select the NIBP cuff size.	NA Neonatal patient: **Neonatal** cuff
Use default inflation pressure	Enable automatic selection of initial cuff inflation pressure.	Enabled
Inflation pressure	Select the cuff initial inflation pressure.	• When **Cuff size** is **Adult** or **Pediatric**: **135** mmHg • When **Cuff size** is **Neonatal**: **100** mmHg
Show on main screen	Select the display items on the main screen.	**Site**, **Patient position**
Completed NIBP volume	Select the volume of tone that sounds when an NIBP measurement is complete.	**3**
Cycling settings	Select the amount of time between automatic measurements.	**5 min** Neonatal patient: **10 min**
1st BP series	Select the first BP series measurement time.	**Interval**: **5 min**
	Select the BP series measurement repeat time.	**Repeat**: **4**

Setting	Description	Default value
2nd BP series	Select the second BP series measurement time.	**Interval**: **15 min**
	Select the BP series measurement repeat time.	**Repeat**: **4**
3rd BP series	Select the third BP series measurement time.	**Interval**: **30 min**
	Select the BP series measurement repeat time.	**Repeat**: **2**
4th BP series	Select the fourth BP series measurement time.	**Interval**: **60 min**
	Select the BP series measurement repeat time.	**Repeat**: **1**

SpO_2 default settings

Select the **Configurations** > **Parameter Setup** > **SpO2** vertical tab.

Setting	Description	Default value
Site	Select the measuring site.	**Finger**
Pleth scale	Select the waveform display scale.	• GE TruSignal SpO_2: **Auto** • Nellcor/Masimo SpO_2: **1x**
Show on main screen	Select the display items on the main screen.	• GE TruSignal/Masimo SpO_2: **Site**, **Waveform**, **PI** • Nellcor SpO_2: **Site**, **Waveform**
SpO2 response (GE TruSignal SpO_2 only.)	Select the averaging time.	**Normal**
Sensitivity (Masimo SpO_2 only.)	Select the SpO_2 sensor sensitivity level.	**Normal**
Averaging (Masimo SpO_2 only.)	Select the averaging time.	**8s** Neonatal patient: **12s**

Temperature default settings

Select the **Configurations** > **Parameter Setup** > **Temp** vertical tab.

Setting	Description	Default value
Completed Temp volume	Select the volume of tone that sounds when a temperature measurement is complete.	**3**

Electromagnetic compatibility

Standards compliance

In addition to the standards listed in the user documentation, the system is also compatible with the following Electromagnetic disturbances – Requirements and tests standard:

- IEC 60601-1-2/ EN 60601-1-2

Compliance with the standard IEC 60601-1-2 / EN 60601-1-2 applies only to those products that are currently being manufactured and shipped. It does not apply to older devices or devices that have their software upgraded.

Essential performance in EMC

Parameter	Essential performance
General	• No loss of or change to user settings, stored data or clinical mode. • No permanent loss of display or unrecoverable loss of function due to equipment damage. • No loss of patient data, mode of operation, or stored data during loss of AC mains or battery power > 10 s. • Ability to generate a technical alarm during abnormal operation. • Resumption of normal operation without data loss within 10 seconds following exposure to electrosurgery.
NIBP measurement accuracy	• The measurement of the cuff pressure reading ≤2 mmHg
SpO_2 saturation measurement value accuracy	GE TruSignal, Nellcor, Masimo: • Adult/Pediatric (70 to 100%): ±2 • Neonatal (70 to 100%): ±3
Temperature measurement accuracy	• Welch Allyn: ± 0.1°C (± 0.2°F) from 26.7 to 43.3°C (80 to 110°F) • Exergen: ± 0.1°C (± 0.2°F) from 16.0 to 43.0°C (61 to 110°F) • HeTaida: ◦ ± 0.3°C (± 0.5°F) from 34.0 to 34.9°C (93.2 to 94.8°F) ◦ ± 0.2°C (± 0.4°F) from 35.0 to 42.0°C (95.0 to 107.6°F) ◦ ± 0.3°C (± 0.5°F) from 42.1 to 43.0°C (107.8 to 109.4°F)

Parameter	Essential performance
Pulse rate accuracy	• GE TruSignal: ± 2 bpm without motion, ± 3 bpm with motion and ± 5 bpm for low perfusion • Nellcor: ± 3 bpm • Masimo: ± 3 bpm without motion and ± 5 bpm with motion • NIBP: ± 5 % or ± 5 bpm, whichever is greater

Electromagnetic emissions

Guidance and manufacturer's declaration — electromagnetic emissions **The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.**		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11*	Group 1	The monitors use RF energy only for their internal function. Therefore, RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11*	Class A	The equipment 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 fluctuations/flicker emissions IEC 61000-3-3	Complies	
* Deviation from IEC 60601-1-2: tested with the test setup defined in IEC 80601-2-49.		

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.

Electromagnetic immunity

Guidance and manufacturer's declaration — electromagnetic immunity **This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.**			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical Fast Transient/Burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration — electromagnetic immunity This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	± 0.5 kV, ± 1 kV differential mode ± 0.5 kV, ± 1 kV, ± 2 kV common mode	
Voltage dips IEC 61000-4-11	U_t = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 315 degrees) U_t = 0%, 1 cycle U_t = 70%, 25/30 cycles (0 degrees)	U_t = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 315 degrees) U_t = 0%, 1 cycle U_t = 70%, 25/30 cycles (0 degrees)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_t = 0%, 250/300 cycles	U_t = 0%, 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the equipment requires continued operation during power mains interruptions, it is recommended that the equipment be powered from an uninterruptible power supply or a battery.
Power Frequency Magnetic Field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz and 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_t is the AC mains voltage prior to application of the test level.			

Electromagnetic immunity for RF

Guidance and manufacturer's declaration — electromagnetic immunity This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz*1		Portable and mobile RF communications equipment should not be used closer to any part of the equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance for 1 W: d = 1.2 √P 150 kHz to 80 MHz

Guidance and manufacturer's declaration — electromagnetic immunity **This device is intended for use in the electromagnetic environment specified below. It is the responsibility of the hospital to assure that the device is used in such an environment.**			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Radiated RF IEC 61000-4-3[*2]	3 V/m[*3] 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	d = 1.2 √P 80 MHz to 800 MHz. d = 2.3 √P 800 MHz to 2.7 GHz 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[*4] should be less than the compliance level in each frequency range[*5]. Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE
At 80 MHz and 800 MHz, the higher frequency range applies.

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

[*1] The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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

[*3] For more information, see section Proximity field immunity compliance.

[*4] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the equipment.

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

Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device.

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter in watts (W)	Separation distance in meters (m) according to frequency of transmitter		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	d = 1.2 √P	d = 1.2 √P	d = 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance [d] in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE
At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE
These guidelines may not apply in all instances. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Proximity field immunity compliance

Guidance and manufacturer's declaration — electromagnetic immunity (IEC/EN 60601-1-2)

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity compliance level (V/m)	Immunity test level (V/m)
385	380 to 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1 kHz sine	2	0.3	28	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
745							
780							
810	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
870							

Guidance and manufacturer's declaration — electromagnetic immunity (IEC/EN 60601-1-2)							
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity compliance level (V/m)**	**Immunity test level (V/m)**
930							
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
1845							
1970							
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5500							
5785							

NOTE
The distance values represent the recommended separation distance between interfering equipment and the monitor, modules, and accessories.

Guidance and manufacturer's declaration — Test specifications for enclosure part immunity to proximity magnetic fields		
Test frequency	**Modulation**	**Immunity test level (A/m)**
134.2 kHz	Pulse modulation[a)] 2.1 kHz	65[b)]
13.56 MHz	Pulse modulation[a)] 50 kHz	7.5[b)]

[a)] The carrier shall be modulated using a 50% duty cycle square wave signal.

[b)] r.m.s (root mean square), before modulation is applied.

Guidance and manufacturer's declaration — electromagnetic immunity (AIM STANDARD 7351731, MEDICAL ELECTRICAL EQUIPMENT AND SYSTEM ELECTROMAGNETIC IMMUNITY TEST FOR EXPOSURE TO RADIO FREQUENCY IDENTIFICATION READERS)				
Test frequency	**RFID standard the test is based on**	**Distance**	**Immunity compliance level**	**Immunity test level**
134.2 kHz	ISO 14223	2.5 cm	65 A/m RMS	65 A/m RMS
13.56 MHz	ISO/IEC 14443-3 (Type A)	1.0 mm	7.5 A/m RMS	7.5 A/m RMS
13.56 MHz	ISO/IEC 14443-4 (Type B)	1.0 mm	7.5 A/m RMS	7.5 A/m RMS
13.56 MHz	ISO/IEC 15693 (ISO 18000-3 Mode 1)	1.0 mm	5.0 A/m RMS	5.0 A/m RMS
13.56 MHz	ISO 18000-3	5.0 cm[*1]	8 A/m	12 A/m
433 MHz	ISO/IEC 18000-7	20.0 cm	3 V/m	3 V/m
860 - 960 MHz	ISO/IEC 18000-63 Type C	20.0 cm	54 V/m	54 V/m
2.45 GHz	ISO/IEC 18000-4 Mode 1	20.0 cm	54 V/m	54 V/m

Guidance and manufacturer's declaration — electromagnetic immunity (AIM STANDARD 7351731, MEDICAL ELECTRICAL EQUIPMENT AND SYSTEM ELECTROMAGNETIC IMMUNITY TEST FOR EXPOSURE TO RADIO FREQUENCY IDENTIFICATION READERS)				
Test frequency	**RFID standard the test is based on**	**Distance**	**Immunity compliance level**	**Immunity test level**
NOTE The distance values represent the recommended separation distance between interfering equipment and the monitor.				
*1 RFID readers emitting RF per ISO 18000-3 Mode 3 at 13.56 MHz should be more than 5 cm away from the device during patient monitoring.				

Minimizing electromagnetic interference

Electromagnetic interference (EMI) can cause erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site of use to determine the source of this disruption, and take the listed actions to eliminate the source:

- Turn equipment in the vicinity off and on to isolate the interfering equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this device.

The device can radiate radio frequency energy and, if not installed and used in accordance with these instructions, may itself cause harmful interference with other susceptible devices in the vicinity.

Abbreviations

List of abbreviations

The following abbreviations appear in the monitor software and manuals. Some abbreviations listed have multiple meanings but are differentiated by the context in which they appear.

/min	beats per minute, breaths per minute
°C	Celsius degree
°F	Fahrenheit degree
µ	micro
a	arterial
AAMI	Association for the Advancement of Medical Instrumentation
AC	alternating current
Amp	amplitude
ANATEL	Agência Nacional de Telecomunicações
ANSI	American National Standards Institute
ATMP	atmospheric pressure
ATPD	atmospheric/ambient temperature and pressure, dry gas
Auto	continuous NIBP measurement mode
Axil	axillary temperature
bpm	beats per minute
C	central
cc	cubic centimeter
CIC	Clinical Information Center
CISPR	International Special Committee on Radio Interference
CPU	central processing unit
CSA	Canadian Standards Association
d	day
dB	decibel
DC	direct current
DEMO	demonstration (mode)
Dia; DIA	diastolic pressure
e	estimated
ED	emergency department
EMC	electromagnetic compatibility
EMI	electromagnetic interference

ESD	electrostatic discharge electrostatic sensitive devices
ESU	electrosurgical unit
F	foot (describing location) frontal
Fib	fibrillation
Fr	French (unit of measure for a Catheter diameter scale)
ft	feet foot
g	gram
g/dl	grams per deciliter
g/l	grams per liter
GND	ground
h	hour
Hb	hemoglobin
HbO_2	oxyhemoglobin
Hct	hematocrit
Hemo	hemodynamic
hPa	hectopascal
Hz	hertz
I.U.	international unit
ICASA	Independent Communications Authority of South Africa
ICU	intensive care unit
ID	identification
IEC	International Electrotechnical Commission
in	inch
IP	internet protocol
ISO	International Standards Organization
J	joule
kcal	kilocalorie
KCC	Korea Communications Commission
kg	kilogram
kJ	kilojoule
kPa	kilopascal
l	liter
l/min	liters/minute
Lab	laboratory
LAN	local area network
lb	pound

LCD	liquid crystal display
LED	light-emitting diode
Man	manual
Man/Spont	manual/spontaneous
MAP	mean arterial pressure
Max.	maximum
mbar	millibar
mcg/l	microgram per liter
mcmol/l	micromole per liter
Mean; M	mean blood pressure
mEq	milliequivalent
mEq/l	milliequivalent per liter
MetHb	methemoglobin
mg	milligram
mg/dl	milligram per deciliter
mI.U.	milli International Unit
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury
mmol	millimol
mmol/l	millimole per liter
mol	mole
MRI	magnetic resonance imaging
MRN	medical record number
ms	millisecond
N	neutral
N/A	not applicable
Neo	neonate
ng/l	nanogram per liter
ng/ml	nanogram per milliliter
NIBP	non-invasive blood pressure
NICU	neonatal intensive care unit
NTPD	normal temperature and pressure, dry gas
O2	oxygen
OR	operating room
Oxy	oxygenation
P	pressure

Pa	pascal
PBSA	predicted body surface area
PBW	predicted body weight
pcs	pieces
PDF	portable document format
Peds	pediatrics
PIC	patient interface cable
Pleth	plethysmographic pulse waveform
PN	part number
PR	pulse rate
Rect	rectal temperature
Resp Rate	respiration rate (total) (measured)
RF	radio frequency
RMS	average (root mean square) power
RR	respiration rate
s	second
Skin	skin temperature
SN	serial number
SpO2	oxygen saturation
STAT	five-minute continuous NIBP measurement mode
SW; sw	software
Sys; SYS	systolic pressure
T	temperature temporal
Tab	tabular
Temp	temperature
UI	user interface
v	venous
Vent	ventilator
WLAN	wireless local area network
yrs	years

Symbols glossary

Symbols glossary

ISO 7010:2019 Graphical symbols — Safety colors and safety signs — Registered safety signs			
Symbol	**Standard reference number**	**Symbol title and description from standard**	**GE description**
	ISO 7010-M002	Refer to instruction manual/booklet	Follow instructions for use. ISO 7010.
	ISO 7010-W001	General warning sign	General warning sign. ISO 7010.
	ISO 7010-W012	Warning; Electricity.	WARNING. Electric shock hazard. This equipment must be serviced by qualified service personnel only. ISO 7010.

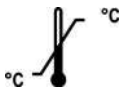
ASTM F2503–13: Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	ASTM F2503 Clause 7.3.3	MR unsafe	MR Unsafe. Indicates that the device is not intended for use in an MR environment.

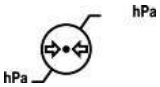
IEC 60417:2002: Graphical symbols for use on equipment			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	IEC 60417-5134	Electrostatic sensitive devices To indicate packages containing electrostatic sensitive devices, or to identify a device or a connector that has not been tested for immunity to electrostatic discharge.	Electrostatic sensitive device.
	IEC 60417-5334	Defibrillation-proof type BF applied part To identify a defibrillation-proof type BF applied part complying with IEC 60601-1.	Type BF (IEC 60601-1) defibrillator-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, excluding direct cardiac application.

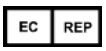
IEC 60417:2002: Graphical symbols for use on equipment			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	IEC 60417-5336	Defibrillation-proof type CF applied part To identify a defibrillation-proof type CF applied part complying with IEC 60601-1.	Type CF (IEC 60601-1) defibrillator-proof protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient including direct cardiac application.
	IEC 60417-5307	Alarm, general To indicate an alarm on a control equipment.	• Alarm priority indicator: High (red). Indicates a high priority alarm. • Alarm priority indicator: Medium (yellow). Indicates a medium priority alarm. • Alarm priority indicator: Low (cyan). Indicates a low priority alarm.
	IEC 60417-5319	Alarm inhibit To identify the alarm inhibit on control equipment.	Alarm off indicator. The indicator may not display at the central station or on a remote bedside monitor.
	IEC 60417-5576	Bell cancel To identify the control whereby a bell may be switched off or to indicate the operating status of the bell.	Bell cancel. Audio off.
	IEC 60417-5576	Bell cancel, temporary To indicate the operating status of the bell being temporarily cancelled.	Audio pause. Temporary audio off.
	IEC 60417-5019	Protective earth; protective ground To identify any terminal which is intended for connection to an external conductor for protection against electric shock in case of a fault, or the terminal of a protective earth (ground) electrode	Protective earth ground. Connectors grounded to the AC power source.
	IEC 60417-5032	Alternating current To indicate on the rating plate that the equipment is suitable for alternating current only; to identify relevant terminals.	Alternating current. Green indicator on the front panel: the device is being used on mains power.
	IEC 60417-5021	Equipotentiality To identify the terminals which, when connected together, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.	Equipotentiality. Connect device to a potential equalization conductor.

IEC 60417:2002: Graphical symbols for use on equipment			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	IEC 60417-5140	Non-ionizing electromagnetic radiation To indicate generally elevated, potentially hazardous, levels of non-ionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	Non-ionizing electromagnetic radiation. Interference may occur in the vicinity of this device.
	IEC 60417-5988	Computer network To identify the computer network itself or to indicate the connecting terminals of the computer network.	Network connection indicator.
	IEC 60417-5009	Stand-by To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.	Standby indicator.
	IEC 60417-5569	Locking, general To identify on a control that a function is locked or to show the locked status.	Locked. Touchscreen lock key.
	IEC 60417-5570	Unlocking To identify on a control that a function is not locked or to show the unlocked status.	Unlocked.
	IEC 60417-5001B	Battery, general To identify a device related to the power supply by primary or secondary battery, for instance a cover for the battery compartment, or the connector terminals.	Battery (monitor). Located on the battery slot cover.
	IEC 60417-5546	Battery check To identify a control to check the condition of a primary or secondary battery or to identify the battery condition indicator.	Battery (monitor): The green symbol indicates that the battery is being charged.

ISO 7000:2019 Graphical symbols for use on equipment — Registered symbols			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	ISO 7000-1641	Operating instructions Indicates the need for the user to consult the instructions for use.	Consult operating instructions. / Operating instructions.

ISO 7000:2019 Graphical symbols for use on equipment — Registered symbols			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	ISO 7000-0434A	Caution Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	Caution. ISO 7000.
	ISO 7000-3082	Manufacturer Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC	Manufacturer name and address.
	ISO 7000-2497	Date of manufacture Indicates the date when the medical device was manufactured.	Date of manufacture. This symbol indicates the date of manufacture of this device. The first four digits identify the year, the following two digits identify the month, and the last two digits identify the day. Country of origin may appear within the symbol (country codes per ISO 3166-1).
	ISO 7000-2492	Batch code Indicates the manufacturer's batch code sot that the batch or lot can be identified.	Batch or lot number.
	ISO 7000-2498	Serial number Indicates the manufacturer's serial number so that the medical device can be identified.	Device serial number.
	ISO 7000-2493	Catalogue number Indicates the manufacturer's catalogue number so that the medical device can be identified.	Catalogue or orderable part number.
	ISO 7000-0621	Fragile, handle with care Indicates a medical device that can be broken or damaged if not handled carefully.	Fragile. Handle with care.
	ISO 7000-0626	Keep dry Indicates a medical device that needs to be protected from moisture.	Keep dry. Protect from rain.
	ISO 7000-0632	Temperature limit Indicates the temperature limits to which the medical device can be safely exposed.	Temperature limitations.

ISO 7000:2019 Graphical symbols for use on equipment — Registered symbols			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	ISO 7000-2620	Humidity limitation Indicates the range of humidity to which the medical device can be safely exposed.	Humidity limitations.
	ISO 7000-2621	Atmospheric pressure limitation Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	Atmospheric pressure limitations.
	ISO 7000-1051	Do not re-use Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	Do not reuse.
	ISO 7000-2760	Product information; Information point Identifies a place where information may be found, especially in an emergency.	Information point sign. Identifies a place where information may be found.
	ISO 7000-3315	Home position To identify the control that takes the display to the "home" page of the menus or to a known (user-defined) location in the display hierarchy.	Home. Return to the main display.
	ISO 7000-1135	General symbol for recovery/recyclable To indicate that the marked item or its material is part of a recovery or recycling process.	Recycled materials or may be recycled.
	ISO 7000-0623	This way up To indicate correct upright position of the transport package.	This way up.
	ISO 7000-2607	Use by date To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging.	Use by.

ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements			
Symbol	**Standard reference number**	**Symbol title from standard**	**GE description**
	ISO 15223-1: 5.1.2	Authorized representative in the European Community Indicates the authorized representative in the European Community.	European authorized representative.

GE Medical Systems *Information Technologies*, Inc.
9900 Innovation Drive
Wauwatosa, WI 53226 USA

GE Medical Systems SCS
283 Rue de la Minière
BUC 78530 France

GE HealthCare

www.gehealthcare.com