Portrait™ Mobile Monitoring Solution

User Manual

Software version 1

Portrait™ Mobile Monitoring Solution
English
5815148-01
1st edition

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

For technical documentation purposes, the abbreviation GE is used for the legal entity name, GE Medical Systems *Information Technologies*, Inc., and GE Healthcare Finland Oy.

Contents

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Legal manufacturer information

Manufacturer information

Portrait™ HUB01, SBT01, SpO2 P-SA01, SpO2 P-SP01, SpO2 P-W01, SpO2 P-SE01, RR P-RR01
CE 0537
GE Healthcare Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki Finland Tel: +358 10 39411 www.gehealthcare.com

Portrait™ CSS01, CVA01, CAU01	
CE 0197	EC REP
GE Medical Systems *Information Technologies*, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA www.gehealthcare.com	GE Medical Systems SCS 283 Rue de la Miniere 78530 BUC, France

Portrait™ RRP01, MMP01, BCH01, AAB01
CE
GE Healthcare Finland Oy Kuortaneenkatu 2 FI-00510 Helsinki Finland Tel: +358 10 39411

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Standards

Standards compliance

The system complies with the following standards.

- IEC 60601–1:2005 + A1:2012
- IEC 60601–1–2:2014
- IEC 60601–1–8:2006 + A1:2012
- IEC 62366–1:2015/COR1:2016
- IEC 62304:2015
- IEC 60601–1–6:2010 + A1:2013
- ISO 80601–2–61:2017
- ISO 80601–2–49:2018

Type BF defibrillator-proof APPLIED PART per IEC 60601–1 Clause 6

Type CF defibrillator-proof APPLIED PART per IEC 60601–1 Clause 6

Power supply mains plug is the means for isolation from supply mains.

The Central Viewer computer must comply with the following relevant standards: IEC 62368-1:2020+A11:2020 A and/or IEC 60950-1:2005+A1:2009+A2:2013.

The EHL Platform hardware must comply with the following relevant standards: IEC 62368-1:2020+A11:2020 A and/or IEC 60950-1:2005+A1:2009+A2:2013.

IEC 60601-1

- Type of protection against electrical shock:
  - Charger and power supply: Class II
  - Alarming unit: USB connection to a PC
  - SpO_2 and respiration sensors, Hub, and sensor battery: Internally powered medical equipment.
  - Hub and sensor batteries: Class II during charging
- 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:
  - Hub: IP67

  - Sensor battery: IP67
  - SpO_2 sensors P-SA01 and P-SP01, and respiration sensor: IP67
  - SpO_2 sensors P-SE01 and P-W01: IP44
  - All SpO_2 sensors with battery, respiration sensor with battery: IP44
  - Charger: IPX2
  - Power supply unit of the charger: IPX0
  - Alarming unit: IPX1
- Mode of operation: Continuous.

Safe and proper operation should always be verified with the device manufacturer's instructions for use, and system standards IEC 60601-1 clause 16 and the requirements of the local authorities must be complied with.

SpO_2 standards compliance

- ISO 80601-2-61:2017
- Type BF defibrillator-proof per IEC 60601–1 Clause 6

Impedance respiration standards compliance

- Type CF defibrillator-proof per IEC 60601–1 Clause 6

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Introduction to this manual

Manual intended use

This manual is an integral part of the Portrait™ Mobile Monitoring Solution system. 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 a prerequisite for proper performance and correct operation and ensures patient and user safety.

The list below indicates the compatible products (brands, models and descriptions as applicable) with which this manual is to be used.

- Portrait™ CVA01, Central Viewer Application
- Portrait™ CAU01, Clinical Alarming Unit
- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ CSS01, Core Services
- Portrait™ SpO2 P-SA01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SP01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-W01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SE01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ RR P-RR01, Wearable Respiration Rate Sensor
- Portrait™ RRP01, RR Electrode Patch
- Portrait™ BCH01, Bedside Charger
- Portrait™ SBT01, Sensor Battery
- Portrait™ MMP01, Mobile Patient Monitor Pouch
- Portrait™ BWM01, Bedside Charger Wall Mount
- Portrait™ BTM01, Bedside Charger Table Mount
- Portrait™ AAB01, SpO2 Attachment Accessory Band

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 system should never replace nor impede the human intervention and required patient care provided by clinical professionals.

Training requirements

No product-specific training is required for the use of the Portrait™ Mobile Monitoring Solution.

Manual conventions

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

Item	Description
bold	Indicates hardware keys and connectors.
bold italic	Indicates software terms.
+	Indicates keyboard keys to select simultaneously.
>	Indicates menu options to select consecutively.
X	Supported
-	Not supported
select	The word select means choosing and confirming.
NOTE	Note statements provide application tips or other useful information.

Naming conventions

In this manual, the following naming conventions are used:

- Portrait™ Mobile Monitoring Solution: system
- Portrait™ CVA01, Central Viewer Application: Central Viewer
- Portrait™ CAU01, Clinical Alarming Unit: alarming unit
- Portrait™ HUB01, Mobile Patient Monitor: Hub
- Edison™ HealthLink Platform: EHL Platform
- Portrait™ CSS01, Core Services: Core Services
- Portrait™ monitoring network: monitoring network
- Portrait ™ SpO2 P-SA01, SpO2 P-SP01, SpO2 P-W01, SpO2 P-SE01, Wearable Pulse Oximetry Sensor: SpO_2 sensor
  - Wearable SpO_2 Parameter is used to refer to the combination of the sensor and sensor battery
- Portrait™ RR P-RR01, Wearable Respiration Rate Sensor: respiration sensor
- Portrait™ RRP01, RR Electrode Patch: respiration patch
  - Wearable RR Parameter is used to refer to the combination of the sensor, sensor battery, and respiration patch
- Portrait™ BCH01, Bedside Charger: charger
- Portrait™ SBT01, Sensor Battery: sensor battery
- Portrait™ MMP01, Mobile Patient Monitor Pouch: Hub pouch
- Portrait™ BWM01, Bedside Charger Wall Mount: charger wall mount
- Portrait™ BTM01, Bedside Charger Table Mount: charger table mount
- Portrait™ AAB01, SpO2 Attachment Accessory Band: attachment band

- Portrait™ Mobile Monitoring Solution Configuration user interface: Config UI

For technical documentation purposes, the abbreviation GE is used for the legal entity names, GE Medical Systems *Information Technologies*, Inc., and GE Healthcare Finland Oy.

Illustrations and names

This manual uses illustrations as examples only. Illustrations in this manual may not necessarily reflect all 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.

Ordering manuals

A paper copy of this manual will be provided upon request. Contact your local GE representative and request the paper manual part number on the first page of the manual.

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 (e.g., 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 third party software notices

The system uses third party software and libraries in its application to perform some of its functions and operations.

To obtain the latest version of these software notices:

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 document.

Product availability

NOTE Due to continual product innovation, design and 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 for availability.

Trademarks

GE, GE Monogram, Edison, and Portrait are trademarks of General Electric Company.

Third party trademarks

ProSim is a trademark of Fluke Biomedical.

XP logo and XP Power are trademarks of XP Power.

Super Sani-Cloth is a trademark of PDI, Inc.

CaviWipes is a trademark of Metrex Research, LLC.

Manufacturer responsibility

GE 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.

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.

Related manuals

Portrait™ Mobile Monitoring Solution Service Manual

Portrait™ Mobile Monitoring Solution Privacy and Security Manual

Wireless LAN Configuration Guide

Portrait™ Mobile Monitoring Solution Third Party Software Notices

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Safety and intended use

Safety message signal words

Safety message signal words designate the severity of a potential hazard. The signal words danger, warning, caution, and notice are used throughout this manual to point out hazards and to designate a degree or level of seriousness. A hazard is defined as a source of potential injury to a person. Learn their definitions and significance.

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.

The order in which safety messages are presented in no way implies the order of importance.

Safety symbols

U.S. only: For a list of all product-related symbols with their standard references, see the symbols glossary.

Symbol	Explanation
	Follow instructions for use. ISO 7010. This symbol indicates mandatory action and it is identified by a blue background and a white symbol.
	MR Unsafe. Indicates that the device is not intended for use in an MR environment. This symbol is identified by a white background, red or black circular band, and a black symbol.

Symbol	Explanation
	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.

Reporting of serious incidents

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

To report to GE, 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 product as stated on its identification plate affixed on the product
- The SystemID/serial number/lot number of the product
- Date of incident
- Description of incident, including any patient or user impact/injury
- Your contact information (facility, address, contact name, title, and telephone number)

Danger safety messages

No danger safety messages apply to this system.

Warnings

System warnings

WARNING BURN INJURY. To avoid burn injuries, do not disconnect the sensor battery and leave the Wearable SpO_2 or RR Parameter attached to the patient while performing defibrillation. Keep sensor batteries connected to sensors or remove the Wearable SpO_2 or RR Parameters completely from the patient. Do not allow defibrillation patches to come into contact with conductive portions of the Wearable SpO_2 or RR Parameters

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

WARNING EXCESSIVE LEAKAGE CURRENT. Do not use a multiple socket outlet or extension cord in a medical electrical system.

WARNING FIRE. To avoid the risk of fire, do not expose the Hub or sensor batteries to high temperatures.

WARNING INTERFACING OTHER EQUIPMENT. Connect only items that are specified as part of the system and as compatible. For more information, see the list of compatible devices.

WARNING LOSS OF MONITORING. Connect only items that are specified as part of the system and as compatible. Using incompatible components can result in loss of monitoring. For more information, see the list of compatible devices.

WARNING LOSS OF MONITORING. A loss of network connectivity may result in a loss of patient monitoring. To ensure patient safety, always keep the patient under close surveillance and check on them regularly.

WARNING LOSS OF MONITORING. Before discharging a patient on the Central Viewer, always check that the patient no longer needs monitoring to avoid loss of data.

WARNING LOSS OF MONITORING. Before removing the patient and Hub assignment on the Central Viewer, always check that the patient no longer needs monitoring to avoid loss of data.

WARNING LOSS OF MONITORING. Before unassigning the patient, always check that the monitoring of that patient can be stopped. Unassigning the Hub from the patient will result in loss of monitoring.

WARNING LOSS OF MONITORING. Radio-frequency identification (RFID) readers that operate at 2.45 GHz frequencies may cause a loss of network connectivity. Do not use such devices close to the system.

WARNING MAGNETIC INTERFERENCE. The system may interfere with other devices that are sensitive to magnetic fields. To avoid this risk, do not position the system components close to such devices.

WARNING PATIENT HARM. To avoid harm to the patient caused by the radiated energy of this system, always check the equipment functionality and then change the component location or orientation if needed.

WARNING PERSONAL INJURY. Damaged equipment or accessories must be replaced immediately. Using damaged equipment or accessories may result in the risk of electrical shock, fire, high temperature, exposure to internal toxic materials, inability to effectively clean the device, excessive mechanical pressure or unexpected loss of function.

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

WARNING RADIO INTERFERENCE. If you notice any unusual functionality or non-functionality in other nearby equipment, change the location or orientation of the system components as needed.

WARNING UNEXPECTED SYSTEM PERFORMANCE. Compatibility is critical to safe and effective use of this device. Only use components that are listed as part of the system and as compatible. Using incompatible components can result in loss of monitoring. For more information, see the list of compatible devices.

WARNING UNEXPECTED SYSTEM PERFORMANCE. External radiating devices (e.g. cell phones, brachytherapy devices, x-ray devices) may disturb the measurement. Do not use such devices close to the system.

WARNING UNEXPECTED SYSTEM PERFORMANCE. Radio-frequency identification (RFID) readers that operate at frequencies 134.2 kHz or13.56 MHz may negatively impact the system performance. Do not use such devices close to the system.

EMC warnings

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, including cables specified by the manufacturer. Otherwise the performance of this device/system may degrade.

WARNING DEGRADED PERFORMANCE. Do not use an RFID reader operating at a low frequency such as 134.2 kHz and 13.56 MHz close to any part of the Hub and sensors. Otherwise there is a risk of degraded performance of the impedance respiration measurement.

- Impedance respiration measurement value may be out of the measurement accuracy range and respiration waveform noise may be randomly high when the respiration sensor is too close to such RFID readers. When these RFID emissions are removed, the measurement returns to expected measurement accuracy within 60 seconds without any changes to settings.

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

WARNING LOSS OF MONITORING. To avoid losing the Hub and sensor connectivity and thus patient monitoring, do not use an RFID reader operating at the frequency of 2.45 GHz close to any part of the Hub and sensors.

WARNING LOSS OF MONITORING. 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 system. Consult qualified personnel regarding system configuration.

WARNING LOSS OF MONITORING. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation due to electrical interference, or to increased equipment temperature due to heat generated by the other equipment . If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Consult qualified personnel regarding device/system configuration.

WARNING MR UNSAFE. Do not use the system in an environment containing an MRI magnet to avoid risks to the patient, user, or devices.

WARNING UNEXPECTED SYSTEM BEHAVIOR. Use only approved accessories listed in the product manual. Other accessories may cause unexpected system behavior, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

Operation warnings

WARNING INACCURATE READINGS. 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.

WARNING INCORRECT ALARM PROFILE. Make sure that you enter the correct date of birth for the patient to ensure a correct alarm profile. A wrong alarm profile may result in false or missing alarms.

WARNING INCORRECT OR MIXED PATIENT DATA. Always make sure that you have discharged the previous patient, removed the patient and Hub assignment, and unpaired the sensor before you start monitoring a new patient. Failure to do so will result in mixed patient data.

WARNING LOSS OF MONITORING. Make sure to always lock the Hub screen when not interacting with it. Locking the screen will prevent unintentional interactions, which could lead to interrupted monitoring.

WARNING LEAKAGE CURRENT. To avoid excessive patient leakage current, do not simultaneously touch the patient and the pins on the charger.

WARNING LEAKAGE CURRENT TO PATIENT. To avoid leakage current to the patient, make sure that the sensors and connectors do not touch any electrically conductive material including earth.

WARNING MISSED EVENTS. To avoid missing any events, lock the Hub screen when not in clinical use to protect it from ghost touches caused by static electricity building up on the screen. Also make sure that there are no liquids on the screen, and avoid EMI or ESD interference.

WARNING PATIENT SAFETY. If the accuracy of any value displayed is questionable, first check that the sensors are properly attached and determine the patient's vital signs by alternate means. Then, verify that the monitoring system is working correctly.

WARNING PATIENT SAFETY. In case the Hub does not receive a configuration from the Core Services for some reason, it will use the factory defaults. Always check the settings to ensure patient safety.

WARNING PATIENT SAFETY. Take special care when using small or loose components around the patient to avoid the risk of choking or suffocation. Always check that such components are located so that they do not cause a risk to the patient.

WARNING PATIENT SAFETY. When using an electrosurgery unit, note that the measurement devices do not incorporate the means to protect against burns in case of a defective or wrongly positioned ESU return electrode. To avoid burns at the measurement sites, ensure the following:

- The ESU return electrode is properly connected to the patient.
- The ESU return electrode is near the operating area.
- Parameter devices are far from the surgical site and the ESU return electrode.

WARNING PATIENT SAFETY. The Hub is designed for use on one patient at a time. Trying to use the Hub to monitor more patients simultaneously results in incorrect monitoring data.

WARNING PERSONAL INJURY. Route the cable of the alarming unit in such a way that it will not present a stumbling hazard.

WARNING STRANGULATION. Route all cables away from patient's throat to avoid possible strangulation.

WARNING UNEXPECTED SYSTEM PERFORMANCE. To prevent erroneous readings, do not use physically damaged sensors or cables. Discard a damaged sensor or cable immediately. Never repair a damaged sensor or cable never use a sensor or cable repaired by others

Defibrillation 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 products.

WARNING DEFIBRILLATOR PRECAUTIONS. To ensure proper defibrillator protection, do not place the defibrillation paddles on top of the respiration sensor when it is not connected to a sensor battery.

WARNING ELECTRICAL SHOCK. To avoid the risk of electrical shock, do not touch the patient, table, bed, instruments, sensors, or the Hub during defibrillation.

Alarm warnings

WARNING MISSED ALARMS. Always make sure that the necessary alarm limits and priorities are active and set according to the patient's clinical condition while the patient is being monitored. Ask an authorized user to check such settings of the alarm system that are available only to them (for example, alarm delays). Inappropriate or extreme reduction of the alarm system or patient settings can lead to missed detection of critical events.

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. There is a risk of missing alarms when the same type of devices in the same care area are using different alarm pre-sets. Always keep the patient under close surveillance

WARNING MISSED ALARMS. To avoid missing alarms and noticing the deterioration of the patient condition, always keep the patient under close surveillance and do not rely exclusively on the audible alarms of the Hub or Central Viewer.

WARNING MISSED ALARMS. When you change alarm settings (like alarm volume or similar), the ability of the system to alert you of alarm conditions may be impacted. Always keep the patient under close surveillance to avoid missing any alarms.

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 UNEXPECTED SYSTEM BEHAVIOR. Use only approved accessories listed in the product manual. Other accessories may cause unexpected system behavior, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

Battery warnings

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

WARNING EXPLOSION OR FIRE. Do not damage the rechargeable Lithium-Ion battery. A damaged battery can cause an explosion or fire, and can result in personal injury and/or property damage. To prevent injury or damage:

- Do not use or charge the battery if it appears to be damaged. Signs of damage include, but are not limited to, discoloration, warping, and leaking battery fluid.
- Do not expose the battery to fire, high temperature, or direct sunlight.
- Do not immerse the battery in water.
- Do not drop or puncture the battery.
- Do not open the battery or short-circuit its contacts.

WARNING PERSONAL INJURY OR PROPERTY DAMAGE. Avoid contact with the rechargeable Lithium-Ion battery if it appears to be leaking. Battery fluid is corrosive, and contact with it can result in personal injury and/or property damage. To prevent injury or damage:

- If the battery leaks, avoid contact with the battery fluid.
- If the battery fluid gets into your eyes, immediately rinse your eyes with clean water and seek medical attention. Do not rub your eyes.
- If a leaking battery gets in contact with your skin or clothing, immediately use clean water to wash off the battery fluid.

Care warnings

WARNING EQUIPMENT DAMAGE, UNEXPECTED PERFORMANCE. Always adhere to the manufacturer instructions when cleaning or disinfecting the system components. Incorrect cleaning may result in damage to the equipment and unexpected performance, such as loss of monitoring.

WARNING EQUIPMENT DAMAGE, UNEXPECTED PERFORMANCE. Do not use any automated cleaning or disinfection processes for the Portrait Mobile Monitoring Solution system components. Incorrect cleaning may result in damage to the equipment and unexpected performance, such as loss of monitoring.

WARNING LEAKAGE CURRENT. To avoid the risk of unacceptable leakage current that could result in risk to the patient or user, always clean the sensor-battery interface.

Respiration warnings

WARNING APNEA EVENTS. The device may not detect all episodes of inadequate breathing, nor does it distinguish between central, obstructive, and mixed apnea events. Therefore, do not use it as an apnea monitor.

WARNING LOSS OF MONITORING. To avoid the risk of loss of monitoring due to dry respiration electrode gel, periodically check the patient and the respiration patch.

WARNING PATIENT SAFETY. Implantable Minute Ventilation Rate Responsive Pacemakers may react with the respiration sensor and cause the pacemaker to execute pacing with the maximum programmed rate. Before pairing the sensor and Hub, always check that the patient does not have this type of pacemaker. Failing to do so may compromise patient safety.

WARNING UNEXPECTED SYSTEM PERFORMANCE. Movement artifact may affect the accuracy of the respiration measurement. To avoid inaccurate readings, instruct the patient about the effect of movement on the measurement and ensure that the sensor patch is properly attached to the patient.

SpO_2 warnings

WARNING INACCURATE READINGS. Make sure that there are no light-emitting devices close to the SpO_2 sensor because they might interfere with the measurement and cause inaccurate readings.

WARNING PATIENT SAFETY. Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore does 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 DISCOMFORT. Prolonged monitoring can cause patient discomfort, such as skin reaction, pressure points or elevated temperature of the SpO_2 sensor. To avoid patient discomfort, periodically check the patient and change the sensor location.

WARNING PATIENT INJURY. To avoid patient injury, always check the compatibility of the SpO_2 measurement components prior to use. Incompatible components can result in degraded performance, device malfunction, and patient injury.

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.

Cautions

Alarm cautions

CAUTION MISSED ALARMS. Use care when setting parameter alarm limits to the maximum permitted limits as this may compromise the alarm system and lead to missed alarms.

CAUTION MISSED EVENTS. Exercise care when changing the alarm priority of the SpO_2 low alarm to be lower than Medium as this is not compliant with ISO 80601-1-61:2017 clause 208.6.1.2.101 and may lead to missed events.

System cautions

CAUTION EQUIPMENT DAMAGE, PATIENT INJURY. Always store the Hub and sensor batteries in the charger while not in use. Equipment that is not properly placed in the charger may fall and harm the patient or result in damage to the equipment itself.

CAUTION EQUIPMENT DAMAGE, PATIENT INJURY. To avoid the risk of injury, always check that the Hub, Wearable SpO_2 and RR Parameters, and accessories are safely attached. Equipment that is not properly attached may fall and harm the patient or result in damage to the equipment itself.

Operation cautions

CAUTION ALLERGIC REACTION. Periodically check the patient to make sure that they have not developed any allergic reaction to the system components. If any unusual reaction develops, discontinue the measurement and remove the system component(s).

CAUTION PATIENT DISCOMFORT. To avoid a stressful environment and patient discomfort caused by audible alarms, check that the Hub is not in close proximity to the patient's ear and change its location if needed.

Disposal cautions

CAUTION CONTACT WITH TOXIC MATERIALS. To avoid any contact with potentially toxic materials, dispose of the products described in this manual, as well as their accessories and packaging, in compliance with the guidelines regulating the disposal of each product . If you have any questions concerning disposal of a product, please contact GE or its representatives.

Respiration cautions

CAUTION PATIENT DISCOMFORT. Prolonged monitoring can cause patient discomfort, such as skin reaction, pressure points or elevated temperature of the respiration sensor. To avoid patient discomfort, periodically check the patient and change the sensor location.

Intended use statements

Refer to the graphics describing the system components and measurement setups to identify each device.

Portrait™ Mobile Monitoring Solution intended use

The Portrait™ Mobile Monitoring Solution is intended to acquire, store, calculate, display and export patient monitoring data as well as provide real time alarming for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg).

Physiological parameters and waveforms supported are:

- Pulse oximetry (SpO_2/pulse rate)
- Respiration rate (RR)

Continuous pulse oximetry and respiration rate monitoring may be used for patients at risk of cardiorespiratory and infectious complications.

The Portrait™ Mobile Monitoring Solution is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Mobile Monitoring Solution is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Central Viewer Application (Portrait CVA01) intended use

The Portrait™ Central Viewer Application (Portrait™ CVA01) provides monitoring station capability running as an application for the Portrait Mobile Monitoring Solution on a PC platform that meets minimum system requirements. It provides the ability to view real-time data for multiple patients and historical data for a single patient including configurable visual and audible alarm notifications.

The Portrait™ Central Viewer Application is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Core Services (Portrait CSS01) intended use

The Portrait™ Core Services are a set of software services that enable the communication and interaction of the Portrait™ Monitoring Solution components and will integrate into existing healthcare facility infrastructure and clinical information systems. The Portrait™ Core Services can transmit patient physiological trends and numerics (IHE PCD DEC) and alarm events (IHE PCD ACM) outbound. The Portrait™ Core Services can also receive HL7 ADT information to admit patients to the Portrait™ Monitoring Solution.

Portrait™ Clinical Alarming Unit (Portrait CAU01) intended use

The Portrait™ Clinical Alarming Unit (Portrait™ CAU01) is a required accessory to the Portrait™ Central Viewer Application that provides audio alarming capability.

The Portrait™ Clinical Alarming Unit is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Mobile Patient Monitor (Portrait HUB01) intended use

The Portrait™ Mobile Patient Monitor (Portrait™ HUB01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous monitoring of oxygen saturation (SpO_2), pulse rate (PR) and respiration rate (RR) parameters. The Portrait™ Mobile Patient Monitor enables non-invasive continuous monitoring of patients by acquiring signals from body-worn sensors through a Medical Body Area Network (MBAN) connection as well as displaying trends and events. The device can be configured to provide local audible and visual alarms and can also provide real-time, trend and event data to Portrait™ Core Services.

The Portrait™ Mobile Patient Monitor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Mobile Patient Monitor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor P-SA01 (Portrait SpO2 P-SA01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO_2 P-SP01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) is intended for use with pediatric patients (3 years of age and older, and weighing 15 kg to 30 kg) for

continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SE01, Portrait SpO2 P-W01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01) intended use

The Portrait™ SpO2 Attachment Accessory Band (Portrait AAB01) is intended to provide a means to secure the Portrait™ Wearable Pulse Oximetry Sensor with Portrait™ Sensor Battery to the patient's wrist.

The Portrait™ Attachment Accessory Band is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01) intended use

The Portrait™ Wearable Respiration Rate Sensor (Portrait P-RR01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The Wearable Respiration Rate Sensor acquires parameter data from the patient and transmits it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Respiration Rate Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Respiration Rate Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ RR Electrode Patch (Portrait RRP01) intended use

The Portrait™ RR Electrode Patch (Portrait RRP01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The electrode patch transfers carrier signals from the wearable respiration rate sensor and transfers impedance and biopotential signals from the patient and transmits them to the wearable respiration rate sensor.

The Portrait™ RR Electrode Patch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ RR Electrode Patch is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Sensor Battery (Portrait SBT01) intended use

The Portrait™ Sensor Battery (Portrait SBT01) is intended for use as a power supply for the Portrait™ wearable sensors and to provide wireless communication to a host device.

The Portrait™ Sensor Battery is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Sensor Battery is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Bedside Charger (Portrait BCH01) intended use

The Portrait™ Bedside Charger (Portrait BCH01) is intended for charging the Portrait™ Sensor Batteries and the Portrait™ Mobile Patient Monitor (including while the Portrait Mobile Patient Monitor is in use).

The Portrait™ Bedside Charger is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Bedside Charger is not intended for use in a controlled Magnetic Resonance (MR) environment.

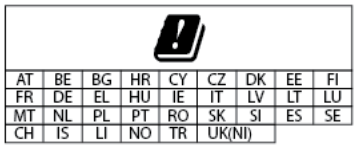
Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01) intended use

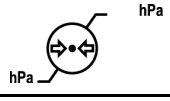
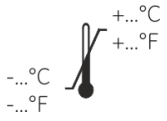
The Portrait™ Mobile Patient Monitor Pouch (Portrait MMP01) is an optional accessory intended to enable the Mobile Patient Monitor to be carried while the patient is ambulatory.

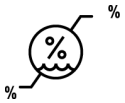
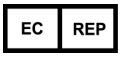
The Portrait™ Mobile Patient Monitor pouch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

Equipment markings

Also refer to the explanations regarding safety symbols.

Marking	Explanation
	Hub power button icon.
IP67	Degree of ingress protection. This equipment is protected against ingress of dust, and against ingress of water in harmful quantity in immersion up to 1 meter of submersion.
IPX2	Degree of ingress protection. IP X2: This equipment is protected against water drops falling vertically over a 15° range.
IPX1	Degree of ingress protection. IPX1: This equipment is protected against harmful effects of dripping water per IEC 60529.
IP44	NOTE: This marking does not appear on the equipment, but it applies to the P-SE01 and P-W01 SpO_2 sensors, to the combination of SpO_2 or respiration sensor and sensor battery. Degree of ingress protection. Protection assured against solid objects that are over 1 mm, and against water splashing from any angle.
	Radio Equipment Directive (2014/53/EU) marking. Only indoors usage is permitted with 5150 to 5350 MHz WLAN. This marking applies to all EU countries and countries under EU agreements.
	Alarming unit: alarm off.
Input: 12 V ⎓ 3.0 A (max)	Input rating, charger.
INPUT/输入:100-240V~50/60Hz,1.0A	Input rating, power supply unit of the charger.
OUTPUT/输出:12.0V ⎓3.0A	Output rating, power supply unit of the charger.
	Energy efficiency rating.
	Output connector polarity.
	Do not reuse.
Max 72h	Maximum use time 72 hours.
	Use by.

Marking	Explanation
	Manufacturer address, may include date of manufacture as in this example. If date is marked: the first four digits identify the year, the following two digits identify the month, and the last two digits identify the day.
	Manufacturing year (YY) and week (WW).
	Manufacturer (of the power supply unit of the charger).
	Manufacturing date. The first four digits identify the year, the following two digits identify the month, and the last two digits identify the day.
	Batch or lot number.
	Catalogue or orderable part number.
	Device serial number.
	Every device has a unique marking for identification. The UDI marking appears on the device label.
	Indicates that this product is a medical device.
	The protection is ensured by double insulation and does not require a safety connection to electrical earth (ground).
	Indoor use only.
	Model.
Portrait 	Wearable Respiration Rate Sensor for measuring respiration rate.
Portrait 	Wearable Pulse Oximetry Sensor for measuring pulse oximetry and pulse rate.
	Respiration (patch).
	Pull open here, do not cut.
	Atmospheric pressure limitations.
	Temperature limitations.

Marking	Explanation
	Humidity limitations.
	Keep dry.
	Fragile. Handle with care.
	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.
	Do not use if the package is broken.
	Recycled materials or may be recycled.
	European authorized representative.
	European Union Conformity Mark.
	Conformity mark. Indicates that the product is certified for both the U.S. and Canadian markets, to the applicable U.S. and Canadian standards.
Rx Only U.S.	**CAUTION** U.S. Federal law restricts this device to sale by or on the order of a physician.
	Underwriters Laboratories product certification mark.
	USA and Canada: UL recognized component mark.
	TÜV certification mark.
	TÜV certification with the GS or “Geprüfte Sicherheit” (tested safety) mark.

Marking	Explanation
	China only. The number in the symbol indicates the EFUP period in years, as explained below. This symbol indicates the product contains hazardous materials in excess of the limits established by the Chinese standard GB/T 26572. Requirements for Concentration Limits for Certain Hazardous Substances in Electronic Information Products. The number in the symbol is the Environment-friendly Use Period (EFUP), which indicates the period during which the hazardous substances or elements contained in electronic information products will not leak or mutate under normal operating conditions so that the use of such electronic information products will not result in any severe environmental pollution, any bodily injury or damage to any assets. The unit of the period is "Year". In order to maintain the declared EFUP, the product shall be operated normally according to the instructions and environmental conditions as defined in the product manual, and periodic maintenance schedules specified in Product Maintenance Procedures shall be followed strictly. Consumables or certain parts may have their own label with an EFUP value less than the product. Periodic replacement of those consumables or parts to maintain the declared EFUP shall be done in accordance with the Product Maintenance Procedures. This product must not be disposed of as unsorted municipal waste, and must be collected separately and handled properly after decommissioning.
	China only. Chinese Compulsory Certification as required by AQSIQ.
FCC ID:	USA only: Radio type approval label.
IC	Canada only. Industry Canada certification number indicates that this product meets the applicable Industry Canada technical specifications.
	Australia and New Zealand only. RCM compliance. Indicates compliance with electrical safety, EMC, electromagnetic energy, and telecommunications requirements applicable to each product.
R-NZ	New Zealand only. Radio Type Approval Label for New Zealand.
	South Africa only. Approved under ICASA (Independent Communications Authority of South Africa) requirements.
TRA Registered No	United Arab Emirates only. United Arab Emirates Telecommunications Authority (TRA) conformity mark indicating the product registration number.
Dealer No	United Arab Emirates only. United Arab Emirates dealer number.
Assembled in Austria	Country of origin Austria.
Assembled in China	Country of origin China.
Assembled in Finland	Country of origin Finland.

Marking	Explanation
Assembled in Mexico	Country of origin Mexico.
Assembled in USA Made in USA	Country of origin USA.

Unique Device Identifier (UDI)

 (01)00000000000000 (21)XXX0000000000 (11)000000 or  	Unique Device Identifier. (UDI) Every medical device has a unique marking for identification. The UDI marking appears on the device labeling. Note that these are only examples of UDI markings. The device may have a linear barcode, a DataMatrix code, or only alphanumeric identifiers with no barcode. Also, the identifiers vary per product.

The characters used in the UDI marking represent specific identifiers.

In the barcode example above:

- Device identifier:
  - (01) = GS1 global trade item number (GTIN) of the device.
  - 0000000000000 = Global trade item number.
- Production identifiers:
  - (21)= GS1 application identifier for the serial number of the device.
  - XXX0000000000 = Serial number.
  - (11) = GS1 application identifier for the manufacturing date of the device.
  - 000000 = 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.

CE marking application year

CE marking application year: 2021

5

System description

Short description of the system

The Portrait™ Mobile Monitoring Solution consists of the Core Services hosted on the EHL Platform, Hub, Wearable SpO_2 Parameter, Wearable RR Parameter, Central Viewer software hosted on an off-the-shelf computer, alarming unit, and charger. The system can be used for monitoring adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) within a hospital or healthcare facility. The system acquires, stores, calculates, displays and exports patient physiological parameter data, alarms, and information. It supports pulse oximetry (SpO_2/pulse rate) and respiration rate parameters. Measurement values are displayed as graphic or numeric values, like waveforms and numbers, and when applicable, also as alarm messages.

The Core Services enable the communication and interaction of system components and will integrate into existing healthcare facility infrastructure and clinical information systems. The Core Services provide system configuration, administration, data storage, and transmission of patient physiological trends and events.

The Hub enables non-invasive continuous monitoring of patients by acquiring signals from Wearable SpO_2 and RR Parameters through a Medical Body Area Network connection (MBAN). The device allows for access to real-time monitoring data of the patient, in addition to recent physiologic parameter trends and events with local alarming capability.

Wearable SpO_2 and RR Parameters acquire parameter data from the patient and transmit it to the Hub through the Medical Body Area Network connection.

The Central Viewer software provides the ability to view patient real-time and historical data including configurable visual and audible alarm notifications.

The alarming unit provides standards-compliant audible alarm annunciation for the Central Viewer subsystem as well as for a power failure alarm for the Central Viewer computer.

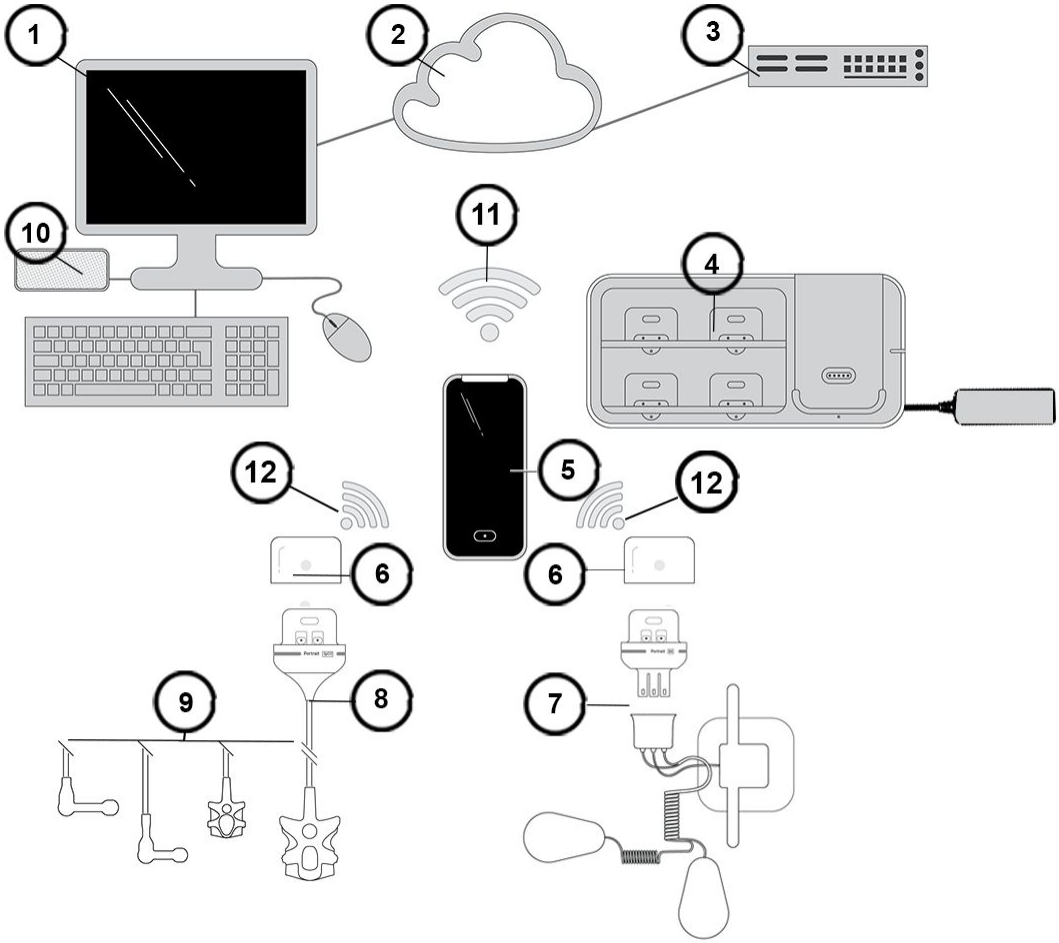
For all physical and performance specifications, refer to the technical specifications provided.

Clinical benefits

The clinical benefit of the Portrait™ Mobile Monitoring Solution is to provide real-time data of monitored parameters, alarms, trends, and events to support decision making of licensed healthcare practitioners for clinical assessment and context of patient status.

System components

All components listed below can be used within the patient environment, except for the non-medical grade devices: the Central Viewer computer, alarming unit, and the EHL Platform.



1. Central Viewer CVA01 software with off-the-shelf computer, keyboard and mouse
2. Monitoring network
3. Core Services CSS01 software hosted on the EHL Platform
4. Charger BCH01 with power supply unit
5. Hub HUB01
6. Sensor batteries SBT01
7. Respiration sensor P-RR01 and respiration patch RRP01
8. SpO_2 sensor P-SA01
9. SpO_2 sensors P-SP01, P-SE01, P-W01
10. Alarming unit CAU01
11. Wireless local area network, WLAN
12. Medical body area network, MBAN

Core Services overview

The Core Services provide centralized software services that enable the communication and interaction of the Hub and Central Viewer in a secure manner within a healthcare facility. The Core Services provide clinical, operational, configuration, and serviceability functionality to support the system. These services include physiological data storage and licensing.

Hospital enterprise network

The hospital enterprise network is the network infrastructure to which the Core Services are connected. The Core Services use the hospital enterprise network for making the centralized software services available to the Hub, Central Viewer, and other devices and systems, which interact with the monitoring system.

Central Viewer and alarming unit overview

The Central Viewer subsystem consists of the Central Viewer software, the alarming unit, and a computer running the Central Viewer software.

The Central Viewer is a standalone software application meant for monitoring and indicating alarms for up to 24 patients at a time. The Central Viewer software is the primary clinical interface, showing waveforms, real-time numerics, recent trends, alarms, and historical events. It is intended to run on a customer-provided computer. The Central Viewer software also allows the clinician to admit and discharge patients, edit patient demographic information, acknowledge alarms, and edit the alarm limit settings for any patient being viewed.

The alarming unit provides standards-compliant audible alarm annunciation for the Central Viewer subsystem as well as for a power failure alarm for the Central Viewer computer, and it is a mandatory component of the system. The alarming unit is a standalone, microprocessor controlled audible alarming device. In addition to annunciating alarm conditions, the alarming unit can also detect if it loses communication with the Central Viewer (due to cable disconnection, power loss, or Central Viewer lock up condition) and plays an audio alarm to inform users that the Central Viewer subsystem is not operational.

Introduction to the Central Viewer

NOTE Always make sure that the computer running the Central Viewer application is positioned so that you can view its screen to avoid missing any alarms. Also check that the computer's display brightness is suitable for the care environment and adjust as necessary.

The Central Viewer application should automatically start upon system power up.

If you need to manually start the Central Viewer application, power on the Central Viewer hardware and double-click the Viewer application icon.

Connect the Central Viewer computer to hospital-grade power sockets only.

For all service and maintenance instructions and hardware-related issues, refer to the service manual and the hardware manufacturer's documentation

Introduction to the alarming unit

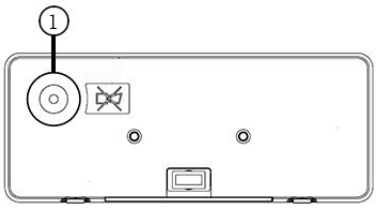
The alarming unit is connected to the Central Viewer computer with a USB cable. This cable is integrated in the alarming unit and cannot be removed.

WARNING PERSONAL INJURY. Route the cable of the alarming unit in such a way that it will not present a stumbling hazard.

There is one LED indicator on the front of the alarming unit:

The LED indicates the following:

- Flashing green: the device is powered up and waiting to authenticate the application (for example when the computer is on, but the application is not up and running).
- Solid green: the device has been authenticated and is communicating with the Central Viewer.
- Flashing yellow: the device has not been authenticated and is not communicating with the Central Viewer. This can happen, for instance, when the Central Viewer application is turned off erroneously or the computer has lost power. The yellow LED also flashes if there is a fault in the alarming unit itself. In all of these cases the audible power failure alert is active. If necessary, you can silence the audible power failure alert by pressing the button (1) on the back of the alarming unit. This will disable the power failure alarm until the computer power is restored.



1. Audio on/off button

For all service and maintenance instructions and hardware-related issues, refer to the service manual.

Hub and sensors overview

The Hub collects and displays real-time monitoring data from the wireless sensors that are specifically designed for ambulatory patients. The Hub can visually and audibly annunciate alarms, and the alarming behavior can be modified by selecting the appropriate monitoring mode (***REMOTE*** or ***LOCAL***). The Hub also shows the signal quality indicators, real-time monitoring numerics and waveforms for pulse oximetry, pulse rate, and respiration measurements. You can navigate between various views of this data. In addition, the Hub shows alarm limits, the battery status of both the Hub and paired sensors, the Medical Body Area Network connection status, and trends from the past four hours.

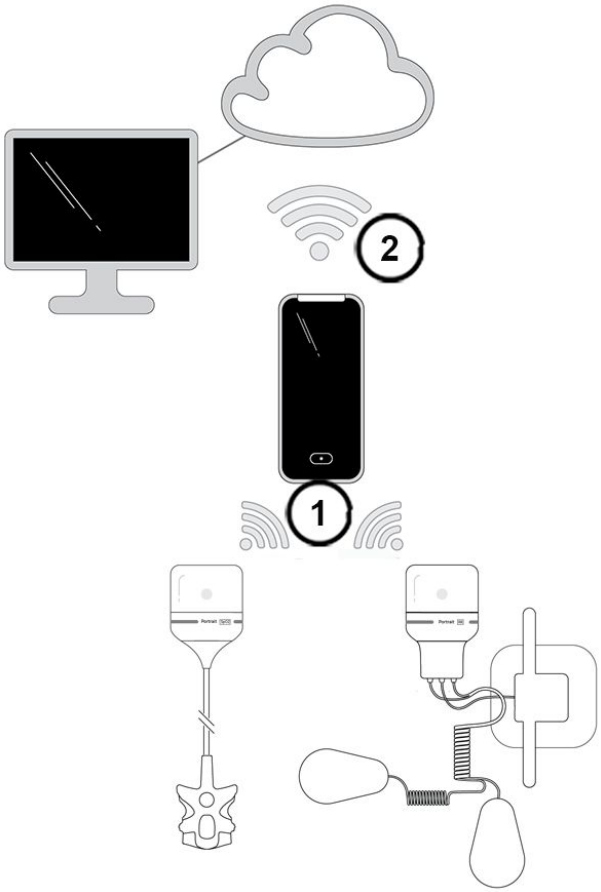
The Portrait™ Mobile Monitoring Solution uses the following wireless technologies:

- Near Field Communication, NFC: complies with ISO/IEC 18000–3
- Wireless local area network, WLAN: complies with IEEE 802.11abgn
- Radio-frequency identification, RFID: complies with GS1 EPC Class 1 Gen 2
- Medical Body Area Network, MBAN

The Hub, sensors, sensor batteries, and charger are all equipped with passive RFID tags to support RFID tagging. The RFID tags alone do not form a functioning system: an RFID reader and a host system application are also needed. These are not part of the Portrait™ Mobile Monitoring Solution itself.

Monitoring starts via Near Field Communication (NFC) technology when a sensor is paired with the Hub by simply tapping it to the rear of the Hub. Sensors communicate with the Hub using a proprietary wireless MBAN, and the Hub then sends the data to the Central Viewer using a wireless local area network (WLAN).

The following graphic illustrates the WLAN and MBAN in the system:



1. MBAN
2. WLAN

The sensors can send data simultaneously, allowing for multiparameter monitoring. Pairing or unpairing a sensor will automatically adjust the data flow from the sensor to the Hub and then to the Central Viewer when online.

The Hub has two monitoring modes, ***REMOTE*** and ***LOCAL***:

- The ***REMOTE*** monitoring mode displays alarms on the Central Viewer only. They are indicated on the Hub (visually and audibly) only if you manually activate the screen by pressing the asterisk key or the power key (shortly, <1.5 s) and entering the passcode.
- The ***LOCAL*** monitoring mode displays alarms on both the Central Viewer and Hub. In this monitoring mode the Hub screen activates automatically whenever there are alarms.

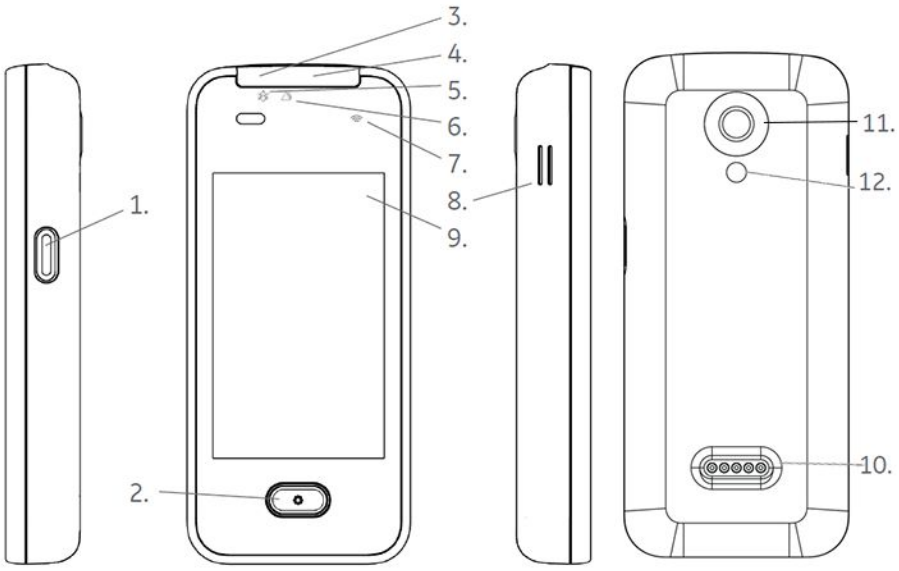
Introduction to the Hub

NOTE

Pay attention to the following when using the Hub:

- When you are with a patient, always make sure that the Hub is positioned so that you can operate it and view the screen to avoid missing any alarms.
- Do not place the Hub too close to the patient's ear to avoid patient discomfort.
- Do not place the Hub in direct contact with the patient. Use the pouch accessory or place the Hub in the patient's pocket.

The following graphic lists various parts of the Hub hardware.



1. Power key
   - Short press (<1.5 s): powers on the Hub. When the Hub is powered on and the screen is locked, activates or deactivates the screen.
   - Long press (1.5 s): shuts down the Hub. A confirmation is always needed to continue with the shutting down.
2. * (asterisk) key
   - Activates the screen.
   - When the screen is active and the passcode has been accepted, enters or exits a menu.
   - Confirmation key for acknowledging alarms, removing a measurement, and unassigning the patient from the Hub.
3. Audio silence LED area
4. Active alarms LED area
5. Audio silence indicator
6. Alarm indicator
7. Wireless network connection LED indicator
8. Speaker

9. Graphical user interface screen
10. Connector for the charger
11. Camera (not in use)
12. Flash (not in use)

LED indicators on the Hub

The three LED indicators show the following:

LED	Description and functionality
	LED indicator for audio silencing (audio off). • Illuminated in cyan color when audible alarm volume is set to zero. This indicator also lights up when the Hub is powering on. • In ***REMOTE*** monitoring mode: Only lights up if the screen is active.
	LED indicator for alarms. • Illuminated with active alarms in cyan, yellow, or red color according to the alarm priority: low, medium, high. This indicator also blinks red quickly if the Hub has been powered on, but there is a hardware failure. • In ***REMOTE*** monitoring mode: Only lights up if the screen is active or if the Hub loses network connection while there are active alarms.
	LED indicator for network connection, green or amber color. • Blinking amber slowly: the Hub is searching for a WLAN or EHL Platform server connection. • Alternating between darker and lighter green: the Hub is connected to the WLAN and EHL Platform server.

NOTE The brightness of all LED indicators adjusts to the ambient light.

Hub vibration and audio indications

Hub vibration and audio indications support the graphic user interface to inform the user regarding the following:

- Vibration:
  - Hub powering on
  - Near Field Communication (NFC) reading

  Vibration length is about 0.5 seconds.
- Audio:
  - Audio functionality test when powering on the Hub.
  - Alarm indication: always in local monitoring mode, and in remote monitoring mode if the screen is active and passcode has been accepted or the Hub loses the network connection. ***Network connection lost*** situation itself does not trigger an audible alarm (only visual alarm is provided). This reduces the risk of missing any clinical alarms even in those cases where network loss would affect several devices simultaneously.

  You can adjust the audio volume for alarms.

Introduction to the sensors

There are four SpO_2 sensors with different types of probes. The respiration sensor is used with a disposable respiration patch. The sensors acquire physiological data from the patient. All sensors are wearable and wireless, communicating with the Hub via an MBAN connection. The communication is only possible after a sensor battery is connected to a sensor and the sensor has been paired with the Hub. Each sensor can only be paired with one Hub at a time.

The use of the sensors is discussed in more detail in the measurement sections.

Introduction to sensor batteries

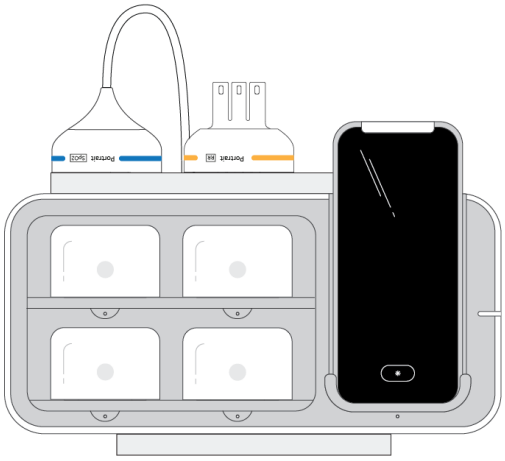
NOTE Always make sure that you have additional charged sensor batteries ready for use in case the current battery discharges completely during monitoring. Loss of power will result in loss of monitoring.

A sensor battery:

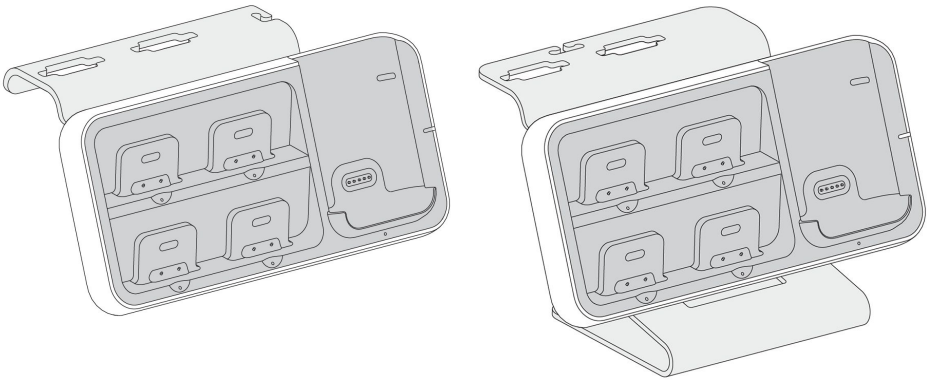
- Powers up a sensor when connected to it
- Enables pairing of a sensor to the Hub
- Enables MBAN communication to the Hub
- Gives LED status indications of the MBAN connection, sensor connection, and battery charge.

Introduction to the charger

The charger is meant for charging the sensor and Hub batteries. It has four smaller charging slots for sensor batteries and one larger charging slot for the Hub. All sensor battery charging slots can be used in any order and a sensor battery can be put in any slot. The charger can also be used for storing the sensors while they are not in use, see the following graphic.



The charger can be used with an optional wall mount (on the left) or with a table mount (on the right):



When using the charger with a table mount, always place it on a flat surface and in a place where the risk of accidentally causing it to fall or being exposed to fluid splashes is minimal.

The charger powers on automatically when it is plugged into the mains. Ensure an easy access to disconnect the charger mains plug from the mains.

Make sure that the batteries and the Hub are always securely inserted (not loose) in their slots to enable charging.

System installation points to note

- The environmental operating conditions specified in technical specifications must be ensured at all times.
- The system is designed to comply with the requirements of IEC 60601–1.

System installation is performed by qualified service personnel and installation instructions can be found in:

- Portrait™ Mobile Monitoring Solution Service Manual

6

Graphical user interface

User interface indicators

The following indicators appear in the Central Viewer, Hub, or Config UI graphical user interface.

Indicator	Explanation
	General warning sign. Displays when the ***SpO2 low - alarm priority*** setting deviates from the recommendation of international alarm safety standards.
	Alarm acknowledgement. The background color varies according to the alarm priority (cyan, yellow, red). Information signal is indicated with a gray background.
	Timed alarm acknowledgement. The background color varies according to the alarm priority (cyan, yellow, red). Information signal is indicated with a gray background.
	Infinite alarm acknowledgement. The background color varies according to the alarm priority (cyan, yellow, red). Information signal is indicated with a gray background.
	High and low alarm limit separator. The color is the same as that of the parameter.
	Signal quality indicator, SQI. The color is the same as that of the parameter. The more filled circles, the stronger the signal.
– – –	Invalid data, or no data available (e.g., sensors not attached to the patient).
	Confirm.
	Close.
	Patient data.
	Pacemaker: patient has a pacemaker.
	Pacemaker: unknown whether or not the patient has a pacemaker.

Indicator	Explanation
	Loading data.
	Processing.
	Refresh.
	Signal search indicator.
	Connection to the CSS01 Core Services is working.
	No connection to the CSS01 Core Services.
	WLAN. The number of segments corresponds to the signal strength: the more segments, the stronger the signal.
	Not connected to a wireless network.
	Control in the menus: Back/Erase
	Access to other menus or views.
	Access to other menus or views.
	Access to other menus or views.
	Access to other menus or views.
	REMOTE monitoring mode.
	LOCAL monitoring mode.
	MBAN connection; check connection between the Hub and sensor.
	Battery empty.
	Battery indicator (red). The battery charge is <5%.
	Battery indicator. The higher the charge, the bigger the bar within the indicator.
	Battery is full indicator.

Indicator	Explanation
	Battery is charging indicator.
	Pair a sensor.
	Unpair a sensor.
	Locked screen.
	Alarm volume.

Central Viewer

Multiple Patient View

The Multiple Patient View provides simultaneous views of real-time patient information for multiple patients within a care area. The view is separated into distinct areas for each patient called slots. These slots display a room and bed that is configured in the Config UI. If a patient is admitted into an individual slot, the Multiple Patient View will display the patient name and the real-time numeric data. The Multiple Patient View will also display the highest priority, most recent alarm for the patient and highlights the parameter value according to the alarm priority.

The Multiple Patient View can have 8, 16, or 24 patient slots.

- Main header area: Displays at all times. Displays the care area name, the time in 24-hour format (HH:MM), system messages related to the Central Viewer, volume control, and access to the applications menu ().
- Patient header: Displays in each patient slot. Displays the room, bed number if applicable, pacemaker information (***Yes*** with  indicator, ***No***, ***Unknown*** with  indicator) and patient name (if configured to be shown). Depending on the number of configured rows and columns, the patient slot may not have enough space to completely display the patient name. This is indicated by ellipses (...). The whole name is shortened from the end: in other words, the last name is listed first with as many characters as there is space for (max. 30), followed by the first name according to the space left (max. 30 characters).
- Alarm message area: Displays in each patient slot. Displays the highest priority, most recent unacknowledged alarm for the patient with a background color according to the alarm priority level.
- Parameters: Displays the parameters monitored for the patient. If there is an alarm for this parameter, the parameter value is highlighted according to the alarm priority.

Single Patient View

The Single Patient View provides a detailed view of an individual patient and is accessed by selecting an individual slot in the Multiple Patient View. The Single Patient View displays the following information for an individual patient:

- Real-time numeric values

- Alarm limits
- Waveforms
- Signal quality indicators for each displayed real-time numeric value
- Trends with event markers
- A list of active events

Only the parameters currently being monitored for a patient appear in the Single Patient View.

- Main header area: Displays at all times. Displays the care area name, the time in 24-hour format (HH:MM), system messages related to the Central Viewer, and volume control.
- Alarm display unit area: Displays alarms for other patients in the care area.
- Patient header: Displays the room number, bed number (if applicable), patient name, up to two patient identifiers, sex, date of birth, pacemaker information (***Yes*** with indicator, ***No***, ***Unknown*** with **?** indicator) and Hub identifier. Provides access to actions menu.
- Active alarms area: Displays the active alarms for this patient (highest priority, most recent unacknowledged alarm at the top of the list).
- Live data area: Displays the real-time data for the patient, including waveforms, limit configurations, signal quality indicator, and parameter numerics.
- Trends area: Displays the trended data for the individual patient for the previous 2, 4, 8, 12, or 24 hours

To return to the Multiple Patient View, close the Single Patient View by selecting the X indicator in the upper right corner of the screen.

Alarm display unit area

An alarm display unit area is shown at the top of the Single Patient View to provide visibility to active alarms on other patients configured to the same Central Viewer. Selecting an alarm message opens the Single Patient View for the alarming patient.

An alarm message is displayed in the alarm display unit area when there is an active, unacknowledged alarm of high or medium priority for another patient. Only one alarm message is displayed per patient; if there are multiple alarms for a patient, only the most important (highest priority, most recent unacknowledged) alarm is displayed. If there are more than one alarms of the same importance, only the most recent one of those is displayed. An alarm message remains visible until the alarm is acknowledged or the triggering condition clears.

Alarm messages are sorted from left to right by priority and then by time. For instance, two high priority alarms and two medium priority alarms would be shown as:

- First alarm from the left = the most recent high priority alarm
- Second alarm from the left = a previous high priority alarm
- Third alarm from the left = the most recent medium priority alarm
- Fourth alarm from the left = a previous medium priority alarm

A maximum of six alarm messages are displayed at once.

The alarm display unit area contains the following information:

- The priority of the alarm is indicated by the color of the alarm display unit area. High priority alarms are red, medium priority alarms are yellow.

- The patient location is indicated as room number-bed.
- The alarm message.

Actions menu

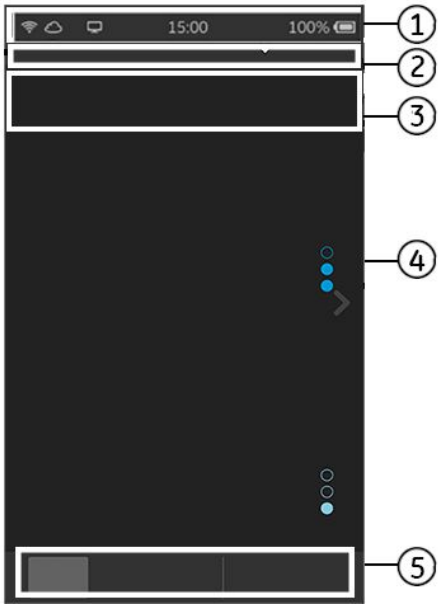
The actions menu can be accessed by hovering the mouse pointer over the menu, or by selecting the patient name in the Single Patient View. To close the menu, move the mouse pointer away from the menu or select elsewhere in the Single Patient View.

- ***Edit Patient Information***: Edits the patient demographics.
- ***Edit Alarm Settings***: Adjusts physiological limit alarm settings for the patient.
- ***Remove Hub***: Removes the patient from the assigned Hub and releases the Hub for a new patient.
- ***Discharge Patient***: Discharges the patient and releases the Hub, removing them from monitoring and allowing a new patient to be admitted in this room and bed. Historical data for this patient will no longer be available.

Hub

Hub screen elements

The following describes the elements of the Hub screen.



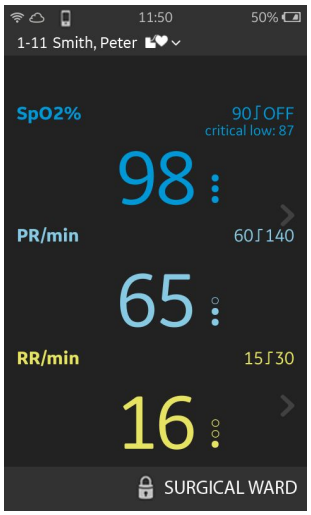
1. Main header area: WLAN indicator, Core Services connection indicator, monitoring mode indicator (local or remote), time of day in 24–hour format (HH:MM), battery charge status (of the Hub).
2. Patient information: room and bed, patient last name, first name, indicators of a truncated name (...) and pacemaker as applicable. You can open the ***Patient details*** menu by touching this slot. The ***Patient details*** menu also shows patient identification 1 and 2, the date of birth, and the gender of the patient, according to what has been entered on the Central Viewer. In addition the menu includes the selection ***End monitoring***.

3. Alarm area: alarm messages, indicator of the alarms list (...), acknowledgement control (timed or indefinite) with background color according to alarm priority level, and the selection ***Reactivate alarms*** at the end of the list.
4. Data area (***LIVE*** view, ***TRENDS*** view, detailed view, menu).
5. Toolbar: possibility to pair or unpair sensors and access to the ***LIVE*** and ***TRENDS*** views. In detailed view: connection check  .

Hub locked view

The Hub locked view can have different content according to the status of patient admission, sensor pairing, and monitoring mode:

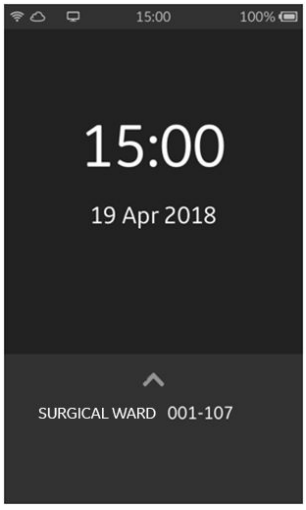
Local monitoring, assigned patient and ongoing monitoring



In this example:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- 90/OFF (90/***OFF***) = Pulse oximetry alarm limits
- critical low: 87 (***critical low: xx***, where xx is 87 in this example) = Critical low limit set for SpO_2
- SpO2% (***SpO2%***) = Pulse oximetry label and unit of measure
- PR/min (***PR/min***) = Pulse rate label and unit of measure
- RR/min (***RR/min***) = Respiration rate label and unit of measure
- Arrows on the right of the screen = access to the detailed view of each parameter; touch the arrow or swipe your finger from right to left
- SURGICAL WARD = Care area
- = locked screen indicator

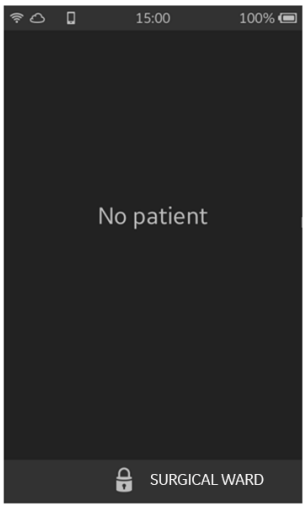
Remote monitoring, assigned patient



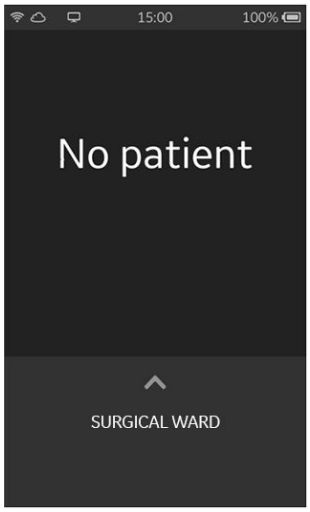
In this example:

- 15:00 = time
- 19 Apr 2018 = date
- SURGICAL WARD 001–107 = Care area, room and bed
- Arrow at the bottom of the screen = access to the passcode view for unlocking the screen; touch the arrow or swipe your finger upwards on screen

Local or remote monitoring, no assigned patient



LOCAL mode

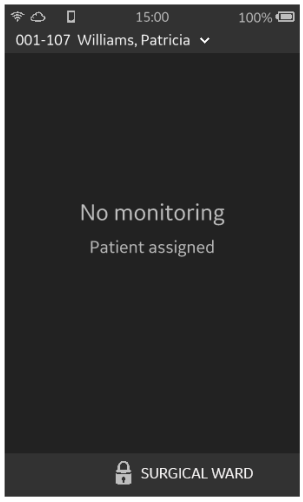


REMOTE mode

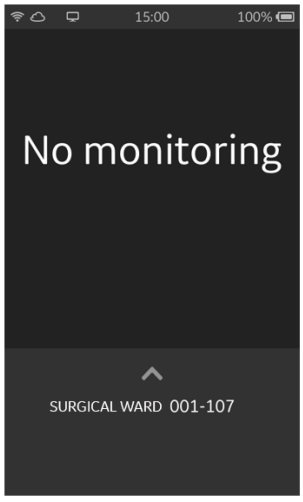
In these examples:

- No Patient (***No patient***) = there is no assigned patient
- SURGICAL WARD = Care area
- Arrow at the bottom of the screen = access to the passcode view for unlocking the screen; touch the arrow or swipe your finger upwards on screen
- = locked screen indicator

Local or remote monitoring, assigned patient and no monitoring



LOCAL mode



REMOTE mode

In these examples:

- SURGICAL WARD 001–107 = Care area, room and bed
- Williams, Patricia = patient's last name, first name
- No monitoring (***No monitoring***) = there is no ongoing monitoring

- Patient assigned (***Patient assigned***) = there is an assigned patient
- Arrow at the bottom of the screen = access to the passcode view for unlocking the screen; touch the arrow or swipe your finger upwards on screen
- = locked screen indicator

Hub passcode view

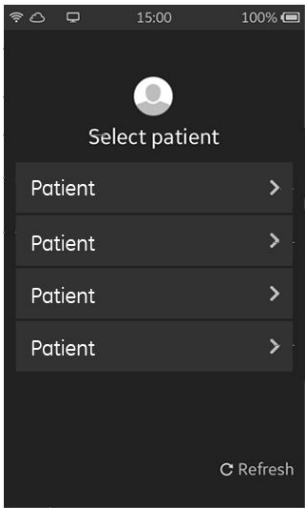
The passcode view appears when the Hub is powered up or the screen is activated.

In this example:

- Enter passcode (***Enter passcode***) = Title of the view for entering the passcode
- 1 to 0 = number keys for entering the passcode
- = Confirm key (turns gray when entering the passcode)
- = Back to previous view or delete the last digit you entered

Hub patient list

The patient list contains patients that have been admitted to the monitoring system, but have not been assigned to a Hub.

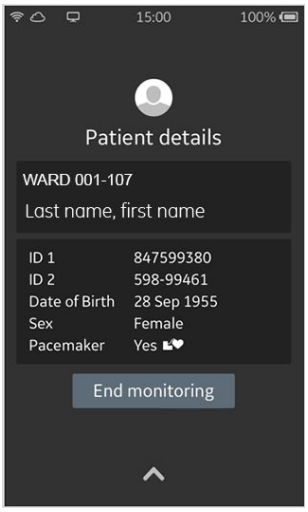


In this example:

- Select patient (***Select patient***) = Title of the view for selecting a patient
- Gray rows with text Patient = admitted patients currently not assigned to a Hub. In the actual Hub user interface the text Patient is replaced by real patient information like unit, bed, room, patient last and first names, pacemaker indication. You can select a patient by touching their row on screen
- Refresh (***Refresh***) = Selection for updating the patient list

Hub patient details

The contents of the patient details view are defined during configuration. The information is entered on the Central Viewer and you can only read it on the Hub.

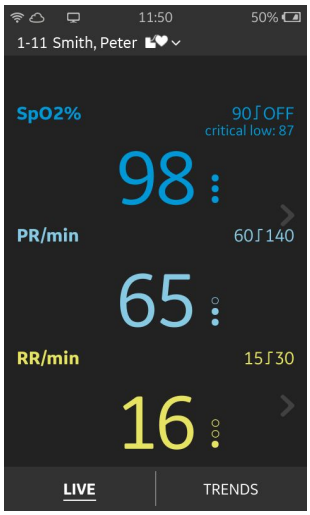


In this example:

- Patient details (***Patient details***) = Title of the view showing patient-related information
- WARD 001–107 = Unit, room, and bed as entered during patient admission
- Last name, first name = Patient's last and first names as entered on the Central Viewer
- ID 1, ID 2 = Patient identification as entered on the Central Viewer
- Date of Birth (***Date of Birth***) = Patient's date of birth as entered on the Central Viewer (format: DD-MMM-YYYY)
- Sex (***Sex***) = Patient's gender as entered on the Central Viewer
- Pacemaker (***Pacemaker***) = Indicator of the patient having a pacemaker. ***Yes*** with the indicator means that the patient pacemaker has been identified. Other options are ***No*** (no indicator) and ***Unknown*** with the indicator ?.
- End monitoring (***End monitoring***) = Selection to end the monitoring of this patient on the Hub.

Hub LIVE view

The Hub ***LIVE*** view can contain data for one or more parameters, depending on which sensors have been paired. It shows numeric values, parameter labels and units, active alarm limits, signal quality indicators, and possible alarm or information messages.



In this example:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- 90/OFF (90/***OFF***) = Pulse oximetry alarm limits
- critical low: 87 (***critical low: xx***, where xx is 87 in this example) = Critical low limit set for SpO_2
- SpO2% (***SpO2%***) = Pulse oximetry label and unit of measure
- PR/min (***PR/min***) = Pulse rate label and unit of measure
- RR/min (***RR/min***) = Respiration rate label and unit of measure
- LIVE (***LIVE***) = ***LIVE*** view (currently active)
- TRENDS (***TRENDS***) = Access to ***TRENDS*** view (historical data)
- Arrows on the right of the screen = access to the detailed view of each parameter; touch the arrow or swipe your finger from right to left

Viewing the Hub LIVE view

1. Make sure that you have completed the patient connections and paired the sensor(s) with the Hub.

2. Activate the screen. Note that you may need to enter the passcode to unlock the Hub.

   The ***LIVE*** view opens showing the numeric value(s) for the measured parameter(s). The ***LIVE*** view can contain data for one or more parameters, depending on the paired sensors.

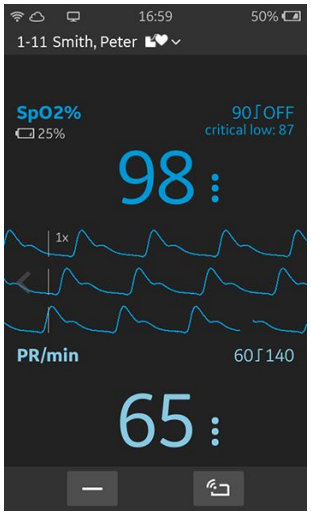
3. If you cannot see the parameter on screen, make sure that the sensor has been correctly paired.

   - If you can see the parameter data area for this measurement without any values, the measurement is not connected to the patient, or there is a problem with the patient connection. Check all connections.

   You can pair sensors by selecting the plus indicator at the bottom left of the screen: 

Hub detailed view

The Hub detailed view shows the parameter name, alarm limits, numeric measurement data, and cascaded waveforms of the measured parameter(s). Also the signal quality indicators ⋮ are visible in the detailed view. The sensor battery status is displayed under the parameter label and unit of measure indication.



In this example:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- SpO2% (***SpO2%***) = Pulse oximetry label and unit of measure
- 90/OFF (90/***OFF***) = Pulse oximetry alarm limits
- critical low: 87 (***critical low: xx***, where xx is 87 in this example) = Critical low limit set for SpO_2
- Numeric values 98 and 65 = SpO_2 and PR measurement values
- PR/min (***PR/min***) = Pulse rate label and unit of measure
- 60/140 = Pulse rate alarm limits
- ❮ in the waveform area = touch the arrow or swipe your finger from left to right to return to the ***LIVE*** view
-  = Unpair the sensor
-  = Check connection of the selected parameter

Viewing the Hub detailed view

1. Unlock the Hub screen if it is locked.

   The ***LIVE*** view opens.

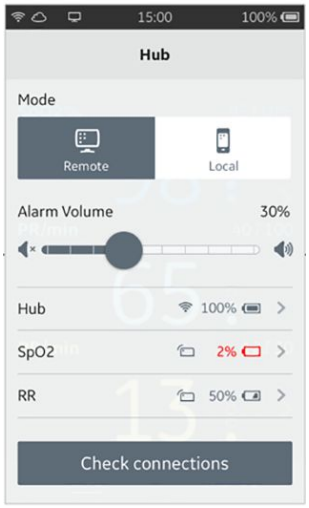
2. Touch the data area of the parameter you wish to see, or swipe your finger from right to left.

   The detailed view opens, showing the numeric values and waveforms of the selected parameter.

3. Touch the arrow on screen or swipe your finger from left to right to return to the ***LIVE*** view

Hub menu

You can check various device-related functionalities regarding the sensors, sensor batteries, or the Hub through the menu on the Hub. This menu is accessible from any view by pressing  on the Hub.



In this example:

- Hub (***Hub***) = This text is replaced by the device name if a name has been given during configuration.
- Mode (***Mode***) = Title for the monitoring mode selection area. It is available when there is an assigned patient.
- REMOTE (***REMOTE***) = Selection for ***REMOTE*** monitoring mode.
- LOCAL (***LOCAL***) = Selection for ***LOCAL*** monitoring mode.
- Alarm volume (***Alarm Volume***) = Adjustment bar for ***Alarm Volume***. This setting applies to the Hub alarm volume only. It is available when there is an assigned patient.
- Hub (***Hub***) = Access to the ***Hub*** device submenu (touch the area or tap the arrow >).
- SpO2 (***SpO2***) = Access to the ***SpO2*** device submenu (touch the area or tap the arrow >).
- RR (***RR***) = Access to the ***RR*** device submenu (touch the area or tap the arrow >).
- Check connections (***Check connections***) = ***Check connections*** key.

Checking Hub-related information

1. Press  .
2. Select ***Hub***.
3. Select any of the following to see the related details:
   a. ***Battery***
   b. ***WLAN***
   c. ***Information***
   d. ***Regulatory Markings***
   e. ***Manufacturer***
4. You can return to previous menu by selecting < on top of the screen in each menu. Once in the main menu, you can close the menu by swiping down on screen or by pressing  .

Checking sensor-related information

1. Press  .

2. Select ***SpO2*** or ***RR***.
3. Select any of the following to see the related details:
   a. ***Battery***
   b. ***Sensor Status***
   c. ***Device Information***
4. You can return to the main menu by selecting < on top of the screen in each menu. Once in the main menu, you can close the menu by swiping down on screen or by pressing  .

7 Managing patients and monitoring

Admitting a patient

To start monitoring, you must first admit the patient to the Central Viewer. Admitting assigns a patient to a patient slot.

1. Select an available patient slot in the Multiple Patient View. Available patient slots display ***Admit Patient***.

   The ***Admit Patient*** window appears. The room and bed number of the selected patient slot appear in the header. To change the room and bed, close the window and select the slot assigned to the desired room and bed.

2. Complete the ***Admit Patient*** information.

   - ***First name***: Maximum length 30 characters.
   - ***Last name***: Maximum length 30 characters.
   - ***Patient ID 1***: A site-specific patient identifier. Consult your site policy regarding the use of this field. The name of the ***Patient ID 1*** field can be changed during the system configuration.
   - ***Patient ID 2***: A site-specific patient identifier. Consult your site policy regarding the use of this field. The name of the ***Patient ID 2*** field can be changed during the system configuration.
   - ***Date of birth***: The date of birth of the patient. Enter the day and the year, and select the month from the drop-down list. A default alarm profile is automatically selected based on the date of birth entered.
   - ***Sex***: The gender of the patient.
   - ***Profile***: The alarm profile to use for this patient. If needed, you can change or select a profile here. If the calculated age of the patient is less than three years old, a warning message is displayed and a profile is not chosen automatically because the monitoring system is not intended for patients younger than three years old and weighing less than 10 kg. Once the ***Admit Patient*** information is submitted, the alarm profile cannot be changed.

     WARNING INCORRECT ALARM PROFILE. Make sure that you enter the correct date of birth for the patient to ensure a correct alarm profile. A wrong alarm profile may result in false or missing alarms.

   - ***Pacemaker***: The pacemaker indication for the patient. If ***Yes*** is selected, a pacemaker indicator  will display with the patient data.

WARNING PATIENT SAFETY. Implantable Minute Ventilation Rate Responsive Pacemakers may react with the respiration sensor and cause the pacemaker to execute pacing with the maximum programmed rate. Before pairing the sensor and Hub, always check that the patient does not have this type of pacemaker. Failing to do so may compromise patient safety.

3. Select ***Admit*** to save the patient demographics, or select ***Cancel*** to cancel patient admission and return to the previous screen (the window closes and no changes are saved).

   If patient demographics are successfully saved, the Single Patient View for the patient is displayed with the entered demographic information. If required fields were omitted, or fields contain invalid inputs, an error message appears.

Editing patient demographics

You can edit the demographics of an admitted patient.

1. Select ***Edit Patient Information*** from the Single Patient View action menu.

   The ***Edit Patient Information {0}-{1}*** (X-Y = room-bed) window appears.

2. Edit, add, or remove patient information. Fields marked with an asterisk are required.

   - ***First name***: Maximum length 30 characters.
   - ***Last name***: Maximum length 30 characters.
   - ***Patient ID 1***: A site-specific patient identifier. Consult your site policy regarding the use of this field. The name of the ***Patient ID 1*** field can be changed during the system configuration.
   - ***Patient ID 2***: A site-specific patient identifier. Consult your site policy regarding the use of this field. The name of the ***Patient ID 2*** field can be changed during the system configuration.
   - ***Date of birth***: The date of birth of the patient. Enter the day and the year, and select the month from the drop-down list. The alarm profile is not changed if the date of birth is edited. If alarm settings need to be adjusted after changing the date of birth, use ***Edit Alarm Settings***.
   - ***Sex***: The gender of the patient.
   - ***Pacemaker***: The pacemaker indication for the patient. If ***Yes*** is selected, a pacemaker indicator will display with the patient data.

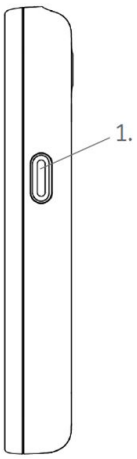
     WARNING PATIENT SAFETY. Implantable Minute Ventilation Rate Responsive Pacemakers may react with the respiration sensor and cause the pacemaker to execute pacing with the maximum programmed rate. Before pairing the sensor and Hub, always check that the patient does not have this type of pacemaker. Failing to do so may compromise patient safety.

3. Select ***Save*** to save the edited patient demographics, or select ***Cancel*** to cancel editing and return to the previous screen (the window closes and no changes are saved).

   If patient demographics are successfully saved, the Single Patient View for the patient is displayed with the edited demographic information. All other aspects of the patient, such as assignment to a Hub, remain unchanged. If required fields were omitted, or fields contain invalid inputs, an error message appears.

Powering on the Hub

The Hub is powered on with the power key (1.) located on the side of the Hub:



1. Press the power key (short press <1.5 s).

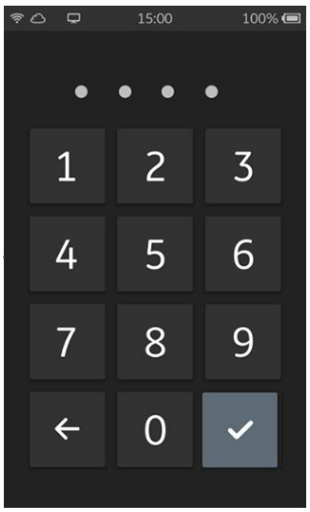
   You can feel a short vibration of the Hub when it is powered on. If the Hub is not powered on when you press the key, place it into the charger.

Unlocking the Hub screen

If the Hub screen is locked, you need to enter the passcode to unlock it. The passcode is configured in the Config UI and it is the same for all Hubs in the same care area. For more information on the configuration, refer to the service manual.

1. Enter your passcode with the on-screen keypad.

   As you select the numbers, each selected number is displayed as a small ellipse above the keypad. The confirm key ✔ is also activated (it turns gray):



2. Once you have given all the digits of your passcode, select the confirm key.

   If the code is correct, the screen unlocks. If the code is not correct, the ellipses are replaced with the text ***Enter passcode***. Enter the correct passcode to unlock the screen. If you do not remember the correct passcode, contact your system administrator.

Selecting a patient

The Hub acts as a monitoring device for one patient at a time. Once you have powered on the Hub and entered the passcode, the ***Select patient*** list opens. The list contains patients that have been admitted to the monitoring system, but have not been assigned to a Hub. In case there are no admitted patients in the system, the ***No patients*** view opens instead. In this case, admit the patient to the Central Viewer first.

If you see this indicator instead of a list of patients, the list is being refreshed and will soon appear.

Once the list of patients appears:

1. Select your patient by touching the patient name, or by swiping to the left.

   Once you have selected the patient, the ***Confirm patient*** menu opens.

   If you selected the wrong patient, you can return to the patient list by selecting ***Cancel***.

2. Select ***Confirm***.

   The patient is now selected to the Hub and an animation about pairing devices starts.

You may encounter the following problems when trying to select a patient:

- Patient does not appear on the patient list: try refreshing the list by selecting ***Refresh*** or by swiping down. If that does not help, check that the patient has been admitted to the Central Viewer, then retry.

- ***Patient is not available*** appears: another Hub has already been assigned to this patient, or the patient has been discharged remotely. Check the patient and Hub assignments and patient admission status on the Central Viewer.
- ***No wireless network*** appears: there is no wireless network connection. Make sure that the Hub is within the network coverage range. If that does not help, contact service personnel.
- ***No connection to patient monitoring services*** appears: the Hub is not connected to the Core Services. Make sure that the Hub is within the network coverage range. If that does not help, contact service personnel.
- ***No license available*** appears: there are no available monitoring licenses. Unassign one Hub or wait until a license becomes available again.

Attaching measurement devices to the patient

1. Attach the Wearable SpO_2 Parameter and/or the Wearable RR Parameter to the patient:

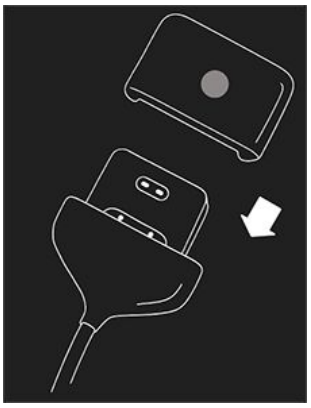
For more detailed information on each measurement, refer to the parameter-specific instructions.

Pairing the first sensor

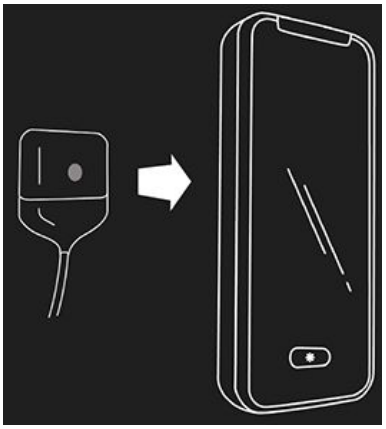
You need to create a wireless connection between the Hub and sensor to start monitoring a patient. This is done by pairing them.

To pair the sensor, follow the animation on the Hub screen.

1. Connect the sensor battery to the sensor:



2. Create the wireless connection by tapping the sensor to the rear of the Hub:



You will feel a short vibration of the Hub during the pairing to indicate that the pairing was successful. If you did not feel the vibration, check that you are holding the sensor as in the graphic. Then check that the Hub battery is charged (this icon is displayed:) and that the sensor has not been paired to another Hub (LED indicator on the sensor battery is blinking amber slowly).

If you have not connected the sensor battery to the sensor prior to trying to pair the sensor, you will see a prompt and graphic on the screen instructing you to complete it.

The measurement appears on the Hub screen and you can now pair another sensor for a different parameter by tapping it to the rear of the Hub. If the measurement does not appear, check that the Hub battery is fully charged and that the sensor is not paired to another Hub. Wait for about 30 seconds and try to pair again.

Pairing another sensor

If you are starting to measure a new parameter when the Hub already has an ongoing measurement, you can do it by pairing another sensor.

1. Activate the screen. Note that you may need to enter the passcode to unlock the Hub.

   The ***LIVE*** view opens.

2. Select the plus (+) indicator at the bottom left of the screen: +

   The text ***Pair another sensor*** and a related graphic appear on screen.

3. Pair the sensor by tapping it to the rear of the Hub. The sensor must have a battery connected.

   The new measurement appears on the Hub screen.

Unpairing a sensor

1. Touch the data area of the parameter, or swipe your finger from right to left.

   The detailed view appears.

2. Select the minus indicator at the bottom left of the screen: −

   A message appears asking if you wish to stop measuring this parameter.

3. Press  to remove the measurement from the screen, or select X on the upper right corner of the message to continue the measurement.
4. Disconnect the measurement from the patient.
5. Clean the devices as instructed.
6. Insert the sensor battery to the charger if it is not needed.

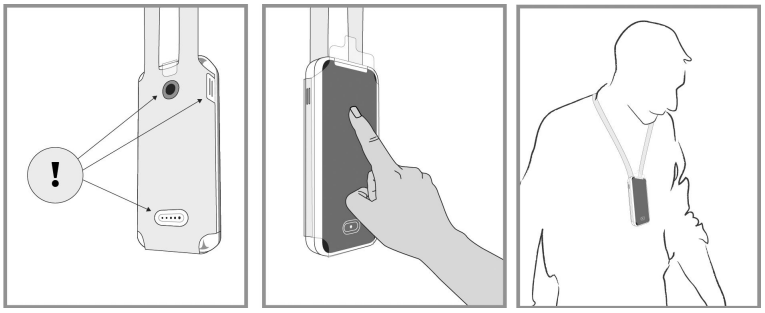
Moving a patient to a new bed

When moving a patient to a new bed, follow these instructions. If needed, you can find more detailed instructions in other sections describing patient management.

1. Discharge the patient on the Central Viewer.
2. Admit the patient on the Central Viewer using the slot assigned to the desired room and bed.
3. Select the patient from the ***Select patient*** list on the Hub.
4. Pair the sensor(s).
5. Check that the alarm settings are suitable for the patient.

Using the Hub pouch

The optional Hub pouch can be used to allow patients more mobility while keeping the Hub safe at the same time. You can use and charge the Hub without taking it out of the pouch (see graphic below).



1. Insert the Hub into the pouch. Check that the Hub parts indicated with the exclamation mark are aligned with the pouch as in the graphic.

   It is especially important that the speaker is not covered by the pouch to avoid missing any audible alarms.

2. Instruct the patient that they can wear the Hub pouch when moving around with the Hub. The Hub pouch can be worn in different ways: neck, shoulder, back etc.

   If the pouch or Hub get wet, dry them to ensure correct functioning of the speaker and touchscreen. Always replace a dirty or broken Hub pouch.

Unassigning the patient from the Hub

Unassigning a patient from a Hub ends the monitoring, deletes the patient data from this Hub, and clears the sensor(s) and Hub pairing. It also allows the Hub to be used for another patient. You can do this at either the Hub or the Central Viewer.

1. Unassign the patient using the Hub:
   a. Activate the screen and enter the passcode.
   b. Tap the patient name to access the patient detailed view.
   c. Select ***End monitoring***.

      A message appears asking you to confirm that you wish to end monitoring.

   d. Press  to unassign the patient from the Hub, or select the X on the upper right corner of the message to return to the previous view without clearing the Hub and patient assignment.

   The assignment between the patient and the Hub is cleared. The message ***Patient data removed*** appears. The patient stays admitted to the monitoring system until discharged from the Central Viewer.

2. Unassign the patient from the Hub using the Central Viewer:
   a. Select a patient slot in the Multiple Patient View.
   b. From the Single Patient View action menu, select ***Remove Hub***.

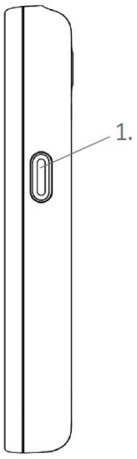
      The ***Remove Hub?*** menu appears.

   c. Select ***Yes, Remove*** to unassign the patient from the Hub, or select ***Cancel*** to return to the previous screen without clearing the Hub and patient assignment.

After selecting ***Yes, Remove***, the assignment between the patient and the Hub is cleared and the devices can be used for a different patient after cleaning and disinfection. The patient stays admitted to the monitoring system until discharged from the Central Viewer.

Shutting down the Hub

Make sure that the Hub is not needed for monitoring a patient before shutting it down. The Hub is shut down with the power key (1.) located on the side of the Hub:



1. Press the key for 1.5 seconds.
   - If the screen was active with a measurement and passcode accepted, a text appears asking you if you want to end patient monitoring, remove patient data from the Hub, and shut down. Confirm shut down.
   - If the screen was off, the locked screen appears. To proceed with the shut down procedure, enter the passcode and when the screen is active, press the key again and then confirm the shut down.

The text ***Shutting down...*** appears. The screen goes blank once the Hub is shut down.

If you want the Hub to be off while in the charger, place it into the charger while the shut down is still ongoing. Otherwise the Hub will turn on as you place it into the charger.

Discharging a patient

Discharging a patient on the Central Viewer removes the patient from continuous monitoring and deletes patient information and measurement data. After discharging the patient that patient slot is free for a new monitoring session.

1. Select ***Discharge Patient*** from the Single Patient View action menu.

   The ***Discharge Patient?*** form appears.

2. Select ***Yes, Discharge*** to discharge the patient, or select ***Cancel*** to return to the previous screen without discharging the patient.

After selecting ***Yes, Discharge*** all patient monitoring data is immediately removed. Any paired sensors are also removed. The Multiple Patient View appears, with the patient slot available for new patient admission.

8

Battery management

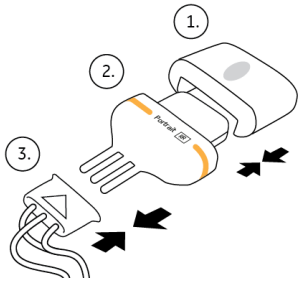
Safety precautions

Familiarize yourself with the safety chapter of this manual for all safety precautions related to the system. Some warnings or cautions may also be listed with detailed instructions in this chapter.

Connecting and disconnecting sensor batteries

1. To connect a battery, push it into the sensor:

Respiration sensor:

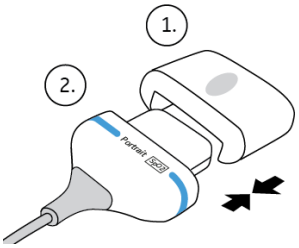


1 = sensor battery

2 = sensor

3 = respiration patch connector

SpO_2 sensor:



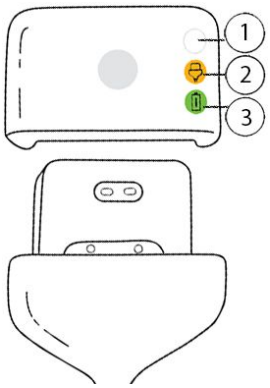
1 = sensor battery

2 = sensor

2. To disconnect a battery, pull it off the sensor.
3. Place the battery into the appropriate slot in the charger if not in use.

LED indicators on sensor batteries

There are three LED indicators on each sensor battery:



1. MBAN connection
2. Sensor connection
3. Battery charge

The following table describes their functionality.

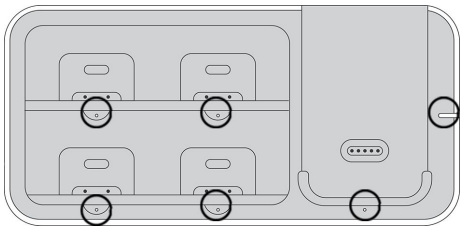
LED	Description and functionality
	MBAN connection indicator. • Blinking amber slowly: the sensor battery is connected to the sensor, but sensor has not been paired with the Hub. • Blinking amber quickly: MBAN connection to the Hub is lost. • Three slow blinks in green: the sensor battery is connected to the sensor and the sensor has been paired with the Hub. • Blinking slowly in green, combined with an intensity change sequence of all three LED indicators (brighter/dimmer): connection check between the Hub and a sensor is ongoing. • Blinking sequence in light turquoise, combined with a blinking sequence of all three LED indicators: boot-up sequence.
	Sensor connection indicator. • Blinking amber slowly: the sensor battery is disconnected from the sensor. • Blinking amber quickly: the connected sensor is faulty. • Three slow blinks in green: the sensor battery is connected to the sensor. • Blinking slowly in green, combined with an intensity change sequence of all three LED indicators (brighter/dimmer): connection check between the Hub and a sensor is ongoing. • Blinking sequence in light turquoise, combined with a blinking sequence of all three LED indicators: boot-up sequence.
	Battery charge indicator. • Blinking amber with medium rate: the sensor battery has charge left for less than 1 hour, but for more than 5 minutes. • Blinking amber quickly: the sensor battery has charge left for less than 5 minutes. • Blinking slowly in green, combined with an intensity change sequence of all three LED indicators (brighter/dimmer): connection check is ongoing. • Blinking sequence in light turquoise, combined with a blinking sequence of all three LED indicators: boot-up sequence.

To save power, these LED indicators are off when:

- The sensor battery is in the charger
- The sensor battery is disconnected (the indicators turn off after 40 seconds of no movement)
- Monitoring is ongoing (except in error situations, see the table above)

LED indicators on the charger

The charger has six LED indicators: one LED for each charging slot, and one LED indicating power on/off of the charger itself. The following graphic shows the LED locations highlighted with circles:



The LED indicators on the battery charger indicate the following:

LED	Description
	Power LED indicator (beside the Hub slot, on the right) is illuminated with solid clear light: The charger is plugged into mains. **NOTE** In case of a power loss, this LED goes off and charging is stopped until the power is returned.
	LED indicators in the slots are blinking amber slowly: • The LED indicators of all charger slots are blinking: there is an error in the charger. • The LED indicator of a slot is blinking: There is an error in the sensor battery or Hub currently in that slot. Unplug the charger from the mains and then plug it in again, or remove the sensor battery or the Hub from the slot and then reinsert it. If the LED indicators are still blinking, contact qualified service personnel.
	The LED indicator of a slot is illuminated with solid amber: There is an internal process ongoing (such as charging) for the sensor battery or Hub in this slot.
	The LED indicator of a slot is illuminated with solid green: The sensor battery or Hub is ready to use.

About Hub and sensor batteries

The Hub indicates its own battery capacity and that of the paired sensors with battery icons and numeric values (0 to 100%). The Hub battery status is always visible in the main header area, and the sensor battery status is visible in the detailed parameter views. You can access detailed battery information by pressing  on the Hub.

The following messages are also triggered on the Hub and at the Central Viewer, together with audible alarms:

- ***Hub battery low***: this alarm is triggered when the Hub battery capacity decreases to the configured alarming limit (5%, 10%, 15% capacity left)
- ***Charge Hub***: this alarm is triggered when the Hub has 3% battery capacity left or when the battery voltage drops below its low limit, whichever occurs first. If the battery discharges completely, the Hub will shut down. Charging time for empty to fully charged is eight hours, but may be slower at elevated temperatures.
- ***SpO2 battery low***: this alarm is triggered when the sensor battery capacity decreases to the configured alarming limit (5%, 10%, 15% capacity left)
- ***Change SpO2 battery***: this alarm is triggered when the sensor battery has 3% battery capacity left or when the battery voltage drops below its low limit, whichever occurs first. If the battery discharges completely, the sensor will shut down. Charging time for empty to fully charged is five hours, but may be slower at elevated temperatures.
- ***Resp battery low***: this alarm is triggered when the sensor battery capacity decreases to the configured alarming limit (5%, 10%, 15% capacity left)
- ***Change Resp battery***: this alarm is triggered when the sensor battery has 3% battery capacity left or when the battery voltage drops below its low limit, whichever occurs first. If the battery discharges completely, the sensor will shut down. Charging time for empty to fully charged is five hours, but may be slower at elevated temperatures.

The Hub battery life is 16 hours and that of the sensor batteries is 32 hours. However, there are certain factors that can shorten this time — for example:

- Hub: screen activity, active alarms, marginal wireless connection
- SpO_2 sensor battery: patient's skin pigmentation or the size of their fingers, marginal wireless connection
- Respiration sensor battery: marginal wireless connection

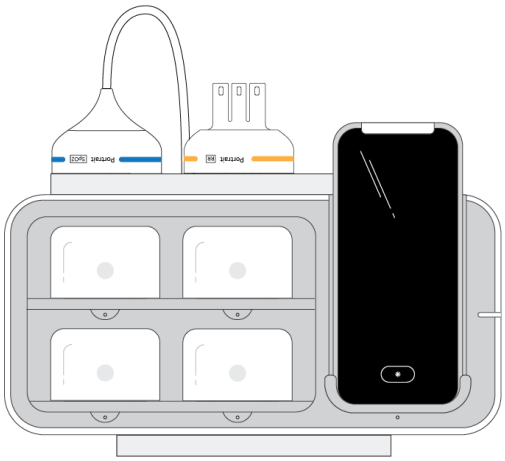
Charging batteries

If there are indications of a battery needing charging, replace it with a fully charged one (sensor batteries) or place the Hub in the charger if not there already. This ensures that patient monitoring can continue uninterrupted. Return the used sensor battery to the charger.

The Hub can be in clinical use while it is in the charger, but note that keeping the screen on will increase the power consumption and device temperature. This may slow down the charging, especially in high ambient temperatures. Also note that you can charge the Hub without taking it out of the pouch.

1. If you are charging a sensor battery: disconnect the battery from the sensor.
2. Clean all device surfaces carefully as instructed in the cleaning instructions. Pay special attention to the connection interface.

3. Place the sensor battery into any of the four battery slots in the charger, or the Hub into the dedicated slot:



Ensure that the sensor battery or the Hub is firmly in its slot.

4. When the battery is fully charged, the LED indicator of that slot is lit with solid green.
5. You can now remove the Hub from the charger. Remove the sensor battery from the charger only when you take it into use.

Charging an empty sensor battery

Charging time from empty to fully charged is five hours. Charging may be slowed down at elevated temperatures and it may be disabled at extreme temperatures (at the limits or outside of the specified operating temperature range).

When charging a sensor battery that has been left without charging for a long period of time (weeks or months), proceed as usual by placing it into one of the battery slots in the charger. The LED indicator of that slot should light with solid amber in about 10 seconds. If the LED indicator starts blinking amber instead, do the following:

1. Remove the battery from the charger.
2. Clean all battery surfaces carefully as instructed in the cleaning instructions. Pay special attention to the connection interface.
3. Place the battery back into the charger.

   The LED indicator should now light with solid amber. If the LED indicator starts blinking again, contact qualified service personnel.
4. Wait until the LED indicator of that slot is lit with solid green.
5. Remove the sensor battery from the charger only when you take it into use.

Checking the Hub battery status

The Hub battery status indicator is displayed in the upper right corner of the Hub screen. If you need to see more technical details, you can do it by entering the Hub menu.

1. Press  .
2. Select ***Hub***.
3. Select ***Battery***.

   Detailed information about the battery appears.
4. You can return to the main menu by selecting repeatedly < on top of the screen.

   You can close the menu by swiping down on screen or by pressing  .

Checking the status of a sensor battery

The sensor battery status indicators are always displayed in detailed views under the measurement labels. In ***LIVE*** view the indicators are displayed if the battery charge is getting low. If you need to see more technical details, you can do it by entering the Hub menu.

1. Press  .
2. Select ***SpO2*** or ***RR*** according to which sensor battery you need to check.
3. Select ***Battery***.

   Detailed information about the battery appears.
4. You can return to the main menu by selecting repeatedly < on top of the screen.

   You can close the menu by swiping down on screen or by pressing  .

Changing a sensor battery

NOTE Always check that you have additional charged sensor batteries ready to be taken into use in case the current battery discharges completely during monitoring. Loss of power will result in loss of monitoring.

When you see indications about the sensor battery charge getting low, change the battery.

Note that if you change the battery while monitoring is ongoing, the waveforms and values are lost.

1. Disconnect the current battery from the sensor.
2. Take a new, fully charged battery from the charger and connect it to the sensor.

3. You may wish to check the MBAN connection, but this is optional:
   a. Unlock the Hub screen if it is locked.

      The ***LIVE*** view opens.

   b. Press  on the Hub.
   c. Select ***Check connections***.

      The message ***Check response on sensors*** appears. It disappears once the check is complete. Also the battery MBAN LED indicator shows the connection status.
4. Insert the battery with low charge into the charger.

About the lithium-ion battery

The lithium-ion (Li-Ion) battery is a rechargeable battery containing lithium-ion cells. Each battery contains an integrated electronic fuel gauge and a safety protection circuit.

The following are facts about lithium-ion battery technology:

- The battery discharges on its own, even when it is not installed in the equipment. This discharge is the result of the lithium-ion cells and the bias current required for the integrated electronics.
- The capacity loss of the battery degrades significantly at higher temperatures.
- As the battery ages, the full-charge capacity of the battery degrades and is permanently lost. As a result, the amount of charge that is stored and available for use is reduced.

Battery recycling


This product[1] contains Lithium-Ion batteries. At the end of their service life, batteries in this product must be recycled or disposed 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.

- USA: You may follow the battery manufacturers instructions on the battery to recycle it. Alternatively, you may return GE product batteries to GE for recycling. For information about returning batteries to GE, contact your authorized GE Service representative or contact GE Equipment Services at 1-800-437-1171.
- Canada: Contact the approved battery stewardship program in your province for information on recycling your batteries.
- Other countries: Recycle batteries through your local, regional or national collective scheme in accordance with your local or national regulations.

[1] Hub and sensor batteries

9

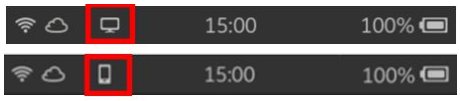
Hub and modes

About modes

You can select one of the two use modes on the Hub, ***REMOTE*** or ***LOCAL***:

- The ***REMOTE*** mode displays alarms on the Central Viewer only. They are indicated on the Hub (visually and audibly) only after you manually activate the screen by pressing the asterisk key and entering the passcode. The only exception is a case where the Hub is disconnected from the network and a new alarm is triggered: as the alarm cannot be communicated to the Central Viewer, the Hub will indicate it locally. In this mode, the Hub cannot be used as a primary alarming or viewing device.
- The ***LOCAL*** mode displays alarms on both the Central Viewer and Hub. In this mode the Hub screen activates automatically whenever there are alarms. Measurement data is available also when the Hub is locked. However, you need to unlock the Hub to acknowledge alarms.

The mode indicator (highlighted here with red) in the left corner of the main header area shows which mode is in use:

	***REMOTE***
	LOCAL

Selecting the use mode

You can select the use mode from the Hub menu. You can access the menu from any view.

1. Press  .
2. Select ***REMOTE*** or ***LOCAL***.
3. Confirm the selection.

   The corresponding use mode indicator appears in the main header area:

   -  = ***REMOTE***
   -  = ***LOCAL***
4. You can return to the previous view by swiping down on screen or by pressing  .

10

Alarms

Safety precautions

Familiarize yourself with the safety chapter of this manual for all safety precautions related to the system. Some warnings or cautions may also be listed with detailed instructions in this chapter.

Alarm conditions

There are two types of alarm conditions: physiological and technical.

Physiological alarm conditions are triggered by a patient measurement being outside the parameter limits or by apnea. Only high and medium priority alarms are available for clinical review in trends data or in the Single Patient View events. You can find more information on them in the alarm log files.

Technical alarm conditions are triggered by an electrical, mechanical, or other failure of the equipment, or by failure of a sensor or component.

Alarm priority levels

Priority level	Color	Priority definition
High	Red	Requires an immediate response
Medium	Yellow	Requires a prompt response
Low	Cyan (blue)	Requires awareness of this condition
Informational	Gray	Provides additional information and is not an actual alarm.

Active alarms

Active alarms for a patient are sorted from top to bottom, by acknowledgement and then by priority and then by time. Unacknowledged alarms are sorted to the top of the list in a priority order. Within each priority group the most recent alarms are sorted higher.

On the Hub only one alarm is visible at a time in the alarm area. To see more alarms, select •••.

Alarm signals and user position

Alarm signals are designed to alert the user visually and audibly. The signals should be detectable up to a distance of 1 meter/3.3 feet from the alarming device.

Visual alarm indicators

Visual alarm indicators have the following characteristics:

Alarm location	Priority level				
	High	Medium	Low	Informational	Characteristics
Hub alarm area, Central Viewer alarm message area (Single Patient View)	White text inside a red box.	Black text inside a yellow box.	Black text inside a cyan box.	Black text inside a gray box.	Only alarms for the displayed patient appear. The alarms are displayed until the condition is resolved.
Hub alarm area, Central Viewer alarm message area (Multiple Patient View)	White text inside a red box.	Black text inside a yellow box.	Black text inside a cyan box.	Black text inside a gray box.	The highest priority, most recent unac-knowledged alarm is dis-played until the condition is re-solved.
Central Viewer only: alarm display unit area (Single Patient View)	White text inside a red box.	Black text inside a yellow box.	No indication (normal color).	No indication (normal color).	Other patients than the one displayed in this slot: Only the highest priority, most recent alarm from each alarming patient is displayed in the alarm message area until the condition is resolved or the alarm is acknowledged.
Hub and Central Viewer: Measurement numerics	White text inside a red box.	Black text inside a yellow box.	Black text inside a cyan box.	No indication (normal color).	The measurement numeric displays in the alarming state until the condition is resolved. A measurement numeric value that is related to an alarm is highlighted accordingly.

About alarm messages

For all alarm messages, refer to the tables listed at the end of this manual. The tables list the actual alarm message texts, their location on screen, their possible causes, and suggestions for actions.

Auditory alarm indicators

Alarm signals indicate that an alarm condition is present. The alarm priority levels are also indicated.

The following table lists alarm signals for different alarm priority levels with the audible tone pattern (IEC 60601-1-8).

Priority level			
High	**Medium**	**Low**	**Informational**
Repeats a pattern of 5-beep tones played two times	Repeats pattern of 3-beep tones	1-beep tone repeatedly	None

Alarm settings on the Central Viewer

By default, limits for physiological alarms are determined by the profile selected during patient admission.

Alarm settings for an individual patient can be changed from the default. The following setting adjustments are available:

- ***SpO2 high***, ***SpO2 low***
- ***PR high***, ***PR low***
- ***RR high***, ***RR low***
- ***Apnea delay: seconds***

Alarm priorities and alarm delays are not adjustable on the Central Viewer, they can only be adjusted in the Config UI. The critical low limit for SpO_2 is indirectly adjustable on the Central Viewer: if you change the ***SpO2 low*** alarm limit, the critical low limit will also change.

Adjusting alarm limit settings

To adjust alarm settings for an individual patient:

1. Open the Single Patient View for the patient.
2. Open the ***Edit Alarm Settings*** form:
   a. Select the patient's name to show the actions menu and select ***Edit Alarm Settings***, or
   b. Select the high-low limit displayed above the numeric (only available if a patient is already assigned to a Hub and is undergoing monitoring).

3. Adjust the alarm settings by moving the sliders to the desired values, by pressing the up or down arrows with a field selected, or by entering values in the available fields.

   - The profile used to set default values is displayed at the top of the ***Edit Alarm Settings*** form. Settings modified from a default value are highlighted in blue. Select ***Reset to Default*** to set all alarm values to the default values. Note that this means reverting to the settings currently configured for the selected care profile, not the settings that the patient was admitted with.
   - The high limit for SpO_2% is disabled by moving the slider to the right of the range. The limit indicates ***OFF***.
   - The critical low limit for SpO_2% is defined by the care area configuration as a specific percentage below the defined low limit for SpO_2% . This percentage cannot be modified. As the low limit is adjusted, the critical low limit changes and is displayed in the ***Edit Alarm Settings*** form.

4. Select ***Save*** to update the alarm settings to the modified values. When you select ***Save***, modified alarm settings take effect immediately.

   Select ***Cancel*** to return to the Single Patient View without modifying alarm settings.

Adjusting alarm volume on the Central Viewer

You can adjust the alarm volume of the computer running the Central Viewer application. This setting does not affect the alarm volume of the computer or the Hub, but it does change the volume of the alarming unit. You can access the setting from any view.

1. Select 

from the upper right corner of the screen.

   The alarm volume adjustment bar appears.

2. Move the volume adjustment handle to the desired volume level:

Where: MIN (***MIN***) = configured minimum volume

   The selected volume is shown as a percentage number above the adjustment bar. You cannot select a volume below the configured minimum volume setting (shown as ***MIN*** on the control bar).

Adjusting alarm volume on the Hub

You can adjust the alarm volume from the Hub menu. This is a patient-specific setting so it is only available when there is an admitted patient selected on the Hub. It is independent from the Central Viewer. You can access the menu from any view. The minimum allowed volume can be configured for the care unit through Config UI with service access rights. By default it is 70%.

NOTE Make sure that you adjust the volume so that it is suitable for the care environment and does not cause discomfort to the patient.

NOTE When the Hub is out of network range, the alarm volume is increased to 50% if it was set below that level.

1. Press  .
2. Move the ***Alarm Volume*** adjustment handle to the desired volume level on the volume bar:

   The selected volume is shown as a percentage number on the right above the adjustment bar. If there is no volume, the percentage information is replaced by the text ***OFF*** and cyan color on the audio silence LED area above the audio silence indicator.
3. You can return to the previous view by swiping down on screen or by pressing  .

Alarm acknowledgement

Alarm acknowledgement silences the audio and alarm light notification of all active alarms for that patient. The visual alarm indication will still be present. Any additional new alarms that occur after acknowledgement are audible.

You can acknowledge physiological and technical alarms of any priority. The acknowledge alarm key is enabled if there are unacknowledged alarms. The key functionality is either infinite or timed acknowledgement according to the system configuration:

-  : this key indicates infinite acknowledgement, meaning that the alarm will stay silenced until it is manually reactivated or ends. After the alarm has ended, new alarm events for the same alarm will be unacknowledged (audible). The background color of the alarm in question is determined by the alarm priority (gray, cyan, yellow, red).
- 

  : this key indicates timed acknowledgement, meaning that the alarm sounds will be reactivated automatically after two minutes. The background color of the alarm in question is determined by the alarm priority (gray, cyan, yellow, red). Alarms can also be reactivated manually during this time.

For more information on how to configure the system, see the Configuration instructions and the Service Manual.

Acknowledging alarms

You can acknowledge active alarms on the Central Viewer or on the Hub.

1. Hub only: You can select ▪▪▪ to expand the list of all active alarms, but this step is optional.

2. Select  (infinite acknowledgement) or  (timed acknowledgement).

   The background color of the key is determined by the alarm priority.

3. Hub only: Confirm by pressing  , or select X on the upper right corner of the message if you do not wish acknowledge the alarm.

   All active alarms are now silenced and display with the acknowledgement indicator. The visual alarm indication remains displayed until the condition that triggered it is resolved.

Reactivating alarms

Reactivating an alarm restores its audio portion. You can reactivate a patient's acknowledged alarms using the Hub or the Central Viewer.

1. Select ***Reactivate alarms***.

   All active alarms for the patient are reactivated.

Checking alarm function

When the Hub starts up, it plays the startup sound and flashes the alarm LED indicator with different colors. Check that these signals are clear before taking the Hub into use. Additionally, the operation of the alarm system can be tested with the following steps.

1. 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 the measured SpO_2 values.
2. Confirm that the following alarm notification events occur:
   - The audible alarms sound the correct tone.
   - The alarm indicators illuminate.
   - The SpO_2 numeric value flashes with the correct background color.
3. Acknowledge the alarms and confirm that the alarms are paused.
4. Return the parameter alarm limit to the original value.

Alarms during power cycle

If the Hub shuts down during ongoing monitoring for any reason, and is then restarted after it has been placed to the charger, alarm configurations are not affected regardless of the length of the power interruption. The Hub will get the previous settings from the network. If the Hub is off network, it will use the last stored settings.

The Central Viewer will get the previous settings from the network after power cycle. The Core Services maintains all configuration settings in the system even through a power loss.

The alarming unit provides standards-compliant audible alarm annunciation for the Central Viewer subsystem as well as for a power failure alarm for the Central Viewer computer. The alarming unit can detect if it loses communication with the Central Viewer e.g. due to power loss, and plays an audio alarm to inform users that the Central Viewer subsystem is not operational

Alarm logs

Alarm conditions, their priorities, and start and end times are recorded in the alarm log. Also alarm configurations and their changes are logged.

The alarm log is stored in the persistence server. In the event that the Hub is disconnected from the server for any reason (even if the server is offline or powered down), it will store up to four hours of offline data for inclusion in the alarm log once reconnected.

During a planned or unplanned server shut down, logs of the system shutting down are captured, and maintained through loss of power.

The alarm log storing capacity is 1000 most recent alarms per patient for a period of seven days. In case there are more than 1000 alarms for a patient, the earliest alarms are deleted. Alarms older than seven days are automatically deleted from the logs.

Once the expired data is deleted from the log, it cannot be retrieved.

The alarm logs are available through Config UI with service access rights.

11 Parameter filtering and signal quality

Parameter filtering

When configured, the parameter filter calculates a moving average of the calculated parameter values. The averaging time can be configured with the Config UI. Using the parameter filter makes the values more accurate but may delay the visibility of changes. Also increasing the averaging time reduces fast variations in parameter values.

The averaging is weighted using the estimated reliability (SQI) and time of each value. Short periods of artifact in original values will have limited effect on the displayed value. Also, recent values will have higher weight than older values. When used together with the parameter filtering, the SQI reflects the reliability of the filtered value

If the original measurement is reliable and the value clearly violates the alarm limit, the value is updated faster to decrease the delay to alarms. Similarly, if the value is reliable and returns within the alarm limits, the value is updated faster to reduce unnecessary alarms. The fixed alarm delays are still applied.

Signal quality indicator (SQI)

The signal quality indicator (SQI) displays the estimated reliability of a parameter value. On the Central Viewer the SQI is only available in the Single Patient View. On the Hub it is available in ***LIVE*** and detailed views.

The SQI is represented by filled circles:

● ● ●	Indicates a reliable signal: accurate value.
○ ● ●	Indicates an average signal: slightly increased likelihood of inaccurate values.
○ ○ ●	Indicates a weak signal: increased likelihood of inaccurate values.
○ ○ ○	Indicates no signal: no reliable value available.

Each parameter (respiration, SpO_2 and PR) has its own SQI. Even if SpO_2 and PR are calculated based on the same pleth waveform, their measurement principles are different and therefore the reliability of the values is not the same. The following factors affect both of these measurements:

- Signal amplitude
- Motion artifacts
- Noise
- Ambient light interference

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Impedance respiration

Safety precautions

Familiarize yourself with the safety chapter of this manual for all safety precautions related to the system. Some warnings or cautions may also be listed with detailed instructions in this chapter.

Portrait™ Wearable Respiration Rate Sensor (Portrait RR P-RR01) intended use

The Portrait™ Wearable Respiration Rate Sensor (Portrait P-RR01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The Wearable Respiration Rate Sensor acquires parameter data from the patient and transmits it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Respiration Rate Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Respiration Rate Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ RR Electrode Patch (Portrait RRP01) intended use

The Portrait™ RR Electrode Patch (Portrait RRP01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of respiration rate (RR) parameter. The electrode patch transfers carrier signals from the wearable respiration rate sensor and transfers impedance and biopotential signals from the patient and transmits them to the wearable respiration rate sensor.

The Portrait™ RR Electrode Patch is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ RR Electrode Patch is not intended for use in a controlled Magnetic Resonance (MR) environment.

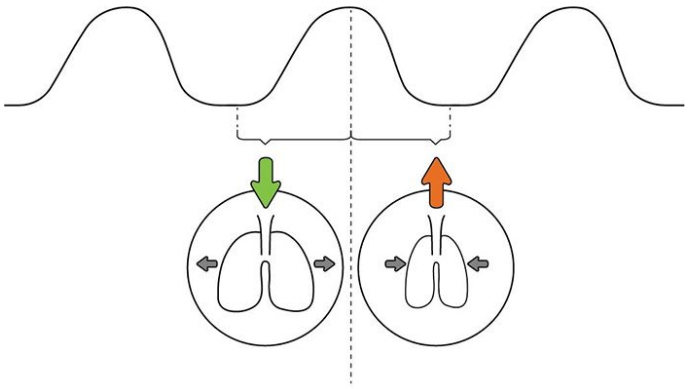
Respiration measurement limitations

- Impedance respiration is intended for patients over three years old and weighing ≥10 kg (22 lb).
- Motion artifact (such as mobile (walking) patient, shivering, and interference from the beating heart) may interfere with the respiration measurement, reduce the respiration rate accuracy, and/or disable apnea detection. Respiration measurement can only detect central type apnea. Apnea cannot be detected in the presence of any breathing effort or motion of the patient.
- The Hub must be kept in the proximity of the Wearable RR Parameter to enable reliable MBAN connection.
- Electrical devices, such as infrared heaters, that emit electromagnetic disturbance, may cause artifacts or disable the respiration measurement completely.
- In some rare cases the respiration rate and pulse rate values of the patient may be very close to each other, resulting in too low respiration rate values and false alarms.
- Irregular cardiac rhythm of the patient may cause suboptimal performance of the respiration measurement.
- You can only use one impedance respiration measurement on a patient at a time.

Respiration measurement description

Respiration measurement is based on the variation of the bio-impedance of the patient's thorax. To measure impedance, the respiration sensor sends a small electric current to the patient through the electrodes placed on the chest. Air flowing in and out, as well as changes in geometry, change the electrical properties of the chest. The impedance respiration waveform reflects those changes.

The following graphic illustrates how inhalation and exhalation are reflected in the respiration waveform:

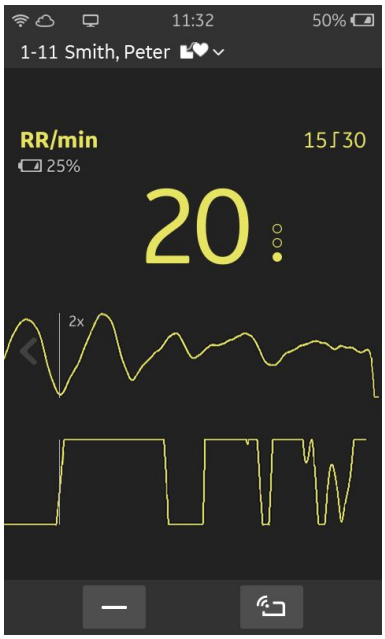


Inhale Exhale

The Hub analyzes peaks and valleys in the waveform that correspond to breaths, calculates the frequency of the breathing in breaths per minute, and forwards the value to the Central Viewer. The Hub also has a counter for the time since the last breath was detected. If that time exceeds a preconfigured time limit, the monitoring system generates an apnea alarm. Alarm limits are configurable for high and low respiratory rate and apnea time.

In addition to true breaths, patient motion can also change the impedance of the chest, and is thus visible in the impedance waveform. Motion artifact can be several times larger in amplitude than normal breathing.

The following graphic illustrates how motion artifact is reflected in the respiration waveform:



In this example:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- RR/min (***RR/min***) = respiration rate label and unit of measure

The top row below the RR value 20 shows the waveform during breathing. At the end of the top row, and during the entire second row, the waveform shows large artifacts caused by a moving patient. Patient motion reduces the RR value reliability, which is indicated by the SQI indicator having only one filled circle.

Waveform scale is indicated on the top row (in this example: 2x).

Respiration measurement practicalities

Instruct the patient regarding the following issues. Always consider your hospital guidelines as well.

- The respiration sensor should be detached before having a shower. The respiration patch can be left attached.
  - After the shower:
    - Check that the electrodes are properly attached to the skin and that there is no skin irritation. If the electrodes are no longer properly attached or the adhesive no longer holds, replace the respiration patch.
    - Make sure that the respiration patch connector is completely dry before reconnecting the sensor.

Respiration 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 Electrosurgery interference.
- Defibrillator discharge may affect the respiration measurement. Defibrillation recovery time after discharge is ≤15 seconds.
- Materials used in accessories are not toxic. Accessories do not contain natural rubber latex.
- Preferably use the measurement sites as indicated in the instructions delivered with the respiration patch to ensure reliable and accurate measurement.

- Do not use damaged sensors or respiration patches.
- Always check the patient and the measurement site if the accuracy of the respiration data is questionable.
- Respiration rate may be shown as 0 without an apnea alarm if the patient's respiration frequency and amplitude are very low. Apnea alarm appears if there are no detected breaths during user-configurable apnea alarm time.
- Check that the electrode gel is not dry.
- Check the respiration patch expiration date.
- Check that the electrodes have good skin contact.
- Check the patient skin periodically for any signs of skin irritation. Replace the electrode patch at least every 72 hours and more often if you notice any skin irritation. Always consider your hospital guidelines as well.
- Patient skin preparation and electrode placement are important for measurement accuracy.
- Intermittent mechanical ventilation: During spontaneous breathing the ventilator may at times support the patient's ventilation with an extra inspiration. If these ventilator inspirations are substantially larger than the spontaneous breaths, the respiration calculation may count only the inspirations and expirations produced by the ventilator.

Respiration measurement setup

Preparing the patient's electrode sites

Excessive body hair or skin oil reduces electrode contact with the skin and decreases the quality of the respiration signal. When preparing the electrode sites (especially the skin below the electrode gel area), avoid bones close to skin, obvious layers of fat, wounds, scar tissue, or major muscles.

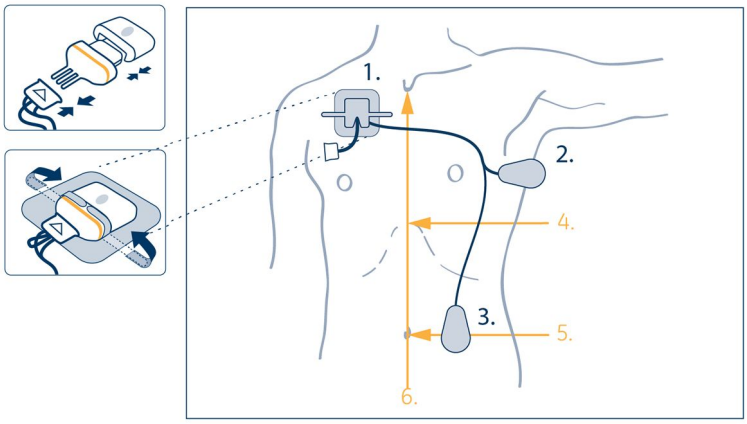
1. Clip hair from the electrode site only if necessary.
2. Clean the skin if necessary. Use dry gauzes to remove skin oil and dead or abraded skin. Always consider your hospital guidelines as well.

Starting the respiration measurement

The following steps describe the high-level sequence of starting the measurement. Steps 3 to 6 can be done in any order, the sequence given is only an example. See also the detailed instructions for sensor pairing and patient connections.

1. Admit the patient to the Central Viewer.
2. Assign the patient to the Hub.

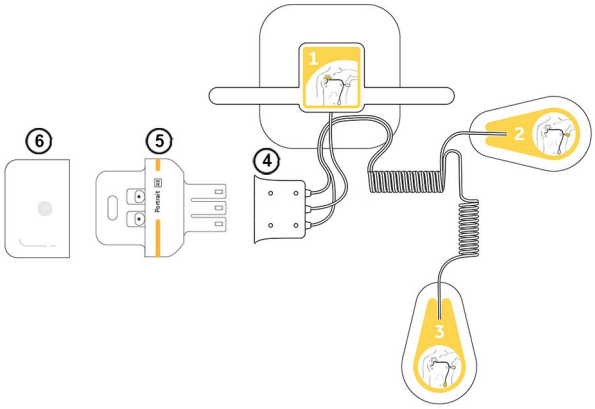
3. Attach the respiration patch to the patient as indicated in the graphic:



where:

- 1 to 3 = Electrodes 1 to 3
- 4 = Xiphoid process
- 5 = Navel
- 6 = Sternum

4. Connect the sensor connector to the respiration patch connector, and connect the battery to the sensor:



where:

- 1 to 3 = Electrodes 1 to 3
- 4 = Respiration patch connector
- 5 = Sensor
- 6 = Battery

5. Attach the respiration sensor to the respiration patch with the adhesive tape on the patch.

6. Pair the sensor and Hub.

   If the patient has a pacemaker and its status is either known or unknown, a notification similar to the following safety statement appears on the Hub:

   WARNING PATIENT SAFETY. Implantable Minute Ventilation Rate Responsive Pacemakers may react with the respiration sensor and cause the pacemaker to execute pacing with the maximum programmed rate. Before pairing the sensor and Hub, always check that the patient does not have this type of pacemaker. Failing to do so may compromise patient safety.

   You can close the notification from the X icon on the upper right corner of the display.

7. Check the measurement.

Checking the respiration measurement

Perform the following checks to ensure that the measurement is working.

1. On the Hub:
   a. Check that the wireless network connection LED on the Hub is lit and keeps alternating between dimming and brightening green.
   b. Check that the learning animation (three dots in a horizontal line) and the message ***Learning*** are displayed. When they disappear, you can see the measurement parameter (RR) on the Hub screen.
   c. Check the measurement value and the signal quality indicator to ensure measurement quality.
2. On the Central Viewer:
   a. Check that the parameter waveform and signal quality indicator are displayed in the Single Patient View and the parameter values in the Single and Multiple Patient Views.

Removing respiration electrodes

1. Support the skin at the peel line when removing the electrodes.
2. Remove the electrodes slowly.
3. Wipe the electrode gel from the skin with dry gauze.

Troubleshooting the measurement

Refer to the troubleshooting chapter in this manual for guidance regarding the most common measurement-related problems. You can find a list of error messages and alarms in the messages chapter.

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Pulse oximetry and pulse rate

Safety precautions

Familiarize yourself with the safety chapter of this manual for all safety precautions related to the system. Some warnings or cautions may also be listed with detailed instructions in this chapter.

Portrait™ Wearable Pulse Oximetry Sensor P-SA01 (Portrait SpO2 P-SA01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SA01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO_2 P-SP01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SP01) is intended for use with pediatric patients (3 years of age and older, and weighing 15 kg to 30 kg) for continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-W01, Portrait SpO2 P-SE01) intended use

The Portrait™ Wearable Pulse Oximetry Sensor (Portrait SpO2 P-SE01, Portrait SpO2 P-W01) is intended for use with adult and pediatric patients (3 years of age and older, and weighing more than 10 kg) for continuous physiologic monitoring of oxygen saturation (SpO_2) and pulse rate (PR) parameters. The Wearable Pulse Oximetry Sensor acquires parameter data from the patient and transmit it to the sensor battery for communication to a host device through the Medical Body Area Network (MBAN) connection.

The Portrait™ Wearable Pulse Oximetry Sensor is intended for use under the direct supervision of a licensed practitioner, or by personnel trained in proper use of the equipment in a professional healthcare facility.

The Portrait™ Wearable Pulse Oximetry Sensor is not intended for use in a controlled Magnetic Resonance (MR) environment.

SpO_2 and pulse rate measurement limitations

- Pulse oximetry and pulse rate measurements are intended for patients over three years old and weighing ≥10 kg (22 lb).
- Poor perfusion may affect the accuracy of the measurement.
- Movement artifact may affect the accuracy of the measurement.
- Ambient light conditions (such as surgical lights, especially xenon light sources; fluorescent lights; direct sunlight; dimmable LED lights; patient's mobile device in the same hand) may interfere with the measurement accuracy.
- To avoid erroneous measurement data, do not use a blood pressure cuff on the same arm as the SpO_2 sensor.
- The Hub must be kept in the proximity of the Wearable SpO_2 Parameter to enable reliable MBAN connection.
- The pulse oximeter may not reflect true arterial blood oxygen saturation when dyshemoglobin levels are elevated.
- You can only use one SpO_2 measurement on a patient at a time (one Wearable SpO_2 Parameter with one Hub).

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 pulse oximetry is calibrated to display functional oxygen saturation.

The actual measurement of arterial oxygen saturation is done 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.

SpO_2 measurement quality

SpO_2 and pulse rate measurement interference

The following types of interference can influence the function of SpO_2 and pulse rate measurement:

- Excessive patient activity, especially of the arm or the fingers of the hand that is used for the measurement.
- Incorrect SpO_2 sensor application, for example placement on an extremity with a blood pressure cuff, arterial catheter, or intravascular line, or a too tight application.
- Externally applied coloring agents with opaque materials, such as nail polish.
- High ambient light conditions, like conditions created from one or more of the following sources:
  - Surgical lights, especially xenon light sources
  - Fluorescent lights
  - Direct sunlight
  - Dimmable LED lights
  - Backlight of liquid crystal displays (LCD), for example in mobile devices and computer monitors
- Venous pulsation
- Dysfunctional hemoglobin
- Poor (low) peripheral perfusion
- Arterial occlusion proximal to the probe
- Loss of pulse (cardiac arrest)
- Arrhythmia
- Electromagnetic interference (EMI)
- Ventilator-induced pressure change
- SpO_2 measurement only: Intravascular dyes, such as idocyanine or methylene blue.

SpO_2 waveform quality

Under normal conditions, the SpO_2 waveform corresponds to (but is not proportional to) the arterial pressure waveform. The SpO_2 waveform can provide guidance to the user in the identification of good peripheral perfusion.

The information in the following table is adapted from Jubran A (1998) Pulse oximetry. In: Tobin MJ (ed) Principles and practice of intensive care monitoring. McGraw-Hill, New York, pp 261–287.

Examples of pulse oximetry waveforms

	Normal waveform
	Low perfusion waveform
	Motion artifact

If noise (artifact) is seen on the waveform because of poor SpO_2 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. Also motion at the sensor site is indicated by noise spikes in the normal waveform. Pulse rate is determined from the SpO_2 waveform, which can be disrupted by hemodynamic pressure disturbances.

The SQI value and the stability of the displayed SpO_2 and pulse rate values can also be used as an indication of signal validity. On-screen messages help you ensure successful monitoring. For instance, messages like ***Artifact*** or ***Low perfusion*** indicate that you should check the patient, connections, and measurement site.

SpO_2 and pulse rate measurement practicalities

- Check the application site every four hours (or more frequently if perfusion is poor) and change site if necessary.
- Instruct the patient regarding the following issues. Always consider your hospital guidelines as well.
  - Avoid using mobile devices with the same hand as the SpO_2 sensor, as ambient light can interfere with the measurement.
  - Ambulatory patients: The SpO_2 sensor should be placed on the non-dominant hand to avoid motion artifact.

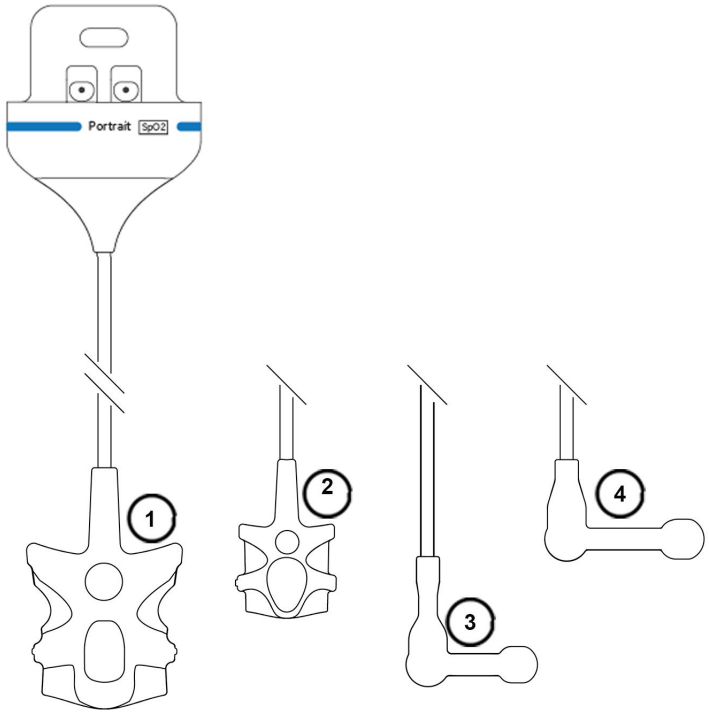
SpO_2 and pulse rate points to note

- This equipment is suitable for use in the presence of electrosurgery, as tested according to IEC 80601-2-49 clause 202.8.102 Electrosurgery interference.
- Defibrillator discharge may affect the SpO_2 measurement. Defibrillation recovery time after discharge is ≤15 seconds.
- Sensors are not made with natural rubber latex.
- Materials used in accessories are not toxic.
- Use dry and clean sensors only.
- Do not use damaged sensors.
- Pulse rate (PR) numerical data cannot be used for arrhythmia analysis.
- SpO_2 waveform is not normalized. Amplitude of the displayed plethysmographic waveform reflects the strength of the arterial blood pulsation at the measurement site.

- Always check the patient and the measurement site if the accuracy of the SpO_2 data is questionable.

SpO_2 and pulse rate measurement setup

The following graphic describes the options available for the SpO_2 and pulse rate measurement setup.



1. Portrait™ SpO2 P-SA01 sensor with finger tip probe, suitable for adult and pediatric patients weighing >30 kg (66 lb)
2. Portrait™ SpO2 P-SP01 sensor with pediatric finger tip probe, suitable for pediatric patients weighing 15 to 30 kg (33 to 66 lb)
3. Portrait™ SpO2 P-SE01 sensor with sensitive skin finger tip probe, suitable for adult and pediatric patients weighing ≥10 kg (22 lb)
4. Portrait™ SpO2 P-W01 sensor with wrap finger tip probe, suitable for adult and pediatric patients weighing ≥10 kg (22 lb)

Preparing the SpO_2 and pulse rate connection

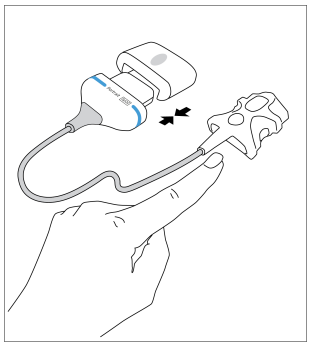
1. Select a well-perfused site, and use a non-dominant hand if possible.
2. Clean the application site if necessary (remove nail polish, for example).

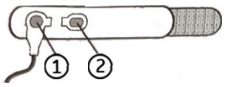
Starting the SpO_2 and pulse rate measurement

The following steps describe the high-level sequence of starting the measurement. Steps 3 to 5 can be done in any order, the sequence given is only an example. See also the detailed instructions for sensor pairing and patient connections.

1. Admit the patient on the Central Viewer.
2. Select the patient on the Hub.

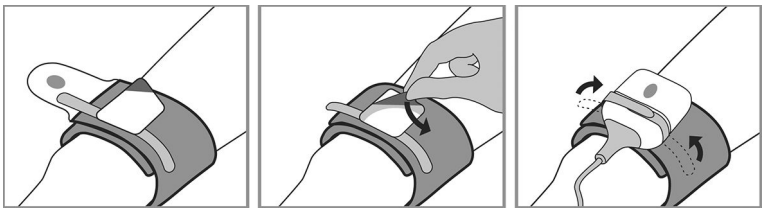
3. Connect the sensor battery to the sensor and attach the probe to the patient's finger:



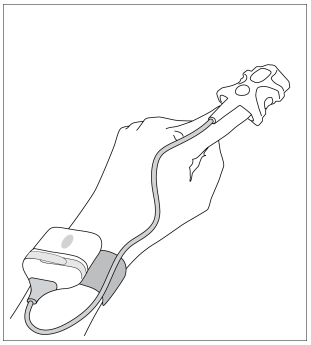
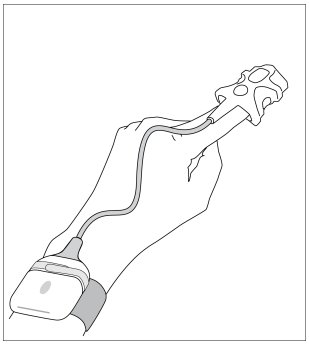


When using a wrap sensor, make sure to position the light source (1) directly opposite the detector (2). This graphic shows the attachment of the probe to the attachment accessory band.

4. Wrap the attachment band to the patient's wrist. Peel off the adhesive liner, place the back of the sensor to the revealed adhesive area and attach the Velcro support straps around the sensor:



5. Adjust the cable length according to the size of the patient's hand by positioning the sensor in one of the ways shown below.


or


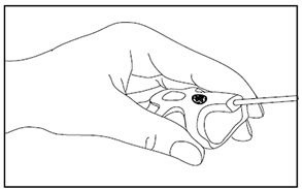
Make sure that the attachment band is not too loose or too tight.

6. Secure the cable to the back of the hand to minimize probe movement. Do not restrict circulation.
7. Pair the sensor and Hub.
8. Check the measurement.

Using the P-SA01 and P-SP01 sensors

These P-SA01 and P-SP01 sensor-specific instructions explain the use in more detail. Also follow the generic instructions for starting the SpO_2 measurement.

1. Press both sides of the probe gently to make the probe more rounded. This will help when inserting the finger.



2. Align the probe with the GE logo upwards and insert the finger all the way to the end of the probe.

Using the P-W01 and P-SE01 sensors

These P-W01 and P-SE01 sensor-specific instructions explain the use in more detail. Also follow the generic instructions for starting the SpO_2 measurement.

Note the following:

- The sensor tape and foam are for single-patient use only.
- Sensitivity to the adhesive tape may cause an allergic reaction.

1. Slide the probe through the slits in the wrap. Alternatively, align the star on the tape with the light source.
2. Ensure a good contact between the probe and the measurement site. Do not restrict circulation.

To replace the wrap:

1. Gently remove the worn wrap.
2. Clean the light source and detector.
3. Place the sensor in a new wrap.

Checking the SpO_2 and pulse rate measurement

Perform the following checks to ensure that the measurement is working.

1. On the Hub:
   a. Check that the wireless network connection LED on the Hub is lit and keeps alternating between dark and light green.
   b. Check that the pulse search animation (three dots in a horizontal line) and the message ***Pulse search*** are displayed. When they disappear, you can see the measurement parameter (SpO_2, PR) on the Hub screen.
   c. Check the measurement values and the signal quality indicator to ensure measurement quality.
2. On the Central Viewer:
   a. Check that the parameter waveform and signal quality indicators are displayed in the Single Patient View and the parameter values in the Single and Multiple Patient Views.

Troubleshooting the measurement

Refer to the troubleshooting chapter in this manual for guidance regarding the most common measurement-related problems. You can find a list of error messages and alarms in the messages chapter.

SpO_2 functional testers

You can verify the functionality of pulse oximeter sensors 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).

14

Trends

About trends on the Central Viewer

Similar to trends on the Hub, the trends on the Central Viewer also show the most representative values of a patient's physiological parameter data for each minute. In the case of the Central Viewer, the trend data undergoes an additional smoothing process. The purpose of this smoothing is to remove brief changes and normal variations in the physiological trend data acquired by the Hub. This makes it easier to observe and recognize any gradual and/or ongoing changes in the patient's data and assess the general trend direction over several minutes or hours.

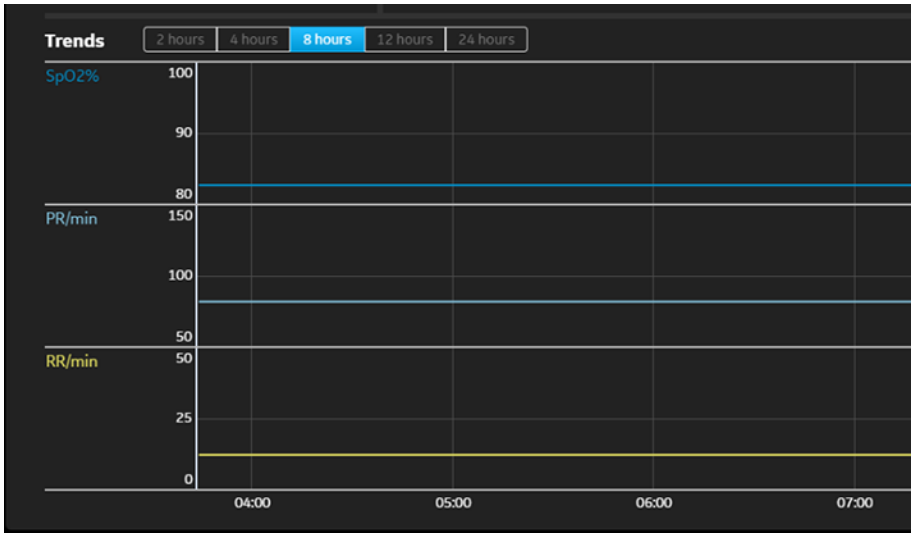
Consequently, the trends on the Central Viewer may show differences in the data when compared to trends on the Hub. It is important to remember that any observed differences do not indicate that the trend data from either device is incorrect or inaccurate; those differences occur because the trends on the Central Viewer have been further smoothed to provide a specific and focused view on the longer-term changes in the data.

Physiological alarms are also displayed in trends on the Central Viewer; these alarms can be seen as event windows in the trend area. However, only those events that occurred at a high or medium priority level are available for clinical review.

Viewing trends on the Central Viewer

1. Navigate to the Single Patient View for the patient.
2. From the ***Trends*** area, select the appropriate time interval (***X hours***, where X = 2, 4, 8, 12, or 24).

   The trend area displays the data in the time interval selected. It can contain one or more parameters, depending on the measurement setup. The trend view does not update automatically. You need to exit it and then reopen the Single Patient View to update the trends.



In this example:

- Trends = ***Trends*** area title
- 2 hours, 4 hours, 8 hours, 12 hours, 24 hours = trend time interval selections
- SpO2% = pulse oximetry label and unit of measure
- PR/min = pulse rate label and unit of measure
- RR/min = respiration rate label and unit of measure
- Vertical axis = trend scales
- Horizontal axis = time (HH:MM)

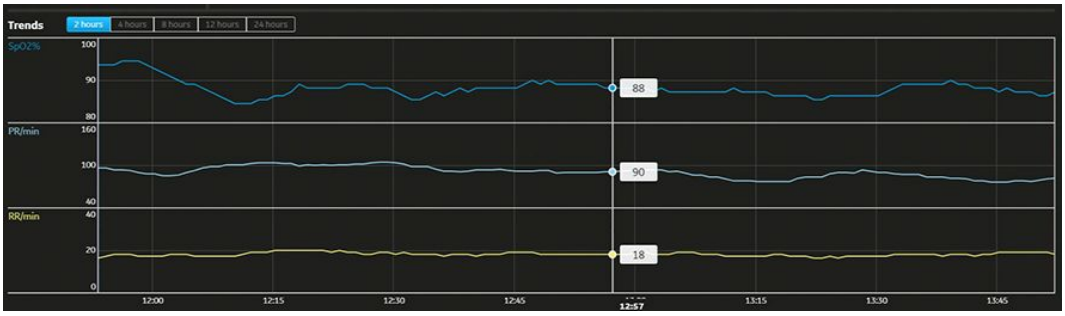
If there is no trend data available for a given time period, that is indicated with a break in the data. If the data is outside of the trend scale displayed, it is indicated with a dashed line for the data.

Using the trend cursor on the Central Viewer

Once in the ***Trends*** view, you can use the trend cursor to view the trended value(s) at the selected moment of time. When hovering the cursor over an event marker in the Single Patient View you can see the high and low limits of that event at the time the event occurred. However, for an ***SpO2 critically low*** event, only the low limit is displayed, and for an ***Apnea*** event, only the apnea seconds setting is displayed. For these two alarms the other limits cannot be set.

1. Using a mouse, do one of the following:
   - Hover the trends cursor over the trends graph to display the data.
   - Select a spot on the trends graph to lock the indicator to a particular spot of interest to follow that data. Selecting again will unlock the indicator.

   The trend cursor (vertical line) appears:



Where:

- Trends (***Trends***) = ***Trends*** area title
- 2 hours, 4 hours, 8 hours, 12 hours, 24 hours (***X hours***) = trend time interval selections
- SpO2% (***SpO2%***) = pulse oximetry label and unit of measure
- PR/min (***PR/min***) = pulse rate label and unit of measure
- RR/min (***RR/min***)= respiration rate label and unit of measure
- Numeric values 88, 90, and 18 = ***SpO2***, ***PR***, and ***RR*** trended values at the selected time
- Vertical axis = trend scales
- Horizontal axis = time (HH:MM), where the time selected with the cursor is highlighted

About trends on the Hub

Trends show the average values of a patient's physiological parameter data for each minute. For this reason, trends may not always show all changes in the patient's data, even when that data is related to physiological alarms. The physiological parameter trends from the past four hours may be viewed in the Hub ***TRENDS*** view. The trends are updated each minute with the most recent trend value shown on the right and the oldest on the left. The trend scale depends on the selected alarm limits; therefore, the trends will also be updated if the alarm limits are changed on the Central Viewer.

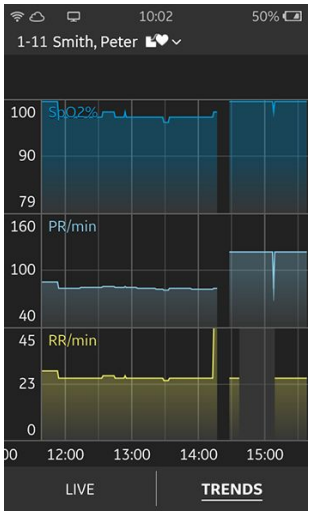
Viewing trends on the Hub

1. Unlock the Hub screen if it is locked.

   The ***LIVE*** view opens.

2. Select ***TRENDS*** from the toolbar.

   The trend view opens. It can contain one or more parameters, depending on the measurement setup.



In this example:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- SpO2% (***SpO2%***) = pulse oximetry label and unit of measure
- PR/min (***PR/min***) = pulse rate label and unit of measure
- RR/min (***RR/min***) = respiration rate label and unit of measure
- LIVE (***LIVE***) = access to the ***LIVE*** view
- TRENDS (***TRENDS***) = access to ***TRENDS*** view (currently viewed)
- Vertical axis = trend scales
- Horizontal axis = time (HH:MM)

Black areas in the trends indicate that there is no trend data available for a given time period. Gray background color indicates that there is no sensor paired for a given time period.

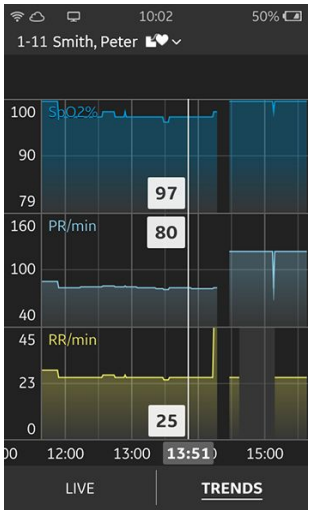
3. Select ***LIVE*** to return to the ***LIVE*** view.

Using the trend cursor on the Hub

Once in the ***TRENDS*** view, you can use the trend cursor to view the 1–minute average value(s) at the selected moment of time

1. Touch the trend area.

   The trend cursor (vertical line) appears:



Where:

- 1–11 = room-bed identification
- Smith, Peter = patient's last name, first name
- SpO2% (***SpO2%***) = pulse oximetry label and unit of measure
- PR/min (***PR/min***) = pulse rate label and unit of measure
- RR/min (***RR/min***) = respiration rate label and unit of measure
- LIVE (***LIVE***) = access to the ***LIVE*** view
- TRENDS (***TRENDS***) = access to ***TRENDS*** view (currently viewed)
- Numeric values 97, 80, and 25 = SpO_2 , PR and RR 1–minute average values at the selected time
- Vertical axis = trend scales
- Horizontal axis = time (HH:MM), where the time selected with the cursor (13:51) is highlighted

The cursor stays on screen until you exit the ***TRENDS*** view.

You can move the cursor by touching another location in the trend area, or by dragging the cursor to left or right. If you touch the trend scale area, the cursor moves to the oldest time available.

15 Cleaning, disinfection, and care

Safety precautions

Familiarize yourself with the safety chapter of this manual for all safety precautions related to the system. Some warnings or cautions may also be listed with detailed instructions in this chapter.

Cleaning, disinfection, and care overview

The following cleaning, disinfection, and care information applies to devices, device components, supplies, and accessories manufactured by GE.

For cleaning, disinfection, and care information for devices, device components, supplies, and accessories made by manufacturers other than GE, see the applicable instructions for use provided by the manufacturer.

Visual inspection, cleaning, and disinfection frequency

Carefully inspect devices visually to verify proper function. Evidence of damage and wear on a device may include but is not limited to discoloration, excessive scratches, wear, and cracks. Improperly functioning devices, damaged, and excessively worn devices should not be used.

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.

The following table indicates the frequency of visual inspection, cleaning, and disinfection procedures.

Device	Visual inspection	Cleaning	Disinfection
Hub, sensors, sensor batteries, charger	• Before and after each patient use • Before and after cleaning or disinfection	• After each patient use • When in use and visible soil is present	• After each patient use • Perform disinfection after cleaning, not before • Always consider your hospital guidelines as well
Alarming unit	• Before and after use • Before and after cleaning	• Monthly and when visible soil is present	• Not needed

Cleaning

General cleaning instructions

Follow these instructions to clean the device and other non-applied parts unless the other parts provide part-specific instructions. Non-applied parts refer to those parts of the system that are not in direct contact with the patient.

Cleaning points to note

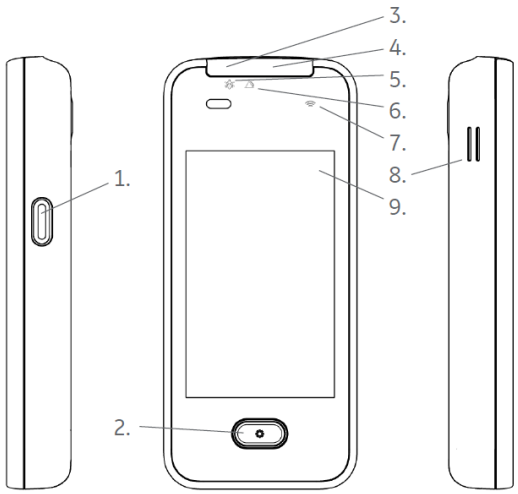
- Warranty does not cover any damages caused by using substances or methods not approved by GE.
- Always dilute cleaning and disinfectant agents according to their manufacturer's instructions. Always consider your hospital guidelines as well.
- Your hospital guidelines permitting, all cleaning and disinfection activities can be carried out at the bedside.
- Do not let liquid pool around connection pins. If this should happen, blot dry with a soft, non-linting cloth.
- Do not use excessive drying techniques, such as oven, forced heat, or sun drying.
- Do not spray cleaner directly on the display screen.
- Never connect any device or applied part to a patient until it is thoroughly dry.
- If you discover any signs of deterioration or damage in the device, discontinue its use.

Permitted detergents

The following permitted detergents can be used to clean the device and other non-applied parts unless there are separate part-specific instructions. Non-applied parts refer to those parts of the system that are not in direct contact with the patient.

- CaviWipes wipes
- Super Sani-Cloth (purple top)

Cleaning procedure for the Hub



1. Power key
2. * (asterisk) key
3. Audio silence LED area
4. Active alarms LED area
5. Audio silence indicator
6. Alarm indicator
7. Wireless network connection LED indicator
8. Speaker
9. Graphical user interface screen
10. Connector for the charger
11. Camera (not in use)
12. Flash (not in use)

Initiate cleaning and disinfection as soon as possible after use (recommended within 1 hour). Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparing the Hub for cleaning

1. Remove the device from the charger and Hub pouch, if they are in use. Dispose of the used pouch according to your hospital guidelines.

2. If the Hub is not in clinical use, make sure that it is powered off. If the Hub is powered on:

   a. Activate the screen by pressing the * key and entering the passcode with the on-screen keyboard. Confirm with the ✔ key.

   b. Press the power key for 1.5 seconds.

      When the Hub screen is facing you, the power key is located on the right hand side of the Hub.

   c. Confirm that you wish to continue with the shut down.

3. If the Hub is in clinical use, make sure that the screen is locked (you can see texts ***No patient*** or ***No monitoring***, or only the current date and time (***REMOTE*** monitoring mode), or measurement values with the lock indicator at the bottom of the screen (***LOCAL*** monitoring mode). If the Hub is not locked, lock it by pressing the power key.

4. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

Cleaning the Hub

In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed.

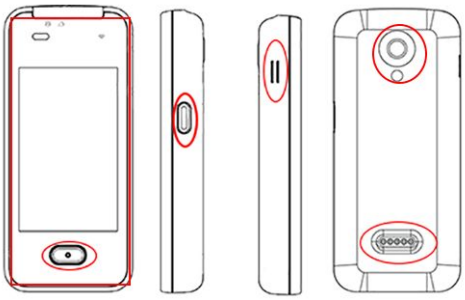
1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.

2. Wring excess liquid from the cloth (wet but not dripping).

3. Wipe the exterior surface. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.

   - Pay special attention to hard-to-clean areas (marked here with red), like grooves and crevices:

     Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.

4. Replace soiled and/or dry wipes or non-linting cloths as needed.

5. Repeat the cleaning until the device is visibly clean.

6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.

7. Rinse the device thoroughly using a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).
8. Allow the device to air dry until it is visually dry, or dry thoroughly with a soft, clean, non-linting cloth before placing the device into the charger.
   - Pay special attention to metal parts (marked here with a red ellipse) when drying device to avoid corrosion:

   Drying times may vary based on the environmental conditions. Do not let fluid pool around connection pins to avoid corrosion. If this happens, blot dry with a cotton swab or soft cloth.

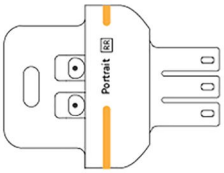
Post-cleaning inspection

Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Cleaning procedure for the respiration sensor



Initiate cleaning and disinfection as soon as possible after use (recommended within 1 hour). Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparing the respiration sensor for cleaning

1. Remove the sensor battery from the sensor.

where:

- 1 = sensor battery
- 2 = sensor
- 3 = respiration patch connector

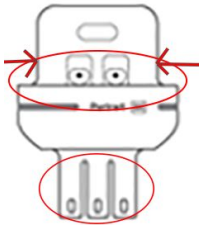
2. Disconnect the respiration patch from the respiration sensor. Dispose of the used respiration patch according to your hospital guidelines.
3. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

Cleaning the respiration sensor

In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed.

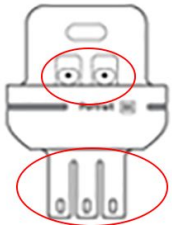
1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.
2. Wring excess liquid from the cloth (wet but not dripping).
3. Wipe the exterior surface. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.
   - Pay special attention to hard-to-clean areas (marked here with red), like grooves and crevices:



   - Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.
   - Do not damage sensor connector pins when cleaning or drying.
4. Replace soiled and/or dry wipes or non-linting cloths as needed.
5. Repeat the cleaning until the device is visibly clean.
6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.
7. Rinse the device thoroughly using a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).

8. Allow the device to air dry until it is visually dry, or dry thoroughly with a soft, clean, non-linting cloth before taking the device into use or placing it into the charger.
   - Pay special attention to metal parts (marked here with red) when drying device to avoid corrosion:



   Drying times may vary based on the environmental conditions. Do not let fluid pool around connection pins to avoid corrosion. If this happens, blot dry with a cotton swab or soft cloth.

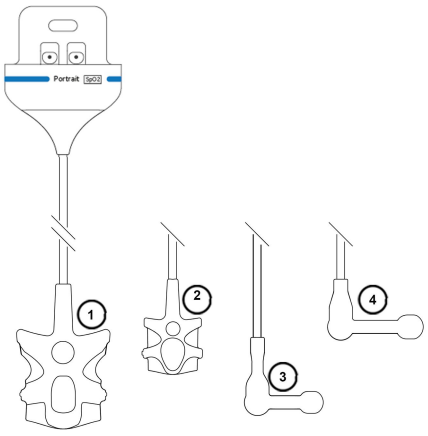
Post-cleaning inspection

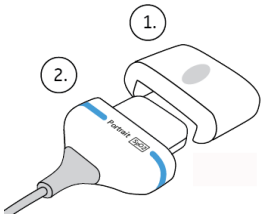
Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Cleaning procedure for the SpO_2 sensors





where:

- 1 = sensor battery
- 2 = sensor

1. SpO2 P-SA01 sensor with finger tip probe
2. SpO2 P-SP01 sensor with pediatric finger tip probe
3. SpO2 P-SE01 sensor with sensitive skin probe
4. SpO2 P-W01 sensor with wrap probe

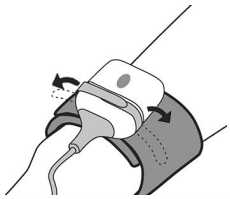
Initiate cleaning and disinfection as soon as possible after use (recommended within 1 hour). Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

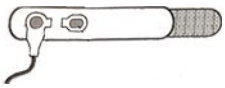
Preparing the SpO_2 sensors for cleaning

1. Remove the sensor battery from the sensor.

2. Remove the wrist band:



3. When using the P-SE01 or P-W01, also remove the probe attachment accessories from the sensor:



4. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

Cleaning the SpO_2 sensors

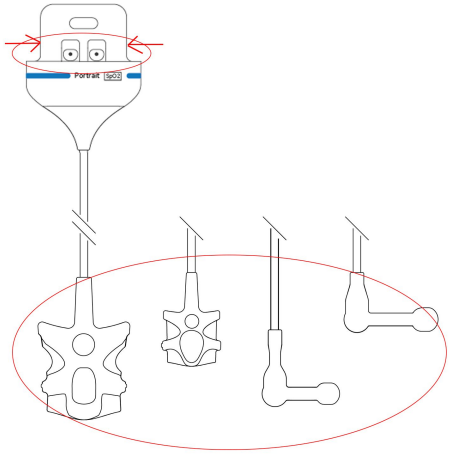
In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed. Finger probes (P-SA01, P-SP01) can be turned inside out to enable easy cleaning of the inner surface.

1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.

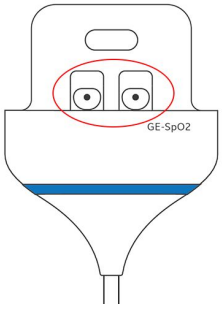
2. Wring excess liquid from the cloth (wet but not dripping).

3. Wipe the cable and all sensor surfaces, including the lenses. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.
   - Pay special attention to hard-to-clean areas (marked here with red), like grooves and crevices:



     Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.
   - Finger probes can be turned inside out to enable easy cleaning of the inner surface.
   - Do not damage sensor connector pins when cleaning or drying.
4. Replace soiled and/or dry wipes or non-linting cloths as needed.
5. Repeat the cleaning until the device is visibly clean.
6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.
7. Rinse the device thoroughly using a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).
8. Allow the device to air dry until it is visually dry, or dry with thoroughly with a soft, clean, non-linting cloth before placing the device into the charger.

   Drying times may vary based on the environmental conditions. Do not let fluid pool around connection pins to avoid corrosion. If this happens, blot dry with a cotton swab or soft cloth.
   - Pay special attention to metal parts (marked here with red) when drying device to avoid corrosion:



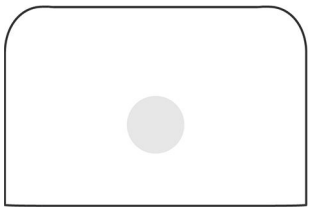
Post-cleaning inspection

Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Cleaning procedure for sensor batteries



Initiate cleaning and disinfection as soon as possible after use (recommended within 1 hour). Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparing a sensor battery for cleaning

1. Remove the sensor and attachment accessories from the battery, or remove the battery from the charger.

SpO_2 sensor

Respiration sensor

2. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

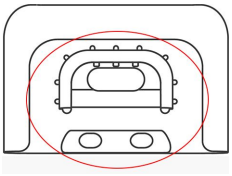
Cleaning sensor batteries

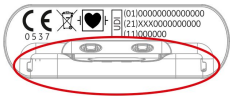
In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed.

1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.

2. Wring excess liquid from the cloth (wet but not dripping).
3. Wipe the exterior surface. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.
   - Pay special attention to hard-to-clean areas (marked here with red), like grooves and crevices):

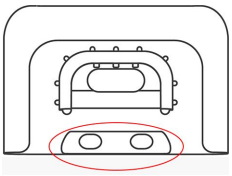




   - Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.
4. Replace soiled and/or dried wipes or non-linting cloths as needed.
5. Repeat the cleaning until the device is visibly clean.
6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.
7. Rinse the device thoroughly using a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).
8. Allow the device to air dry until it is visually dry, or dry with thoroughly with a soft, clean, non-linting cloth before placing the device into the charger.

   Drying times may vary based on the environmental conditions. Do not let fluid pool around connection pins to avoid corrosion. If this happens, blot dry with a cotton swab or soft cloth.

   - Pay special attention to metal parts (marked here with red) when drying device to avoid corrosion:



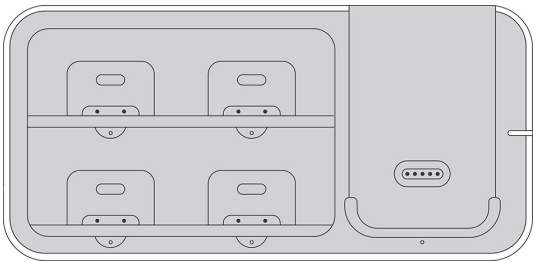
Post-cleaning inspection

Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Cleaning procedure for the charger



Initiate cleaning and disinfection as soon as possible after use (recommended within 1 hour). Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparing the charger for cleaning

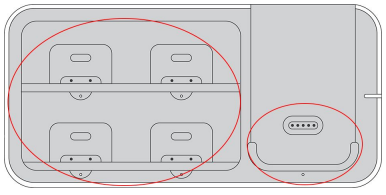
1. Remove sensor batteries, sensors, and Hub from the charger.
2. Unplug the power cord from the wall outlet.
3. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

Cleaning the charger

In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed.

1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.
2. Wring excess liquid from the cloth (wet but not dripping).
3. Wipe the exterior surface. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.
   - Pay special attention to hard-to-clean areas (marked here with red), like grooves and crevices:

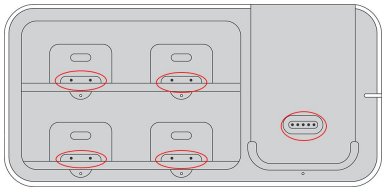
     

     Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.
4. Replace soiled and/or dry wipes or non-linting cloths as needed.
5. Repeat the cleaning until the device is visibly clean.
6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.

7. Rinse the device thoroughly using a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).
8. Allow the device to air dry until it is visually dry, or dry with thoroughly with a soft, clean, non-linting cloth.

   Drying times may vary based on the environmental conditions. Do not let fluid pool around connection pins to avoid corrosion. If this happens, blot dry with a cotton swab or soft cloth.

   - Pay special attention to metal parts (marked here with red) when drying device to avoid corrosion:



Post-cleaning inspection

Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Cleaning procedure for the alarming unit

NOTE If you need to disconnect the alarming unit for cleaning, remember to reconnect it after cleaning.

Initiate cleaning daily and if any visible soil is present. Remove any soil as soon as possible by wiping the device to prevent the drying of soil on the device as described in following procedures.

Soiled devices must be separated from non-contaminated devices to avoid contamination of personnel or surroundings.

Preparing the alarming unit for cleaning

1. Visually ensure that the device is intact. Evidence of damage may include, but is not limited to, discoloration, excessive scratches, wear, and cracks.

Cleaning the alarming unit

In case there is some dried or gross soil, perform pre-cleaning by wiping with a soft, clean non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F) until visible dried or gross soil is removed.

1. Dampen a soft non-linting cloth with detergent or use ready-to-use detergent wipes.

   Prepare the detergent according to the manufacturer's instructions.
2. Wring excess liquid from the cloth (wet but not dripping).
3. Wipe the exterior surface. Ensure that the entire surface is wet and make sure all surfaces are uniformly cleaned.
   - Pay special attention to hard-to-clean areas, like grooves and crevices. Use cotton swabs to access hard to reach areas. Do not use any sharp tools to clean the device.
4. Replace soiled and/or dry wipes or non-linting cloths as needed.
5. Repeat the cleaning until the device is visibly clean.
6. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.
7. Rinse the device thoroughly using a soft, clean, non-linting cloth saturated with lukewarm tap water (temperature range 27 to 44°C, 81 to 111°F).
8. Dry thoroughly with a soft, clean, non-linting cloth before taking it into use.

Post-cleaning inspection

Inspect devices visually after cleaning and prior to disinfection for the following:

- Cleanliness
  - If there is any visible soil present, repeat the cleaning procedure until no visible soil remains.
- Damage, including, but not limited to, corrosion (rust, pitting), discoloration, excessive scratches, flaking, cracks, and wear
- Missing or worn device labeling or marking

Do not use devices that are not functioning properly or are damaged, or have unrecognizable markings, or missing or worn device labeling or marking.

Disinfection

Disinfection points to note

- Always clean before disinfecting.
- Always dilute cleaning and disinfectant agents according to their manufacturer's instructions. Always consider your hospital guidelines as well.
- Use only the permitted substances.
- Your hospital guidelines permitting, all cleaning and disinfection activities can be carried out at the bedside.
- Before drying a surface after wiping it, wait the minimum time required according to the substance manufacturer's instructions.

- Visually ensure that no substance residue remains on the device.

Permitted disinfectants

All third party trademarks are property of their respective owners.

Trademark names and product availability may vary by country.

- CaviWipes wipes
- Super Sani-Cloth (purple top)

Disinfection procedure

Ensure that a thorough cleaning of the device has been performed prior to disinfection

Charger: Unplug the power cord from the wall outlet.

Disinfecting the devices

The following disinfection instructions apply to the Hub, SpO_2 and respiration sensors, sensor batteries, and charger. Any device-specific instructions are indicated.

1. Apply disinfectant solution to a clean non-linting cloth or use approved disinfectant wipes.
2. Wipe the entire device surface. Treated surfaces must remain visibly wet for a time indicated in the disinfectant manufacturer's documentation.
3. Apply additional disinfectant solution or use additional fresh disinfectant wipes to ensure that the device remains wet continuously per the disinfectant manufacturer's instructions for contact time.
   - Pay special attention to hard to reach areas like recessed areas and ridges. To identify these, refer to the graphics in the cleaning instructions. To disinfect them, dampen a cotton swab with the disinfectant solution.
   - Hub: Do not use any sharp tools when disinfecting the device.
4. Discard disposable wipes or non-linting cloths according to your hospital guidelines. Do not reuse wipes.
5. Manually rinse the device by wiping it for 30 seconds using a sterile, soft, non-linting cloth saturated with purified water (PURW) (temperature range 27 to 44°C, 81 to 111°F).
   a. Repeat two additional times for a total of three rinse cycles, using fresh purified water and a new sterile cloth for each cycle.
6. Dry the device:
   a. Hub, sensors, sensor batteries: Dry using a sterile, non-linting cloth until the device is visually dry before placing it into the charger or taking it into use
   b. Charger: Dry using a sterile, non-linting cloth until the device is visually dry before taking it into use
7. Charger: connect the charger back into a wall socket when it is dry.

Care

Care schedules

- Check daily that the Hub, sensors, sensor batteries, charger, alarming unit, and the hardware running the Central Viewer application are clean and intact.
- Check the battery capacity of the Hub and sensors daily.
- Always consider your hospital guidelines as well.

See the service manual for more comprehensive checks.

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Periodic maintenance

Daily checks

- Check that the accessories, cables, cable connectors, Hub, sensors, sensor batteries, and hardware running the Central Viewer are clean and intact.
- Check the charge of the Hub and sensor batteries.

Preventive maintenance

- There is no other preventive maintenance than cleaning and daily checks.
- For battery maintenance, refer to the chapter discussing battery management.
- For all service and maintenance instructions, refer to the service manual.

About service and maintenance during monitoring

Service or maintenance tasks cannot be performed to any part of this equipment while they are in use with the patient. However, some settings can be changed in the Config UI while monitoring is ongoing.

For more information regarding service and maintenance procedures, refer to the service manual.

17

Troubleshooting

Troubleshooting the Central Viewer

Problem	Solution
Cannot admit a new patient	• Retry admitting the patient. • Restart the Central Viewer. • If the problem persists, contact qualified service personnel.
Cannot select the bed and room	• Contact qualified service personnel.
Incorrect or missing trends	Hub is outside the WLAN coverage range. • Check that the Hub is powered on and within the WLAN coverage range. • Check the patient. • If the problem persists, contact qualified service personnel.
Numeric data is not updating	• Check that the correct patient is assigned to the Hub. • Check the measurement setup and ensure proper attachment to the patient. • If the problem persists, contact qualified service personnel.
Numeric data seems incorrect	• Check the measurement setup and ensure proper attachment to the patient. • Check that the respiration electrode gel is not dry. • Contact qualified service personnel.

Problem	Solution
Loss of audible and/or visual alarms	• Check that the alarm limits and priorities are set correctly for your care area. • Check the alarm volume. • Check that the alarming unit is connected to the Central Viewer computer. • Check the alarm function as instructed in the relevant section of this manual. • Contact qualified service personnel.
Loss of monitoring or parameter(s)	Loss of monitoring: • Check that the Hub is powered on and within the WLAN coverage range. • Check that the patient is assigned to the Hub. Loss of parameter(s): • Check the patient. • Check the measurement setup and ensure proper attachment to the patient. • Check that the sensors are within the range of the Hub. • Contact qualified service personnel.

Troubleshooting the Hub

Problem	Solution
Sensor and Hub pairing fails	There may be a stronger NFC reader (like a cell phone) in close proximity. • Increase the distance between the Hub and other NFC devices and retry. • Check the sensor placement on the patient.
Patient cannot be selected	There are several possible reasons for this and the solution depends on the cause: • Patient does not appear on the patient list: try refreshing the list by selecting ***Refresh*** or by swiping down. If that does not help, check that the patient has been admitted to the Central Viewer, then retry. • ***Patient is not available*** appears: another Hub has already been assigned to this patient, or the patient has been discharged remotely. Check the patient and Hub assignments and patient admission status on the Central Viewer. • ***No wireless network*** appears: there is no wireless network connection. Make sure that the Hub is within the network coverage range. If that does not help, contact service personnel.

Problem	Solution
	• ***No connection to patient monitoring services*** appears: the Hub is not connected to the Core Services. Make sure that the Hub is within the network coverage range. If that does not help, contact service personnel. • ***No license available*** appears: there are no available monitoring licenses. Unassign one Hub or wait until a license becomes available again.
Monitoring is lost	Environmental interference or configuration errors prevent the MBAN from working properly. • Check the environment for any interfering devices and remove as necessary. • If the problem persists, contact qualified service personnel to check the MBAN configuration. There may be problems with power supply (cables, batteries etc.) or with the WLAN. • Check battery charges and replace batteries as needed. • Contact qualified service personnel.
Loss of audible and/or visual alarms	• Check that the alarm limits are set correctly for your care area. • Check the alarm volume adjustment. • Check the use mode (***REMOTE*** or ***LOCAL***) and change as needed. • Check patient connections. • Contact qualified service personnel.
Waveforms seem incorrect or have artifact	There are several possible reasons for this and the solution depends on the cause: • Patient movement: Instruct the patient about the effect of movement on the measurement. • Environmental interference: Check the environment for any interfering devices and remove as necessary. • Sensor out of range: Reposition the Hub closer to the sensor. • Sensor blocked: Reposition the sensor. • Broken or damaged sensor: Check the sensor and replace as necessary. • Poor lead or sensor preparation, placement, or attachment, or dry electrode gel: Check sensor position and connections and correct as necessary.
Incorrect or missing trends	Sensor is out of range. • Reposition the Hub closer to the sensor.

Troubleshooting the respiration measurement

Problem	Solution
What can I do if the respiration measurement fails?	• Check electrode quality (e.g. that the gel is not dry) and positioning. • Check that the SQI for respiration shows a good signal. • Other electrical devices may interfere with the measurement. Reposition as needed.
Respiration rate value variations are too fast.	• Contact an authorized clinical user and ask them to increase the averaging time for respiration rate in the Config UI.
Respiration rate value responds too slowly.	• Contact an authorized clinical user and ask them to decrease the averaging time for respiration rate in the Config UI.
Respiration rate values are too low and trigger false alarms	In some rare cases the respiration rate and pulse rate values of the patient may be very close to each other, resulting in too low respiration rate values and false alarms.
Respiration rate value is 0, but there is no apnea alarm.	Respiration rate may be shown as 0 without an apnea alarm if the patient's respiration frequency and amplitude are very low. Apnea alarm appears if there are no detected breaths during user-configurable apnea alarm time.
Patient apnea is not detected.	Respiration measurement can only detect central type apnea. Apnea cannot be detected if there is any breathing or motion by the patient.
What if the respiration signal is poor?	The signal may be disturbed by motion, the electrode placement may be poor, or the electrode gel may be dry. Reposition the electrodes or replace the respiration patch as needed.
What does motion artifact look like, what problems can it cause, and how can it be corrected?	Motion artifact occurs with excessive motion of the patient. In other words, for example the patient moving his upper body can cause motion artifact. Motion artifact can be reduced, if not eliminated, by good skin to electrode contact and optimal placement of the respiration electrodes.
Why is the measurement not displayed after connecting the sensor?	The sensor is out of range: • Reposition the Hub closer to the sensor. No measurement data is displayed due to hardware failure or an unrecognized or defective sensor: • Check the MBAN connection. • Check that the accessories are compatible. • Check that the sensor is associated to the Hub. • Change the sensor.

Problem	Solution
	If the problem persists, contact qualified service personnel.

Troubleshooting the SpO_2 and pulse rate measurements

Problem	Solution
SpO_2 signal is poor	• Check the sensor and sensor position. • Check the probe and probe position. • Check that the patient is not shivering, moving, or does not have tremors. • The patient's pulse may be too low to measure. • The perfusion may be too low. Change sensor site.
SpO_2 or PR value variations are too fast.	• Contact an authorized clinical user and ask them to increase the averaging time for SpO_2 or PR in the Config UI.
SpO_2 or PR value responds too slowly.	• Contact an authorized clinical user and ask them to decrease the averaging time for SpO_2 or PR in the Config UI.
Why does the pulse oximeter sometimes read differently than a blood gas analyzer?	Blood gas analyzers calculate the O_2 saturation based on normal values for pH, $PaCO_2$, Hb, temperature, and so on (a normal oxyhemoglobin dissociation curve). Depending on the patient's physiologic 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 or erroneous readings. Error messages are possible. Shielding the sensor with opaque tape, the posey wrap, or other dark or opaque material can increase oximetry accuracy, verified by good waveform and signal strength.
What does electrosurgical interference look like and how can it be minimized?	Electrosurgical interference is most obvious on the displayed waveform. It is 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.

Problem	Solution
	• Keeping the sensor cable away from the power cord of the electrosurgical unit.
What does motion artifact look like, what problems can it cause, and how can it be corrected?	Motion artifact occurs with excessive motion of the sensor. In other words, for example the patient moving his hands can cause motion artifact. Motion artifact can be reduced, if not eliminated, by selecting the non-dominant hand of the patient.
Why is the measurement not displayed after connecting the sensor?	The sensor is out of range: • Reposition the Hub closer to the sensor. No measurement data is displayed due to hardware failure or an unrecognized or defective sensor: • Check that the accessories are compatible. • Check that the sensor is associated to the Hub. • Change the sensor. If the problem persists, contact qualified service personnel.

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Alarm messages

Alarms related to the respiration rate measurement

Alarm priorities are given in the section discussing alarm specifications.

Make sure that you are familiar with the generic layout of the Hub and Central Viewer screens. This will help you identify where the following alarm messages appear. The alarm location is indicated with the following abbreviations:

- al. area = alarm area
- data = data area

Physiological messages

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Apnea*** • ***APN*** Central Viewer: • ***Apnea*** • ***APN***	• al. area • data	No breathing detected during the time that has been set as the apnea limit.	• Check the patient. • Check electrode placement and skin to electrode contact.
Hub: • ***Resp artifact*** • ***Artifact*** Central Viewer: • ***Resp artifact***	Hub: • al. area • data Central Viewer: • al. area	Respiration signal quality is very low due to patient movement or poor electrode contact.	• Check the patient. • Check electrode placement and skin to electrode contact.

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Learning***	• data	The patient's breathing pattern is being learned because the measurement has just been started or because of very large artifacts in the signal.	• Replace the respiration patch. • Wait until the message disappears.
Hub: • ***RR high*** • ***RR low*** Central Viewer: • ***RR high*** • ***RR low***	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient. • Check electrode placement and skin to electrode contact. • Adjust alarm limits on the Central Viewer if necessary.

Technical messages

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Check Resp patch*** • ***Check patch*** Central Viewer: • ***Check Resp patch***	Hub: • al. area • data Central Viewer: • al. area	The respiration patch is not properly connected to the patient or the sensor is not properly connected to the respiration patch.	• Check the respiration patch placement and skin to electrode contact. • Check the sensor and respiration patch connection.
Hub: • ***Resp battery low*** Central Viewer: • ***Resp battery low***	• al. area	Sensor battery charge is low.	• Charge the battery. • Replace the battery.
Hub: • ***Change Resp battery*** Central Viewer: • ***Change Resp battery***	• al. area	Sensor battery is empty.	• Replace the battery and put the empty one into the charger.
Hub: • ***Clean Resp battery interface*** • ***Clean battery interface*** Central Viewer: • ***Clean Resp sensor interface***	Hub: • al. area • data Central Viewer: • al. area	There is dirt in the sensor or battery.	• Check and clean the sensor and battery.
Hub: • ***No Resp battery*** • ***No battery*** Central Viewer: • ***No Resp battery***	Hub: • al. area • data Central Viewer: • al. area	Battery has been removed from the sensor.	• Connect a sensor battery.

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Weak Resp connection*** Central Viewer: • ***Weak Resp connection***	• al. area	Connection between the Hub and sensor is poor and there was a data loss between the Hub and the sensor.	• Place the Hub closer to the patient. • If the problem persists, contact qualified service personnel.
Hub: • ***Resp connection lost*** • ***Connection lost*** Central Viewer: • ***Resp connection lost***	Hub: • al. area • data Central Viewer: • al. area	Connection between the Hub and sensor was lost due to too long a distance between them (for instance, the patient has walked away from the Hub).	• Check the distance between the sensor and the Hub. • Make sure the patient understands how far they can move from the Hub without losing the wireless connection. • If the problem persists, contact qualified service personnel.
Hub: • ***Resp device overheating*** • ***Device overheating*** Central Viewer: • ***Resp device overheating***	Hub: • al. area • data Central Viewer: • al. area	Sensor battery surface temperature is too high. The maximum surface temperature of the devices being worn by the patient (Hub, sensor battery and wearable sensors) will never exceed 43°C (The device will shut down before the temperature reaches 43°C). When the surface temperature is approaching 43°C, an overheating alarm is given, allowing the clinician to take appropriate action to ensure the time of exposure is limited based on the condition of the patient.	• Check the sensor battery and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the sensor battery.

Alarms related to the SpO_2 and pulse rate measurement

Alarm priorities are given in the section discussing alarm specifications.

Make sure that you are familiar with the generic layout of the Hub and Central Viewer screens. This will help you identify where the following alarm messages appear. The alarm location is indicated with the following abbreviations:

- al. area = alarm area
- data = data area

Physiological messages

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***PR high*** • ***PR low*** Central Viewer: • ***PR high*** • ***PR low***	• al. area • data	Measurement values are equal to or outside the alarm limits.	• Check the patient. • Adjust alarm limits on the Central Viewer if necessary.
Hub: • ***Pulse search***	• al. area	SpO_2 and PR values are not yet available due to ongoing signal control and data acquisition.	• Reposition the probe. • Clean the application site (remove nail polish, for instance). • If the problem persists, contact qualified service personnel.
Hub: • ***SpO2 artifact*** • ***Artifact*** Central Viewer: • ***SpO2 artifact***	Hub: • al. area • data Central Viewer: • al. area	Artifact detected.	• Check the patient. • Check the sensor and sensor positioning.
Hub: • ***SpO2 high*** • ***SpO2 low*** Central Viewer: • ***SpO2 high*** • ***SpO2 low***	• al. area	Measurement values are equal to or outside the alarm limits.	• Check the patient. • Adjust alarm limits on the Central Viewer if necessary.
Hub: • ***SpO2 critically low*** Central Viewer: • ***SpO2 critically low***	• al. area	Measurement values are equal to or outside the critical alarm limit. If the ***SpO2 critically low*** alarm is triggered before the ***SpO2 low*** alarm delay has expired, these two alarms are triggered simultaneously.	• Check the patient. • Adjust alarm limits on the Central Viewer if necessary.
Hub: • ***SpO2 low perfusion*** • ***Low perfusion*** Central Viewer: • ***Low perfusion***	Hub: • al. area • data Central Viewer: • al. area	Low perfusion at the measurement site.	• Check the sensor and sensor positioning. • Check the measurement site (for instance, is the patient's hand or finger cold).

Technical messages

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Pulse search***	• al. area	SpO_2 and PR values are not yet available due to ongoing signal control and data acquisition.	• Reposition the probe. • Clean the application site (remove nail polish, for instance). • If the problem persists, contact qualified service personnel.
Hub: • ***Check SpO2 probe*** • ***Check probe*** Central Viewer: • ***Check SpO2 probe***	Hub: • al. area • data Central Viewer: • al. area	Prolonged pulse search. The signal is too noisy for measuring SpO_2. Peripheral perfusion is too low for measuring SpO_2.	• Check the sensor and connections. • Check the patient. • Isolate noise sources. • Change the measurement site.
Hub: • ***SpO2 probe off*** • ***Probe off*** Central Viewer: • ***SpO2 probe off***	Hub: • al. area • data Central Viewer: • al. area	SpO_2 probe is off the patient.	• Check the connections and adjust as needed.
Hub: • ***Faulty SpO2 probe*** • ***Faulty probe*** Central Viewer: • ***Faulty SpO2 probe***	Hub: • al. area • data Central Viewer: • al. area	SpO_2 probe is faulty (open or short circuit failure).	• Check the probe and replace if necessary.
Hub: • ***SpO2 battery low*** Central Viewer: • ***SpO2 battery low***	• al. area	Sensor battery charge is low.	• Charge the battery. • Replace the battery.
Hub: • ***Change SpO2 battery*** Central Viewer: • ***Change SpO2 battery***	• al. area	Sensor battery is empty.	• Replace the battery and put the empty one into the charger.
Hub: • ***Clean SpO2 battery interface*** • ***Clean battery interface*** Central Viewer: • ***Clean SpO2 sensor interface***	Hub: • al. area • data Central Viewer: • al. area	There is dirt in the sensor.	• Check and clean the sensor.

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***No SpO2 battery*** • ***No battery*** Central Viewer: • ***No SpO2 battery***	Hub: • al. area • data Central Viewer: • al. area	Battery has been removed from the sensor.	• Connect a sensor battery.
Hub: • ***Weak SpO2 connection*** Central Viewer: • ***Weak SpO2 connection***	• al. area	MBAN connection is poor and there was a data loss between the Hub and the sensor.	• Place the Hub closer to the patient. • If the problem persists, contact qualified service personnel.
Hub: • ***SpO2 connection lost*** • ***Connection lost*** Central Viewer: • ***SpO2 connection lost***	Hub: • al. area • data Central Viewer: • al. area	Connection between the Hub and sensor was lost due to too long a distance between them (for instance, the patient has walked away from the Hub).	• Check the distance between the sensor and the Hub. • Make sure the patient understands how far they can move from the Hub without losing the wireless connection. • If the problem persists, contact qualified service personnel.
Hub: • ***SpO2 device overheating*** • ***Device overheating*** Central Viewer: • ***SpO2 device overheating***	Hub: • al. area • data Central Viewer: • al. area	Sensor battery surface temperature is too high. The maximum surface temperature of the devices being worn by the patient (Hub, sensor battery and wearable sensors) will never exceed 43°C (The device will shut down before the temperature reaches 43°C). When the surface temperature is approaching 43°C, an overheating alarm is given, allowing the clinician to take appropriate action to ensure the time of exposure is limited based on the condition of the patient.	• Check the sensor battery and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, replace the sensor battery.

Alarms related to device issues

Alarm priorities are given in the section discussing alarm specifications.

Make sure that you are familiar with the generic layout of the Hub and Central Viewer screens. This will help you identify where the following alarm messages appear. The alarm location is indicated with the following abbreviations:

- al. area = alarm area
- data = data area

Alarm message	Location	Possible explanations	Suggested actions
Hub: • ***Charge Hub*** Central Viewer: • ***Charge Hub***	• al. area	The Hub battery has no charge left.	• Charge the Hub.
Hub: • ***Hub battery low*** Central Viewer: • ***Hub battery low***	• al. area	The Hub battery charge is getting low.	• Charge the Hub.
Hub: • ***Hub charging failure*** Central Viewer: • ***Hub charging failure***	• al. area	The Hub battery cannot be charged.	• Check the Hub battery and the charger. • If the problem persists, contact qualified service personnel.
Hub: • ***Hub overheating*** Central Viewer: • ***Hub overheating***	• al. area	The temperature of the Hub is too high. The maximum surface temperature of the devices being worn by the patient (Hub, sensor battery and wearable sensors) will never exceed 43°C. (The device will shut down before the temperature reaches 43°C). When the surface temperature is approaching 43°C, an overheating alarm is given, allowing the clinician to take appropriate action to ensure the time of exposure is limited based on the condition of the patient.	• Check the Hub and ensure that it is not covered by anything that might lead to overheating. • If the problem persists, contact qualified service personnel.
Hub: • ***Network connection lost*** Central Viewer: • ***Network connection lost. Please contact your system administrator.*** • ***Network connection lost***	Hub: • al. area Central Viewer: • al. area • data	There has been a loss of network communication due to a technical fault or the device being in a shadow region.	• Reconnect to the network. • Make sure you are not in a shadow region. • If the problem persists, contact qualified service personnel.
Central Viewer: • ***Speaker disconnected.***	• main header	Alarming unit is not connected to the Central Viewer computer.	Connect the alarming unit to the Central Viewer omputer.
Central Viewer: • ***External speaker error. Please contact your system administrator.***	• main header	There is a problem with the alarming unit speaker.	• Contact qualified service personnel.

19 Technical specifications

Design, environmental, and physical specifications

For additional specifications, refer to the documentation provided with your equipment. For more information on products that can be used with the system, refer to the list of Compatible devices.

Operating altitude: The system shall meet specifications when subjected to altitudes corresponding to pressure readings from 620 mbar to 1060 mbar.

NOTE An average pressure reading of 620 mbar corresponds to an altitude of 3950 m (12,959 ft) and 1060 mbar corresponds to an altitude of –380 m (–1247 ft).

Non-operating altitude: The system shall meet specifications after being subjected to altitudes corresponding to pressure readings from 500 mbar to 1060 mbar.

NOTE An average pressure reading of 500 mbar corresponds to an altitude of 5486 m (18,000 ft).

WARNING INACCURATE READINGS. 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.

FCC information

- Hub FCC ID: 2AO8L-HUB01; contains FCC ID: 2AO8L-WL18DBMOD
- Sensor battery FCC ID: 2AO8L-SBT01

This device complies with part 15 and Part 95 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

CAUTION UNEXPECTED SYSTEM PERFORMANCE. Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Radio Equipment Directive (RED) information

This device complies with Radio Equipment Directive (2014/53/EU). Only indoors usage is permitted with 5150 to 5350 MHz WLAN.

ISED information

- Hub ISED IC: 25821-HUB01, contains ISED IC: 25821-WL18DBMOD
- Sensor battery ISED IC: 25821-SBT01

This device complies with Industry Canada's license-exempt RSSs. Operation is subject to the following two conditions:

1. This device may not cause interference; and
2. This device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1. l'appareil ne doit pas produire de brouillage;
2. l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

5150-5350 MHz band is restricted to indoor operation only.

La bande 5150-5350 MHz est restreinte à une utlisation a l'intérieur seulement.

High-power radars are allocated as primary users (i.e. priority users) fo the bands 5250-5350 MHz and 5650-5860 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Les radars de haute puissance sont désignés utilisateurs principaux (c.-à-d., qu'ils ont la priorité) pour les bandes 5250-5350 MHz et 5650-5860 MHz, et ces radars pourraient causer du brouillage et/ou des dommages aux dispositifs LAN-EL.

RF exposure information

The Portrait™ Hub01 and Portrait™ SBT01 have been tested and meet the applicable limits (RED EN 50566:2017, FCC 47CFR §2.1093 and ISED RSS-102, Issue 5) for radio frequency exposure (Specific Absorption Rate, SAR). The SAR refers to the rate at which the body absorbs RF energy. The highest reported SAR values for Portrait™ Hub01 and Portrait™ SBT01 are as follows:

- Portrait™ Hub01:
  - Body SAR 1.42 W/kg (limit 1.6 W/kg over 1 g of tissue)
  - Body SAR 1.15 W/kg (limit 2.0 W/kg over 10 g of tissue)
  - Limb SAR 1.15 W/kg (limit 4.0 W/kg over 10 g of tissue)
- Portrait™ SBT01
  - Body SAR 0.91 W/kg (limit 1.6 W/kg over 1 g of tissue)
  - Body SAR 0.33 W/kg (limit 2.0 W/kg over 10 g of tissue)

Technical specifications, Hub

Size (H x W x D)	14.1 x 6.3 x 2.1 cm (5.6 x 2.5 x 0.8 in)
Weight	223 g (0.5 lb)
Operating temperature	0 to 35°C (32 to 95°F)
Operating humidity	5 to 95% RH non-condensing
Operating pressure	620 to 1060 hPa
Storage temperature	-20 to 40°C (–4 to 104°F)
Transport temperature	-20 to 50°C (–4 to 122°F)
Storage and transport humidity	5 to 95% non-condensing
Storage and transport pressure	500 to 1060 hPa
Fluid ingress	IP67
Operating time	16 hours with full battery
Charging time at 25°C	8 hours from empty to full capacity

Technical specifications, charger

Size (H x W x D)	11.5 x 23.8 x 4.3 cm (4.5 x 9.4 x 1.7 in)
Weight	412 g (0.9 lbs) wall mount: 603 g (1.3 lbs) table mount: 908 g (2 lbs)
Operating temperature	0 to 37°C (32 to 98.6°F)
Operating humidity	10 to 90% RH non-condensing
Operating pressure	620 to 1060 hPa
Storage and transport temperature	-20 to 60°C (–4 to 140°F)
Storage and transport humidity	5 to 90% non-condensing
Storage and transport pressure	500 to 1060 hPa

Fluid ingress	IPX2
Power supply	• Type: Switching power adaptor • Model: ACM36US12–XZ1110A • Manufacturer: XP Power™ • Fluid ingress: IPX0 • Rated input voltage: 100 to 240 Vac 50/60 Hz • Rated output voltage: 12 Vdc • Rated output power: 3.0 A • Rated input power: 1.0 A

Technical specifications, sensors

Size (H x W x D)	• SpO2 P-SA01: 27.2 x 5.3 x 1.9 cm (10.7 x 2.1 x 0.7 in) • SpO2 P-SP01: 23.6 x 5.3 x 1.9 cm (9.3 x 2.1 x 0.7 in) • SpO2 P-W01: 26.2 x 5.3 x 1.9 cm (10.3 x 2.1 x 0.7 in) • SpO2 P-SE01: 27.1 x 5.3 x 1.9 cm (10.7 x 2.1 x x 0.7 in) • RR P-RR01: 6.9 x 5.3 x 1.9 cm (2.7 x 2.1 x x 0.7 in)
Weight	• SpO2 P-SA01: 52 g (1.8 oz) • SpO2 P-SP01: 43 g (1.5 oz) • SpO2 P-W01: 38 g (1.3 oz) • SpO2 P-SE01: 38 g (1.3 oz) • RR P-RR01: 34 g (1.2 oz)
Operating temperature	0 to 40°C (32 to 104°F)
Operating humidity	5 to 95% RH non-condensing
Operating pressure	620 to 1060 hPa
Storage and transport temperature	• Sensors: -30 to 70 °C (–22 to 158°F), storage less than 1 month • Respiration patch: storage +10 to 30°C (50 to 86°F) up to 18 months, transport –10 to +50°C (14 to 122°F)
Storage and transport humidity	5 to 95% non-condensing
Storage and transport pressure	500 to 1060 hPa
Fluid ingress	• SpO2 P-SA01, SpO2 P-SP01, and RR P-RR01: IP67 • SpO2 P-W01 and SpO2 P-SE01: IP44

Technical specifications, sensor batteries

Size (H x W x D)	3.6 x 5.3 x 1.7 cm (1.4 x 2.1 x 0.7 in)
Weight	31 g (1.1 oz)

Operating temperature	0 to 40°C (32 to 104°F)
Operating humidity	5 to 95% RH non-condensing
Operating pressure	620 to 1060 hPa
Storage and transport temperature	Storage: -20 to 40°C (–4 to 104°F) Transport: –20 to 50°C (–4 to 122°F)
Storage and transport humidity	5 to 95% non-condensing
Storage and transport pressure	500 to 1060 hPa
Fluid ingress	IP67
Operating time	32 hours with full capacity
Charging time at 25°C	5 hours from empty to full capacity

Technical specifications, alarming unit

Size (H x W x D)	16.8 x 6.8 x 4.8 cm (6.6 x 2.7 x 1.9 in)
Weight	268 g (9.5 oz)
Operating temperature	0 to 40°C (32 to 104°F)
Operating humidity	5 to 95% RH non-condensing
Operating pressure	620 to 1060 hPa
Storage and transport temperature	-40 to 70°C (–40 to 158°F)
Storage and transport humidity	5 to 95% non-condensing
Storage and transport pressure	500 to 1075 hPa
Fluid ingress	IPX1

Minimum requirements, Central Viewer

Computer requirements

Ports	Digital Video Interface (HDMI or DisplayPort) (required if display is not built into the computer) One Gigabit Ethernet port (minimum) Three USB ports (USB 2.0 or greater) (minimum)
Accessories	Language-specific keyboard (hardwired preferred) Mouse (hardwired preferred)
Processor type	Intel Core i5, i7, i9
Processor speed	2.7 GHz (minimum)

RAM	8 GB (minimum) 16 GB preferred
Storage type	SSD preferred
Storage size	120 GB (minimum)
Free disk space	1 GB (minimum)

Monitor requirements

Size	20 inches (50 cm) (minimum)
Resolution	1920 x 1080 (minimum)
Refresh rate	60 Hz (minimum)
Ports	Digital Video Interface (HDMI or DisplayPort) (required if display is not built into the computer)

Operating system requirements

Operating system type	Windows 10 Professional (minimum)
Operating system version	10.0.17763 (minimum)
Display settings	1920 x 1080 (exact) 60 Hz refresh rate (minimum)

Technical specifications, EHL Platform

Refer to the documentation delivered with the server hardware.

20 Alarm specifications

Auditory alarm volume, IEC tones

Tested in accordance with IEC 60601-1-8 subclause 6.3.3.2 with alarm volume control set to maximum level (100%) and minimum level (10%)..

Alarming unit

Alarm volume setting	Maximum sound pressure level
100%	High priority alarm: 68 dB(A) Medium priority alarm: 67 dB(A) Low priority alarm: 56 dB(A)
70%	High priority alarm: 61 dB(A) Medium priority alarm: 60 dB(A) Low priority alarm: 52 dB(A)
10%	High priority alarm: 46 dB(A) Medium priority alarm: 42 dB(A) Low priority alarm: 37 dB(A)

Hub

Alarm volume setting	Maximum sound pressure level
100%	High priority alarm: 63 dB(A) Medium priority alarm: 61 dB(A) Low priority alarm: 50 dB(A)
70%	High priority alarm: 54 dB(A) Medium priority alarm: 53 dB(A) Low priority alarm: 39 dB(A)
10%	High priority alarm: 36 dB(A) Medium priority alarm: 36 dB(A) Low priority alarm: 27 dB(A)

Audio alarm sound tolerances

Tolerances for sounds (total pulse duration with rise and fall times) are:

- Time < 5 s: ±5%

- Time ≥ 5 s: ±1 s
- Frequencies: ±5 Hz

IEC alarm tone sound patterns

Priority	Corresponding sound pattern
High	• Beep “C” (523 Hz/100 ms) Silence (100 ms) • Beep “F” (698 Hz/100 ms) Silence (100 ms) • Beep “G” (784 Hz/100 ms) Silence (300 ms) • Beep “A” (880 Hz/100 ms) Silence (100 ms) • Beep “B” (988 Hz/100 ms) Silence (1 s) • Beep “C” (523 Hz/100 ms) Silence (100 ms) • Beep “F” (698 Hz/100 ms) Silence (100 ms) • Beep “G” (784 Hz/100 ms) Silence (300 ms) • Beep “A” (880 Hz/100 ms) Silence (100 ms) • Beep “B” (988 Hz/100 ms) Silence (5 s)
Medium	• Beep “C” (523 Hz/200 ms (Silence (200 ms) • Beep “G” (784 Hz/200 ms) Silence (200 ms) • Beep “B” (988 Hz/200 ms) Silence (19 s)
Low	Beep “C” (523 Hz/200 ms) Silence (25 s)

Auditory information signal characteristics

Measurement and start-up related information signals		
Signal	**Frequency (Hz)**	**Duration (ms)**
Start-up sound	523	200
Power failure (alarming unit)	2700 ±300	500
Communication failure (alarming unit)	2700 ±300	200

Alarm delay specifications

The disclosed alarm system delays are measured by simulator or respective methods, which represent optimal signals. Possible interferences and poor quality signals in a clinical environment may extend the disclosed alarm system delays.

The alarm generation consists of two components: the delay to detect the alarm condition by the algorithm and the constant signal generation delay. Both of these components are included in each alarm system delay. For some alarms, the signal generation delay is configurable. The measurements are done using the default adult alarm delay.

The Hub sends the alarm to the network simultaneously as it generates the local alarm signals. The additional delay from the alarm signal generation on the Hub to the alarm signal generation at the Central Viewer is typically <2 s. If the connection is

lost, ***Network connection lost*** alarms are generated on the Hub and on the Viewer (delays reported below).

The determination of an alarm condition has nominal factors (such as signal quality and movement artifact) that may affect the ability to derive the parameter value.

The following disclosures list the alarm system delays as an average and include the delay of the first activated priority alarm.

Alarms with alarm delays of more than 10 s are specified with the average, minimum, and maximum values obtained from five trial measurements.

NOTE Any alarm delays that are less than 5 s are given as <5 s.

Alarm delay specifications for impedance respiration alarms

The following table lists the alarm delays for physiological alarms related to the impedance respiration measurement. Any alarm delays that are less than 5 s are given as <5 s.

Physiological alarms

Alarm	Limit range	Limit increment	Alarm delay
Apnea	10 to 60 s	1 s	32 s (average) (32 to 32 s range)
RR high	4 to 80 breaths per minute	1 breath per minute	32 s (average) (32 to 33 s range)
RR low	4 to 80 breaths per minute	1 breath per minute	24 s (average) (24 to 25 s range)

Technical alarms

Alarm	Alarm delay
Change Resp battery	50 s (average) (45 to 57 s range)
Check Resp patch	30 s (average) (30 to 31 s range)
Clean Resp battery interface	<5 s
No Resp battery	<5 s
Resp battery low	48 s (average) (41 to 55 s range)
Resp connection lost	10 s (average) (9 to 10 s range)
Resp device overheating	<5 s
Weak Resp connection	<5 s

Alarm delay specifications for SpO_2 and PR alarms

The following table lists the alarm delays for physiological alarms related to the pulse oximetry and pulse rate measurements. Any alarm delays that are less than 5 s are given as <5 s.

The alarm delay is the sum of the alarm condition delay and a user-configurable alarm signal generation delay. In the measurements performed to obtain these readings the signal generation delay was the adult default setting:

- 20 s for ***PR high***, ***PR low***, and ***SpO2 high***
- 60 s for ***SpO2 low***
- 0 s for ***SpO2 critically low***

Physiological alarms

Alarm	Limit range	Limit increment	Alarm delay
PR high	10 to 120 beats per minute	1 beat per minute	45 s (average) (45 to 46 s range)
PR low	30 to 240 beats per minute	1 beat per minute	40 s (average) (40 to 40 s range)
SpO2 high	70 to 100%	1%	19 s (average) (19 to 20 s range)
SpO2 low	70 to 100%	1%	33 s (average) (32 to 33 s range)
SpO2 critically low	1 to 15%	1%	14 s (average) (13 to 14 s range)

Technical alarms

Alarm	Alarm delay
Check SpO2 probe	29 s (average) (29 to 30 s range)
SpO2 probe off	33 s (average) (33 to 34 s range)
Faulty SpO2 probe	<5 s
SpO2 battery low	54 s (average) (54 to 55 s range)
Change SpO2 battery	46 s (average) (37 to 54 s range)
Clean SpO2 battery interface	<5 s
No SpO2 battery	<5 s
Weak SpO2 connection	<5 s
SpO2 connection lost	10 s (average) (9 to 10 s range)
SpO2 device overheating	<5 s

Alarm delay specifications for technical issues

The following table lists the alarm delays for technical alarms. Any alarm delays that are less than 5 s are given as <5 s.

Alarm	Alarm delay
Charge Hub	<5 s
Hub battery low	<5 s
Hub charging failure	<5 s
Network connection lost (Hub)	WLAN connection lost: 33 s (average) (32 to 33 s range) Connection to Central Viewer lost: 193 s (average) (187 to 204 s range)
Network connection lost (Central Viewer)	37 s (average) (37 to 38 s range)

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Parameter specifications

SpO_2 displayed saturation values

Portrait™ pulse oximetry technology is 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 80601-2-61:2017 Annex FF (Simulators, calibrators and functional testers for pulse oximeter equipment).

SpO_2 summary of clinical studies used to establish accuracy claims

Accuracy of Portrait™ sensor technology

The Portrait technology with Portrait sensors P-SA01, P-SP01, P-SE01, and P-W01 has 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 a laboratory co-oximeter. Subjects comprised both healthy adult men and women and spanned a range of ages and skin pigmentations.

For more detailed information, refer to the supplemental analysis graphs (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

Portrait™ technology with Portrait sensors P-SA01, P-SP01, P-SE01, and P-W01 has been validated for motion accuracy in controlled hypoxia studies with healthy non-smoking adult volunteers over the specified saturation SpO_2 range(s). The motion artifact was induced by the subject and was non-repetitive with frequency varying between 1 to 5Hz. The following motion types were used: tapping motion, rubbing/clenching motion with hand in prone and supine positions. The infrared signal amplitude in motion periods was in average 2.5 times the signal amplitude in no motion periods. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by CO-oximetry. Subjects comprised both adult men and women and spanned a range of skin pigmentations.

SpO_2 test methods used to establish accuracy claims during low perfusion

Portrait™ technology with Portrait sensors P-SA01, P-SP01, P-W01, and P-SE01 has been validated for SpO_2 low perfusion accuracy in bench top testing using a Fluke Biomedical ProSim™ 8 Vital Signs Simulator with signal strength setting of 0.2% modulation and oxygen saturation levels of 70 to 100% at a pulse rate of 90 bpm.

SpO_2 test methods used to establish pulse rate accuracy

Portrait™ technology with Portrait sensors P-SA01, P-SP01, P-W01, and P-SE01 has been validated for pulse rate accuracy in bench top testing using a Fluke Biomedical ProSim™ 8 Vital Signs Simulator at 0.2% modulation in the pulse rate range of 30 to 250 beats per minute (bpm) at SpO_2 of 90%.

SpO_2 performance specifications

The following specifications apply to all SpO_2 sensors.

SpO_2 measurement value and display range	0 to 100%
SpO_2 measurement value accuracy	The accuracy is specified in terms of the root-mean-square (RMS) difference between the measured values and the reference values (A_{rms}). 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. For more detailed information, refer to the SpO_2 supplemental analysis graphs. • SpO_2 (70 to 100%): ≤2% • Low perfusion SpO_2 (70 to 100%): ≤3% • With motion: SpO_2 (70 to 100%): ≤3%
SpO_2 display resolution	1 digit (% of SpO_2)
Wavelength of SpO_2 sensor LEDs	This information can be especially useful to clinicians such as those performing photodynamic therapy. Pulse oximetry sensor LED peak wavelengths are within 600 to 1000 nm and the maximum optical output power for each LED is less than 15 mW.
Pulse oximetry peripheral pulse rate measurement (PR) display range	30 to 300 beats per minute
Pulse oximetry peripheral pulse rate accuracy (A_{rms})	• ≤2 bmp (30 to 250 bpm) • Low perfusion: ≤2 bmp (30 to 250 bpm) • With motion: ≤5 bmp (30 to 250 bpm)
Pulse oximetry peripheral pulse rate display resolution	1 bpm
Pulse oximetry SpO_2 and pulse rate measurement data update period	< 30 s

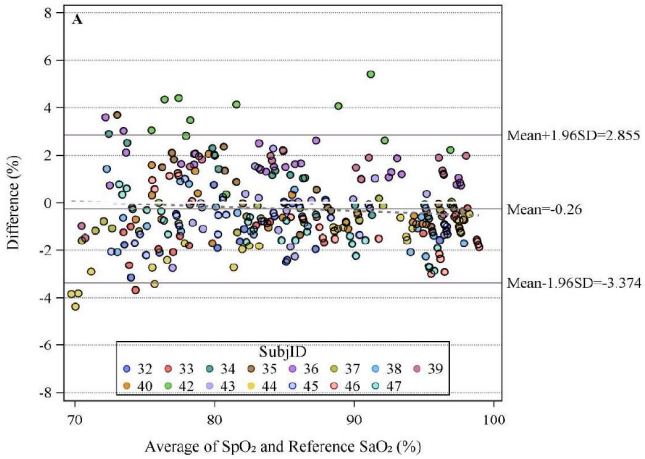
SpO_2 supplemental analysis graphs

Additional accuracy information for Portrait™ sensors

The table information provides supplemental data analysis for Portrait sensors' measurement accuracy.

The following modified Bland-Altman plots show SpO_2 data by sensor type.

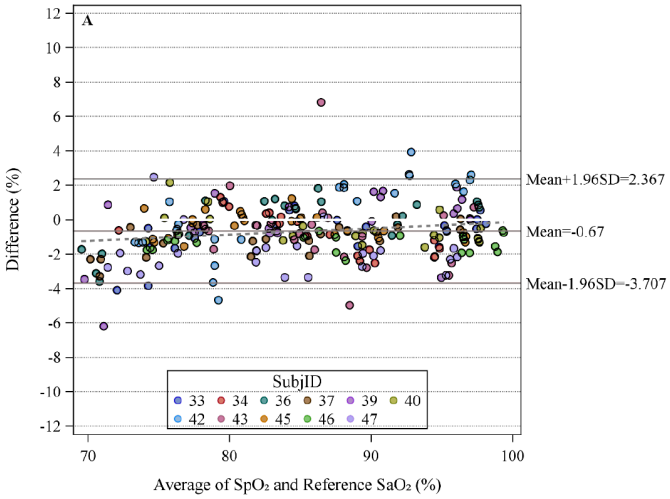
Bland-Altman plot for SpO_2 - P-SA01 sensor, non-motion



SpO_2 - P-SA01 sensor measured accuracy, non-motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
1.888	1.696	1.611

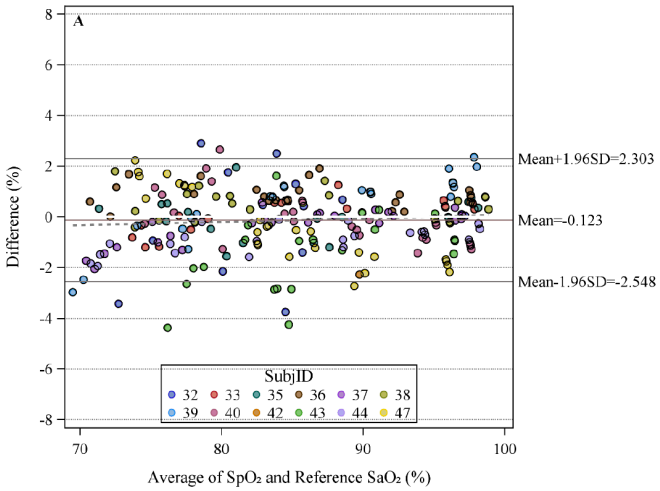
Bland-Altman plot for SpO_2 - P-SA01 sensor, motion



SpO_2 - P-SA01 sensor measured accuracy, motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
1.687	1.553	1.497

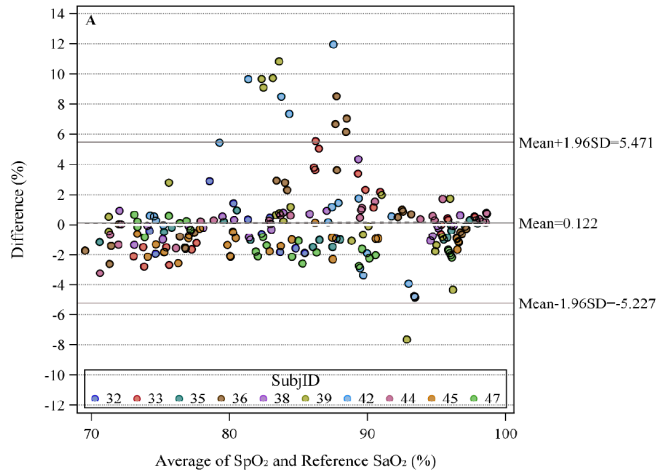
Bland-Altman plot for SpO_2 - P-SP01 sensor, non-motion



P-SP01 sensor accuracy, non-motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
1.48	1.383	1.185

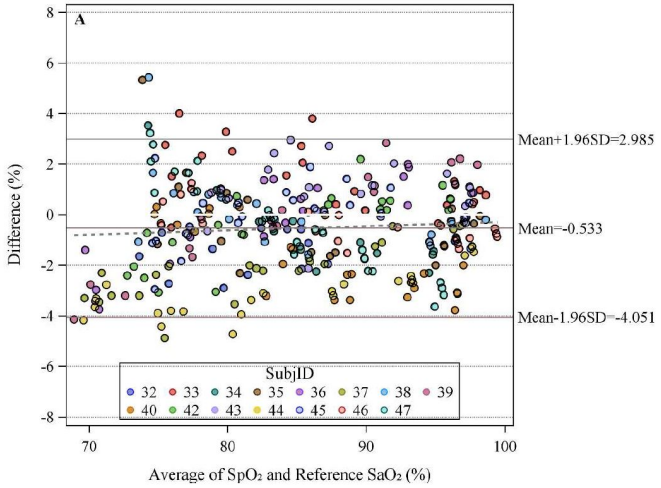
Bland-Altman plot for SpO_2 - P-SP01 sensor, motion



P-SP01 sensor accuracy, motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
1.312	3.639	2.654

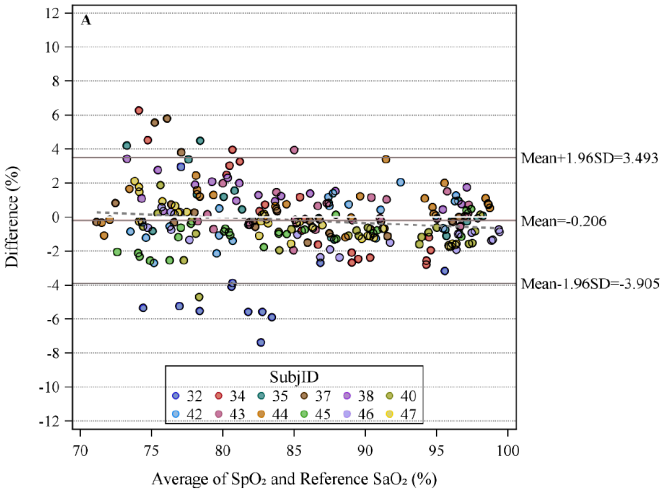
Bland-Altman plot for SpO_2 - P-W01 sensor, non-motion



P-W01 sensor accuracy, non-motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
2.169	1.638	1.525

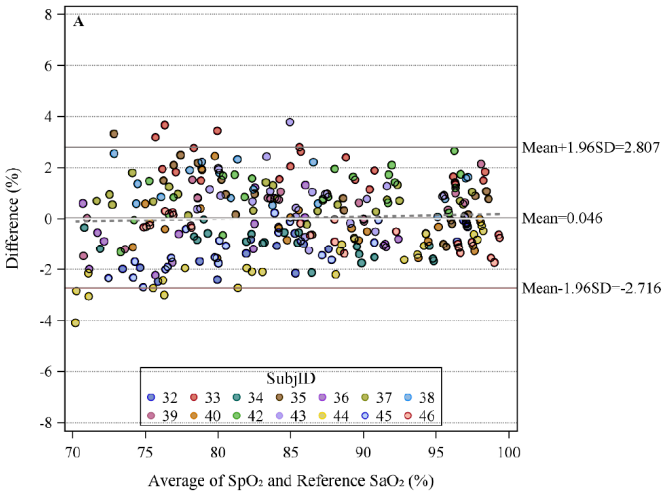
Bland-Altman plot for SpO_2 - P-W01 sensor, motion



P-W01 sensor accuracy, motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
2.625	1.739	1.237

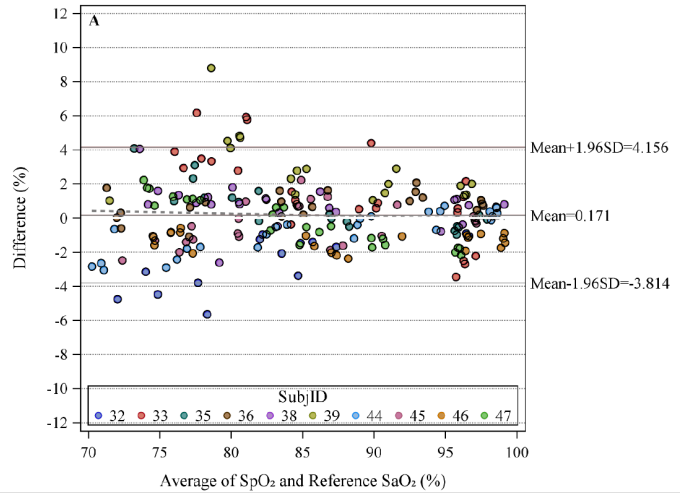
Bland-Altman plot for SpO_2 - P-SE01 sensor, non-motion



P-SE01 sensor accuracy, non-motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
1.669	1.348	1.121

Bland-Altman plot for SpO_2 - P-SE01 sensor, motion



P-SE01 sensor accuracy, motion

Accuracy 70-80% (Arms)	Accuracy 80-90% (Arms)	Accuracy 90-100% (Arms)
2.261	2.287	1.391

Impedance respiration performance specifications

Impedance respiration measurement value and display range	0 to 99 breaths per minute
Impedance respiration measurement accuracy	4 to 60 breaths per minute: ±3 breaths per minute
Impedance respiration measurement precision	1 breath per minute
Impedance respiration measurement input impedance range	100 Ω to 1850 Ω
Impedance respiration measurement total current applied to patient	<100 µArms

22

Abbreviations

List of abbreviations

The following abbreviations appear in the software or in the device manuals.

Abbreviation	Explanation
Apr	April
Aug	August
BF	Type BF: Applied parts electrically connected to the patient, but not directly to the heart
bpm	Beats per minute
CF	Type CF: Applied parts electrically connected to the heart of the patient
Dec	December
EAS	Electronic article surveillance
ECG	Electrocardiogram
EMC	Electromagnetic compatibility
EMI	Electromagnetic interference
ESD	Electrostatic discharge
Feb	February
Hb	Hemoglobin
HbO_2	Oxygen carrying hemoglobin
Hz	hertz
ID	Identifier
IrMod%	Infrared modulation percentage
Jan	January
Jul	July
Jun	June
LED	Light emitting diode
Mar	March
May	May
MBAN	Medical Body Area Network

Abbreviation	Explanation
MR, MRI	Magnetic resonance imaging
NFC	Near field communication
Nov	November
O_2	Oxygen
Oct	October
$PaCO_2$	Partial pressure of carbon dioxide in the arteries
pH	Hydrogen ion concentration
PR	Pulse rate
PURW	Purified water
RF	Radio frequency
RFID	Radio-frequency identification
RR	Respiration rate
SaO_2	Arterial oxygen saturation
Sep	September
SpO2	Arterial blood oxygen measured with pulse oximetry
SQI	Signal quality indicator
WLAN	Wireless local area network

A

Skills checklist

Safety

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
SYSTEM SAFETY PRECAUTIONS • System warnings (22) • System cautions (30)		
OPERATION SAFETY PRECAUTIONS • Operation warnings (25) • Operation cautions (30)		
ALARM SAFETY PRECAUTIONS • Alarm warnings (27) • Alarm cautions (30)		
ACCESSORIES SAFETY PRECAUTIONS • Accessories warnings (28)		
BATTERY SAFETY PRECAUTIONS • Battery warnings (28)		
CARE SAFETY PRECAUTIONS • Care warnings (28)		
RESPIRATION SAFETY PRECAUTIONS • Respiration warnings (29) • Respiration cautions (31)		
SpO_2 SAFETY PRECAUTIONS • SpO_2 warnings (29) • Respiration cautions (31)		

Recommended reading	Completed	Not applicable
DISPOSAL SAFETY PRECAUTIONS • Disposal cautions (31)		
SYMBOLS AND MARKINGS • Safety symbols (21) • Equipment markings (34)		

System introduction

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
SHORT DESCRIPTION OF THE SYSTEM • Short description of the system (41)		
SYSTEM COMPONENTS • System components (42)		
CORE SERVICES, CENTRAL VIEWER AND ALARMING UNIT • Core Services overview (43) • Central Viewer and alarming unit overview (43) • Introduction to the Central Viewer (43) • Introduction to the alarming unit (44)		
HUB AND SENSORS • Hub and sensors overview (45) • Introduction to the Hub (47) • LED indicators on the Hub (48) • Hub vibration and audio indications (48) • Introduction to the sensors (49)		
SENSOR BATTERIES AND CHARGER • Introduction to sensor batteries (49) • Introduction to the charger (49)		

Graphical user interface

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
USER INTERFACE INDICATORS • User interface indicators (51)		
CENTRAL VIEWER • Multiple Patient View (53) • Single Patient View (53)		
HUB • Hub screen elements (55) • Hub locked view (56) • Hub passcode view (58) • Hub patient list (58) • Hub patient details (58) • Hub LIVE view (59) • Hub detailed view (60) • Hub menu (61)		

Configuration

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
• About configuration settings (177) • Config UI Patient default profiles configuration (177)		

Managing patients and monitoring

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
ADMISSION AND DEMOGRAPHICS • Admitting a patient (63) • Editing patient demographics (64)		
PATIENT SELECTION • Powering on the Hub (65) • Unlocking the Hub screen (65) • Selecting a patient (66)		
MEASUREMENT DEVICES • Attaching measurement devices to the patient (67)		

Recommended reading	Completed	Not applicable
SENSOR PAIRING AND UNPAIRING • Pairing the first sensor (67) • Pairing another sensor (68) • Unpairing a sensor (69)		
PATIENT AND BED CHANGE • Moving a patient to a new bed (69)		
ENDING MONITORING AND DISCHARGE • Unassigning the patient from the Hub (70) • Shutting down the Hub (70) • Discharging a patient (71)		

Battery management

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
SENSOR AND HUB BATTERIES • Connecting and disconnecting sensor batteries (73) • LED indicators on sensor batteries (73) • About Hub and sensor batteries (75)		
CHARGING BATTERIES • LED indicators on the charger (75) • Charging batteries (76) • Charging an empty sensor battery (77)		
CHECKING BATTERIES • Checking the Hub battery status (77) • Checking the status of a sensor battery (78)		
CHANGING A SENSOR BATTERY • Changing a sensor battery (78)		
BATTERY RECYCLING • Battery recycling (79)		

Hub modes

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
• About modes (81) • Selecting the use mode (81)		

Alarms

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
ABOUT ALARMS • Alarm conditions (83) • Alarm priority levels (83) • Active alarms (83)		
ALARM INDICATORS • Visual alarm indicators (84) • Auditory alarm indicators (85)		
ALARM SETTINGS • Alarm settings on the Central Viewer (85) • Adjusting alarm limit settings (85) • Adjusting alarm volume on the Central Viewer (86) • Adjusting alarm volume on the Hub (86)		
ALARM ACKNOWLEDGEMENT • Alarm acknowledgement (87) • Acknowledging alarms (87) • Reactivating alarms (88)		
CHECKING ALARM FUNCTION • Checking alarm function (88)		

Parameter filtering and signal quality

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
• Parameter filtering (91) • Signal quality indicator (SQI) (91)		

Impedance respiration

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
ABOUT THE MEASUREMENT • Respiration measurement limitations (94) • Respiration measurement description (94) • Respiration points to note (95)		
MEASUREMENT SETUP • Preparing the patient's electrode sites (96) • Starting the respiration measurement (96) • Preparing the patient's electrode sites (96) • Removing respiration electrodes (98)		

Pulse oximetry and pulse rate

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
ABOUT THE MEASUREMENT • SpO_2 and pulse rate measurement limitations (100) • SpO_2 measurement description (100) • SpO_2 and pulse rate measurement interference (101) • SpO_2 waveform quality (101) • SpO_2 and pulse rate measurement practicalities (102) • SpO_2 and pulse rate points to note (102)		
MEASUREMENT SETUP • SpO_2 and pulse rate measurement setup (103) • Preparing the SpO_2 and pulse rate connection (103) • Starting the SpO_2 and pulse rate measurement (103) • Checking the SpO_2 and pulse rate measurement (105)		

Trends

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
TRENDS ON THE CENTRAL VIEWER • About trends on the Central Viewer (107) • Viewing trends on the Central Viewer (107) • Using the trend cursor on the Central Viewer (108)		
TRENDS ON THE HUB • About trends on the Hub (109) • Viewing trends on the Hub (109) • Using the trend cursor on the Hub (110)		

Cleaning, disinfection, and care

To familiarize yourself with these functions and features, study the topics listed as recommended reading. The numbers in brackets refer to the page numbers in the manual. As you proceed, mark your completed tasks in the table.

Recommended reading	Completed	Not applicable
GENERIC INSTRUCTIONS • Cleaning, disinfection, and care overview (113) • Visual inspection, cleaning, and disinfection frequency (113)		
CLEANING INSTRUCTIONS • Cleaning points to note (114) • Permitted detergents (114)		
CLEANING THE HUB • Cleaning procedure for the Hub (115) • Preparing the Hub for cleaning (115) • Cleaning the Hub (116)		
CLEANING THE RESPIRATION SENSOR • Cleaning procedure for the respiration sensor (117) • Preparing the respiration sensor for cleaning (118) • Cleaning the respiration sensor (118)		
CLEANING THE SpO_2 SENSORS • Cleaning procedure for the SpO_2 sensors (119) • Preparing the SpO_2 sensors for cleaning (120) • Cleaning the SpO_2 sensors (120)		
CLEANING THE BATTERIES • Cleaning procedure for sensor batteries (122) • Preparing a sensor battery for cleaning (122) • Cleaning sensor batteries (122)		

Recommended reading	Completed	Not applicable
CLEANING THE CHARGER • Cleaning procedure for the charger (124) • Preparing the charger for cleaning (124) • Cleaning the charger (124)		
CLEANING THE ALARMING UNIT • Cleaning procedure for the alarming unit (125) • Preparing the alarming unit for cleaning (125) • Cleaning the alarming unit (126)		
DISINFECTION INSTRUCTIONS • Disinfection points to note (126) • Permitted disinfectants (127) • Disinfection procedure (127) • Disinfecting the devices (127)		
CARE INSTRUCTIONS • Care schedules (128)		

B

Quick workflow overview

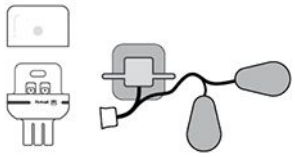
Quick workflow instructions

These instructions are NOT meant to be sufficient guidance for using the system. Before starting monitoring, ensure that you have read and understood the manual.

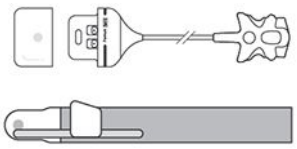
1.

2.

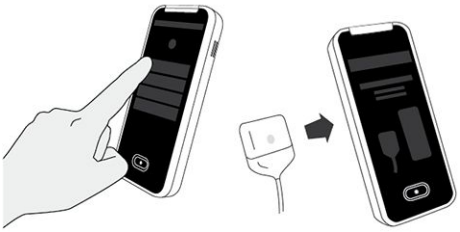
2 a



2 b



3.



4.

1. Admit a new patient on the Central Viewer.
2. Attach the Wearable SpO_2 and RR Parameters to the patient (2 a sensor battery, respiration sensor, respiration patch; 2 b sensor battery, SpO_2 sensor; attachment band)
3. Select the patient on the Hub and pair sensors to the Hub.
4. Ensure that measurement data is visible locally on the Hub at the patient bedside and remotely on the Central Viewer.

C

Default settings and configuration

About configuration settings

There are certain system default configuration settings that are available for an authorized clinical user. These settings can be found in Config UI > ***Configuration*** > ***Default Profiles*** > ***Patient***, and they are password-protected.

Certain settings have different defaults per ***Care profile*** (***Age 3-4***, ***Age 5-6***, ***Age 7-12***, ***Age 13-17***, ***Adult***). Changes to the patient default profiles are not available to already admitted patients. The changes made will be applied to the next admitted patient after the changes have been saved.

The Config UI includes many other settings as well, but they are only available with service access rights.

WARNING PATIENT SAFETY. In case the Hub does not receive a configuration from the Core Services for some reason, it will use the factory defaults. Always check the settings to ensure patient safety.

Config UI Patient default profiles configuration

Navigate to Config UI > ***Configuration*** > ***Default Profiles*** > ***Patient***.

NOTE When the system is first installed, the care profile defaults in the patient default settings are customized for the age-specific profiles. Selecting ***Reset All*** for a care profile will reset them to the common ***Facility***-level settings. If you wish to revert them back to the factory default settings, you need to enter those factory default values manually.

Setting	Description	Unit of measure	Options	Default value
Alarm settings				
Enable timed alarm acknowledgement		n/a	***Yes*** or ***No***	***Yes***
Alarm acknowledgement time	Not adjustable. Duration for timed alarm acknowledge-ment.	***Seconds***	n/a	120

Setting	Description	Unit of measure	Options	Default value
Alarm volume - Hub		***Percent***	0, 10, 20, 30, 40, 50, 60, 70, 80, 90, 100	100
Mode settings				
Hub monitoring mode		n/a	***Local| Remote***	***Local***
Resp limit alarms				
RR high - alarm on	Not adjustable.	n/a	n/a	***Yes***
RR high - alarm limit	Select the threshold alarm limit for the ***RR high*** alarm.	***Breath/Min***	4 to 80	***Age 3-4***: 40 ***Age 5-6***: 30 ***Age 7-12***: 30 ***Age 13-17***: 30 ***Adult***: 30 ***Facility***: 30
RR high - alarm priority	Select the priority level for the ***RR high*** alarm.	n/a	***High| Medium| Low| Info***	Low
RR high - alarm delay	Select the delay after which the ***RR high*** alarm is triggered.	***Seconds***	15, 30, 90, or 120	***Age 3-4***: 15 ***Age 5-6***: 15 ***Age 7-12***: 15 ***Age 13-17***: 15 ***Adult***: 30 ***Facility***: 15
RR low - alarm on	Not adjustable.	n/a	n/a	***Yes***
RR low - alarm limit	Select the alarm limit for the ***RR low*** alarm.	***Breath/Min***	4 to 80	***Age 3-4***: 15 ***Age 5-6***: 15 ***Age 7-12***: 10 ***Age 13-17***: 8 ***Adult***: 8 ***Facility***: 15
RR low - alarm priority	Select the priority level for the ***RR low*** alarm.	n/a	***High| Medium| Low| Info***	***Medium***
RR low - alarm delay	Select the delay after which the ***RR low*** alarm is triggered.	***Seconds***	5, 10, 15, 20, or 30	***Age 3-4***: 5 ***Age 5-6***: 5 ***Age 7-12***: 10 ***Age 13-17***: 10 ***Adult***: 15 ***Facility***: 5
Apnea - alarm on	Not adjustable.	n/a	n/a	***Yes***

Setting	Description	Unit of measure	Options	Default value
Apnea - limit	Select the time after which the ***Apnea*** alarm is triggered.	***Seconds***	10 to 120	20
Apnea - alarm priority	Select the priority level for the ***Apnea*** alarm.	n/a	***High/Medium***	***High***
Resp settings				
RR averaging time		***Seconds***	0 to 60	10
SpO2 & PR limit alarms				
SpO2 high - alarm on	Select whether or not the ***SpO2 high*** alarm is enabled (on or off).	n/a	***Yes*** or ***No***	***No***
SpO2 high - alarm limit	Select the threshold alarm limit for the ***SpO2 high*** alarm.	***Percent***	70 to 100	100
SpO2 high - alarm priority	Select the priority for the ***SpO2 high*** alarm.	n/a	***High| Medium| Low| Info***	***Medium***
SpO2 high - alarm delay	Select the delay after which the ***SpO2 high*** alarm is triggered.	***Seconds***	5, 10, 15, 20, or 30	***Age 3-4***: 10 ***Age 5-6***: 10 ***Age 7-12***: 15 ***Age 13-17***: 20 ***Adult*** ***Facility***: 10
SpO2 low - alarm on	Not adjustable.	n/a	n/a	***Yes***
SpO2 low - alarm limit	Select the threshold alarm limit for the ***SpO2 low*** alarm.	***Percent***	70 to 100	90

Setting	Description	Unit of measure	Options	Default value
SpO2 low - alarm priority	Select the priority for the ***SpO2 low*** alarm. If you set the priority value so low that it deviates from the recommendation of international alarm safety standards, the value will be accompanied by ⚠ and a warning message appears.	n/a	***High| Medium| Low| Info***	***Medium***
SpO2 low - alarm delay	Select the delay after which the ***SpO2 low*** alarm is triggered. If the ***SpO2 critically low*** alarm is triggered before the ***SpO2 low*** alarm delay has expired, these two alarms are triggered simultaenously.	***Seconds***	5, 10, 15, 20, 30, 60, or 90	***Age 3-4***: 20 ***Age 5-6***: 20 ***Age 7-12***: 30 ***Age 13-17***: 60 ***Adult***: 60 ***Facility***: 20
SpO2 critical low (% points below set SpO2 low limit)	Delta setting that should be used against the ***SpO2 low*** limit for determining the critical low limit setting.	***Percent***	1 to 15	***Age 3-4***: 3 ***Age 5-6***: 3 ***Age 7-12***: 3 ***Age 13-17***: 6 ***Adult***: 6 ***Facility***: 3
SpO2 critical low - alarm priority	Not adjustable. This is the priority for the ***SpO2 critically low*** alarm.	n/a	n/a	***High***
PR high - alarm on	Not adjustable.	n/a	n/a	***Yes***

Setting	Description	Unit of measure	Options	Default value
PR high - alarm limit	Select the threshold alarm limit for the ***PR high*** alarm.	***Beats/Min***	30 to 240	***Age 3-4***: 140 ***Age 5-6***: 140 ***Age 7-12***: 140 ***Age 13-17***: 150 ***Adult***: 150 ***Facility***: 140
PR high - alarm priority	Select the priority for the ***PR high*** alarm.	n/a	***High| Medium| Low| Info***	***Medium***
PR high - alarm delay	Select the delay after which the ***PR high*** alarm is triggered.	***Seconds***	5, 10, 15, 20, or 30	***Age 3-4***: 15 ***Age 5-6***: 15 ***Age 7-12***: 15 ***Age 13-17***: 20 ***Adult***: 20 ***Facility***: 15
PR low - alarm on	Not adjustable.	n/a	n/a	***Yes***
PR low - alarm limit	Select the threshold alarm limit for the ***PR low*** alarm.	***Beats/Min***	30 to 240	***Age 3-4***: 60 ***Age 5-6***: 60 ***Age 7-12***: 50 ***Age 13-17***: 50 ***Adult***: 50 ***Facility***: 60
PR low - alarm priority	Select the priority for the ***PR low*** alarm.	n/a	***High| Medium| Low| Info***	***Medium***
PR low - alarm delay	Select the delay after which the ***PR low*** alarm is triggered.	***Seconds***	5, 10, 15, 20, or 30	***Age 3-4***: 15 ***Age 5-6***: 15 ***Age 7-12***: 15 ***Age 13-17***: 20 ***Adult***: 20 ***Facility***: 15
SpO2 & PR settings				
SpO2 averaging time	Select the time for SpO_2 averaging.	***Seconds***	0 to 60	10
PR averaging time	Select the time for PR averaging.	***Seconds***	0 to 60	30

D

Compatible devices

Hub (HUB01) compatibility

The Portrait™ Mobile Patient Monitor HUB01 is compatible with the following Portrait™ Mobile Monitoring Solution components:

- Portrait™ CSS01, Core Services
- Portrait™ CVA01, Central Viewer Application
- Portrait™ SpO2 P-SA01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SP01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-W01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SE01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ RR P-RR01, Wearable Respiration Rate Sensor
- Portrait™ RRP01, RR Electrode Patch
- Portrait™ SBT01, Sensor Battery
- Portrait™ BCH01, Bedside Charger
- Portrait™ MMP01, Mobile Patient Monitor Pouch
- Portrait™ Software Service Tool

SpO_2 sensor (SpO2 P-SA01, P-SP01) compatibility

The Portrait™ SpO2 P-SA01 and Portrait™ SpO2 P-SP01 Wearable Pulse Oximetry Sensors are compatible with the following products:

- Portrait™ SBT01, Sensor Battery
- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ Software Update Cable
- Portrait™ Software Service Tool
- Portrait™ AAB01, SpO2 Attachment Accessory Band

SpO_2 sensor (P-SE01) compatibility

The Portrait™ SpO2 P-SE01 Wearable Pulse Oximetry Sensor with small wrap is compatible with the following products:

- Small replacement foam wrap, TS-RWS
- Medium replacement foam wrap, TS-RWM
- Replacement tape, TS-RTW
- Portrait™ SBT01, Sensor Battery
- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ Software Update Cable
- Portrait™ Software Service Tool
- Portrait™ AAB01, SpO2 Attachment Accessory Band

SpO_2 sensor (P-W01) compatibility

The Portrait™ SpO2 P-W01 Wearable Pulse Oximetry Sensor with large wrap is compatible with the following products:

- Large replacement foam wrap, TS-RWL
- Replacement tape, TS-RTW
- Portrait™ SBT01, Sensor Battery
- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ Software Update Cable
- Portrait™ Software Service Tool
- Portrait™ AAB01, SpO2 Attachment Accessory Band

Respiration rate sensor (P-RR01) compatibility

The Portrait™ RR P-RR01 Wearable Respiration Rate Sensor is compatible with the following products:

- Portrait™ SBT01, Sensor Battery
- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ Software Update Cable
- Portrait™ Software Service Tool
- Portrait™ RRP01, RR Electrode Patch

Sensor battery (SBT01) compatibility

The Portrait™ SBT01 Sensor Battery is compatible with the following products:

- Portrait™ HUB01, Mobile Patient Monitor
- Portrait™ SpO2 P-SA01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SP01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-W01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ SpO2 P-SE01, SpO2 Wearable Pulse Oximetry Sensor
- Portrait™ RR P-RR01, Wearable Respiration Rate Sensor
- Portrait™ BCH01, Bedside Charger
- Portrait™ Software Service Tool

Bedside charger (BCH01) compatibility

The Portrait™ BCH01 Bedside Charger is compatible with the following products:

- Portrait™ SBT01Sensor Battery
- Portrait™ HUB01 Mobile Patient Monitor
- Portrait™ Software Service Tool
- XP Power™ ACM36US12–XZ1110A Power Supply

Alarming unit (CAU01) compatibility

The Portrait™ CAU01 Alarming Unit is compatible with the following products:

- Portrait™ CSS01, Core Services
- Portrait™ CVA01, Central Viewer Application

Mounts compatibility

Portrait™ BWM01 Bedside Charger Wall Mount and Portrait™ BTM01 Bedside Charger Table Mount are compatible with the Portrait™ BCH01 Bedside Charger.

E

Supplies and accessories

List of supplies and accessories

Materials used in accessories are not toxic. Accessories do not contain natural rubber latex.

Product code	Description
TS-RWL	SpO2 Sensor Foam (large)
TS-RWM	SpO2 Sensor Foam (medium)
TS-RWS	SpO2 Sensor Foam (small)
TS-RTW	SpO2 Sensor Tape, disposable
5514246	Portrait™ MMP01 Mobile Patient Monitor Pouch
5514165	Portrait™ AAB01 SpO2 Attachment Accessory Band
5514119	Portrait™ RRP01 RR Electrode Patch

F

Electromagnetic compatibility

IEC 60601-1-2

The system complies with IEC 60601–1–2:2014.

According to parameter-specific standard requirements for ESU (electrosurgical unit) tests, the equipment is protected against malfunction caused by electrosurgery.

EMC warnings

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, including cables specified by the manufacturer. Otherwise the performance of this device/system may degrade.

WARNING DEGRADED PERFORMANCE. Do not use an RFID reader operating at a low frequency such as 134.2 kHz and 13.56 MHz close to any part of the Hub and sensors. Otherwise there is a risk of degraded performance of the impedance respiration measurement.

- Impedance respiration measurement value may be out of the measurement accuracy range and respiration waveform noise may be randomly high when the respiration sensor is too close to such RFID readers. When these RFID emissions are removed, the measurement returns to expected measurement accuracy within 60 seconds without any changes to settings.

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

WARNING LOSS OF MONITORING. To avoid losing the Hub and sensor connectivity and thus patient monitoring, do not use an RFID reader operating at the frequency of 2.45 GHz close to any part of the Hub and sensors.

WARNING LOSS OF MONITORING. 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 system. Consult qualified personnel regarding system configuration.

WARNING LOSS OF MONITORING. Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation due to electrical interference, or to increased equipment temperature due to heat generated by the other equipment . If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally. Consult qualified personnel regarding device/system configuration.

WARNING MR UNSAFE. Do not use the system in an environment containing an MRI magnet to avoid risks to the patient, user, or devices.

WARNING UNEXPECTED SYSTEM BEHAVIOR. Use only approved accessories listed in the product manual. Other accessories may cause unexpected system behavior, damage the equipment or system, result in increased emissions or decreased immunity of the equipment or system, or interfere with the measurement.

About EMC disturbance

NOTE Electromagnetic disturbance may cause, for example, temporary loss of measurement or changes in the values or the appearance of the waveforms (such as excessive noise or a sine wave) on the Portrait Mobile Monitoring Solution.

Essential performance in EMC

The parameter accuracy values in the following table are applicable when the compliance levels listed in the immunity tables of this appendix are used.

When the accuracies listed below cannot be met, the system generates an alarm or recovers to normal operation within 10 or 30 seconds after exposure to transient electromagnetic disturbance, according to the parameter-specific IEC 80601-2-49 and ISO 80601-2-61 standards.

Impedance respiration	
Impedance respiration rate accuracy	±3 breaths per minute (4 to 60 breaths per minute)

SpO_2 essential performance when signal strength is indicated as normal (⋮) and no messages about questionable signal quality are displayed	
Pulse oximetry saturation measurement value accuracy (a root-mean-square difference for adult and pediatric patients per ISO 80601-2-61, Clause 201.12.1.101.1)	SpO_2 (70 to 100%): ±2
Pulse oximetry peripheral pulse rate accuracy (a root-mean-square difference for adult and pediatric patients)	PR (30 to 250 bpm): ±2 bpm

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 Portrait™ CVA01, CAUO1, and HUB01 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	

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 60601–1–2 test level**	**Compliance level**	**Electromagnetic environment — guidance**
Electrostatic Discharge (ESD)	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV,	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV,	Floors should be wood, concrete or ceramic tile. If floors are

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 60601–1–2 test level**	**Compliance level**	**Electromagnetic environment — guidance**
IEC 61000-4-2	± 15 kV air	± 15 kV air	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	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode	± 0.5 kV, ± 1 kV differential 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.		
NOTE	The EHL Platform computer must always be powered from an uninterruptible power supply.		

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[c]	3 Vrms 150 kHz to 80 MHz[a] 25 MHz to 80 MHz[b] 6 Vrms 150 kHz to 80 MHz[c] 25 MHz to 80 MHz[b c]	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
Radiated RF IEC 61000-4-3	3 V/m[d] 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[e] should be less than the compliance level in each frequency range[f]. 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.

[a] Charger and cables for power supply and alarming unit

[b] Respiration patch leadwire cable

[c] 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.

[d] For more information, see section Proximity field immunity compliance.

[e] 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.

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

NOTE SpO2 sensor exempted from test per IEC 60601–1–2 Table 6 note c).

NOTE Amplitude modulation at frequency 2 Hz used for testing the respiration sensor, sensor battery, and Hub.

Recommended separation distances

Recommended separation distances between portable and mobile RF communications equipment and the device.

This device is intended for use in the electromagnetic environment on 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 2.5 GHz	
	d = 1.2 √P	d = 3.5 √P	d = 4.4 √P	d = 1.2 √P	d = 3.5 √P	d = 2.3 √P	d = 7.0 √P
0.01	0.12	0.35	0.44	0.12	0.35	0.23	0.70
0.1	0.38	1.1	1.4	0.38	1.1	0.73	2.2
1	1.2	3.5	4.4	1.2	3.5	2.3	7.0
10	3.8	11	14	3.8	11	7.3	22
100	12	35	44	12	35	23	70

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, 4th Edition)

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

Guidance and manufacturer's declaration — electromagnetic immunity (IEC/EN 60601-1-2, 4th Edition)							
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**Immunity compliance level (V/m)**	**Immunity test level (V/m)**
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							
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 system components.						

Guidance and manufacturer's declaration — electromagnetic immunity (AIM STANDARD 7351731 Rev 2.00, MEDICAL ELECTRICAL EQUIPMENT AND SYSTEM ELECTROMAGNETIC IMMUNITY TEST FOR EXPOSURE TO RADIO FREQUENCY IDENTIFICATION READERS)					
Test frequency	**RFID standard the test is based on[1]**	**System component**	**Distance**	**Immunity compliance level**	**Immunity test level**
134.2 kHz	ISO 14223	All system components	2.5 cm	65 A/m RMS	65 A/m RMS
13.56 MHz	ISO/IEC 14443-3 (Type A)	All system components	1.0 mm	7.5 A/m RMS	7.5 A/m RMS
13.56 MHz	ISO/IEC 14443-4 (Type B)	All system components	1.0 mm	7.5 A/m RMS	7.5 A/m RMS
13.56 MHz	ISO/IEC 15693 (ISO 18000-3 Mode 1)	All system components	1.0 mm	5.0 A/m RMS	5.0 A/m RMS
13.56 MHz	ISO 18000-3 Mode 3	All system components	1.0 mm	12 A/m	12 A/m RMS

Guidance and manufacturer's declaration — electromagnetic immunity (AIM STANDARD 7351731 Rev 2.00, MEDICAL ELECTRICAL EQUIPMENT AND SYSTEM ELECTROMAGNETIC IMMUNITY TEST FOR EXPOSURE TO RADIO FREQUENCY IDENTIFICATION READERS)					
Test frequency	**RFID standard the test is based on[1]**	**System component**	**Distance**	**Immunity compliance level**	**Immunity test level**
433 MHz	ISO/IEC 18000-7	All system components	20.0 cm	3 V/m	3 V/m
860 - 960 MHz	ISO/IEC 18000-63 Type C	All system components	20.0 cm	54 V/m	54 V/m
2.45 GHz	ISO/IEC 18000-4 Mode 1	All system components[2]	20.0 cm	54 V/m	54 V/m
To avoid performance degradation, ensure that there is enough distance between RFID readers emitting RF (per the above listed standards) and the system components. **NOTE** The distance values represent the recommended separation distance between interfering equipment and the monitor. [1] Tests are based on standard AIM7351731. [2] RFID readers that operate at frequencies 2.45 GHz may cause a loss of network connectivity.					

Applicable RF receiver and transmitter specifications

Refer to the Portrait™ Mobile Monitoring Solution Privacy and Security Manual for the technical specifications.

Portrait HUB01/SBT01/P-SA01/P-SP01/P-W01/P-SE01/P-RR01

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