GE Healthcare

B125/B105 Patient Monitor
Technical Manual

B125/B105 Patient Monitor
English
2092703-001 G

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

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1

About this manual

Intended use of this manual

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

This manual contains instructions necessary to install, maintain and service the device to the assembly level. It gives an overview of the patient monitoring system and contains information needed for system installation. Information for the planned and corrective maintenance of the device is also provided.

Use the manual as a guide for installation, maintenance and repairs considered field repairable. Where necessary the manual identifies additional sources of relevant information and technical assistance.

See each module's Technical Manual for introduction, troubleshooting, disassembly and reassembly, service parts section.

See the supplemental information manual for the technical specifications, default settings and compatibility information, including electromagnetic compatibility.

See the user's manual for the instructions necessary to operate the device safely in accordance with its function and intended use.

Intended audience of this manual

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

About these devices

Refer to the user's manual for important information about the Patient Monitor B125/B105, including intended use of these devices, important safety information and detailed instructions for clinical use of these products.

Safety precautions

Refer to the user's manual for important system safety messages. Safety messages specific to parts of the system are found in the relevant section. Read all the safety information before using the monitor for the first time.

Manual conventions

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

Item	Description
bold	Indicates hardware terms.
bold italic	Indicates software terms.
italic	Indicates terms for emphasis.
>	Indicates menu options to select consecutively.
CARESCAPE Network	CARESCAPE Network is used to refer to the MC Network.
select	The word select means choosing and confirming.
NOTE	Note statements provide application tips or other useful information.

Related documents

- B125/B105 Patient Monitor User's Manual
- B125/B105 Patient Monitor Supplemental Information Manual
- B125/B105 Patient Monitor Supplies and accessories
- B125/B105 Patient Monitor Software Installation Instructions
- WLAN configuration guide
- WLAN Deployment Guide
- iCollect user's manual
- CARESCAPE Network Configuration Guide
- CIC Pro Clinical Information Center Operator's Manual
- CARESCAPE Central Station User's Manual
- HL7 Reference Manual
- B125/B105 Patient Monitor service for depot instruction

Ordering manuals

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

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.

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 the availability.

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System overview

General safety statements

This device is intended for use under the direct supervision of a licensed health care practitioner.

Contact GE for information before connecting any devices to the equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1 Clause 16 medical electrical systems standard. Refer to the patient monitor's supplemental information manual for compatible parts and accessories.

Periodically, and whenever the integrity of the product is in doubt, test all functions.

The use of accessory equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the patient vicinity
- evidence that the safety certification of the accessory has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1 Clause 16 harmonized national standard.

Safety message signal words

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

DANGER	Indicates a hazardous situation that, if not avoided, will result in death or serious injury.
WARNING	Indicates a hazardous situation that, if not avoided, could result in death or serious injury.
CAUTION	Indicates a hazardous situation that, if not avoided, could result in minor or moderate injury.
NOTICE	Indicates a hazardous situation not related to personal injury that, if not avoided, could result in property damage.

IEC 60601-1

- Type of protection against electrical shock: Class I. Internally powered ME equipment.

- Degree of protection against electrical shock: applied parts are marked with a symbol indicating degree of protection.
- Degree of safety of application in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide: Not suitable.
- Degree of protection against harmful ingress of water: IP21.
- Mode of operation: Continuous.
- Method(s) of sterilization or disinfection recommended by the manufacturer: see the User's Manual.
- Portable monitor.

System components

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

Your system may not include all these components. Consult your local representative for the available components.

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

1. B125 monitor, 12.1' LED display
2. B105 monitor, 10.1' LED display
3. Recorder
4. Acquisition module: E-miniC module, for compatible CO_2 measurement

Network central station

Central stations	Description
	CIC Pro Clinical Information Center The MC Network establishes communication and allows patient data to be sent to an optional CIC Pro Clinical Information Center (central station). See the CIC Pro Clinical Information Center Operator's Manual for operating instructions.
	CARESCAPE Central Station The MC Network establishes communication and allows patient data to be sent to an optional CARESCAPE Central Station. See the CARESCAPE Central Station User's Manual for operating instructions.

Other devices

Other devices	Description
	External display The monitor has the DVI port for the commercial display, which resolution should be 1280*800.
	USB storage device (file system: FAT32) To save and load the settings.

Controls and connectors

Front view

B105 front view (full configuration)

B125 front view

1. Alarm light
2. Transportation handle
3. Hemo connectors
4. Keypad
5. Trim knob

Main side view

B105 side view (full configuration)

B125 side view

1. Guide rail for GCX mounting
2. Battery compartment
3. Guide rail for recorder

Main back view

B105 back view (full configuration)

B125 back view

Multi I/O

1. Extension rack
2. E-miniC module
3. Receptacle for power cord
4. Equipotential connector
5. Multi I/O connector
6. DVI connector
7. Recorder connector
8. USB connector
9. Network connector
10. Nurse call connector
11. Defibrillator connector
12. Serial port

Hemodynamics connectors

1. IBP connector
2. Temperature connector
3. SpO_2 connector
4. ECG and impedance respiration connector
5. NIBP connector

Hemodynamics parameters

The monitor provides different configurations for hemodynamics measurement. The user can identify the configurations from connectors and label.

Identifier	Basic feature			Optional feature	
	ECG	NIBP	SpO_2	IBP	Temperature
SpO2_IBP_T	X	X	GE	X	X
MasimoSpO2_IBP_T	X	X	Masimo	X	X
NellcorSpO2_IBP_T	X	X	Nellcor	X	X
SpO2_T	X	X	GE		X
MasimoSpO2_T	X	X	Masimo		X
NellcorSpO2_T	X	X	Nellcor		X
SpO2	X	X	GE		
MasimoSpO2	X	X	Masimo		
NellcorSpO2	X	X	Nellcor		

E-miniC module

1. Water trap
2. Sample gas inlet
3. Gas outlet

Recorder

1. Recorder door.
2. Tab for removing recorder
3. Power on indicator: Illuminates when connected to power.
4. Symbol indicate the paper install direction.
5. 9-pin connector: connect to monitor.

Keypad

1. On/Off key.
2. AC power status indicator.
3. Battery status indicator.
4. Audio pause key. Temporary audio pause active alarms.

5. Snapshot key. Take up snapshot, which is a set of measured data for this moment.
6. Manual NIBP key. Start a manual NIBP measurement.

Service information

Service requirements

Follow the service requirements listed below.

- Refer servicing of the equipment to qualified service personnel only. Service personnel servicing this product must have an appropriate technical qualification, or equivalent work experience, and be familiar with the service requirements described in this manual and in any related service documentation. Service training for the product is recommended.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to GE or to one of their authorized agents.
- Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the equipment will always be functional when required.

WARNING Do not perform any service activities on the monitor in the patient vicinity while a patient is being connected to the monitor.

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

Equipment identification

Every GE device has a unique serial number for identification. The serial number is written in a device label.

The product code for B125 is SP4.

The product code for B105 is SP3.

The device plate is located on the rear of the patient monitor.

###	##	##	####	#	#
A	B	C	D	E	F

A product code

B year manufactured

C fiscal week manufactured

D production sequence number

E	manufacturing site
F	miscellaneous characteristic

Equipment symbols

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

	On the Hemo connectors: **WARNING** Protection against cardiac defibrillator discharge is due in part to the accessories for pulse oximetry (SpO2), temperature (T) and invasive pressure (P) measurement.
	On the X1, X2 connector, and recorder: **CAUTION** Electric shock hazard. Do not open the cover or the back. Refer servicing to qualified personnel. On the power label at the rear cover: **CAUTION** For continued protection against fire hazard, replace the fuse only with one of the same type and rating. **CAUTION** Disconnect from the power supply before servicing. On the battery cover: **CAUTION** Make sure to use the compatible battery: FLEX-3S3P; Close the battery door to aviod battery drop out.
	Follow instructions for use.
	Consult operating instructions.
	Electrostatic sensitive device. Connections should not be made to this device unless ESD precautionary procedures are followed.
	Non-ionizing electromagnetic radiation. Interference may occur in the vicinity of this device.
	Type BF (IEC 60601-1) protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, excluding direct cardiac application.

	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) protection against electric shock. Isolated (floating) applied part suitable for intentional external and internal application to the patient, including 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.
	Power On/Off key.
	Alternating current. Power indicator. The device is being used on main power.
	Battery. Green lit. Monitor is operated on battery power. Orange lit. Battery is charging. The indicator goes off when the battery is fully charged. Orange flashing. Battery failure or AC/DC failure.
	Audio pause key. Temporary audio off.
	Snapshot key.
	Manual NIBP key. Start a manual NIBP measurement.
	Equipotentiality. Connect device to a potential equalization conductor.
X1	Multi I/O connector.
	DVI connector. Video output connector for digital source.
X2	Recorder connector.

	USB connector.
	Ethernet connector.
	Battery cover open/close indication. The operator should align the up and down arrow, then push the cover to close.
	Gas inlet.
	Gas outlet.
31	Mini D-fend: Add date.
	Recorder.
	Recorder paper install direction.
	Fuse. Replace with identical type and rating fuse.
IP21	Degree of ingress protection.
YYYY-MM-DD	Date of manufacture. This symbol indicates the date of manufacture of this device. The first four digits identify the year and the last two digits identify the month.
	Manufacturer name and address.
PN	Abbreviation for product number.
SN	Device serial number.
UDI	Every device has a unique marking for identification. The UDI marking appears on the device label.

hPa hPa	Atmospheric pressure limitations.
°C °C	Temperature limitations.
60°C -20°C 温度极限	China only. Temperature limitations.
% %	Humidity limitations.
	Keep dry. Protect from rain.
怕雨	China only. Keep dry. Protect from rain.
	Fragile. Handle with care.
易碎物品	China only. Fragile. Handle with care.
	This way up.
向上	China only. This way up.

	This symbol indicates that the waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Please, contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment. The separate collection symbol is affixed to a battery, or its packaging, to advise you that the battery must be recycled or disposed of in accordance with local or country laws. To minimize potential effects on the environment and human health, it is important that all marked batteries that you remove from the product are properly recycled or disposed. For information on how the battery may be safely removed from the device, please consult the service manual or equipment instructions. Information on the potential effects on the environment and human health of the substances used in batteries is available at this url: http://www.gehealthcare.com/euen/weeerecycling/ index.html
	Recycled materials or may be recycled.
LI-ION	Recyclable Lithium-Ion.
	FCC. USA only. Complies with applicable US government (Federal Communications Commission) radio-frequency interference regulations.
Rx ONLY U.S.	Prescriptive Device. USA only. For sale by or on the order of a Physician.
	Russia only. GOST-R mark.
	Eurasian Economic Union countries only. Eurasian Conformity mark. Conformity to applicable technical regulations of Customs Union.
20	China only. 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 User Period (EFUP), which indicates the period during which the toxic or 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.
CMIIT ID	China only. China Ministry of Industry and Information Technology identification number for Radio Transmission Equipment Type Approval.
ANATEL HHHH - AA - FFFF (01) 0789 RRRRRR PPP D	Brazil only. Approved under ANATEL (Agência Nacional de Telecomunicações) requirements.
Segurança Compulsório	Brazil only. INMETRO certificate.
	Australia only. Regulatory Compliance Mark (RCM). The product comply the ACMA (Australian Communications and Media Authority) regulatory requirement.
BE BG CZ DK DE EE IE EL ES FR HR IT CY LV LT LU HU MT NL AT PL PT RO SI SK FI SE UK	This product is restricted to indoor use, Restricted Member States as below: Belgium (BE), Bulgaria (BG), Czech Republic (CZ), Denmark (DK), Germany (DE), Estonia (EE), Ireland (IE), Greece (EL), Spain (ES), France (FR), Croatia (HR), Italy (IT), Cyprus (CY), Latvia (LV), Lithuania (LT), Luxembourg (LU), Hungary (HU), Malta (MT), Netherlands (NL), Austria (AT), Poland (PL), Portugal (PT), Romania (RO), Slovenia (SI), Slovakia (SK), Finland (FI), Sweden (SE) and United Kingdom (UK).
TA-2017/644 ICASA APPROVED	South Africa only. Approved under ICASA (Independent Communications Authority of South Africa) requirements.
	Philippines only. The product comply the NTC (National Telecommunications Commission) requirements.

User interface symbols

The following symbols appear in the software user interface.	
	Alarm off indicator - Displays in the upper right corner of the digit field when physiological alarms for this parameter are turned off. The symbol may not display at the central station.
	Audio alarms off indicator - Displays in the upper left corner of the message field when physiological audible alarms are turned off.
	Alarm pause indicator - Displays in the upper left corner of the message field and indicates that alarms are audio paused.
	Alarms audio pause indicator. Displays in the upper left corner of each alarm message and indicates that alarm audio pause has been activated.
	Network connection indicator. Indicates the monitor is connected to the Local Area Network (LAN).
	Network (WLAN) signal strength. The number of segments corresponds to the signal strength: four segments indicate strong signal, one segment weak signal.
	Network (WLAN) is failed.
	Monitor battery is full.
	Monitor battery is less than 87.5% of run time left.
	Monitor battery is less than 62.5% of run time left.
	Monitor battery is less than 37.5% of run time left.
	Monitor battery is empty when there is less than 12.5% of run time left.
	Monitory battery failure or missing battery.
	Monitor battery is charging.
	Night mode indicator. Indicates the monitor is on the night mode.

The following symbols appear in the software user interface.	
	Snapshot indicator. Indicates the event has an associated snapshot.
	Beat volume icon. Adjust the volume of the QRS beep tone. Also the beat source indicator. Displays next to the selected beat source.
	Respiration indicator. Indicates a breath is detected by the impedance respiration algorithm.
	Lock indicator. Indicates the screen has been locked.
* * *	Masimo SpO_2 only. SpO_2 signal strength indicator. Indicates the signal strength, with three asterisks indicating the strongest signal.
5 min	NIBP progress bar. Indicates the amount of time remaining until the next automatic measurement.

3

Theory of operation

System block diagram

Main components

CPU board

CPU board block diagram

The board is based on AT91 ARM microprocessor. The functions include LVDS display driver, 10/100Mbps on board Ethernet, WLAN communication, USB function, Alarm Light function, Keyboard and Trim Knob control, Audio driver function, nurse call function. The CPU section takes care of the central processing.

The main features are:

- AT91 ARM
- 266 MHz Main CPU clock
- 128 MB SDRAM
- 1 GB NAND flash memory
- 8 MB Data flash memory

Carrier board

Carrier board block diagram

The Carrier board functions include the power supply function, UMBC function.

- The power supply subsystem converts the output voltage of AC/DC unit and battery voltage to various supply voltages for the electronics of monitor. It provides:
  - 3.3V power for monitor system
  - 15V power for UMBC
  - 9V and 15V power for LCD interface board
- The UMBC subsystem provides:
  - RS-485 module bus communication for the Hemo module, E-module, and recorder.
  - A digital marker-out signal for defibrillator.

AC/DC unit

AC/DC insulation diagram

The AC/DC unit is a compact medical power supply based on high-efficiency technology. It is designed for 65 watt continuous output power, universal AC input and 15V output voltage.

Display subsystem

Display

The B105 patient monitor has an integrated 10.1" active matrix color TFT LCD panel with a LED backlight unit.

The B125 patient monitor has an integrated 12.1" active matrix color TFT LCD panel with a LED backlight unit.

They provide wide viewing angle and supports WXGA (1024 * 800 pixels) resolution. The video controller is integrated into the CPU board and it provides LVDS output to the LCD panel through the carrier board. The LCD interface board converts the output voltage from carrier board to various supply voltage for the LCD.

LED backlight unit

The LCD/TP (touch panel) module has an integrated, long-life LED backlight unit that is used to illuminate the LCD display. The LED backlight unit receives the +12 V input voltage from the LCD interface board. The backlight enable signal and brightness control is received from the CPU board.

Touchscreen sensor

The device has a capacitive touchscreen sensor in the front of the LCD panel. The touchscreen sensor detects the presence and location of a touch within the display

area and communicates the information through the LCD interface board to the carrier board.

Recorder unit

The optional recorder assembly consists of a 50 mm recorder and a recorder board. The recorder connect to the carrier board. The RS_485 module bus communication is on the UMBC sybsystem of the carrier board.

Battery

The monitor has a lithium-ion battery, located in the battery compartment. When no power is received from the AC/DC unit, the carrier board connects battery to be the power source. The battery charging is controlled by the power supply subsystem on carrier board.

The screen symbols and monitor LED indicators indicate the battery charging level and possible failure.

NOTE When the monitor is battery powered, the green battery LED is on. When the monitor is mains powered, the green mains LED is on.

User interface parts

The device has a carrier interface board connect the following user interface parts to the carrier board

- Horizontal membranes keypad containing 4 keys, and 2 power indicator LEDs
- Trim knob
- Speaker
- Alarm board
- LCD touch panel

Hemo module

1. IBP connector
2. Temperature connector
3. SpO_2 connector
4. ECG and impedance respiration connector
5. NIBP connector

The Hemodynamic module including the NIBP measurement, 5-lead ECG with the Impedance Respiration measurement, SpO2 with the plethysmographic waveform, two invasive pressure measurements (IBP1 and IBP2) and two temperature measurements (T1 and T2).

There are four parameter circuit boards inside the hemodynamic module for processing the measurement signals. Each processing board has a microcontroller with software.

- NIBP parameter board with pneumatic system, valve and pump unit.
- SpO2 board for Masimo or Nellcor SpO2 measurement. This is the optional board. And according to different configuration, using different board, options are:
  - Masimo MS-2011 board
  - Covidien NELL1GE-S board
- STP board for GE SpO2, IBP and Temperature measurement. According to different configuration, using different board, options are:
  - STP board
  - TP board for Nellcor
  - TP board for Masimo
  - GE SpO2 board
- The ECG board is for 3/5-lead ECG with the Impedance Respiration measurement.

All boards are connected together via module bus flex board connecting voltage and module communication, the module communicates with frame through RS-485 bus.

Serial communication

An RS485 type bus driver makes the serial communication between the module and the frame. The data transmission rate is 500 kbps.

Serial communication diagram of hemo module

Signals and isolation barrier

The communication signals transfer over the isolation barrier by using high isolation voltage (6kV) opto isolators.

Power supply section

- The power for the electronics on the floating part of the STP and the ECG boards is made on each board with the switching power supplies connected to a high voltage isolated transformer. The switching power supplies on the STP and ECG boards are synchronized to the frequency, about 340kHz of the switching power supply on the NIBP board. The NIBP board supplies non-isolated 5 V to the ECG and STP boards. The module uses only Vmod 13.8 to 16 V voltage of the frame.
- The other voltages of the measuring boards are made by the switching power supplies and regulators or the linear regulators. The measuring board is protected against overloading with PTC type automatic fuses.

ECG board

The ECG measurement consists of the functions shown in the diagram. All functions are located in the ECG board except the ECG input unit.

- ECG input unit
  - The ECG input unit consists of the front panel connector and the ECG input connector board with the high voltage protection resistors. The connector for the ECG cable is a green 11-pin rectangle shaped connector.
- Input protection and filtering
  - The input protection is implemented with high voltage protection resistors in the ECG input unit and with protection diodes in the ECG board. The input filtering for ECG measurement is done with passive RC filtering.
- ECG preamplifiers
  - The buffer amplifiers are used for each lead. The “Leads off” detection is implemented by measuring the output level of the input buffer amplifiers with the A/D converter of the CPU. The ECG signals are measured using differential amplifiers.

- ECG amplifiers and baseline restoration
  - The function of the ECG amplifiers and baseline restoration is to amplify the signal and to restore the baseline of the signal in the middle of the display after the change of the signal level, e.g. after the change of the DC offset voltage.
- Pacer detection
  - Pacer detection has been made by using four slew rate detector circuits. The pacer detection amplifiers have been realized at the front of the slew rate detectors independently of the ECG measuring channels.
- Respiration impedance supply
  - The 31.25 kHz sine wave generator is used as the respiration measurement signal supply. Analog switches are used for connecting the sine wave to the ECG leads to be measured.
- Respiration impedance amplifiers
  - Buffer amplifiers are used in respiration measurement. Analog switches are used for selecting the measurement leads. There are also additional amplifiers for increasing the respiration signal gain. When ECG measurement is 5-lead, the respiration measurement is always done between R and F, independently on the ECG lead selection. When ECG measurement is 3-lead, then the respiration measurement is happened at the same lead as the ECG measurement (I, II, or III).
- ECG CPU
  - The CPU is a 16 bit H8/3052 single-chip microcomputer. It contains 128 kbytes of flash memory and 4 kbytes of RAM. The clock frequency is 16 MHz.
- RS485 communication
  - The communication to the CPU board of the monitor uses RS485 protocol. The RS485 driver circuits are optically isolated from the processor of the module.
- Power supply
  - The ECG board has a driver-controlled half-bridge switching power supply with 5 kV isolation. The supply voltages have been regulated with linear regulators.
- ECG filtering
  - There are three ECG filtering modes:

MONITORING	0.5 to 40 Hz
DIAGNOSTIC	0.05 to 145 Hz
ST FILTER	0.05 to 40 Hz

  - The purpose of filtering is to reduce high frequency noise and low frequency (e.g. respiratory) movement artifacts.
  - The monitor filter is used in normal monitoring. The diagnostic filter is used if more accurate diagnostic information is needed. The ST filter gives more accurate information of ST segment, but reduces high frequency noise.
  - The high-pass filters 0.5 Hz and 0.05 Hz are done with software. The monitor sends a command to the hemodynamic module determining which of the corner frequencies 0.5 Hz or 0.05 Hz is to be used.
  - In diagnostic mode the upper frequency is 150 Hz and it is limited by software.

STP board

STP board block diagram

Microprocessor unit

- The CPU is a 16 bit H8/3052 single-chip microcomputer. It contains 128 kbytes of flash memory and 4 kbytes of RAM. The clock frequency is 16 MHz.
- High speed I/O is used to obtain a pulse control sequence necessary for pulse oximetry measurement. Timing for the clock is from the oscillator.

Temperature measurement unit

- The NTC-resistor value in the probe depends on the patient's temperature. It is measured with the following principle.
- The constant current source supplies about 38 µA current through the temperature sensor (400 series NTC resistor). The constant current causes a voltage over the temperature sensor (NTC resistor). The voltage over the temperature sensor is amplified in a differential amplifier stage. The amplified voltage is transferred to a controller of the STP board through an A/D converter.

Temperature measurement principle

Invasive blood pressure measurement unit

- An isolated +5 V voltage is supplied to the pressure transducer. The differential voltage, which depends on the pressure and the supplied voltage, is calculated from the bridge connection (see the formula below).
  $U_{out} = U_{in} \times$ pressure $\times$ 5 µV, where U_{in} is 5 V

  -> U_{out} = 25 µV $\times$ pressure [mmHg]
- Pressure amplification is realized in the instrumentation amplifier. The gain of the amplifier is set to keep the level of the signal transferred to the A/D converter within the measurement range even when there are circumstantial offsets or offsets caused by the transducer. There is a filter before the amplifier to attenuate high frequency disturbances.

Invasive pressure measurement principle

Pulse oximetry measurement section

- LED control signals
  - The D/A converters of the microcontroller on the STP board set the LED intensity adjustment values for the infrared and red LEDs of the SpO_2 probe. The microcontroller on the STP board switches the SpO_2 probe LEDs ON (to the adjusted intensity) and OFF according to the predetermined sequence.
- LED driving circuit
  - Differential amplifiers measure the LED currents (LED current indication) of the SpO_2 probe over the shunt resistors placed in the LED current paths. The LED driving voltages (LED voltage indication) are measured from the driver circuitry. The LED driving circuits also have MOSFET transistor matrix to enable the use of different probe configurations.
- Measured signal preamplification
  - The preamplifier is a bipolar/single-ended current-to-voltage converter with adjustable gain. A higher gain is used for measuring thin tissue. The preamplification stage has also ambient light reduction and a second amplifier stage.
- Red and infrared channel separation
  - It is possible to multiplex the detector signal to four different channels depending on the content of the signal. The detector signal must at least multiplex into infrared and red signals. Other channels are e.g. for diagnostic purposes.

Pulse oximetry measurement principle

NIBP board

NIBP board block diagram

- Signal processing

  - Two signals from the pressure transducers are amplified and sent to the A/D converter. After the converter, digitized signals are sent to the microprocessor for data processing.
  - The NIBP board is controlled with an H8/3052 microprocessor at 16 MHz oscillator frequency.
- Memory
  - The NIBP program memory (processor flash memory) size is 512k x 8. The processor has 4 kBytes RAM and there is also an external RAM memory, the size of which is 128k x 8. Variable values of the NIBP measurement are stored into the external RAM. The EEPROM size is 512 x 8 and it is used to store the calibration values for the pressure transducers, the pulse valve constants gained during measurements, the PC board identification, and the module serial number.
- Software control
  - The software controls valves and a pump. In addition to the individual on/off signals for each component there is a common power switch for the valves and the pump that can be used at pump/valve failures.
  - In addition to external RS485 reset line, the microprocessor system is equipped with its own power-up reset.
- Safety circuit
  - The NIBP board is equipped with an independent safety circuit to disconnect supply voltages from the pump and the valves if the cuff has been pressurized longer than the preset maximum measurement time, or if the pressure of the cuff is inflated over the specified pressure limit. The maximum measurement time values and pressure limits for different measurement modes have been specified in the technical specifications.
- Pneumatics

The module have the following pneumatics parts:

1. NIBP air filter for preventing dust and other parts from entering the air pump and the valves.
2. Air pump for pumping the measuring pressure of the cuff.
3. Deflation valve for producing a linear pressure fall (bleeding) in order to measure the blood pressure of the patient.

4. Safety (Dump) valve. The safety valve is intended to be used for deflating the cuff in single fault case, i.e. to prevent too long a measurement time or too high an inflation pressure of the cuff.
5. Main pressure sensor for measuring the pressure of the blood pressure cuff and the pressure fluctuations caused by arterial wall movement.
6. Safety pressure sensor for detecting the cuff loose, cuff occlusion situations, etc. and for recognizing the pressure sensor fault.
7. Cuff connector for connection and hose identification.

- NIBP pneumatics diagram:

- Power supply section of the NIBP board
  - All connections are established via a module bus connector. The module needs a +15 V power supply to operate. The supply voltage (+15V) is generated in the power supply section of the monitor. The other voltages needed for the operation of the NIBP measurement are made on the NIBP board.

Non-standard connectors and signals

Multi I/O connector

Multi I/O connector (X1)	Pin number	Signal Name	Signal Description
	1	GND	Ground
	2	HHSDME	Reserve for future use
	3	HHSDPE	Reserve for future use
	4	NC	Reserve
	5	D_RXD	Serial Data Receiver for debug
	6	NC	Reserve
	7	SERIAL_TXD	Serial Data Transmitter
	8	SERIAL_CTS#	Handshake signal, ready to send data
	9	GND	Ground

Multi I/O connector (X1)	Pin number	Signal Name	Signal Description
	10	GND	Ground
	11	REMOTE_ON	Reserve for remote on
	12	NC	Reserve
	13	DFB_OUT	Defibrillation output
	14	NC	Reserve
	15	NC	Reserve
	16	SERIAL_RXD	Serial Data Receiver
	17	SERIAL_RTS#	Handshake signal, ready to receive data
	18	GND	Ground
	19	GND	Ground
	20	NURSE_CALL_CON	Nurse call output
	21	V_REMOTE	Reserve for remote on
	22	V_REMOTE	Reserve for remote on
	23	D_TXD	Serial Data Transmitter for Debug
	24	NC	Reserve
	25	SERIAL_+3v3	3.3V Power Supply
	26	GND	Ground

Nurse call connector

Nurse call connector	Pin number	Signal
	1	GND
	2	NURSE_CALL
	3	NURSE_CALL

Nurse call connector schematics:

Recommended cable design:

Serial port connector

Serial port connector	Pin number	Signal Name
	1	GND
	2	SERIAL_TXD
	3	SERIAL_RXD
	4	NC
	5	GND
	6	NC
	7	SERIAL_CTS
	8	SERIAL_RTS
	9	NC

Recorder connectors

Recorder connector (X2, On the monitor)	Pin number	Signal Name	Signal Description
	1	RS485–	Modbus RS485–
	2	RS485+	Modbus RS485+
	3	GND	Ground
	4	GND	Ground
	5	F2_EN	Reserve
	6	F2_DET	Reserve
	7	VMOD	+15V power supply
	8	VMOD	+15V power supply
	9	GND	Ground

Serial port connector (On the recorder)	Pin number	Signal Name	Signal Description
	1	NC	Not connect
	2	GND	Ground
	3	MOD_VDD	+15V power supply
	4	GND	Ground
	5	RS485+	Modbus RS485+
	6	NC	Not connect
	7	GND	Ground
	8	MOD_VDD	+15V power supply
	9	RS485–	Modbus RS485–

Defibrillator synchronization connector

Defibrillator Synchronization connector	Pin number	Signal
	1	Digital defibrillator synchronization marker out signal
	2	NC
	3	GND
	4	GND
	5	GND
	6	GND
	7	GND

Measurement principle

ECG measurement principle

Electrocardiography analyzes the electrical activity of the heart by measuring the electrical potential produced with electrodes placed on the surface of the body.

ECG reflects:

- electrical activity of the heart
- normal/abnormal function of the heart
- effects of anesthesia on heart function
- effects of surgery on heart function

See the user's manual for electrodes' positions and other information.

Respiration measurement principle

Impedance respiration is measured across the thorax between ECG electrodes. The respiration signal is made by supplying current between the electrodes and by

measuring the differential current from the electrodes. The signal measured is the impedance change caused by breathing. The respiration rate is calculated from these impedance changes, and the respiration waveform is displayed on the screen.

Pulse oximetry measurement principle

A pulse oximeter measures the light absorption of blood at two wavelengths, one in the near infrared (about 940 nm) and the other in the red region (about 660 nm) of the light spectrum. These wavelengths are emitted by LEDs in the SpO_2 probe, the light is transmitted through peripheral tissue and is finally detected by a PIN-diode opposite the LEDs in the probe. The pulse oximeter derives the oxygen saturation (SpO_2) using an empirically determined relationship between the relative absorption at the two wavelengths and the arterial oxygen saturation SaO_2.

In order to measure the arterial saturation accurately, pulse oximeters use the component of light absorption giving variations synchronous with heart beat as primary information on the arterial saturation.

A general limitation of pulse oximetry is that due to the use of only two wavelengths, only two hemoglobin species can be discriminated by the measurement.

The modern pulse oximeters are empirically calibrated either against fractional saturation SaO_2frac;

$$SaO_2frac = \frac{HbO_2}{HbO_2 + Hb + Dyshemoglobin} \qquad \text{Formula 1}$$

or against functional saturation SaO_2func;

$$SaO_2func = \frac{HbO_2}{HbO_2 + Hb} \qquad \text{Formula 2}$$

Functional saturation is more insensitive to changes of carboxyhemoglobin and methemoglobin concentrations in blood.

The oxygen saturation percentage SpO_2 measured by the module is calibrated against functional saturation SaO_2func. The advantage of this method is that the accuracy of SpO_2 measurement relative to SaO_2func can be maintained even at rather high concentrations of carboxyhemoglobin in blood. Independent of the calibration method, pulse oximeters are not able to correctly measure oxygen content of the arterial blood at elevated carboxyhemoglobin or methemoglobin levels.

Plethysmographic pulse wave

The plethysmographic waveform is derived from the IR signal and reflects the blood pulsation at the measuring site. Thus the amplitude of the waveform represents the perfusion.

Pulse rate

The pulse rate calculation is done by peak detection of the plethysmographic pulse wave. The signals are filtered to reduce noise and checked to separate artifacts.

The following illustration shows the absorption of infrared light in the finger:

The following illustration shows the layout and schematic diagram of pulse oximetry probe parts:

The standard probe is a finger clamp probe which contains the light source LEDs in one half and the photodiode detector in the other half. Different kinds of probes are available from GE.

NIBP measurement principle

NIBP (Non-Invasive Blood Pressure) is an indirect method for measuring blood pressure.

The NIBP measurement is performed according to the oscillometric measuring principle. The cuff is inflated with a pressure slightly higher than the presumed systolic pressure, and deflated at a speed based on the patient's pulse, collecting data from the oscillations caused by the pulsating artery. Based on these oscillations, values for systolic, mean, and diastolic pressures are calculated.

The following parts are necessary for the NIBP measurement:

- a parameter module
- twin hose (adult or infant model)
- blood pressure cuffs (various sizes)

Invasive blood pressure measurement principle

To measure invasive blood pressure, a catheter is inserted into an artery or vein. The invasive pressure setup, consisting of a connecting tubing, a pressure transducer, an intravenous bag of normal saline, all connected together by stopcocks, is attached to the catheter. The transducer is placed at the same level with the heart, and is electrically zeroed.

The transducer is a piezo-resistive device that converts the pressure signal to a voltage. The monitor interprets the voltage signal so that pressure data and pressure waveforms can be displayed.

Temperature measurement principle

The temperature is measured by a probe whose resistance varies when the temperature changes, called NTC (Negative Temperature Coefficient) resistor.

The resistance can be measured by two complementary methods:

- Applying a constant voltage across the resistor and measuring the current that flows through it.
- Applying a constant current through the resistor and measuring the voltage that is generated across it.

These modules use the constant current method. The NTC resistor is connected in series with a normal resistor and a constant current is applied through them. The temperature dependent voltage can be detected at the junction of the resistors, thus producing the temperature signal from the patient. The signal is amplified by analog amplifiers and further processed by digital electronics.

4

Pre-installation requirements

Unpacking

WARNING EXCESSIVE LEAKAGE CURRENT. If the device has been transported or stored outside operating temperature range allow it to stabilize back to operating temperature range before removing it from the plastic bag.

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

1. Confirm that the packing box is undamaged. If the box is damaged, contact the shipper.
2. Open the top of the box and carefully unpack all components.
3. Confirm that all components are undamaged. If any of the components is damaged, contact the shipper.
4. Confirm that all components are included. If any of the components is missing, contact your GE Healthcare distributor.

Checking the compatibility of all system components

WARNING BEFORE INSTALLATION. Compatibility is critical to safe and effective use of this device. Please contact your local sales or service representative prior to installation to verify equipment compatibility.

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

WARNING The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity performance of the equipment or system.

WARNING For detailed instructions and information regarding supplies and accessories, always refer to their own instructions for use.

Verify the compatibility of all system components prior to the installation of the patient monitor. For a list of the compatible devices, supplies and accessories, see the Supplemental Information Manual, and Supplies and accessories.

1. Check the compatibility of the displays and display cables.
2. Check the compatibility of the network.
3. Check the compatibility of the supplies and accessories.
4. Check the compatibility of the peripheral devices. For a list of the compatible peripheral devices, see the supplemental information manual.

Network infrastructure

Ensure that an applicable network infrastructure is in place before the installation of a monitor.

Collect the network configuration information from the hospital IT or the related project documentation and installation files.

Checking MC Network infrastructure

The MC Network infrastructure must be installed according to the CARESCAPE Network Configuration Guide.

1. Ensure that the installation site of the monitor has a wall jack and a network patch cable for the MC Network.
2. Collect the required information ready for network configurations: refer to Configuration chapter.

Checking wireless MC Network infrastructure

The wireless MC Network infrastructure must be installed according to the 2000716-003 WLAN Configuration Guide and DOC1314463 WLAN Deployment Guide.

1. Ensure that the wireless coverage area is adequate for the installation.
2. Collect the required information ready for network configurations: refer to Configuration chapter.

Checking HL7 Network infrastructure

The HL7 Network infrastructure must be installed according to HL7 reference manual.

1. Collect the required information ready for network configurations: refer to Configuration chapter.

Installing the mounting hardware

Refer to the Supplies and accessories for compatible mounting hardware.

1. Ensure that all the applicable/required mounting hardware is properly installed prior to the installation of the monitor:
   - Mounting hardware for the patient monitor, either for a stand-alone installation or for an installation to an anesthesia machine or to a ventilator.

Power and environmental requirements

Check the patient monitor's supplemental information manual for power and environmental requirements.

WARNING Operation of the monitor outside the specified performance range may cause inaccurate results.

CAUTION Do not use or store equipment outside the specified temperature, humidity, or altitude ranges.

Checking environmental requirements

1. Install the monitor to a location that meets the specified environmental requirements of operating temperature, humidity and atmospheric pressure.
2. Place each device in a location with sufficient ventilation. Observe the ventilation openings of a device and make sure not to obstruct them.

Checking power requirements

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

1. Ensure that he installation site has hospital-grade grounded power outlets and power cords for all system components.

Checking EMI & RFI interference

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

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

CAUTION EMC. Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Changes or modifications to this device/system not expressly approved by GE 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.

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

1. Ensure that the monitor is isolated from sources of strong electromagnetic and radio frequency interference.

   Refer to the patient monitor's supplemental information manual for more information.

5

Hardware installation

Hardware installation

WARNING The parameter modules are not able to withstand unpacked drops from a height of 1 m without damage. If a module is dropped, please service it before taking it back into use.

WARNING After transferring or reinstalling the monitor, always check that it is properly connected and all parts are securely attached.

WARNING SITE REQUIREMENTS - Do not route cables or tubing in a way that they may present a stumbling hazard.

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

WARNING EXCESSIVE TOUCH CURRENT - To avoid excessive patient leakage current, do not simultaneously touch the patient and the electrical connectors located at the rear panel of the monitor or within the module housing or frames.

WARNING Never install equipment above the patient.

WARNING Use only manufacturer approved mounts.

WARNING To prevent liquids from entering the monitor, do not tilt the monitor.

WARNING Do not connect a monochrome display to the monitor. Visual alarm indicators may not appear properly.

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

WARNING Use only AC power cords recommended or manufactured by GE.

WARNING EXCESSIVE LEAKAGE CURRENT To avoid summation of leakage currents when interfacing the device with other equipment, the devices may only be interconnected with each other or to parts of the system when it has been determined by qualified biomedical personnel that there is no danger to the patient, the operator, or the environment as a result. In those instances where there is any element of doubt concerning the safety of the connected devices, the user must contact the manufacturers concerned (or other informed experts) for proper use. In all cases, safe and proper operation should be verified with the applicable manufacturer's instructions for use, and system standards IEC60601-1 clause 16 must be complied with.

WARNING POWER SUPPLY - The device must be connected to a properly installed power outlet with protective earth contacts only. If the integrity of the protective earth conductor is in doubt, disconnect the monitor from the power line, and use it with the battery option, if available. All devices of a system must be connected to the same power supply circuit. Devices which are not connected to the same circuit must be electrically isolated when operated.

WARNING MISSED ALARMS - Do not use with Mobile Care Server Version 5.2 and earlier.

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

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

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

Installing battery

Battery test button

When the battery is not inserted into the monitor, you can check its status by using the TEST button on the battery itself. Push the button and check the green charging level indicators to see how much charge is left:

- Four LEDs illuminated: 75% to 100% of full-charge capacity.

- Three LEDs illuminated: 50% to 74.9% of full-charge capacity.
- Two LEDs illuminated: 25% to 49.9% of full-charge capacity.
- One LED illuminated: 10% to 24.9% of full-charge capacity.
- One LED flashing: < 10% of full-charge capacity.

Inserting and removing battery

1. Open the battery cover by pressing the battery cover and slide out.
2. Insert the battery with the test indicator side up and the connector end first all the way into the battery slot.
3. Close the battery door carefully. Align the up and down arrow, then slide battery cover to the left to close.

4. To remove the battery, open the battery cover and pull the battery out from the cord.

Checking the battery charge with monitor software

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

1. Select the > ***Battery*** .
2. Check the battery status that appears.

NOTE When the battery charge complete, the ***Capacity Percent*** may not reach to 100%.

Mounting the monitor

The monitor has an integrated GCX mounting plate. This facilitates all mounting options for the monitor.

Refer to the Suppliers and accessories to identify the compatible mounting hardware for the patient monitor.

Install the monitor to the mounting hardware according to the installation instructions included with the mounting hardware.

Connecting a display

NOTE All installations must be compliant with IEC 60601-1 clause 16 and local electrical codes.

NOTE Make sure that all cables are securely connected.

You can connect one secondary, clone display to the monitor.

1. Check the compatibility of the display.

   The resolution of the external display should be 1280*800.

2. Ensure that the display is installed to the mounting hardware according to the installation instructions included with the mounting hardware.
3. Refer to the display's user manual for more information about the display installation.

Connecting E-module

To use the E-module, your device need to be pre-configured with the extension rack.

1. With the module properly oriented (module release latch facing down), align the insertion guide slot in the module with the insertion guide in the extension rack.
2. Push the module into the module frame until it clicks.

Connecting the recorder

Please make sure the monitor is pre-configured with recorder fixing plate.

1. Use cable to connect the recorder to the **X2** connector on the monitor.
2. When the monitor is power on, make sure the power indicator on recorder is lit.

Single recorder connector line

Inserting the recorder

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

Removing the recorder

1. Pull the recorder outwards by the tab. Make sure not to drop it when it comes out.

Connecting Multi I/O adapter

1. Using Multi I/O connect line connect Multi I/O adapter and monitor.

Connecting to the mains power

1. Connect power cords to the mains power supply inlet and to a wall outlet on all system components that require AC mains power input.

2. Secure all power cords by routing through the retaining clips or cable clamps, as applicable.

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

Connecting network

Network compatibility

The monitor has been verified to be able to work in CARESCAPE* Network environment.

The monitor has EMR connectivity. The monitor HL7 (Health Level Seven) message match with IHE PCD-01 OBR/OBX format. There are three ways to acquire trended vital sign data from patient monitor:

- HL7 directly from monitor
- HL7 from the CARESCAPE Gateway

On the CARESCAPE network,

- The monitor is compatible with the following devices:
  - CARESCAPE Central Station v1, v2
  - CARESCAPE Gateway v1
  - Mobile Care Server v6.0
  - Ascom Mobile Monitoring Gateway (MMG) version 3.03
  - CARESCAPE CIC Pro Clinical Information Center v5.1.0
- The bedside monitor can simultaneously communicate with a maximum of 4 central stations, 1 Gateway server, 1 Mobile Care Server and up to 1,000 other monitoring devices.

Network diagram

CARESCAPE Network

- HL7 outbound from monitor though CNI V2 switch.

NOTE Need unity network and HL7 network license.

Hospital Network

- HL7 outbound from monitor though hospital switch.

NOTE Need HL7 network license.

Connecting to the MC Network

Tools needed:

- a MC Network patch cable

1. Connect the one RJ-45 connector to the network port in the rear panel of the patient monitor.
2. Connect the other RJ-45 connector to the corresponding port on the wallbox.
3. Turn on the monitor and setup the network configuration, if needed.
4. Check that the network symbol and message ***Network made*** are displayed in the screen.

Connecting iCollect

iCollect and other data acquisition systems can be connected to serial connector of the monitor, the Multi-I/O is needed.

Tools needed:

- 9 pin serial port connect line

1. Connect the Multi I/O adapter the monitor, if needed.
2. Using 9 pin serial port connect line to connect the monitor and PC.

NOTE Refer to the iCollect User's Manual for more information about the iCollect.

After hardware installation

After hardware installation, please:

- Perform installation checkout: refer to Chapter 8: Installation check
- Configure the monitor: refer to Chapter 7: Configuration

6

Using service interface

Service interface

The monitor has a ***Basic Service*** menu, which is a useful tool to example monitor functions and troubleshoot in case a fault occurs.

To access the service menu, select > ***Service*** > enter ***Username*** (service), ***Password*** (Wh1teF1sh) > select ***Login***.

Page 1

Page 2

NOTE The pictures in this chapter are for reference only. Details on the menu page can vary depending on the software version and the configuration of your device.

Parameters

NOTE Parameter values in this section are only for reference.

Gas unit

Sample Flow Gain	Displays the sampling pump gain value and gives access to adjust the sampling pump gain.
Zero Valve	Displays the state of zero valve, and gives access to control the zero valve.
Pump	Displays the state of sampling pump, and gives access to control sampling pump on/off.
Noise Meas	Displays the state of noise measurement, and gives access to activate or deactivate noise measurement.
Confirm	Confirm the sample flow gain adjustment.
CO2(%)	Real time CO2 concentrations.
Noise(%)	Standard deviation of CO2 concentration.
mV	CO2 channel A-E signal scaled to mV.
Gain	User gain. It is scaled as (User gain)/(Factory gain).
Ambient	Ambient pressure is measured every 30 min.
Amb-Work(mbar)	Ambient pressure, sampling system internal pressure.
Sample Flow	Calculate from differential pressure and is adjusted by the module.
Sample Flow Zero	Value as measured during initialization when the pump is off.

STP module

Cable	Display the connection state of P1, P2, T1, T2 and GE SpO2
Value	Display the value of P1, P2, T1, T2
SpO2	Display the value of GE SpO2

STP calibration

Protection	Protection for the configuration and calibrations.
Calibrate T1/T2	Calibrating the temperature channels T1 and T2.
Calibrate P1/P2	Calibrating the invasive blood pressure channels P1 and P2.
Start Calibration	A wizard item to finish calibration operations.

ECG module

Cable type	Shows the leadwire set connected: 3 lead or 5 lead.
Electrode	Shows ***ON*** when each of these electrodes is connected.

NIBP module

Calibration Check	On/off the calibration check.
Pressure(mmHg)	Display the real time cuff pressure.
Protection	On/off calibration protection.
Calibration	Start/stop the calibration.
Pressure(mmHg)	Adjust the measured pressure with arrows.
Confirm	Confirm the measured pressure.

NIBP pneumatics

Start Pump	Start/Stop the pump
Open Safe. Valve	Open/Close the safety valve
Open Defl. Valve	Open/Close the deflation valve
Reset Clock	Reset the timer valve for the ***Interval 20 mmHg –> 185 mmHg***
Pressure	Display the measured pressure multiplied by 10. This value is automatically zero-drift compensated.
Zero	Display the difference between the zeroing value in the memory and the current automatic zero-drift compensation multiplied by 10. The value can change between +20 to -20 mmHg. If the zero drift exceeds ±10 mmHg, the module should be recalibrated.
Pump, Safety Valve, Deflate Valve	Display their states.
Interval 20 mmHg –> 185 mmHg	Display the time value for the ***Interval 20 mmHg –> 185 mmHg***
Pressure (mmHg)	Display the real-time pressure value for ***Interval 20 mmHg –> 185 mmHg***

Country settings

National Reqs	Select software features that include national requirements.
Power Frequency	Set power frequency 50Hz or 60Hz.
Language	Select the software languages.

License

Serial Number	Display serial number for this monitor
GESP	GE SpO2
NELL	Nellcor SpO2
MASI	Masimo SpO2
INVP	IBP
TEMP	Temperature
OxyCRG	OxyCRG
NRES	Neonatal Respiration

FARR	Full Arrhythmia
NHL7	HL7 network
UNTY	Unity + HL7 network
WLAN	Wireless network
Import license from USB Disk	Import license files from USB storage device

Service log

Error Log	Display the error history view.
Alarm Log	Display the alarm history view.
Keyboard Log	Display the keyboard file name.
WLAN Log	Disoplay the WLAN history view.
Current file	Display which button on the left you have chosen.
Buttons on the left	Press the button, the content of related keyboard file shall be shown on the right. Each file can contain 100 logs.

Enter/Exit Demo Mode

This selection allows you to enter/exit the demo mode.

Under Demo Mode, the monitor displays the main vital signs' values and waveforms. No need accessories, central station or any other peripheral equipment connect to the monitor.

NOTE	All the values and waveforms the monitor displays are fictional.

NOTE The Demo Mode is only designed for the use of training and demo of operation. It is not intended for clinical use or paitent monitoring and diagnosis.

Set/test

Watchdog Give access to test the watchdog, the monitor will stop refreshing the watchdog after pressing the item

Factory Reset The monitor restores the factory default settings and reset the monitor.

Network

Network configuration

Unit Name Set the unit name for the monitor.

Bed Name Set the bed name for the monitor.

Rtclin DSCP	Tag outgoing packets with a DSCP (Differentiated Services Code Point) marking: realtime clinical information (waveforms, parameters, alarms), realtime network control information (time).
NRtclin DSCP	Tag outgoing packets with a DSCP marking: non-realtime clinical decision support information (admission, histories, full disclosure, printing).
NRtNclin DSCP	Tag outgoing packets with a DSCP marking: non-realtime non-clinical decision support information (service, insite).
MCS IP Address	Set the MCS (Mobile Care Server)'s IP address.
Save Changes	Save changes. When save changes, the monitor will require a restart except MCS IP address changed.
Cancel Changes	Cancel changes.

TCP/IP

IP Address	Set the static IP address of monitor.
Subnet Mask	Set the static subnet mask of monitor.
Default Gateway	Set the static default gateway of monitor.
Speed and Duplex	Set speed and duplex of monitor.
Save changes	Save changes.

Ping

Address	Set the destination IP address for the ping command.
Ping	Press to enable the ping command: send Internet Control Message Protocol (ICMP) echo request packets to the target host and wait for an ICMP response.
Ping Result	Display ping result.
NetFuse LAN Threshold	Set the wired network threshold for received packets per every second
NetFuse WLAN Threshold	Set the wireless network threshold for received packets per every second

NOTE When network traffic overload threshold, the network will disconnect automatically.

HL7 configuration

HL7 Receiver Ip	Set HL7 receiver IP address.

HL7 Receiver Port	Set HL7 receiver port.
HL7 Interval	Set HL7 interval value.
HL7 Patient Class	Set HL7 patient class.
Acknowledgment	Enable/disable acknowledgment check to HL7 server.
Save Changes	Save Changes.

Diagnosis

LED

Red Led	Test the red alarm light on the monitor.
Yellow Led	Test the yellow alarm light on the monitor.
Cyan Led	Test the cyan alarm light on the monitor.

Touch Screen

Display the touch screen status.

Wireless

WLAN status

Radio Enabled	Display the if WLAN radio enabled
Connection Status	Display the WLAN connection status.
Auth Result	Display the authentication status.
AP SSID	Display the access point's SSID.
AP BSSID	Display the access point's MAC address.
Channel/Freq	Display the connected channel and frequency.
IP-address	Display the device IP address (same as in wired MC network).
MAC	Display the device MAC address (same as in wired MC network).
Security Type	Display the security type to be used.
Region	Display the region of device connected in.
Supplicant version	Display the supplicant version which device used.
Driver version	Display the WLAN module driver version.
Firmware version	Display the WLAN module firmware version.
Packets	Display the quantity of packets for Rx and Tx.
Bytes	Display the size of packets for Rx and Tx.
Errors	Display the quantity of error packets for Rx and Tx.
Quality dBm	Display the WLAN Received signal strength indication (RSSI) (dBm): Signal, Noise and Signal-Noise Raito (SNR).

Tx Rate Mbps	Display the WLAN transmit rate (Mbps).
Tx Power dBm	Display the WLAN transmit power (dBm).
QoS Mode	Display the Quality of Service (Qos) mode.
RTS Threshold	Display the RTS threshold value.
Frag. Threshold	Display the Fragmentation Threshold value.

Access Point	Display the AP's BSSID.
Channel	Display the AP used channel.
Quality	Display the AP signal quality.
Authentication	Display the AP used authentication method.

WLAN Configuration — Basic

Manual Config	Enter the manually WLAN configuration menu.

Use File Config	Use the USB file to configure WLAN settings.
Config File	Choose the configuration files from USB storage device.
Apply	Apply changes.

WLAN radio

Radio Enabled	Enable or disable the WLAN radio.
SSID	Set the device Service Set Identifier (SSID).
Frequency Band	Set the WLAN raido frequency band.
Roaming Aggressiveness	Set the WLAN radio back ground scan cycle: Off, Normal, Medium, Aggressive.
Safe Mode	Enable or disable the WLAN safe mode.
Select Channel	Open the Channel Select menu.
Apply	Apply changes.

In ***Channel Select*** menu:

2.4 GHz	Select 1 to 14 channel
5 GHz	Select 36 to 165 channel

NOTE Please confirm the channel list for your own region. Not all the channels suit for your country.

WLAN security

Security

Security	Set the security method.
Encryption	Display the encryption type.
Security Key	Set the security key. Only available when Security is ***WPA-Personal***, or ***WAP2-Personal***.
HEX	Set the security key whether use HEX string.
EAP method	Set the Extensible Authentication Protocol (EAP) method.
Select Certificate	Open the Certificate Select menu. Only available when Security is ***WPA-Enterprise***, or ***WPA2-Enterprise***.
User Name	Enter the user name. Only available when Security is ***WPA-Enterprise***, or ***WPA2-Enterprise***.
Password	Enter the password. Only available when Security is ***WPA-Enterprise***, or ***WPA2-Enterprise***.
Enable 802.11r	Enable the fast roaming feature.

Apply	Apply changes.

Certificate Select

Enable CA Certificate	Enable the Certificate authority (CA) Certificate
Select CA Certificate	Select one CA certificate. Only available when ***Enable CA Certificate*** is selected.
Enable Client Certificate	Enable the Client Certificate.
Select Client Certificate	Select one Client certificate. Only available when ***Enable Client Certificate*** is selected.
Enable Private Key	Enable the private key.
Private Key	Select one Private Key. Only available when ***Enable Private Key*** is selected.
Enable Key Password	Enable the key password.
Private Key Password	Enter the key password. Only available when ***Enable Key Password*** is selected.
Enable Anonymous	Enable the Anonymous access.
Anonymous Identity	Enter the Anonymous Identity. Only available when ***Enable Anonymous*** is selected.
	NOTE The Anonymous Identity should be given by hospital.
Enable Fast Reauth	Enable the Fast Reauth. Speed up the authentication process.
Apply	Apply changes.

WLAN Configuration — Advanced

QoS	Enter the QoS configuration menu.
Security Build	Enter the private key and CSR create menu.
Antenna Config	Enter the Antenna configuration menu.
USB	Enter the WLAN USB disk import menu.

WLAN QoS

Real-Time Clinical Data DSCP	Tag outgoing packets with a DSCP marking: realtime clinical information (waveforms, parameters, alarms), realtime network control information (time).
Non-Real Time Clinical Data DSCP	Tag outgoing packets with a DSCP marking: non-realtime clinical decision support information (admission, histories, full disclosure, printing).
Non-Real Time Non-Clinical Data DSCP	Tag outgoing packets with a DSCP marking: non-realtime non-clinical decision support information (service, insite).

RTS Threshold	Set the RTS Threshold value.
Fragmentation Threshold	Set the Fragmentation Threshold value.
Apply	Apply changes.

WLAN security build

Private Key

Enable Password	Enable the private key password
Password	Enter the password, if the select the ***Enable Password***.
Create	Create the private key.

CSR

NOTE	This menu is available only when private key have been created.
Private Key	Display the private key.

Country Name (2 letter code)	Enter the country name (2 letter code).
State or Province Name	Enter the state or province name.
Locality Name	Enter the locality name.
Organization Name	Enter the organization name.
Organization Unit Name	Enter the organization unit name.
Common Name	Enter the common name.
Email Address	Enter the email address.
Create	Create the CSR.

WLAN antenna configure

2.4 G	Set the 2.4 G antenna type.
5 G	set the 5 G antenna type..
Apply	Apply changes.

WLAN USB

Select Certificate	Select the CA or Client certificate.
Import Certificate	Import the CA or Client certificate to the monitor.
Select Wlan Config	Select the WLAN configuration files.
Import WLAN Config	Import the WLAN configuration files to the monitor.
Export CSR	Export CSR to USB disk.

Software management

Software upgrade

IP Address	Display the IP address of the monitor.
Active Version	Display the active version of the main software.
Inactive Version	Display the inactive version of the main software.

SW Download Enable: Select to enable the main software download.

SW Activate Enable: Select to enable the main software activation.

Module upgrade

IP Address	Display the IP address of the monitor.
Upgrade Module Type	Select the which type of firmware to upgrade.
Active Version	Display the active version of the module firmware.
Inactive Version	Display the inactive version of the module firmware.
Module Download Enable	Select to enable the module firmware download.
Module Upgrade Enable	Select to enable the module firmware activation.

USB disk upgrade

Software	***Select Version***: Select the version of the main software. ***Download***: Download the main software from USB.
NIBP Firmware	***Select Version***: Select the version of the NIBP firmware. ***Download***: Download the NIBP firmware from USB.
ECG Firmware	***Select Version***: Select the version of the ECG firmware. ***Download***: Download the ECG firmware from USB.
RECX Firmware	***Select Version***: Select the version of the RECX firmware. ***Download***: Download the RECX firmware from USB.

7

Configuration

Platform Configuration

The configuration of a monitor consists of platform configuration and clinical configuration.

This chapter describes:

- How to configure the platform ready to take the monitor into use for the first time.
- The configuration tasks need for administration and maintenance.

For information on how to perform the clinical configuration, including modes' settings, refer to the monitor's Supplemental Information Manual.

Adjusting display

Adjusting the display brightness

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

1. Select the .
2. Adjust the display brightness with the ***Brightness***.

Adjusting the slave display

If needed, use the display's OSD menu to adjust the picture on the slave display.

Refer to the display's user manual for details.

Configuring wired CARESCAPE Network

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Network***.

3. Setup below items for ***Network Config***, then select ***Save Changes***.
   a. Enter ***Unit Name***.
   b. Enter ***Bed Name***.
   c. Enter ***MCS IP Address*** to setup the Mobile Care Server's IP address which monitor will talk to.
4. Select ***TCP/IP*** tab.
5. Setup below items for TCP/IP Configuration, then select ***Save Changes***.
   a. Enter a ***IP Address***.
   b. Enter a valid ***Subnet Mask*** level.
   c. Enter a valid ***Default Gateway***.
   d. Select the applicable ***Speed and Duplex*** option.

NOTE The B125/B105 monitors can't be as the Time Master, don't setup B125/B105 monitors with the highest IP address in CARESCAPE network.

The network configurations will be saved and active when the patient monitor is restarted.

Configuring HL7 Network

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Network*** > ***HL7 Config*** tab.
3. Setup below items, then select ***Save Changes***.
   a. Enter ***HL7 Receiver Ip*** for HL7 receiver IP address.
   b. Enter ***HL7 Receiver Port*** for HL7 receiver port.
   c. Select values for ***HL7 Interval***.
   d. Select the ***HL7 Patient Class***.

Configuring wireless CARESCAPE Network

Configuring wireless network via USB disk

NOTE The configuration files should be stored in following path in USB disk: `/wlancfg/`.

1. Insert the USB disk to the monitor.
2. Select the > ***Service*** > enter ***Username*** and ***Password***.
3. Select the ***Basic Service*** tab > ***Page2*** vertical tab > ***WLAN Config***.
4. Select the ***Advanced*** tab > ***USB Disk***.
5. Import the WLAN configuration files by ***Select Wlan Config*** and ***Import WLAN Config***.

6. Select the go back arrow > ***Basic*** tab.
7. Select ***Use File Config*** check box.
8. Select ***Config File*** and ***Apply*** .

Configuring wireless Network basic settings manually

1. Select the ⊞ > 🛠 ***Service*** > enter ***Username*** and ***Password***.
2. Select the ***Basic Service*** tab > ***Page2*** vertical tab > ***WLAN Config*** > ***Manual Config***.
3. Select ***Radio*** tab. Setup the following settings, and select ***Apply***.

Radio

Item	Description	Comments
Radio Enabled	Enable/disable the WLAN radio.	
SSID	Enter the Service Set Identifier (SSID), also known as network name.	The SSID of the wireless client must match the SSID of the wireless infrastructure. A valid SSID includes up to 32 case-sensitive ASCII characters, including space (ASCII decimal 32 to 126).
Adjust the following setting if needed.		
Frequency Band	Select the frequency band for the WLAN radio: • 2.4 GHz • 5 GHz • 2.4 and 5 GHz	The WLAN radio can communicate on the following frequency bands, protocols and data rates: • 2.4 GHz, IEEE 802.11b, up to 11 Mbps • 2.4 GHz, IEEE 802.11g, up to 54 Mbps • 5 GHz, IEEE 802.11a, up to 54 Mbps • 2.4 and 5 GHz, IEEE 802.11n, up to 540 Mbps
Roaming Aggressiveness	Select the back ground scan cycle: • OFF • Low • Medium • High	• Low: when rssi > -75 dbm, every 10 seconds will do scan once, when rssi < -75 dbm, every 5 seconds will do scan once • Medium: when rssi > -70 dbm, every 10 seconds will do scan once, when rssi < -70 dbm, every 5 seconds will do scan once. • High: when rssi > -65 dbm, every 7 seconds will do scan once, when rssi < -65

Item	Description	Comments
		dbm, every 2 seconds will do scan once.
Safe Mode	Enable/disable the safe mode.	When safe mode enabled, the monitor • Only passively scan all supported channels.
Select Channel	Select channels for ***2.4 GHz*** or ***5 GHz***.	Please confirm the available channels for your region. Not all the channels are suit for your country.

4. Select ***Security*** tab. Setup the following settings, and select ***Apply***.

Security

Item	Description	Comments
Security	Choose the confidentiality method. • Open • WPA-Personal • WPA2-Personal • WPA-Enterprise • WPA2-Enterprise	
Encryption	Choose the Encryption method. • TKIP • AES-CCMP	Please consult Hospital IT for Encryption.
Security Key and ***HEX***	Enter the Wifi security password. Select ***HEX*** to use HEX string for the password.	Only available when security is ***WPA-Personal***, or ***WPA2-Personal***. The valid security key should be 8-63 ASCII case-sensitive characters (ASCII decimal 32 to 126), or 64 HEX characters (0-9 and A-F), if HEX have been selected. Please consult Hospital IT for the security key.
EAP method	Select the Extensible Authentication Protocol (EAP) method: • EAP-TLS • TTLS-MSCHAPv2 • PEAP-MSCHAPv2 • PEAP-GTC	Only available when Authentication is ***WPA-Enterprise***, or ***WPA2-Enterprise***. Different EAP method will have difference Certificate selection. Please consult Hospital IT for EAP method.

Item	Description	Comments
User Name and ***Password***	Enter the User Name and Password.	Only available when Authentication is ***WPA-Enterprise***, or ***WPA2-Enterprise***. Please consult Hospital IT for User Name and password.
Select Certificate	• Enable the certificate need to configure • Select the certificate from USB storage device, or enter the password/identity.	Refer to the table below for details.
Enable 802.11r	Enable/disable the fast roaming.	Roaming performance can be negatively impacted (e.g. additional waveform dropout) when using non-fast roaming supported security methods (e.g. WPA-Enterprise).

Certificate Select

Enable CA Certificate ***Select CA Certificate***	1. Import the CA Certificate by USB disk. The Certificate should be provided by hospital IT. For more information, see “Importing and exporting files via USB disk” below. 2. Enable the Certificate Authority (CA) Certificate. 3. Select one CA certificate.
Enable Client Certificate ***Select Client Certificate***	1. The monitor generator CSR. For more information, see “Creating private key and CSR” below. 2. Export CSR files to USB disk, deliver to hospital IT. For more information, see “Importing and exporting files via USB disk” below. 3. Hospital IT generate the Client Certificate, save to USB disk. 4. Import the Client Certificate files to monitor. For more information, see “Creating private key and CSR” below. 5. Enable the Client Certificate. 6. Select one Client certificate.
Enable Private Key ***Private key*** ***Enable Key Password*** ***Private Key Password***	1. The monitor generator Private Key, and Private Key Password (If have). For more information, see “Creating private key and CSR” below. 2. The Private Key will be automatically filled in blank. 3. Enable Private Key. 4. If have the Private Key Password, enable the key password. 5. Enter the Private Key Password.

Enable Anonymous	Enable the Anonymous access.
Anonymous Identity	Enter the Anonymous Identity, which should be provided by hospital IT.
Enable Fast Reauth	Enable the Fast Reauth. Speed up the authentication process

Select ***Apply*** after certificate selecting.

Creating private key and CSR

1. Select the ⊞ > 🛠 ***Service*** > enter ***Username*** and ***Password***.
2. Select the ***Basic Service*** tab > ***Page2*** vertical tab > ***WLAN Config***.
3. Select the ***Advanced*** tab > ***Security Build***.
4. If needed, select ***Enable Password*** and enter the ***Password*** for private key.

   NOTE Remember or recorder the password for private key. When configure certificate, this Private Key Password should be input.

5. Select ***Create*** to create the private key.
6. Select ***CSR*** tab, enter the related information.

   NOTE This tab is available only when Private Key have been created.

7. Select ***Create*** to create the CSR.

Importing and exporting files via USB disk

1. Insert the USB disk to the monitor.
2. Select the ⊞ > 🛠 ***Service*** > enter ***Username*** and ***Password***.
3. Select the ***Basic Service*** tab > ***Page2*** vertical tab > ***WLAN Config***.
4. Select the ***Advanced*** tab > ***USB Disk***.
5. Import or export files via USB disk.

Item	Description	Comments
Select Certificate	Select the CA or Client Certificate file to import.	The Certificate file should be provided by hospital IT. NOTE: The Certificate files should be stored in following path in USB disk: `/ssl/certs/`.
Import Certificate	Import the CA or Client Certificate file from USB disk.	
Select WLAN Config	Select the WLAN Configuration files to import.	The configuration files should be created by hospital IT. NOTE: The configuration files should be stored in following path in USB disk: `/wlancfg/`.

Item	Description	Comments
Import WLAN Config	Import the WLAN Configuration files from USB disk.	
Export CSR	Export the CSR to USB.	The file's path in USB disk is display in the window.

Configuring wireless Network advanced settings manually

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select the ***Basic Service*** tab > ***Page2*** vertical tab > ***WLAN Config*** > ***Advanced*** tab.
3. Select the ***QoS***. Setup the following settings, and select ***Apply***.

QoS

Item	Description	Comments
Real-Time Clinical Data DSCP	Enter tag outgoing packets with a DSCP marking: realtime clinical information (waveforms, parameters, alarms), realtime network control information (time).	Recommended value is 48. Range is 48 to 63.
Non-Real Time Clinical Data DSCP	Enter tag outgoing packets with a DSCP marking: non-realtime clinical decision support information (admission, histories, full disclosure, printing).	Recommended value is 0. Range is 0 to 7.
Non-Real Time Non-Clinical Data DSCP	Enter tag outgoing packets with a DSCP marking: non-realtime non-clinical decision support information (service, insite).	Recommended value is 8. Range is 8 to 23.
RTS Threshold	Configure the RTS Threshold value.	Use the default RTS Threshold value, unless otherwise specified in the wireless network design. A valid RTS Threshold is a numeric value within the range of 64 to 2347.
Fragmentation Threshold	Configure the Fragmentation Threshold value.	Fragmentation Threshold specifies the maximum frame size a wireless device can transmit without fragmenting the frame. Use the default Fragmentation Threshold value, unless otherwise specified in the wireless network design. A valid Fragmentation Threshold is a numeric value within the range of 64 to 2346.

4. Back to the previous menu, select the ***Antenna Config***. Setup the following settings, and select ***Apply***

Item	Description	Comments
2.4 G	Configure the antenna configuration in 2.4 GHz frequency band. • Pri. & Sec. • Pri. only	The antenna configuration options are: • Primary and Secondary antenna worked in the same time • Primary antenna only
5 G	Configure the antenna configuration in 5 GHz frequency band. • Pri. & Sec. • Pri. only	The antenna configuration options are: • Primary and Secondary antenna worked in the same time • Primary antenna only

5. Restart the monitor.

Setting time and date

NOTE The monitor can't be the TIME MASTER in network. If the monitor is connected to the network, it follows the Central Station's time settings and the ***Time and Date*** is gray.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Clinical*** tab > ***Time and Date***.
3. Set up following items, then select ***Confirm***.
   - ***Hour***
   - ***Minutes***
   - ***Year***
   - ***Month***
   - ***Day***
4. Select ***Time Format*** tab, and select the ***Time Format***, if needed.

The manual time configuration takes effect immediately.

Setting time zone

The ***Time Zone*** is enable only when the monitor is not connected to the network and patient is discharged.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Clinical*** tab > ***Time Zone***.
3. Select ***Daylight Savings*** settings.
4. Select ***DST adjustment*** tab to setup DST settings.
5. Select ***Time Source*** tab to setup time sync source.

6. Select ***NTP Config*** tab to setup NTP settings

For more details, see Supplemental Information Manual.

Setting national requirements

Activate France specific defaults for the ECG HR adjustment range and the reminder beep behavior.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Country Settings*** > ***National Reqs***.
3. Select the applicable option:

Value	Description
None	Normal defaults
France	Enables: • Heart Rate high alarm limit maximum 280. • No ***Reminder Volume*** item in ***Alarm Options***. • Reminder beep will sound every 2 minutes when alarms have been silenced permanently.
Germany	Normal defaults

Setting power frequency

WARNING Incorrect power line frequency setting could adversely affect ECG processing.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Country Settings*** > ***Power Frequency***.
3. Select the applicable power line frequency.

Changing passwords

Each account can change the password for itself and the lower level access.

NOTE Username and password are case sensitive.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Change Password***.
3. Select ***clinical*** or ***service*** radio button as required.
4. Enter and retype the new passwords, then select ***Confirm***.

Resetting password

The authorized service personnel can reset the password to factory default password.

It need the activation code. Please contact GE service for activation code.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Reset Password***.
3. Enter the ***Expiration Date*** and ***Activation Code***.
4. Select ***Confirm***.

Transferring settings from a monitor to another

Exporting settings

You can save the user modes' settings to the USB storage device.

1. Discharge the patient. Insert the USB storage device to the USB port of the monitor.
2. Select the > ***Service*** > enter ***Username*** and ***Password***.
3. Select ***Save Modes*** > ***Export all modes to USB Disk***.

When finish to export settings, the screen return back and a message " Export modes successfully." displays on the menu.

Importing settings

You can import the saved user modes' settings from the USB storage device to the monitor.

1. Discharge the patient. Insert the USB storage device to the monitor's USB port.
2. Select the > ***Service*** > enter ***Username*** and ***Password***.
3. Select ***Save Modes*** > ***Import all modes from USB Disk***.

   When finish to export settings, the screen return back and a message " Import modes successfully. Please restart." displays on the menu.
4. Restart the monitor.

License management

- You can upload a license file that contains all acquired activation codes for license by the USB storage device.
  1. Insert the USB storage device with license file.
  2. Select the > ***Service*** > enter ***Username***, ***Password*** > ***Basic Service*** tab > ***License*** > ***Import license from USB Disk***.

  When finish to export settings, the screen return back and a message " Import license successfully. Please restart." displays on the menu.
- You can manually enter the required activation codes for license one by one, from ***License*** menu.

Restart is needed after import the license.

Contact authorized service personnel to acquire license file or activation codes for licenses.

NOTE The license file should be named as SN and stored in following path in USB disk: `/license/SPXXXXXXXXXXX.txt`.

Software management

Software download

Their two methods for software download.

- **From USB storage device**. Insert the USB storage device to the monitor directly to transfer software.
- **From PC**. Transfer software by GE Healthcare Software Transfer Utility (STU), which runs on a service PC. With this application, you can transfer new software to the patient monitor over the CARESCAPE Network or a crossover cable.

The new transferred software is inactive in the patient monitor(s) until you activate it.

For details about software download procedure, please refer to Appendix A: Software Download Instruction.

Activating the software

Before you start:

- Verify the compatibility of the connected bedside and network devices with the new software version that you are activating.
- For traceability – Record the serial number of the monitor where the software is installed to your local service database.
- Contact GE Healthcare to get the latest version of the user and service documentation.

NOTE Loss of monitoring - Software is activated only when the patient monitor is in a patient discharged state. Normal patient monitoring is unavailable until the software activation is completed.

1. For main software: > ***Service*** > enter the username and password > ***Basic Service*** tab > ***Page2*** vertical tab > ***SW Management*** > ***SW Upgrade*** tab. Or,

   For firmware: ***SW Management*** > ***Module Upgrade*** tab > select ***Upgrade Module Type:***

   The software status displays.
2. Check that the software to be activated is listed in the status.
3. For main software: Select ***SW Activate Enable:*** > ***Yes*** to activate the new software.

   For firmware: Select ***Module Upgrade Enable:*** > ***Yes*** to activate the new software.
4. Wait until the software activation completes.
5. Restart the monitor.

8

Installation check

Installation check procedure

The purpose of the installation check is to ensure that the system is properly installed and configured for use.

Service personnel shall perform the following checkout procedure for the monitoring system after the hardware installation and platform configuration is completed:

- Visual inspection
- Electrical safety test

  NOTE The manufacturer has performed the electrical safety test for the patient monitor and acquisition modules during final inspection. You do not have to perform the electrical safety tests during installation checkout, if there is less than 12 months since the patient monitor was manufactured. Check the manufacturing week and year from the device plate.

- Functional check

Performing visual inspection

Perform the following visual inspection to the installed monitoring system:

1. Carefully inspect the patient monitor if any damage.
2. Verify that the patient monitor are properly mounted with specified mounting solutions.
3. Verify that the cables between the patient monitor and the connected peripheral devices are intact, properly connected and secured to the right connectors.
4. Verify that all the network cables, are intact and properly connected to the right connectors.
5. Verify that the module are properly connected and locked.
6. Verify that the battery door are properly locked.

Functional check

The purpose of this functional check is to ensure that the system is properly installed and configured.

Skip the tests that are not applicable for the installed patient monitor.

Checking the startup

1. Turn on the power by press ON/OFF button more than 2 seconds.
2. Verify that the patient monitor starts up normally:
   - The yellow, red and blue alarm lights are lit momentarily.
   - The speaker gives an audible beep.
   - The normal welcoming screen appears with a status bar indicating the progress of the startup procedure.
   - Normal monitoring screen appears and there are no error messages on the screen.

   NOTE If you receive a ***Condition battery*** or a ***Battery failure*** message, refer to the troubleshooting instructions for battery conditioning or replacement.

3. Verify that the battery is fully charged.

   If the battery is not fully charged, keep the monitor connected to the mains until the battery is fully charged. The battery must be fully charged before taking the monitor into use for the first time.

Checking display

Testing picture quality

Perform this test both for the integrated main display and for the connect external display.

1. Verify that all text is readable and all images are clear.
2. Verify that the brightness is good. Adjust if necessary.

Testing touchscreen control

1. Verify the operation of a touchscreen by touching an active digit field. Verify that the related menu is opened.

Checking the time and date

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Clinical*** tab > ***Time and Date***.
3. Check the ***Current Time*** is correct, adjust the time and date if necessary.

   NOTE The monitor can't be set as ***TIME MASTER*** in network. You should adjust the time and date from the central station, if needed.

4. Select back arrow, select ***Time Zone***.
5. Check and adjust the settings if necessary.

Checking the device information

1. Select > ***Monitor Info***.

2. Verify the following:
   a. The version information are identified.
   b. The network information are identified.

Checking parameters

Connect the accessories (no need to connect to simulator or patient), check the monitor displays the following messages or activities.

1. Connect the accessories to monitor (no need to connect to simulator or patient).
2. Admit a patient.
3. Verify the following:
   a. ECG: ***Leads off*** will display in the waveform field.
   b. SpO_2: After connecting the SpO_2 cable and sensor, the sensor will be lit.
   c. NIBP: Press button, ***NIBP cuff loose*** will display in message field.
   d. IBP: After connecting IBP cable and transducer, ***InvBP's not Zeroed*** will display in message field.
   e. Temperature: After connecting the Temperature cable and sensor, ***Performing temp test*** will display in Temperature digit field for a few seconds.
   f. Gas: After installing the gas module, ***Calibrating gas sensor*** will display in CO_2 waveform field for about 1 minutes.

Testing the recorder

1. Select the ***Recorder Setup***.
2. Configure the waveforms:
   - ***Waveform 1***: ***I***
   - ***Waveform 2***: ***II***
   - ***Waveform 3***: ***Resp***
3. Select ***Record Waveforms***.
4. Verify that the recorder starts printing.
5. Let the recorder print for approximately 10 seconds.
6. Select the ***Stop Waveforms*** to stop recording.
7. Verify the following things from the printout:
   - The header line contains the date, time and some other applicable status.
   - The grid is clear.
   - The waveforms labels appear in the printout as configured.

Testing MC Network

Perform the following test only if the patient monitor is connected to a wired MC Network.

1. Check that the CAT-5 cable connector is clean and intact, connect it to the Ethernet network connector.
2. Check that a network symbol is displayed in the upper right corner of the screen.

Testing wireless LAN configuration

Perform the following test only if the patient monitor is connected to a wireless MC Network.

NOTE The wireless network must be properly installed and the patient monitor must be within the wireless coverage area.

1. Check that a network symbol is displayed in the upper right corner of the screen.
2. Reconnect the MC Network cable back to the MC Network connector, if applicable.

Completing the check procedure

1. Select > ***Discharge*** tab > ***Discharge*** > ***YES*** to discard any changes made to the patient monitor configuration during checkout.
2. Disconnect the test setup.
3. Complete the check form.

Verification procedure for wireless MC Network infrastructure

Purpose and scope

The purpose of this verification procedure is to test the operation of the wireless network infrastructure with a wireless transport monitor. To verify the operation, you move the transport monitor throughout the predetermined wireless coverage area and observe that a constant ECG waveform in the central station (CIC/CSCS) which display the view of the wireless monitor during the transport.

Due to the dynamic nature of a wireless environment this test provides only a snapshot of the wireless network at the time of performing the test. This is not a comprehensive test that covers all possible use situations, network traffic situations, radio frequency interferences or takes into account possible other changes in the wireless environment.

Test equipment and documentation needed

Ensure that you have the following equipment and documentation available.

CIC/CSCS

CIC/CSCS with full disclosure license.

NOTE CIC/CSCS with full disclosure license is enable you to view afterwards potential network connectivity issues between the transport monitor and the wireless MC Network, and to print reports about waveform loss situations.

Wireless B125/B105 monitor

- B125/B105 patient monitor with wireless MC Network connection.
- A compatible 5-lead ECG trunk cable and 5-leadwire set.
- A battery operated patient simulator.
- A plastic roll cart for the patient monitor, and the simulator. To avoid RF impairment, do not use metal roll carts.

Documentation about the Wireless LAN infrastructure

- GE WLAN pre-quote questionnaire with all applicable attachments.
- Wireless LAN design documentation, including site survey results.

Test plan

Each wireless installation is unique. As it is often impractical and uneconomical to verify the whole wireless coverage area and all the installed access points, prepare a site specific test plan that covers the areas that are most likely to encounter issues with the wireless communication.

Utilize the information provided in the pre-quote questionnaire, existing design documentation and site survey results, and discuss with the hospital IT specialists and clinical staff to identify the areas that are riskiest for poor wireless communication, and prepare a test plan accordingly.

Take into account the following aspects when preparing a test plan:

- Identify areas with known or obvious low signal strength.
- Identify areas with known sources of radio frequency interference, causing high noise floor and/or poor signal-to-noise ratio.
- Identify the special characteristics in the building layout (floors, wings patient rooms) and construction material used.
- Identify the time and areas of congestion, with high number of wireless clients and a lot of network traffic.
- Identify intended clinical workflow paths, including bedside locations and transport routes.

Prepare the test plan by documenting the intended walking path and test points to the floor plan, preferably to copy of a site survey document that shows the wireless coverage area, the location of wireless access points, signal strengths and sources of known radio frequency interferences.

NOTE In the sample floor plan below, EG1- EG20 represent possible test points. Take into account in your plan that some rooms and areas may not be accessible at the time of performing the survey.

Test setup

The patient monitors and the CIC/CSCS shall be installed, configured and tested to operate in the same MC Network.

CIC/CSCS setup

Configure the CIC/CSCS to capture full disclosure data from the wireless monitor B125/B105. Refer to CIC/CSCS Clinical Information Center Service Manual and CIC/CSCS Clinical Information Center Operator's Manual for detailed instructions.

Setup the wireless B125/B105 monitor

NOTE The ECG cables and patient simulator for the wireless B125/B105 monitors are needed only, if a CIC/CSCS with full disclosure license is available in the MC Network.

NOTE Ensure that the patient monitor battery, the service PC battery and the patient simulator battery are fully charged.

Set up the connections:

1. Set up the monitor and the patient simulator on a roll cart.
2. Connect the ECG cables to the monitor and to the patient simulator.
3. Turn on the patient monitor, and the patient simulator.
4. Configure the patient simulator to output ECG waveform: normal sinus rhythm, hearth rate 80 bpm, amplitude 1mV.

   Refer to the simulator documentation for details on how to use and configure the simulator.

Configure the patient simulator:

1. Configure the ECG1, ECG2 and ECG3 waveform fields to the monitor screen with adequate priority.
2. Select the Setup tab in the ECG menu and configure: ECG1 lead: II, ECG2 lead: V1, ECG3 lead: aVL.
3. Admit a patient in ***Admit/Discharge*** menu.

Test execution

Execute the test procedure according to the test plan. Contact the nursing staff to ensure access to the needed areas before starting the test.

1. Move the roll cart to the starting point of the planned test route.
2. Stop at each test point and perform the following tasks:
   a. On the CIC/CSCS: Verify that ECG waveforms from the transport monitor without any losses.
   b. Mark the network time, RSSI and Transmit Rate to the test form.
   c. If there is a waveform loss situation or the RSSI or the Transmit Rate is lower than specified:
      - Observe the length of the waveform loss and, if possible, potential cause of it, for example roaming or out of range situations.
      - Take a photo of the refreshed ***WLAN Status*** screen.
3. Move the roll cart to the following test point along the walking path and repeat the step 2 at each test point until you have completed the test plan. While moving the roll cart from one test point to another, at all times, verify that there are no losses in the ECG waveforms.

NOTE A momentary, up to 5 seconds waveform loss is normal during roaming. If longer, or repeating waveform losses occur between test points, make this an extra test point and report it the same way as observations in step 2.

Summary and reporting

Include the following documents to the test results:

1. Print the full disclosure reports from the CIC/CSCS about the observed waveform loss situations.
2. Print the snapshots of the WLAN diagnostics screens that you saved into the service PC.
3. Mark to the printouts the id of the test point.

Review and evaluate the test results together with GE personnel and the hospital IT specialists. Summarize, if additional testing is needed and/or if the WLAN infrastructure needs to be changed.

9

Electrical safety tests

Electrical safety tests

Electrical safety tests provide a method of determining if potential electrical health hazards to the patient or operator of the device exist.

Test setup

Test conditions

Perform electrical safety tests under normal ambient conditions of temperature, humidity and pressure.

Test equipment

The test equipment required to perform electrical safety tests is listed below.

Tool	Part number / requirement
Safety Analyzer / Leakage Current Tester	Equivalent to the circuits shown.
Safety Test Body Kit *	P/N M1155870 or equivalent

* Instead of the test bodies included in the safety test body kit, other applicable test bodies with all pins connected together may be used.

Perform electrical safety tests using an electrical safety analyzer according to IEC 60601-1, ANSI/AAMI ES60601-1, EN 60601-1 or CSA C22.2 No. 601.1. The schematics in this section provide a general understanding of the test equipment. Actual configuration of test equipment may vary. Refer to the instructions delivered with the safety analyzer to perform each test.

The patient monitor being tested should be placed on an insulating surface.

NOTE Before proceeding, make sure that all test equipment is properly calibrated, maintained and functioning.

NOTE GE recommends that the qualified personnel performing the tests should record the test results of each electrical safety test, for example by using the installation / maintenance check forms included in this manual.

System setup

These instructions are intended for every component in the system. Ensure that all system components are properly connected to the patient monitor.

Verifying power outlet

1. Verify that the power outlet is wired correctly according to the country's electrical code standard before starting the following electrical safety tests.

The results of the following tests will be inaccurate unless a properly wired power outlet is used.

Verifying power cord and plug

1. Verify that the power cord being used with the patient monitor is undamaged:
   a. Inspect the power cord for wear or damage. If damage is suspected, test for continuity through each conductor of the power cord connector.
   b. Replace the power cord, as necessary, with a regulatory-approved cord for the country of use.

WARNING Use only AC power cords recommended or manufactured by GE.

Ground earth integrity check

There are two alternative methods for checking the ground (earth) integrity: a) Ground continuity test and b) Impedance of protective earth connection. These tests determine whether the device's exposed metal and power inlet's earth (ground) connection has a power ground fault condition.

Perform either test a) or test b) in accordance to your local regulations.

NOTE Refer to the instructions delivered with the safety analyzer to perform each test.

Testing ground continuity

The measuring device (MD) in the diagram below may be a digital multimeter or part of the safety analyzer.

Acceptance criteria:

- For equipment without a power supply cord, the impedance between the protective earth terminal and any accessible metal part which is protectively earthed shall not exceed 0.1 ohms.

- For equipment with a power supply cord, the impedance between the protective earth pin in the mains plug and any accessible metal part which is protectively earthed shall not exceed 0.2 ohms.

Checking impedance of protective earth connection

This test is normally only required as a manufacturing production test to receive safety agency compliance. Some country agencies do require this test after field equipment repairs (i.e., Germany's DIN VDE 0751 standards). Consult your country/local safety agency if in doubt.

Check compliance as follows:

1. A current of 25A from a current source with a frequency of 50 or 60 Hz with a no-load voltage not exceeding 6 V is passed for at least 5 seconds, but not more than 10 seconds, through the protective earth terminal or the protective earth pin in the mains plug and each accessible metal part which could become live in case of failure in basic insulation.
2. The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. It shall not exceed the values indicated.

   When taking this measurement, flex the unit's power cord along its length. There should be no fluctuations in resistance.

Acceptance criteria:

- For equipment without a power supply cord, the impedance between the protective earth terminal and any accessible metal part which is protectively earthed shall not exceed 0.1 ohms.
- For equipment with a power supply cord, the impedance between the protective earth pin in the mains plug and any accessible metal part which is protectively earthed shall not exceed 0.2 ohms.

Testing earth leakage current

This test measures the current leakage flowing from the mains part through or across the insulation into the protective earth conductor of the device under test.

Perform this test both in Normal Condition (NC) and in a Single Fault Condition (SFC), where one of the supply conductors is open at a time. Perform the test with normal and reverse polarity

NOTE Refer to the instructions delivered with the safety analyzer to perform this test.

1. Configure the safety analyzer as follows (NC):
   - Polarity: NORMAL
   - Neutral: CLOSED
2. Power on the device under test.
3. Read and record the current leakage indicated on the safety tester.
4. Configure the safety analyzer as follows (SFC):
   - Polarity: NORMAL
   - Neutral: OPEN
5. Read and record the current leakage indicated on the safety tester.
6. Configure the safety analyzer as follows (SFC):
   - Polarity: REVERSED
   - Neutral: OPEN
7. Read and record the current leakage indicated on the safety tester.
8. Configure the safety analyzer as follows (NC):
   - Polarity: REVERSED
   - Neutral: CLOSED
9. Read and record the current leakage indicated on the safety tester.
10. Power off the device under test.

Acceptance criteria in Normal Condition (NC):

- All readings shall be less than or equal to 300 µA for installations that require compliance to ANSI/AAMI ES60601-1 requirements.
- All readings shall be less than or equal to 500 µA for installations that require compliance to EN 60601-1 / IEC 60601-1 requirements.

Acceptance criteria in Single Fault Condition (SFC) – one of the supply conductors open at a time:

- All readings shall be less than or equal to 1 mA.

Testing enclosure (touch) leakage current

This test measures current leakage through the exposed conductive parts on the device under test.

Perform the test in Normal Condition (NC) and in two different Single Fault Conditions (SFC): 1) earth open and 2) one of the supply conductors open at a time. Perform the test with normal and reverse polarity.

NOTE Refer to the instructions delivered with the safety analyzer to perform this test.

1. Configure the safety analyzer as follows (NC):
   - Polarity: NORMAL
   - Neutral: CLOSED
   - Earth (GND): CLOSED
2. Power on the device under test.
3. Read and record the current leakage indicated on the safety tester.
4. Configure the safety analyzer as follows (SFC):
   - Polarity: NORMAL
   - Neutral: OPEN
   - Earth (GND): CLOSED
5. Read and record the current leakage indicated on the safety tester.
6. Configure the safety analyzer as follows (SFC):
   - Polarity: NORMAL
   - Neutral: CLOSED
   - Earth (GND): OPEN
7. Read and record the current leakage indicated on the safety tester.

8. Configure the safety analyzer as follows (SFC):
   - Polarity: REVERSED
   - Neutral: CLOSED
   - Earth (GND): OPEN
9. Read and record the current leakage indicated on the safety tester.
10. Configure the safety analyzer as follows (SFC):
    - Polarity: REVERSED
    - Neutral: OPEN
    - Earth (GND): CLOSED
11. Read and record the current leakage indicated on the safety tester.
12. Configure the safety analyzer as follows (NC):
    - Polarity: REVERSED
    - Neutral: CLOSED
    - Earth (GND): CLOSED
13. Read and record the current leakage indicated on the safety tester.
14. Power off the device under test.

Acceptance criteria in Normal Condition (NC):

- All readings shall be less than or equal to 100 µA

Acceptance criteria in Single Fault Condition (SFC) – earth open or one of the supply conductors open at a time:

- All readings shall be less than or equal to 300 µA for installations that require compliance to ANSI/AAMI ES60601-1 requirements.
- All readings shall be less than or equal to 500 µA for installations that require compliance to EN 60601-1 / IEC 60601-1 requirements.

Patient leakage current tests

The following table specifies the monitor's component and the related patient connectors to be tested in the Patient (source) leakage current tests and in the Patient (sink) leakage current tests.

Use the safety test body kit, P/N M1155870 (or equivalent), to perform patient leakage current tests. This safety test body kit contains various patient connectors where all pins are shorted out together. For information on which test body to use for each patient connector, refer to the service instructions included in the safety test body kit.

NOTE If not otherwise stated in the table below, each test body is connected directly to the specified connector in the patient module.

Patient connectors to be tested	
Component	**Patient connector**
Host	ECG & SpO2

Testing patient (source) leakage current

This procedure measures the leakage current from an applied part connector of the device to ground.

Perform the test in Normal Condition (NC) and in two different Single Fault Conditions (SFC): 1) earth open and 2) one of the supply conductors open at a time.

Perform the test with normal and reverse polarity.

NOTE Refer to the instructions delivered with the safety analyzer to perform this test.

NOTE Perform this test for all the connected parameter modules and patient connectors specified Table Patient connectors to be tested with each module.

1. Configure the safety analyzer as follows (NC):
   - Polarity: NORMAL
   - Neutral: CLOSED
   - Earth (GND): CLOSED
2. Power on the device under test.
3. Read and record the current leakage indicated on the safety tester.
4. Configure the safety analyzer as follows (SFC):
   - Polarity: NORMAL
   - Neutral: OPEN
   - Earth (GND): CLOSED
5. Read and record the current leakage indicated on the safety tester.
6. Configure the safety analyzer as follows (SFC):
   - Polarity: NORMAL
   - Neutral: CLOSED
   - Earth (GND): OPEN
7. Read and record the current leakage indicated on the safety tester.

8. Configure the safety analyzer as follows (SFC):
   - Polarity: REVERSED
   - Neutral: CLOSED
   - Earth (GND): OPEN
9. Read and record the current leakage indicated on the safety tester.
10. Configure the safety analyzer as follows (SFC):
    - Polarity: REVERSED
    - Neutral: OPEN
    - Earth (GND): CLOSED
11. Read and record the current leakage indicated on the safety tester.
12. Configure the safety analyzer as follows (NC):
    - Earth (GND): REVERSED
    - Neutral: CLOSED
    - Earth (GND): CLOSED
13. Read and record the current leakage indicated on the safety tester.
14. Power off the device under test.
15. Repeat this test for all the connected parameter modules and patient connectors specified in Table Patient connectors to be tested with each module.

Acceptance criteria in Normal Condition (NC):

- All readings shall be less than or equal to 10 µA.

Acceptance criteria in Single Fault Condition (SFC) – earth open or one of the supply conductors open at a time:

- All readings shall be less than or equal to 50 µA.

Testing patient (sink) leakage current

This procedure measures the leakage current from an applied part connector of the device to ground. Perform the test in Normal Condition (NC) with normal and reverse polarity.

NOTE Refer to the instructions delivered with the safety analyzer to perform this test.

WARNING SHOCK HAZARD. The following step causes high voltage at the test body. Do not touch the test body.

NOTE Perform this test for all the connected parameter modules and patient connectors specified in Table Patient connectors to be tested with each module.

1. Configure the safety analyzer as follows:
   - Polarity: NORMAL
   - Neutral: CLOSED
   - GND: CLOSED
2. Power on the device under test.
3. Read and record the current leakage indicated on the safety tester.
4. Configure the safety analyzer as follows:
   - Polarity: REVERSED
   - Neutral: CLOSED
   - GND: CLOSED
5. Read and record the current leakage indicated on the safety tester.
6. Power off the device under test.
7. Repeat this test for all the connected parameter modules and patient connectors specified in Table Patient connectors to be tested with each module

Acceptance criteria:

- All readings shall be less than or equal to 50 µA.

Completing electrical safety tests

1. Disconnect the safety analyzer from the power outlet.
2. Disconnect the test equipment from the patient monitor.
3. Disconnect the patient monitor's power cord from the leakage tester.

10

Maintenance check

Planned and corrective maintenance procedures

This chapter describes the check procedure and the maintenance activities for the device during planned maintenance and after corrective maintenance.

This chapter also covers the battery maintenance information for the patient monitor's lithium-ion battery.

Refer to "E-miniC module" chapter for planned and corrective maintenance check procedures of the E-miniC module.

The cleaning precautions, cleaning requirements, cleaning procedures, and recommended cleaning solutions for the monitor are described in the patient monitor's user's manual. For details about cleaning, disinfecting and sterilizing the accessories, see the instructions for use in the accessory package.

WARNING Only perform maintenance procedures specifically described in the manual.

WARNING Planned maintenance should be carried out annually. Failure to implement the recommended maintenance schedule may cause equipment failure and possible health hazards.

NOTE The manufacturer does not, in any manner, assume the responsibility for performing the recommended maintenance schedule, unless an Equipment Maintenance Agreement exists. The sole responsibility rests with the individuals, hospitals, or institutions utilizing the device.

Record the results of the planned and the corrective maintenance check procedures to the Checkforms.

Planned maintenance

Perform the planned maintenance procedure completely 12 months after installation. Perform the procedure in the following order:

1. Visual inspection
2. Electrical safety test
3. Functional check

Corrective maintenance

Service personnel shall perform the following checkout procedure steps after any corrective maintenance, before taking the monitor back into clinical use:

The detached, replaced or upgraded FRU:	Required check procedure		
	Visual inspections	Electrical safety test	Functional check
Recorder unit (FRU / Upgrade)	Yes	No	Start-up Recorder
Module rail unit	Yes	No	Start-up
Mains fuses Monitor battery (FRU)	Yes	No	Start-up
After detaching or replacing any other part inside the patient monitor.	Yes	Yes	All functional check steps

Performing visual inspection

Perform the following visual inspection to the installed monitoring system:

1. Carefully inspect the patient monitor if any damage.
2. Verify that the patient monitor are properly mounted with specified mounting solutions.
3. Verify that the cables between the patient monitor and the connected peripheral devices are intact, properly connected and secured to the right connectors.
4. Verify that all the network cables, are intact and properly connected to the right connectors.
5. Verify that the module are properly connected and locked.
6. Verify that the battery door are properly locked.

Functional check

The purpose of this functional check is to ensure that the system is properly installed and configured.

Skip the tests that are not applicable for the installed patient monitor.

Checking the startup

1. Turn on the power by press ON/OFF button more than 2 seconds.
2. Verify that the patient monitor starts up normally:
   - The yellow, red and blue alarm lights are lit momentarily.
   - The speaker gives an audible beep.
   - The normal welcoming screen appears with a status bar indicating the progress of the startup procedure.
   - Normal monitoring screen appears and there are no error messages on the screen.

NOTE If you receive a ***Condition battery*** or a ***Battery failure*** message, refer to the troubleshooting instructions for battery conditioning or replacement.

3. Verify that the battery is fully charged.

   If the battery is not fully charged, keep the monitor connected to the mains until the battery is fully charged. The battery must be fully charged before taking the monitor into use for the first time.

Checking display

Testing picture quality

Perform this test both for the integrated main display and for the connect external display.

1. Verify that all text is readable and all images are clear.
2. Verify that the brightness is good. Adjust if necessary.

Testing touchscreen control

1. Verify the operation of a touchscreen by touching an active digit field. Verify that the related menu is opened.

Checking the time and date

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Clinical*** tab > ***Time and Date***.
3. Check the ***Current Time*** is correct, adjust the time and date if necessary.

   NOTE The monitor can't be set as ***TIME MASTER*** in network. You should adjust the time and date from the central station, if needed.

4. Select back arrow, select ***Time Zone***.
5. Check and adjust the settings if necessary.

Checking the device information

1. Select > ***Monitor Info***.
2. Verify the following:
   a. The version information are identified.
   b. The network information are identified.

Checking parameters

Required tools for functional check

NOTE See the Supplies and accessories for compatible accessories.

- A multiparameter patient simulator that supports ECG, invasive pressure, and temperature measurements.
- Adapter cables to GE invasive pressure and temperature connectors.

- For ECG:
  - Multi-Link 5-lead ECG trunk cable, IEC or AHA
  - Multi-Link 5-leadwire set, IEC or AHA
- For invasive pressure:
  - Dual IP adapter cable
- For temperature:
  - Dual temperature adapter cable.
- For SpO2:
  - SpO2 interconnect cable
  - SpO2 finger sensor
- For NIBP:
  - Adult NIBP hose
  - Adult NIBP cuff
  - Infant NIBP cuff hose
  - A rigid cylinder or pipe
  - Digital manometer with a range of at least 0 to 1000 mmHg and accuracy 0.5% FS.
  - Tubing parts to connect a manometer to the NIBP cuff and hose.
- For Defib sync:
  - Multi-Link 5-lead ECG trunk cable, IEC or AHA
  - Multi-Link 5-leadwire set, IEC or AHA
  - Oscilloscope
  - Analog output cable (2000633-001)

NOTE You can alternatively use the GE defib sync tester, 2040582-001, together with the Analog output cable, 2000633-001 and a multiparameter simulator to perform this test. Follow the instructions included with the tester.

Making connections for functional check

1. Turn the monitor on and wait until the normal screen appears.
2. Connect ECG and impedance respiration cables:
   a. Connect the 5-lead ECG trunk cable to the ECG connector.
   b. Connect 5-leadwire set to the trunk cable and to the simulator.
3. Connect SpO_2:
   a. Connect the SpO_2 simulator to the SpO_2 connector on the monitor with the applicable SpO_2 and/or simulator accessories.

4. Connect NIBP:
   a. Connect an adult NIBP hose to the NIBP connector.
   b. Connect an adult NIBP cuff to the hose.
   c. Wrap the cuff around a rigid cylinder or pipe.
   d. Connect the pressure manometer with pressure pump to the NIBP hose and NIBP cuff with a piece off tubing.
   e. Ensure that all of the connections are leak-proof.

5. Connect invasive pressure cables:
   a. Connect the dual invasive pressure adapter cable to the invasive pressure connector.
   b. Connect the multiparameter patient simulator with its invasive pressure adapter cables to the dual invasive pressure adapter cable.
6. Connect temperature cables:
   a. Connect the dual temperature adapter cable to the temperature connector.
   b. Connect the multiparameter patient simulator with its temperature adapter cables to the dual temperature adapter cable.
   c. Check that the simulator is configured for 400 series probes.

7. Connect the analog output cable to the monitor's defibrillator synchronization connector, located on the Multi I/O.

Defibrillator Synchronization connector		Analog output Cable (2000633-001). Related wire color in the Pin number Signal open end of the cable [1])
Pin number	**Signal**	
1	Digital defibrillator syncronization marker out signal	Black
2	NC	Green
3	GND	Red
4	GND	Blue
5	GND	White
6	GND	Yellow
7	GND	Grey

Configuring monitor for functional check

1. Configure ECG measurement:
   a. Select the > ***Screen Setup***. Configure the ECG1, ECG2 and ECG3 waveform fields to the screen with adequate priority.
   b. Select the HR digit field and configure:
      - ***ECG1 Lead***: II
      - ***ECG2 Lead***: V1
      - ***ECG3 Lead***: aVL
      - ***Beat Volume***: 1 or greater
      - ***Size***: 1x
   c. Select the ***Advanced*** tab and configure:
      - ***Pacemaker Detection***: Show
      - ***Primary HR Source***: ECG
2. Configure impedance respiration:
   a. Select the > ***Screen Setup***. Configure the Resp waveform field to the screen with adequate priority.
   b. Select Respiration digit field and configure:
      - ***Measurement***: ***ON***.

1. Brown wire is not connected.

3. Configure SpO_2:
   a. Select the > ***Screen Setup***. Select SpO_2 waveform field to the screen with adequate priority.
4. Configure NIBP:
   a. Select the > ***Screen Setup***. Select ***NIBP*** digit field to the screen with adequate priority.
   b. Select the NIBP digit field and configure:
      - Select ***Use Default Inflation Pressure***
5. Configure invasive pressure measurement:
   a. Select the > ***Screen Setup***. Select ***IBP1***, ***IBP2***, waveform fields to the screen with adequate priority.
   b. Select IBP1 digit field and configure:
      - ***Label***: IBP1
      - ***Scale (mmHg)***: 0-250 mmHg
      - ***Display Format***: Mean
   c. Repeat step b. for IBP2 waveform.
6. Configure temperature:
   a. Select the > ***Screen Setup***. Select ***T1*** and ***T2*** parameter windows to the screen with adequate priority.

Configuring simulator for functional check

For instructions on how to use and configure the simulators, refer to the simulators' documentation.

1. Configure the ECG settings as follows:
   - ***ECG Rhythm***: a normal sinus rhythm
   - ***Heart Rate***: 80–90 bpm
   - ***Amplitude***: 1 mV
2. Configure the impedance respiration settings as follows:
   - ***Baseline impedance***: 1000 Ω
   - ***Amplitude***: 1 Ω
   - ***Respiration rate***: 20 breaths per minute
   - ***Lead selection***: II (LA or LL)
3. Configure the simulator's SpO_2 settings as follows:
   - ***SpO2***: 90–100
4. Configure the simulator's invasive pressure channels IBP1, IBP2 as follows:
   - ***Sensitivity***: 5 μV/V/mmHg
   - ***InvBP output***: 0 mmHg static pressure or atmosphere

5. Configure the simulator's temperature settings for all temperature channels as follows:
   - ***Temperature***: 32 — 40 °C/ 89.6 — 104 °F

Testing ECG measurement

1. Test for normal sinus rhythm.
   a. Check that the monitor displays the ECG leads II, V1 & aVL and the waveforms are noise-free.

      The monitor shall display a 80± 5 bpm heart rate and an audible QRS tone sounds with each QRS complex. If necessary, turn up the QRS volume.
2. Check pacemaker detection:
   a. Configure the simulator's ECG output to Asynchronous Pacemaker Pulse.
   b. Check that pacemaker spikes are shown on the ECG waveform.
   c. Configure the simulator's ECG output to 80 beats per minute, Normal Sinus Rhythm.
3. Check Asystole detection:
   a. Configure the simulator's ECG output to Asystole.
   b. Check that the ***Asystole*** alarm appears on the monitor screen.
   c. Configure the simulator's ECG output to 80 beats per minute, Normal Sinus Rhythm.
4. Check leads off detection:
   a. Detach the RA/R leadwire from the simulator.
   b. Check that the Lead II waveform disappears from the ECG1 waveform field, followed by an ***RA/R lead off*** message.
   c. Check that Lead II is replaced by Lead III in the ECG1 waveform field after a while.
   d. Reconnect the RA/R leadwire to the simulator.
   e. Check that Lead III is replaced with Lead II in the ECG waveform field.

Testing impedance respiration measurement

1. Check the respiration rate:
   a. Check that the RESP waveform is shown.
   b. Check that the ***RR*** value is 20 (±5).
2. Check the apnea detection:
   a. Configure the simulator's Apnea Simulation to 32 sec.
   b. Check that the monitor activates the ***Apnea*** alarm.
   c. Configure the simulator's Apnea Simulation to OFF.

Testing SpO_2 measurement

1. Connect the SpO_2 sensor to your finger and wait until a pulse is found.

2. Check that:
   - The SpO_2 reading appears in the digit field.
   - The plethysmographic waveform appears on the screen.

   You can verify the functionality of a pulse oximeter probe and monitor with a functional SpO_2 tester but you cannot evaluate their accuracy with such a device. However, if a particular calibration curve is accurate for the combination of a pulse oximeter monitor and probe, a functional tester can measure the contribution of a monitor to the total error of a monitor/probe system. The functional tester can then measure how accurately a particular pulse oximeter monitor is reproducing that calibration curve.

Testing NIBP measurement

1. Check the NIBP tubing system for leaks and check if NIBP calibration is required.
   a. Select the > ***Service*** > enter ***Username*** and ***Password***.
   b. Select ***Basic Service*** > ***Parameters*** > ***NIBP***.
   c. Select ***ON*** for the ***Calibration Check***.
   d. Pump a 200 mmHg static pressure according to the manometer. The pressure measured by the device is updated in real-time to the calibration menu. Wait for a while until the pressure stabilizes.
   e. Use the following table to evaluate the NIBP leakage and NIBP calibration status.

Observed results	Conclusion	Recommended action
NIBP is leaking.	Test failed. The NIBP tubing is leaking if the pressure does not stabilize and drops at a rate of 1 mmHg or more for every five seconds.	Troubleshoot the root cause for the NIBP leakage and correct the problem. 1. Check that the external NIBP test setup is not leaking. Correct the root cause for the leak and repeat the NIBP measurement test. 2. Check that the internal NIBP tubing is not leaking. Re-perform all the check out procedures required after performing corrective maintenance to the module.
NIBP is out of calibration.	Test failed. NIBP calibration is required, if the readings in the manometer and in the NIBP calibration menu differ more than ±1 mmHg.	1. Calibrate NIBP. 2. Perform functional check to retest the NIBP measurement.
No leakage and NIBP is accurate.	Test passed. NIBP is working properly, if it is not leaking and it shows accurate readings.	Perform the next step of this procedure.

2. Disconnect the NIBP cuff and manometer from the module.

Testing invasive pressure measurement

1. Zero the tested pressure channel:
   a. Ensure that the simulator's invasive pressure output channel is configured to 0 mmHg static.
   b. Select the digit field of the tested invasive pressure channel, Select ***Zero***.
   c. Check that a ***Zeroing*** message followed by a ***Zeroed*** message is shown in the menu.
2. Test a static pressure:
   a. Configure the simulator's invasive pressure output channel to 200 mmHg static pressure.
   b. Check that a flat pressure line appears on the related waveform field.
   c. Check that the reading in the digit field is 200 ± 10 mmHg.
   - If the measured value is not within the specification limits, recalibrate the measurement.
3. Check the pressure waveform:
   a. Configure the simulator's invasive pressure output channel to Arterial 120/80.
   b. Check that the pressure waveform for the tested invasive pressure channel appears in the waveform window.
   c. Check that the Sys/Dia (Mean) pressure values are shown in the related digit field.

Testing temperature measurement

Perform the following steps to both the temperature channels.

NOTE The 'x' in the Tx refers to the temperature channel being tested.

1. Check that:
   a. Tx temperature matches the configured simulator value chosen earlier ± 0.1 °C/ ± 0.18 °F.
   b. There are no error messages on the screen.
   - If the measured value is not within the specification limits, recalibrate the measurement.

Testing MC Network

Perform the following test only if the patient monitor is connected to a wired MC Network.

1. Check that the CAT-5 cable connector is clean and intact, connect it to the Ethernet network connector.
2. Check that a network symbol is displayed in the upper right corner of the screen.

Testing wireless LAN configuration

Perform the following test only if the patient monitor is connected to a wireless MC Network.

NOTE The wireless network must be properly installed and the patient monitor must be within the wireless coverage area.

1. Check that a network symbol is displayed in the upper right corner of the screen.
2. Reconnect the MC Network cable back to the MC Network connector, if applicable.

Testing the recorder

1. Select the ***Recorder Setup***.
2. Configure the waveforms:
   - ***Waveform 1***: ***I***
   - ***Waveform 2***: ***II***
   - ***Waveform 3***: ***Resp***
3. Select ***Record Waveforms***.
4. Verify that the recorder starts printing.
5. Let the recorder print for approximately 10 seconds.
6. Select the ***Stop Waveforms*** to stop recording.
7. Verify the following things from the printout:
   - The header line contains the date, time and some other applicable status.
   - The grid is clear.
   - The waveforms labels appear in the printout as configured.

Testing defibrillator synchronization marker out signals

1. Test the frequency of the Marker Out signal:
   a. Change the oscillocope Volts scale:

Digital defibrillator synchronization marker out signal: Black Ground: Red Probe Type: x10 Time/Division: 200 ms Volts/Division: 2V	

   b. Check that the signal shown on the oscilloscope screen corresponds with the preceding picture.

2. Test the pulse width of the Marker Out signal:
   a. Change the Time scale on the oscilloscope:

Digital defibrillator synchronization marker out signal: Black Ground: Red Probe Type: x10 Time/Division: 5 ms Volts/Division: 2V	

   b. Check that the signal shown on the oscilloscope screen corresponds to the preceding picture.

- If the test fails, replace the Multi I/O or Carrier board.

Completing the check procedure

1. Select > ***Discharge*** tab > ***Discharge*** > ***YES*** to discard any changes made to the patient monitor configuration during checkout.
2. Disconnect the test setup.
3. Complete the check form.

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Calibration and adjustments

NIBP calibration

NIBP calibration shall be performed:

- If the NIBP Calibration Check failed.
- If the measured value is not within the specification limits.

Required tools for NIBP

- Adult NIBP hose
- Adult NIBP cuff
- Infant NIBP cuff hose
- A rigid cylinder or pipe
- Digital manometer with a range of at least 0 to 1000 mmHg and accuracy 0.5% FS.
- Tubing parts to connect a manometer to the NIBP cuff and hose.

NOTE Use only accurate, properly maintained, calibrated and traceable calibration tools for the parameter calibration to ensure measurement accuracy.

NOTE See the Supplies and accessories for compatible accessories.

Making connections

1. Connect an adult NIBP hose to the NIBP connector.
2. Connect an adult NIBP cuff to the hose.
3. Wrap the cuff around a rigid cylinder or pipe.
4. Connect the pressure manometer with pressure pump to the NIBP hose and NIBP cuff with a piece off tubing.

5. Ensure that all of the connections are leak-proof.

Calibrating NIBP

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Parameters*** > ***NIBP***.
3. Disconnect the hoses from the NIBP connector to enable proper zeroing.
4. Set the ***Protection*** to ***OFF***.

   Menu selection ***Start*** for ***Calibration*** now is enabled.
5. Select ***Start*** to start calibration. The NIBP calibration sequence starts with automatic zeroing. Wait until the message ***Zeroing*** is replaced by the message ***Zeroed***.
6. Pump a 200 mmHg static pressure according to the manometer. The pressure measured by the monitor is updated in real time to the calibration menu.
7. When the pressure is stabilized, check the pressure reading from the manometer.
8. Use arrows to adjust the reading measured by the monitor to match with the manometer reading.
9. Select ***Confirm*** to complete the calibration when the two readings match each other.
10. Wait until a message ***Calibrated*** is shown.
11. Set the ***Protection*** back to ***ON***.

NOTE Calibration protection is set automatically ***On*** after 30 seconds of inactivity, after the NIBP calibration menu is closed, and after zeroing or calibration failure. Set the calibration protection ***Off*** to restart the calibration.

NOTE You can use the calibration check function to verify the calibration after the calibration is completed.

Invasive pressure calibration

Invasive pressure calibration shall be performed:

- Whenever the pressure transducer in use is replaced with a new type of transducer.
- if the invasive pressure functional check failed.
- If the measured value is not within the specification limits.

Required tools

- Pressure manometer with a pressure pump
- Transducer adapter cable
- Invasive pressure transducer

NOTE See the Supplies and accessories for compatible accessories.

NOTE Use only accurate, properly maintained, calibrated and traceable calibration tools for the parameter calibration to ensure measurement accuracy.

NOTE The pressure transducer is a key component in the measurement setup. If possible, perform the invasive pressure calibration with the same type of pressure transducer that is used in daily clinical use.

Making connections

1. Connect the transducer adapter cable to the red Inv BP connector.
2. Connect the invasive pressure transducer to the transducer adapter cable.
3. Connect the pressure manometer with a pressure pump to the transducer's pressure line with a piece of tubing.

Calibrating invasive pressure

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Parameters*** > ***STP*** > ***Calibrations***.
3. Select ***Calibrate P1*** or ***Calibrate P2***.
4. Select ***Start Calibration***.
5. Prepare the transducer for the zeroing by opening the dome stopcock to room air.

6. The monitor will start automatic zeroing of the invasive pressure channel. Wait until the message ***Zeroing*** is replaced by value arrows.
7. Pump a 200 mmHg ± 100 mmHg static pressure with the pressure pump. The pressure measured by the monitor is updated in real-time to the calibration menu.
8. When the pressure is stabilized, check the pressure reading from the manometer.
9. Use arrows to adjust the reading measured by the monitor to match with the manometer reading.
10. Select ***OK***.
11. Wait until the message ***Calibrated*** is shown.

Repeat the above procedure, steps 3 through 11, for the other invasive pressure channel.

Calibrating invasive pressure (by simulator)

There is another method to calibrate IBP by simulator:

- Tools: IBP accessories and simulator.
- Connection: Connect IBP accessories to the monitor and simulator.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Parameters*** > ***STP*** > ***Calibrations***.
3. Select ***Calibrate P1*** or ***Calibrate P2***.
4. Select ***Start Calibration***.
5. Set the P1 or P2 channel to 0 mmHg on the simulator.
6. The monitor will start automatic zeroing of the invasive pressure channel. Wait until the message ***Zeroing*** is replaced by value arrows.
7. Set a pressure of 200 mmHg ± 100 mmHg on the simulator. The pressure measured by the monitor is updated in real-time to the calibration menu.
8. Use arrows to adjust the reading measured by the monitor to match with the simulator.
9. Select ***OK***.
10. Wait until the message ***Calibrated*** is shown.

Repeat the above procedure, steps 3 through 11, for the other invasive pressure channel.

Temperature calibration

Temperature calibration shall be performed:

- After STP/TP board replacement.
- If the measured value is not within the specification limits.

Required tools

- P/N 884515-HEL Temperature calibration plugs
- Dual temperature adapter cable

NOTE See the Supplies and accessories for compatible accessories.

NOTE Use only accurate, properly maintained, calibrated and traceable calibration tools for the parameter calibration to ensure measurement accuracy.

Making connections

1. Connect the dual temperature adapter cable to the brown temperature connector.
2. Check that the dual temperature adapter cable is configured for 400 series probes.

Calibrating temperature

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tab > ***Parameters*** > ***STP*** > ***Calibrations***.
3. Select ***OFF*** for ***Protection***.
4. Select ***Calibrate T1*** or ***Calibrate T2***.
5. Select ***Start Calibration***.
6. Plug in the temperature calibration plug labelled with TEMP 25°C/77°F to the dual temperature adapter cable connector T1 or T2.
7. Select ***Next***.
8. Wait until the value is shown, and select ***Next***.
9. Plug in the temperature calibration plug labelled with TEMP 45°C/113°F to the dual temperature adapter cable connector T1 or T2.
10. Select ***Next***.
11. Wait until the value is shown.
12. Wait until the message ***Done*** is shown.

Repeat the above procedure, steps 3 through 12, for the other temperature channel.

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Troubleshooting

Troubleshooting guidelines

CAUTION Make sure the patient is disconnected from the monitor before performing any service on the device.

NOTE For the E-miniC module troubleshooting, please refer to "E-miniC module" chapter

This chapter focuses on troubleshooting technical problems. Refer to the user's manual for troubleshooting monitoring problems and clinical configuration issues.

If a problem remains, contact technical support for service. To ensure accurate problem solving, please be prepared to provide the following information:

- Product name and serial number or UDI
- Hardware and software versions
- Detailed problem description
- Error messages, if any
- Service Logs
- The troubleshooting you have done so far

Perform the specified corrective maintenance check after any corrective maintenance to the product.

Performing basic troubleshooting

Before beginning any detailed troubleshooting, complete the following steps:

1. Perform visual inspection to be sure that:
   - There is no physical damage.
   - All peripheral devices are connected properly.
   - The patient monitor and the connected peripheral devices are properly powered.
2. Verify the compatibility of all system components.

   For a list of the compatible devices, see the Supplemental Information Manual.

   For a list of the compatible supplies and accessories, see the Supplies and accessories.

3. Verify that the platform and clinical configurations are correct.

   For the clinical configuration see user's manual and for the platform configuration see Configuration chapter.

4. If you suspect loose parts or cable connections inside the monitor, disassemble the monitor to a level needed to perform an internal visual check. Check that:
   - All screws are tightened properly.
   - All cables are connected properly.
   - There are no loose objects inside the patient monitor.

   Perform the electrical safety test and the checkout procedure every time you have disassembled the patient monitor.

Viewing and downloading service log

Viewing service log

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tag >***Service Log***.

   You can view the ***Error Log***, ***Alarm Log***, ***Keyboard Log***, and ***WLAN Log***.

Downloading logs to USB disk

You can download the error log, alarm log, keyboard log, and WLAN log, supplicant log to the USB disk for service use.

1. Discharge the patient first.
2. Select > ***USB Disk***.
3. To download log: select ***Export logs to USB Disk***.

   When finish to download logs, a message "***Export logs successfully.***" displays on the menu.

4. To empty all the files in USB storage device: select ***Empty USB Disk***.

   NOTE All items on the USB disk will be deleted.

   When finish to empty the USB disk, a message "***Empty successfully.***" displays on the menu.

5. To remove the USB Disk: select ***Safe to remove USB Disk***, then remove the USB disk.

Viewing log files

You can download log files to your service PC if needed. To view the log files in USB storage device:

1. Insert the USB storage device to the service PC.
2. Open the log folder in USB storage device, ***Computer*** > USB Disk Driver > ***logs***

   You can see ***alarmlog***, ***keyboardlog***, ***servicelog***, ***wlanlog***, and ***supplicantlog*** folders.

3. Open the folder and choose logs, there are 4 kinds of log files in the folder.
   - alarmlog-SN-timestamp.zip
   - keyboardlog-SN-timestamp.zip
   - servicelog-SN-timestamp.zip
   - wlanlog-SN-timestamp.zip
   - supplicantlog-SN-timestamp.zip
4. To open the file, double click the ***.zip*** file > double click the ***.tar*** file > enter password (123456).

   The supplicantlog-SN-timestamp.zip file not have ***.tar*** file, please direct enter password (123456).

Checking the battery charge with monitor software

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

1. Select the > ***Battery*** .
2. Check the battery status that appears.

NOTE When the battery charge complete, the ***Capacity Percent*** may not reach to 100%.

Network diagnostics

Pinging a TCP/IP network device

You can verify connectivity with a network device on the MC Network using ***Ping***.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tag >***Network*** > ***TCP/IP*** tag > ***Ping*** vertical tag.
3. In the ***Address*** field enter the IP address of a known device on the network.
4. Select ***Ping***.

If you receive a reply, the monitor is able to connect to the network device.

If you do not receive a reply, make sure that the monitor is connected to an active network.

NOTE The monitor withstands a maximum packet loss of 5 packets per 1 million and maximum latency of 250 ms without performance degradation.

Viewing Wireless status

You can view the WLAN status and detected access points for troubleshooting WLAN related problems.

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select ***Basic Service*** tag >***Page2*** vertical tag > ***WLAN Status***.

For more information, see WLAN status (79)

Messages

Messages related to various situations

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Alarm setup changed from Central***	• MF	The alarm setup is retrieved from the central station.	• Check the alarm settings and adjust if necessary.
• ***Alarms reset from Central***	• MF	The alarms were remotely paused from the central station.	• You can activate the alarms by pressing the audio pause key.
• ***Battery empty***	• MF	The monitor is battery powered and less than 5 min of monitoring time is available with battery.	• Charge the battery by using the monitor on main power.
• ***Battery low***	• MF	The monitor is battery powered and less than 20 min of monitoring time is available with battery.	• Charge the battery by using the monitor on main power.
• ***Battery temperature high***	• MF	The battery's temperature is too high.	• Replace the battery. • If the problem persists, replace the carrier board.
• ***Call service UMBC error***	• MF	UMBC communication error, and UMBC communication is disabled.	• Replace the carrier board.
• ***Condition battery***	• MF	Battery is not working properly.	• Replace or remove the battery for conditioning.
• ***DEMO MODE***	• MF	DEMO mode has been enabled.	• To exit the DEMO mode: Contact authorized service personnel.
• ***Default settings returned***	• MF	The monitor settings is returned.	• Check the settings adjust if necessary.
• ***Frame temperature high***	• MF	The temperature inside the frame is over 60°C/140 °F.	• Turn off the monitor, wait for it cool down. • Make sure there is sufficient ventilation. • Check monitor ventilation holes.

Message	Location	Explanation	What to do
• ***Identical IP address noticed***	• MF	Two or more monitors on the network have the same IP address.	• Disconnect the patient monitor that has the identical IP address. • Change the IP address of the patient monitor that has the duplicate IP address.
• ***Identical unit&bed name noticed***	• MF	Two or more monitors in the network have the same unit and bed name.	• Disconnect the patient monitor that has the identical unit and bed name. • Change the unit and bed name of the duplicate patient monitor unit and bed name.
• ***License invalid***	• MF	License is invalid doing start up.	• Check and reset the license. Contact GE service for correct license if required.
• ***Loading failed***	• MF	Loading mode from network has been interrupted.	• Check device or network cable connections.
• ***Loading from network***	• MF	Patient data is being loaded from the network.	• No action required.
• ***Memory ERROR***	• MF	Displays after software download.	• Restart the monitor.
• ***Mode data reset***	• MF	There is error when loading settings from the flash file. This failure may occur during cold start, warm start, upgrade start, revert mode, etc,.	• Replace the CPU board.
• ***Network: HL7***	• MF	When network connection between HL7 TCP Client application and monitor is made.	• No action required.
• ***Network down***	• MF	CARESCAPE Network connection has failed.	• Try to re-establish the connection. • Check the configuration of network. • For more information, see network troubleshooting.
• ***Network down: HL7***	• MF	No HL7 TCP Client is configured to connect to monitor on the network.	• Try to re-establish the connection. • Check the configuration of network. • For more information, see network troubleshooting.
• ***Network made***	• MF	When CARESCAPE network is connected.	• No action required.

Message	Location	Explanation	What to do
• ***No battery backup***	• MF	There is no battery inserted. The battery is not compatible.	• Insert a battery. • Check battery model whether is FLEX-3S3P.
• ***Patient admitted***	• MF	The current patient has been admitted.	• No action required.
• ***Patient discharged***	• MF	The patient has been discharged.	• No action required.
• ***Recorder: cover open***	• MF	The recorder cover is open.	• Close the recorder cover.
• ***Recorder: input voltage high / Recorder: input voltage low***	• MF	There are problems with the recorder input voltage.	• Replace recorder. • Replace the carrier board.
• ***Recorder: out of paper***	• MF	The recorder is out of paper or the recorder cover is open.	• Replace recorder paper. • Close the recorder cover.
• ***Recorder system error x***	• MF	The local recorder is not working.	• Disconnect and reconnect the recorder cable. • Replace recorder.
• ***Recorder thermal array overheat***	• MF	There are problems with the recorder temperature.	• Try stopping the recording as it may help. • Replace the recorder.
• ***Recorder module removed***	• MF	Recorder module has been removed.	• Reconnect the recorder module if you need.
• ***Replace battery***	• MF	Battery is not working properly.	• Replace the battery.
• ***Restart needed***	• MF	The monitor should be restarted.	• Restart the monitor.
• ***Saving to network***	• MF	Saving trend and information to Network.	• No action required.

Messages related to ECG measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Alarm setup changed from Central***	• MF	Any of the ECG alarms (HR, ST alarms) are turned ON/OFF or its limits are adjusted from the Central.	• Check the alarm settings at the Central.
• ***Arrhythmia Paused***	• WF	ECG channels have not been available for analysis for the last 20 seconds or the internal HR calculation has not been updated for the last 30 seconds due to excessive artifact.	• Check the patient status. • Check electrode placement. • Prepare the patient's skin at electrode sites. • Change or move electrodes.
• ***Arrh Paused***	• MF		
• ***Artifact***	• WF	Muscle artifact or high/low frequency noise.	• Check electrode contact. • Check lead placement. • Perform skin preparation. • Reposition/replace electrodes. • Request the patient to remain still.
• ***ECG measurements removed***	• MF	The ECG module inside host has lost ECG communication.	• Open the device, check the Hemo module connection..
• ***ECG module error***	• MF	The ECG module communication problem.	• Open the device, check the Hemo module connection. • Replace the hemo module.
• ***LA/L lead off*** • ***LL/F lead off*** • ***RA/R lead off*** • ***RL/N lead off*** • ***V/C lead off***	• WF	An electrode is disconnected.	• Check the electrodes.
• ***Lead changed***	• WF	The monitor automatically switches the ECG1 waveform selection to a measurable ECG Lead (I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 or V6) if the current ECG1 waveform is not measurable.	• Note that the ECG waveform changes according to the lead it is measured from. Check the lead.
• ***Leads off***	• MF, WF	One or more of the connected electrodes is disconnected and arrhythmia detection is not possible.	• Check the connections.
• ***Learning***	• WF	ST algorithm is in learning phase, message shown e.g. when ECG measurement is started.	• No action required.

Messages related to impedance respiration measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Apnea deactivated*** • ***No breath deactivated*** Not available for FDA countries.	• DF	The case has recently been patient admitted on the monitor, or the measurement has just been started.	• Wait. The message disappears after the monitor detects breaths.
• ***LA/L-lead off*** • ***LL/F-lead off*** • ***RA/R-lead off***	• WF, DF	One of the electrodes is off.	• Check the electrodes and their connections.
• ***Measurement off***	• WF, DF	ECG leads are not connected to the patient.	• Connect the ECG leads to the patient to start the impedance respiration measurement.
• ***Small resp curve***	• DF	Signal amplitude < 0.4 Ohm	• Check the patient status. • Check the electrodes placement.

Messages related to SpO_2 measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Check Device***	• DF	Only for Masimo type. Module malfunction.	• Open the device, reconnect the Hemo module. • If the problem persists, replace the Hemo module.
• ***Check Probe***	• DF	There is no detectable SpO_2 signal, the sensor is faulty or is detached from the patient.	• Check the sensor and connections.

Message	Location	Explanation	What to do
• ***Check SpO2 probe***	• MF	There is no detectable SpO_2 signal, the sensor is faulty or is detached from the patient.	• Check the sensor and connections.
• ***Faulty Probe***	• DF	The sensor has failed, or not compatible.	• Replace the sensor. See the Suppliers and accessories.
• ***Incompatible Probe***	• DF	The sensor is not compatible.	• Replace the sensor. See the Suppliers and accessories.
• ***Incompatible SpO2 Probe***	• MF		
• ***Interference***	• DF	The measurement is disturbed.	• Check the sensor.
• ***Low Perfusion***	• DF	Low perfusion at the measurement point.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• ***Low signal quality***	• DF	Only for Masimo type. The quality of the signal is questionable.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• ***No SpO2 probe*** • ***No Probe***	• MF • DF	Sensor is not connected to the monitor. Sensor is not compatible.	• Check connection between the sensor and the monitor. • Replace the sensor. See the Suppliers and accessories.
• ***No SpO2 pulse*** • ***No Pulse***	• MF • DF	No pulses detected.	• Try another measuring site.
• ***Poor Signal***	• DF	When the low perfusion is detected.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible. • Make sure the patient is not shivering.
• ***Probe Off***	• DF	The sensor may be defective.	• Check the patient status. • Reposition the SpO_2 sensor. • Replace the SpO_2 sensor.
• ***Pulse Search***	• DF	Defective or damaged sensor or cable. Sensor is off of the patient. Detection of a repeatable pulse has stopped.	• Check the sensor and cable. • Reposition or replace sensor.

Message	Location	Explanation	What to do
• ***SpO2 faulty probe***	• MF	The sensor has failed, or not compatible.	• Replace the sensor. See the Suppliers and accessories.
• ***SpO2 measurement removed***	• MF	Only for Nellcor or Masimo type. Hemo module of measuring SpO2 removed.	• Open the device, check Hemo module connection.
• ***SpO2 module error***	• MF	Only for Nellcor or Masimo type. SpO2 module recognize a communication problem.	• Open the device, check Hemo module connection. • Replace the Hemo module connection.
• ***SpO2 probe off***	• MF	The finger or earlobe may be too thin or the sensor is off the patient.	• Check the patient status. • Reposition the SpO_2 sensor. • Replace the SpO_2 sensor.

Messages related to NIBP measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Call service: Error x*** where x = 0 - 99	• DF	0 = RAM test failure 1 = ROM checksum failure 2 = Pump on during idle or over current detected 3 = Startup communication failure with safety CPU 4 = EEPROM protection is off 5 = EEPROM read/write error 6 = Valve stuck closed during cuff typing 7 = Could not save calibration data 8 = PT2 higher than 150 for greater than 15 seconds while idle 9 = Determination time too long 10 = RTK 400Hz timer re-entry 11 = RTK 50Hz timer re-entry 12 = Not in use 13 = RTK overrun	• Open the device, reconnect the Hemo module, and acknowledge the alarm. • If the problem persists, replace the Hemo module.
• ***NIBP call service error***	• MF		

Message	Location	Explanation	What to do
		14 = Too early AUTO START according to module check 15 = Calibration data invalid on initialization or unit never calibrated 16 = Communication timeout between main and safety CPU 17 = Safety CPU report communication timeout 18 = Wrong message rate in communication between main and safety CPU ><+/–2% (480 msg/s)	
• ***Check NIBP***	• MF	Systolic and/or diastolic results missing.	• Check the patient status. • Check NIBP cuff and hoses. • Repeat the measurement.
• ***Cuff loose***	• DF	Loose cuff or cuff hose.	• Check the cuff and cuff hose.
• ***Cuff occlusion***	• DF	Occlusion during measurement or overpressured cuff.	• Check the cuff.
• ***Cuff overpressure*** • ***NIBP cuff overpressure***	• DF • MF	NIBP cuff has exceeded the maximum cuff pressure during an NIBP measurement.	• Check NIBP cuff and hoses. • Repeat the measurement.
• ***Incompatible NIBP***	• MF	NIBP module with firmware version lower than 1.06 inserted	• Upgrade the NIBP firmware. • Replace the Hemo module.
• ***Long measurement time***	• MF, DF	The measurement time is long. The triggering values vary according to the module and inflation limits in use: • >2 min for adult/ child, 75 s to 80 s for infant	• Check the patient status. • Check the cuff and hose connections. • Restart the measurement.
• ***NIBP manual***	• MF	During auto cycling • Loose cuff or cuff hose. • Long measurement time	• Check the cuff and cuff hose whether loose.
• ***NIBP cuff loose***	• MF	Loose cuff or cuff hose.	• Check the cuff and cuff hose whether loose.
• ***NIBP cuff occlusion***	• MF	Occlusion during measurement or overpressured cuff.	• Check the cuff.
• ***NIBP measurement removed***	• MF	Hemo module has lost NIBP communication.	• Open the device, check Hemo module connection.
• ***Select cuff size***	• MF	Try to start NIBP measurement with invalid cuff size selection.	• Select a valid cuff size from NIBP menu.

Message	Location	Explanation	What to do
• ***Unstable zero pressure***	• DF	Pressure is unstable at start of the NIBP measurement.	• Check the patient status. • Check hose and cuff position. • Repeat the measurement. • Calibrate NIBP
• ***Weak pulsation***	• MF, DF	Weak or unstable oscillation signal.	• Check the patient status. • Reposition the cuff. • Repeat the measurement.

Messages related to invasive pressures measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Possible causes	Suggested actions
• ***P1 over range*** / ***P2 over range*** / ***P4 over range*** • ***Over range > 320 mmHg*** or ***Over range > 43 kPa***	• MF • DF	Measurement is over range, or the sensor is faulty. Transducer has not been zeroed correctly.	• Check the patient's pressure by alternative means. • Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Calibrate IBP.
• ***P1 under range*** / ***P2 under range*** / ***P4 under range*** • ***Under range < -40 mmHg*** or ***Under range < -5 kPa***	• MF • DF	Measurement is under range, or the sensor is faulty. Transducer has not been zeroed correctly.	• Check the patient's pressure by alternative means. • Check the cable and connections. • Rezero the transducer. • Replace the sensor. • Replace the transducer. • Calibrate IBP.
• ***Calibrated***	• Menu	Channel calibrated successfully.	• Wait until the message disappears before starting a measurement.
• ***Calibrating***	• Menu	Calibration of a channel is in progress.	• Wait until the calibration is succesfully completed.

Message	Location	Possible causes	Suggested actions
• ***Failed***	• Menu	Pressure calibration failure due to time-out. Pulsating waveform detected during calibration. Gain is beyond the limits (±20% of the default gain.	• Recalibrate. Start inflating the pressure within 45 seconds after the automatic zeroing is completed. • Check the manometer reading to ensure that a static 100 to 300 mmHg pressure is present for calibration. • Replace the transducer and recalibrate.
• ***Failed: P<100***	• Menu	Calibration reference value user entered is less than 100	• Recalibrate. Check the manometer reading to ensure that a static 100 to 300 mmHg pressure is present for calibration.
• ***InvBP's not zeroed*** • ***Not Zeroed***	• MF • DF	There is at least one invasive pressure channel that has not been zeroed.	• Perform zeroing for all channels.
• ***No x transducer***	• MF	No transducer connected to the channel indicated in the message, or the sensor is faulty.	• Connect a transducer. • Check the cable and connections. • Replace the sensor. • Replace the transducer.
• ***STP measurements removed***	• MF	The Hemo parameters have been removed.	• Open the device, check Hemo module connection.
• ***Zero adj > 100 mmHg***	• DF	IBP channel zeroed to over 100 mmHg pressure.	• Repeat the transducer zeroing. • Replace the sensor. • Replace the transducer. • Re-zero the pressure channel.
• ***Zeroed***	• DF	Zeroing was successful.	• No action required. Message is automatically removed after 10 seconds.
• ***Zeroing***	• DF	IBP channel is currently being zeroed.	• No action required. Message is automatically removed and replaced with the zeroing results after completion.
• ***Zeroing failed***	• DF	Pulsating waveform detected. Defective transducer Offset is >150 mmHg.	• Open the transducer to room air and zero the channel. • Replace the transducer, open it to room air, and zero the channel.
• ***Zero ICP separately***	• MF	The ICP channel must be zeroed separately from all other invasive pressures.	• Zero the channel using the ***Zero*** option found under the ICP channel setup menu.

Messages related to temperature measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Explanation	What to do
• ***Performing temp test***	• DF	Temperature is calibrating.	• Wait until the self-check is completed. • Check that no error messages appear.
• ***STP measurements removed***	• MF	The Hemo parameters have been removed.	• Open the device, check the Hemo module connection.
• ***Temperature error*** • ***T1 temperature error / T2 temperature error***	• DF • MF	Hardware or calibration test failure in the measurement device.	• Perform calibration. • Replace the STP module.

Problems and solutions

Start-up failures

Problem	Possible causes	Recommended action
Failure to turn on the patient monitor, when the following conditions apply: • The patient monitor is connected to AC mains. • The Mains voltage indicator is not lit. • Monitor battery is not installed.	Power cord is loose.	Ensure that the power cord is connected properly to the wall outlet and to the patient monitor.
	Blown fuses.	Check the status of the fuses and replace them, if necessary. • Use only fuses with correct rating. • If the fuses are blown repeatedly, investigate the patient monitor carefully for possible short circuits.
	Power cord is faulty.	Check the power cord for wear and damage, and replace if necessary.
	The power outlet does not meet specified requirements.	Check the power outlet being used
	The related cable is loose or fault.	Check the following cable is intact and properly connected. • Cable between AC/DC module and the AC inlet • Cable between AC/DC module and the carrier board
	AC/DC module issue	Replace AC/DC module.

Problem	Possible causes	Recommended action
	Carrier board issue	Replace the carrier board.
Failure to turn on the patient monitor, when the following conditions apply: • The patient monitor is not connected to AC mains. • The monitor is powered from battery.	Battery empty Battery failure Missing battery	Check battery status. Charge or replace the battery.
	Battery interface board loose or fault.	Check battery interface board is intact connected. Replace the battery interface board.
	Carrier board issue	Replace the carrier board.
Failure to turn on the patient monitor, when the following conditions apply: • The patient monitor is connected to AC mains. • A full charged battery is installed.	On/Off key fault	Check the related cables is intact connected. Replace membrane keyboard Replace LCD interface board
	Carrier board issue	Replace the carrier board.
The monitor starts (hear an beep), but the display remains black, or white.	The display cables are loose	Check the display cable is intact and properly connected.
	The display issue	Replace the display panel.
	LCD interface board issue	Replace the LCD interface board.

Battery issue

Problem	Possible cause	Recommended action
The battery LED indicator (on the monitor front panel) orange flashing.	AC Power input over voltage.	• Replace the AC/DC module. • Replace the carrier board.
	Battery over voltage.	• Replace the battery. • Replace the carrier board.
	Battery precharge time-out fault Battery fast charge time-out fault	• Replace the battery. • Replace the carrier board.

User interface issues

Problem	Possible cause	Recommended action
Touchscreen is inoperative.	Touchscreen cable is loose.	Check the touchscreen cable is intact and properly connect to LCD interface board.
	Faulty touchscreen sensor.	Replace the touch display panel.

Problem	Possible cause	Recommended action
Alarm light does not illuminate. (audible alarms work and alarm message is visible)	Alarm interface cable is loose or fault.	Check the alarm interface cable is intact and properly connect to LCD interface board.
	Alarm LED board is fault.	Replace the Alarm LED board.
Keyboard not working, or party working.	Keyboard cable is loose or fault.	Check the keyboard cable is intact and properly connect to LCD interface board.
	Membrane keypad is fault.	Replace the membrane keypad.
Trim knob not working.	Trim knob cable is loose or fault.	Check the cable is intact and properly connect to LCD interface board.
	Trim knob issue.	Replace the trim knob
Audible alarms do not work.	Audible alarm are turned off.	Enable audible alarms from ***Alarms Setup***.
	Speaker failure	Replace the speaker.
	Speaker cable loose or fault	Check the cable is intact and properly connect to LCD interface board.
	Tone generator or audio amplifier failure	Replace carrier board.

Recorder issue

Problem	Possible cause	Recommended action
Recorder does not work.	The recorder connect cable is loose or fault.	Check the recorder connect cable is intact and properly connected.
	Recorder unit failure.	Replace the recorder unit.
	Carrier board issue	Replace the carrier board.
Recorder works but nothing appears on the paper.	Paper installed upsidedown.	Turn the paper roll over.

Acquisition module problems

Problem: an acquisition module does not work with the patient monitor.

- Select the > ***Screen Setup***, check that the parameters are configured to the display.
- Do a visual check to the accessories used with the module. If in doubt, replace the accessories with known good ones.
- Connect another, similar, known good module to the suspect patient monitor and check if the module works normally:
  - YES: The suspect module is most likely faulty. Refer to module's troubleshooting instructions.
  - NO: The problem is most likely in the patient monitor. Continue troubleshooting the problem according to the related troubleshooting chart below.

  Or,

- Connect the suspect acquisition module to another, similar, known good patient monitor and check if the module works normally:
  - YES: The problem is most likely in the patient monitor. Continue troubleshooting the problem according to the related troubleshooting chart below.
  - NO: The suspect module is most likely faulty. Refer to module's troubleshooting instructions.

Possible cause	Recommended action
Incompatible module	Refer to the patient monitor's supplemental information manual document to see the list of compatible modules.
Connection issue	• Check the related cable connection • Replace the interface board ▪ E-module: Replace the E-module interface board ▪ Hemo module: Replace the Hemo interface board
Carrier board is faulty.	Replace the user interface board.

Troubleshooting CARESCAPE Network communication

Traffic types

Two main types of communication occurs in the CARESCAPE Network: Broadcast and Unicast.

- Broadcast traffic is sent from one device to all devices on the network. Examples of CARESCAPE broadcast traffic are device discovery, alarms, and time synchronization.
- Unicast traffic is sent from one device to another specific device on the network. An example of CARESCAPE unicast traffic is patient waveforms.

Flow

- Upstream broadcast: The monitor sends broadcasts to other network devices.
- Downstream broadcast: The monitor receives broadcasts from other network devices.

Problem: No waveforms or parameters are displayed at the Central Station

Network troubleshooting flowchart

Network troubleshooting flowchart A

Parameter issues

NIBP

Problem	Possible cause	Recommended action
Air leakage	Hose or cuff leaking.	• Replace cuff. • Replace cuff hose.
	Leakage inside the module.	Replace the Hemo module.

IBP

Problem	Possible cause	Recommended action
Abnormally low pressure.	Transducer wrongly positioned	Check mid-heart level and reposition transducer.
No pressure.	Defective transducer.	Check or replace transducer.
	Module not connected.	Reconnect the Hemo module.
	Transducer adapter cable not connected to the monitor.	Connect the transducer adapter cable with the transducer to the monitor.
	Invasive pressure channel not configured to the screen.	Configure the invasive pressure channel to the screen.

Temperature

Problem	Possible cause	Recommended action
No temperature displayed.	Temperature channel not configured to the screen.	Configure the temperature channel to the screen.
	Temperature out of measurable range.	The measurement range is between 10 and 45 °C.
	Incompatible temperature probe.	Replace temperature probe.

13 Disassembly and reassembly

Disassembly guidelines

Field repair of the monitor is limited to replacing Field Replaceable Units (FRUs).

WARNING Attempting a field repair on a PCB or a factory sealed component or assembly could jeopardize the safe and effective operation of the module, and void the warranty.

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

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

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

NOTE Only a qualified service technician should perform field replacement procedures.

NOTE Perform the specified corrective maintenance check after any corrective maintenance to the product.

ESD precautions

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

All external connectors of the device are designed with protection from ESD damage. However, if the device requires service, exposed components and assemblies inside are susceptible to ESD damage. This includes human hands, non-ESD protected work stations or improperly grounded test equipment. The following guidelines may not guarantee a 100% static-free workstation, but can greatly reduce the potential for failure of any electronic assemblies being serviced:

- Discharge any static charge you may have built up before handling semiconductors or assemblies containing semiconductors.
- Wear a grounded, antistatic wristband or heel strap at all times while handling or repairing assemblies containing semiconductors.
- Use properly grounded test equipment.
- Use a static-free work surface while handling or working on assemblies containing semiconductors.
- Do not remove semiconductors or assemblies containing semiconductors from antistatic containers until absolutely necessary.
- Do not slide semiconductors or electrical/electronic assemblies across any surface.
- Do not touch semiconductor leads unless absolutely necessary.
- Store the semiconductors and electronic assemblies only in antistatic bags or boxes.
- Handle all PCB assemblies by their edges.
- Do not flex or twist a circuit board.

Reassembly precautions

Reassembly the monitor in reverse order of following disassembly instruction.

Pay attention to the following generic precautions when reassembling the patient monitor:

- Note the positions of any wires, cables or connectors. Mark them if necessary to ensure that they are reassembled correctly.
- Save and set aside all hardware for reassembly.
- GE recommends using the new fasteners (screws, washers, etc.) provided in the FRU kits rather than reusing the old fasteners. Some fasteners are not intended to be re-used .
- When you attach self-tapping screws to light metal parts without existing threads (new light metal FRU parts), use a higher torque than is recommended for reassembled parts, but still not more than 1.6 Nm.

NOTE When you fasten the screws:

- Ensure visually that the screws are properly attached.
- Avoid over tightening by using excess force, as this may damage the existing thread patterns.
- If you use a battery-operated tool, ensure that it is equipped with torque limiter and the torque is properly adjusted.

Required tools

WARNING Due to possible high voltage present, use an insulated screwdriver at all times.

NOTE Use torque wrench and torque screwdriver to comply with the given torques.

- insulated PH1, PH2 screwdrivers, recommended length > 65 mm
- two socket wrenches (5.5 mm and 13 mm)

- an insulated flat blade screwdriver (width 2.5 mm / 0.1 in)
- an antistatic ESD wristband

Preparing for disassembly

1. Turn the monitor off.
2. Disconnect the monitor power cord, first from the wall outlet and then from the monitor.
3. Remove the monitor battery.
4. Disconnect all external cables connected to the monitor.
5. Remove the parameter module.
6. If a mounting is installed, detach the monitor from it.
7. Detach the multi I/O.

Replacing the main fuses

The mains fuses are located on the back of the monitor, inside the AC inlet.

1. Press the snap in the fuse holder of the AC inlet with a flat blade screwdriver to release it.
2. Prize up fuses with a flat blade screwdriver.
3. Replace the fuses with new ones.

NOTE Use only fuses with the same rating.

Detaching the extension rack, hemo module and wireless module

- Detaching the extension rack:
  1. Remove the sheet of the rack, there 3 holes inside the rack can help to remove.
  2. Remove three screws holding rack.
  3. Disconnect the rack cable.

- Replacing the hemo module:
  1. Remove two screw rubbers.
  2. Remove two screws.
  3. Remove the hemo cover.
  4. Pull out the hemo module with the metal sheet.

- Replacing the wireless module:
  1. For no rack device, remove two screws, then open the cover.
  2. Remove two screws of the wireless board.
  3. Disconnect two antennas.

NOTE: When reassemble the wireless module, use the clips to fix the antennas.

Detaching the frame

1. Remove four screws on the back of the monitor.
2. Open the frame box.
3. Disconnect the cable from carrier board to LCD converter board.
4. Disconnect the cable from speaker to LCD converter board.

LCD converter board connectors

1. TP (touch panel) connector
2. 10.1’ LCD display connector
3. Membrane keypad connector
4. Speaker connector
5. 12.1’ LCD display connector
6. Alarm light connector
7. Trim knob connector

Replacing the user interface parts

- Replace the speaker:
  1. Remove 2 screws of the mounting.
  2. Replace the speaker.

- Replace the Trim Knob:
  1. Disconnect the Trim Knob cable (#7).
  2. Remove the Trim Knob cover.
  3. Release the encoder by the socket wrench (13 mm).
  4. Replace the Trim Knob.

- Replace the alarm light:
  1. Disconnect the alarm light cable (#6).
  2. Replace the alarm light board.
- Replace the membrane keypad:
  1. Disconnect the cable (#3) and shield line.
  2. Tear down the membrane keypad on the front cover, and replace.

Replacing LCD converter board, display, and front cover

- Replace the LCD converter board:
  1. Disconnect all the cables on the LCD converter board.
  2. Remove 5 screws on the LCD converter board.
  3. Remove the LCD converter board.
- Replace the touch display panel:
  1. After remove the LCD converter board, remove 9 screws.
  2. Replace the touch display panel.
- Replace the front cover.

NOTE The front cover FRU including membrane keypad, please replace the membrane keypad also.

Detaching the middle cover

1. Remove two screws on the mounting plate.
2. Remove four screws on the middle cover.
3. Lift the middle cover up.

Replacing the handle

1. Remove two screws for the handle.
2. Replace the handle.

Detaching the battery chamber

1. Remove two screws on the mounting plate.
2. Remove the mounting plate.
3. Disconnect the cable from battery board to carrier board.
4. Remove the screw for shield line.
5. Lift the battery chamber up.

Replacing the AC/DC module

WARNING When remove the AC/DC module, don't touch the capacitor and the heat sink. It is highly recommended you to wear the insulating glove to avoid electric shock and overheating.

1. Remove three screws for the AC/DC module.
2. Disconnect the cable.
3. Lift up the AC/DC module.

Replacing the carrier board

1. Remove three screws on the metal cover.
2. Open the metal cover.
3. Remove five screws for carrier board.

NOTE Replace the carrier board battery every 5 years.

Detaching the recorder

1. Open the recorder door and remove the paper roll if installed.
2. Remove two screws and drag the tab out.
3. Remove four screws.
4. Release the cover (side) of the recorder by pressing with a flat blade screwdriver.
5. Remove two screws inside the recorder.
6. Remove 4 screws of the back board.

7. Pull the recorder out of the housing.

14

Service parts

Service parts

Perform the specified corrective maintenance check after any corrective maintenance to the product.

Ordering parts

To order parts, contact your local GE representative. Contact information is available at www.gehealthcare.com. Make sure you have all necessary information at hand.

Front cover

Back cover

Frame

(B105) (B125)
12 13
(4 PLC) (4 PLC)
1 2 12 13
(4 PLC) (4 PLC)
12 13

Hemo box

27
22 23 24 25
(9 PLC) (5 PLC) (2 PLC) (2 PLC) (4 PLC)
3 4 5 10 11 12 13 15 16
(9 PLC) (7 PLC) (2 PLC) (2 PLC)
12 13

Rack and recorder

List of FRUs

Item	Part number	Description
1	2098800-002	FRU Value Monitor B105 Front Cover with Touch Panel[1] • B105 Front Cover with 10.1' touch screen • Screws
2	2098800-003	FRU Value Monitor B125 Front Cover with Touch Panel[2] • B125 Front Cover with 12.1' touch screen • Screws
3	2098800-004	FRU Value Monitor B105 LCD Display and Sheet Metal • 10.1' LCD and frame • Screws
4	2098800-005	FRU Value Monitor B125 LCD Display and Sheet Metal • 12.1' LCD and frame • Screws
5	2098800-103	FRU Value Monitor B125B105 V1.5 Display Converter • LCD interface board • Connect cables and screws

1. When service person replace the B105 front cover, please order 2098800-008 FRU Value Monitor B105 membrane keypad also.
2. When service person replace the B125 front cover, please order 2098800-009 FRU Value Monitor B125 membrane keypad also.

Item	Part number	Description
6	2098800-007	FRU Value Monitor Trim Knob • Trim Knob, encoder • Encoder grounding cable • Spring clip
7	2098800-008	FRU Value Monitor B105 membrane keypad • B105 membrane keypad
8	2098800-009	FRU Value Monitor B125 membrane keypad • B125 membrane keypad
9	2098800-010	FRU Value Monitor Alarm Light and Speaker • Alarm LED board • Speaker • Connect cables
10	2098800-011	FRU Value Monitor Carrier Board • Carrier board • Screws
11	2098800-104	FRU Value Monitor B125B105 V1.5 Frame Connector and Cables • Hemo interface board • Battery interface board • Alarm interface cable • Battery interface cable, battery grounding cable • 10.1 LCD interface cable, 12.1 LCD interface cable • Carrier board to front cover interface cable • Clarmp cable • Hemo interface board bracket • Equipotential plug • Related kinds of screws, nuts, and washers
12	2098800-013	FRU Value Monitor B105 Middle Cover • B105 middle cover • Hemo removal handle, Hemo cover and 2 plugs • B105 Handle foams • Foot pads • Related kinds of screws

Item	Part number	Description
13	2098800-014	FRU Value Monitor B125 Middle Cover • B125 middle cover • Hemo removal handle, Hemo cover and 2 plugs • B125 handle waterproof foams • Foot pads • Related kinds of screws
14	2098800-015	FRU Value Monitor AC/DC module • AC/DC module • Related kinds of screws
15	2098800-016	FRU Value Monitor Wireless module with antennas • Wireless module board • 2 antennas and clips • Screws
16	2098800-119	FRU Value Monitor B125B105 RACK • RACK connection board • RACK shell, RACK cover and plastic sheet • RACK connection cable • 2 waterproof foams
17	2098800-018	FRU Value Monitor Multi-I/O adapter with cable • Multi I/O module • Multi I/O cable
18	2098800-105	FRU Value Monitor B125B105 V1.5 Stand Alone Printer • Assembly: Thermal recorder with module housing • Fixing plastic plate • Recorder connection cable • Y-Type connection cable
19	2098800-106	FRU Value Monitor B125B105 V1.5 Printer Cover, board and cable • Thermal recorder module housing • Recorder connection cable • Y-Type connection cable
20	2098800-022	FRU Value Monitor Handle • Handle • Related kinds of screws
21	2036984-001	B650 BATTERY FLEX-3S3P
22	2098800-109	FRU B125B105 V1.5 HEMO GE STP (SpO2, Temp and IBP)[3] • Hemo module: GE STP (with GE SpO2, Temp and IBP)

3. When service person replace the hemo module, please order 2053489-080 FRU B40B20 HEMO Labels also.

Item	Part number	Description
23	2098800-110	FRU B125B105 V1.5 HEMO GE SPO2 (SpO2 only)[4] • Hemo module: GE SpO2 (with GE SpO2 only)
24	2098800-111	FRU B125B105 V1.5 HEMO NELLCOR (SPO2, TEMP, IBP)[5] • Hemo module: Nellcor (with Nellcor SpO2, Temp and IBP)
25	2098800-108	FRU B125B105 V1.5 HEMO MASIMO (SPO2, TEMP, IBP)[6] • Hemo module: Masimo (with Masimo SpO2, Temp and IBP)
27	2053489-080	FRU B40B20 HEMO Labels • Multi languages HEMO labels
28	2053489-005	FRU B40B20 CPU BATTERY
-	2061869-088	FRU BX0 FILTER POROUS PLASTIC 20U[7] • Filter porous plastic 20U
-	2053489-066	FRU B20B40 HEMO DUMP VALVE SUB ASSY[8]
-	2098800-021	FRU Value Monitor Main Software Recovery CD[9]

4. When service person replace the hemo module, please order 2053489-080 FRU B40B20 HEMO Labels also.
5. When service person replace the hemo module, please order 2053489-080 FRU B40/B20 HEMO Labels also.
6. When service person replace the hemo module, please order 2053489-080 FRU B40/B20 HEMO Labels also. Please notice the part number of B125/B105 Masimo Hemo, don't misuse with B40/20 Masmio Hemo module.
7. Instruction for 2061869-088 refer to Technical Bulletin DOC1815812.
8. Instruction for 2053489-066 refer to accompanying document with the FRU.
9. The software download instruction refer to accompanying document with the FRU.

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E-miniC module

Introduction

This chapter provides information for the maintenance and service of the Single-width Airway module, E-miniC-00.

The Single-width Airway module, E-miniC-00 provides airway and respiratory parameters.

Letter C in the module name stands for CO_2.

Module compatibility

For detailed information regarding module, monitor, and accessory compatibility, see the supplemental information manual.

Airway gases equipment to patient connections with E-miniC, critical care setup

1. E-miniC module
2. Sampling line connector on the water trap
3. Gas sampling line
4. Adapter with sampling line connector
5. Heat and moisture exchanger with filter (HMEF)

Controls and connectors

Front panel of the E-miniC module and the back of the module:

1. Water trap latch
2. Sampling line connector
3. Mini D-fend water trap
4. Sample gas outlet

Connector	Module	Description
D25 connector	E-miniC	Module bus connector

Measurement principles

CO_2 measurement

E-miniC is a side stream gas analyzer, measuring real time concentrations of CO_2. It is a non-dispersive infrared analyzer that measures absorption of the gas sample by using an optical narrow band filter.

The infrared radiation detector is a thermopile.

Concentration of CO_2 is calculated from absorption measured at 4.2 to 4.3 µm.

The following illustrates the absorbance of CO_2:

Main components

Gas sampling system

The sampling system draws a gas sample to the analyzer at a fixed rate. The gas sampling system samples the measured air to the module and removes water and impurities from it. A sampling line is connected to the water trap. The pump draws gas through the sampling line to the miniC sensor. After the measurement, the gas is exhausted from the sample gas out connector.

The sample flow is nominally 150 ml/min.

The following illustrates the MiniC block diagram:

Mini D-fend

The sample is drawn through the sampling line. The gas then enters the module through the water trap where it is divided into two flows, a main flow and a side flow. The main flow goes into the analyzer. This flow is separated from the patient side by a hydrophobic filter. The side flow creates a slight subatmospheric pressure within the Mini D-fend water trap which causes fluid removed by the hydrophobic filter to collect in the bottle.

Zero valve

The main flow passes through a magnetic valve before proceeding to the analyzer. This valve is activated to establish the zero point for the MiniC sensor. When the valve is activated, room air is drawn through a filter into the internal system and the gas sensor.

Nafion tube

A Nafion tube is used between the water trap and the zero valve to balance the sample gas humidity with that of ambient air. The tube will prevent errors caused by the effect of water vapor on gas partial pressure, when humid gases are measured after calibration with dry gases.

Gas analyzers

After the zero valve and Nafion tube, the gas passes through the miniC sensor.

Sample flow differential pressure transducer

The sample flow differential pressure transducer measures pressure drop across a restrictor and calculates the sample flow from the pressure difference.

Working pressure transducer

The working pressure transducer measures differential pressure between the tubing and ambient air near the miniC sensor. The following messages are based on the obtained pressure values: ***Sample line blocked***, ***Check D-fend***, ***Replace D-fend***, and ***Check sample gas outlet***.

Absolute pressure transducer

The absolute pressure transducer measures real-time ambient pressure.

Sampling pump

The gas sampling pump is a membrane pump run by a DC motor. Sample flow is measured with a differential pressure transducer across a known restriction. The motor is automatically controlled to maintain a constant flow even when the Mini D-fend water trap ages and starts to get occluded. It also enables the use of sample tubes with varying lengths and diameters.

NOTE In no occasion is the flow reversed towards the patient.

The following illustrates the gas tubing layout:

MiniC sensor

The miniC sensor is a non-dispersive infrared analyzer measuring absorption of the gas sample at 4.2 to 4.3 µm infrared wavelength, which is selected using an optical narrow band filter. The IR lamp is a filament surrounded by thermal isolation. There is a hole in the isolation, passing radiation to a conical measuring chamber with 3 mm length. From the sample chamber, the radiation goes into a thermopile detector with an optical filter in front of it.

The temperature sensor measures the temperature of the miniC sensor and it is used for temperature compensation.

The miniC sensor is connected to the CPU board and they cannot be replaced separately.

CPU board

The CPU board contains a processor, memories and all the analog signal processing needed. A miniC sensor is attached to the board with a flexible PCB. Also supply voltage and an RS485 serial channel are connected to the CPU board using another flex cable.

Analog signals (CO_2, temperature, absolute and differential pressures, and lamp current signals) are fed to a 16-bit A/D converter. The processor controls the A/D converter and calculates the CO_2 percentage and respiration rate from this data.

The processor controls sample flow by adjusting the pump voltage based on the differential pressure signal. The processor also controls the current of the IR source and keeps it constant.

Calibration data is stored on the EEPROM.

Maintenance check

About the maintenance check procedures

This chapter describes the planned and corrective maintenance check procedures for the product. To help ensure the equipment remains in proper operational and functional order and maintains its essential performance and basic safety, follow the corrective and planned maintenance recommendations. The tests that are related to the essential performance and basic safety are marked with the *.

The cleaning precautions, cleaning requirements, cleaning procedures, and recommended cleaning solutions are described in the monitor's user's manual.

For details about cleaning, disinfecting and sterilizing the accessories, see the instructions for use in the accessory package.

Record the results of the planned and the corrective maintenance check procedures to the eCheckforms delivered in the electronic manual media.

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.

Planned maintenance

WARNING Planned maintenance should be carried out at recommended interval. Failure to implement the recommended maintenance schedule may cause equipment failure and possible health hazards.

Perform the planned maintenance procedure completely every 12 months after installation. Perform the procedure in the following order:

1. Replacement of planned maintenance parts
2. Visual inspection
3. Functional check

Corrective maintenance

Perform the following checkout procedure after any corrective maintenance, before taking the module back into clinical use:

	Required checkout procedure	
Performed service activity	**Visual inspection**	**Functional check**
Front cover, or an other external part, replaced.	All steps	Not applicable
Mini D-fend O-rings	All steps	Perform the following tests: • Check the gas sampling system for possible leakages. * • Check sample flow rate. *
Module case opened either for troubleshooting purpose or for replacing any of the internal parts.	All steps	All steps

Replacement of planned maintenance parts

Required parts

Replace the following parts that wear in use at the recommended interval.

Part number	Description	Pieces	Replacement interval
733382-HEL	Nafion Tube (#11)	1	Once a year
656565	Mini D-fend™ O-ring (#4)	2	Once a year
M1011471	Zero valve air filter (#16)	1	Once every 3 years

GE recommends that you replace the Mini D-fend water trap and the gas sampling line as part of the planned maintenance procedure.

NOTE See the Supplies and accessories for compatible accessories.

Replacing the parts

Refer to following "Service parts" section for details about exploded views.

1. Replace the zero valve air filter once every 3 years.
   a. Use a small flat blade screwdriver to pull the old zero line air filter.
   b. Attach a new zero line air filter into place.
2. Replace the special tube (Nafion) and check the condition of the internal tubing.
   a. Replace the 300 mm nafion tube in the sample gas in line between the Mini D-fend water trap and the zero valve unit.
   b. Check that the tubing inside the module is not contaminated. Any contamination inside the tubing may indicate that the valve or sensor is contaminated, too. This can increase a risk of faulty operation in valve or sensor. The gas sensor is not possible to clean in the field. Therefore, replace the whole miniCO2 assembly with a new one.

   NOTE The nafion tube do not include the silicon fittings they connect to. Use the original silicon fittings unless they are not damaged or leaking.
3. Replace the Mini D-fend O-rings:
   a. Detach the Mini D-fend.
   b. Detach the old rubber O-rings that are around the metal Mini D-fend connectors e.g. using a small flat blade screwdriver. Pay special attention not to scratch the metal Mini D-fend connectors and thus causing leaking.
   c. Set the new rubber O-rings into place and attach a new Mini D-fend.

Performing visual inspection

1. Remove the module and check that:
   a. The front cover is intact.
   b. All connectors are intact, clean and attached properly.
   c. The module casing and the latch are clean and intact.
   d. The metal D-fend connectors and the D-fend O-rings are clean and intact.
   e. The module and the applied parts are clean.

Performing functional check

Required tools for the functional check

For a list of compatible accessories, see the Supplies and accessories.

- A barometer
- A mass flowmeter for measuring air flow, minimum measurement range from 0 to 200 ml/min, accuracy 5% or better in the 0 to 200 ml/min range.
- P/N: 755534-HEL Calibration Gas Regulator

- P/N: M1006864, Calibration Gas Regulator, US only
- P/N: 755580 Calibration Gas, 5% CO2 and air, package of 4 cans
- P/N: 755587 Calibration Gas, CO2, O2, Balance, package of 4 cans, US only
- Mini D-Fend water trap
- 3 m / 10 ft gas sampling line
- A pressure manometer with either an integrated or a separate pressure pump

Making connections for the functional check

1. Disconnect the module from the monitor for the first test.
   - gas sampling system leak test

   For the rest of the functional check steps:
2. Turn the monitor on and wait until the normal screen appears.
3. Ensure that the module is connected to the monitor.
4. Let the module warm up for at least 5 minutes.

Configuring monitor for functional check

1. Configure ***CO2*** waveform to the screen with adequate priority.
2. Select the gas digit field.
3. Select ***21–40%*** for ***FiO2 level***.

Testing CO_2 measurement

1. Gas sampling system leak test *

   Check the gas sampling system for possible leakages.

   a. Disconnect the module from the monitor.

   b. Connect a new Mini D-fend water trap to the module.

   c. Connect a new gas sampling line to the sampling line connector in the water trap.

   d. Connect the other end of the gas sampling line to a pressure manometer and a pressure pump.

   e. Block the "Sample Gas Out" connector.

   f. Pump 100 mmHg ± 20 mmHg pressure to the gas sampling system. Let the pressure stabilize for approximately 10 seconds.

   g. Check that the pressure reading does not drop more than 6 mmHg during 1 minute.

2. Sample flow check *

   Check the sample flow rate.

   a. Connect the module with the gas sampling line to the monitor.
   b. Connect the gas sampling line to the sampling line connector in the water trap.
   c. Connect the other end of the gas sampling line to a flowmeter.
   d. Check the sample flow rate reading from the flowmeter. The flow rate shall be within the specification limit 150 ± 25 ml/min.

   NOTE Readjustment is needed, if the measured value is not within the specification limits. Adjust the sample gas flow rate according to the instructions “Sample flow rate adjustment”.

   NOTE If the sampling pump is noisy it indicates possible problems with motor bearing. In this case it is recommended to replace the noisy sampling pump with a new one.

3. Zero valve operation *

   Test the zero valve functionality.

   a. Connect the gas regulator to the calibration gas container.
   b. Connect the end of the gas sampling line to the regulator on the gas container. Leave the regulator overflow port open to room air.
   c. Select the > ***Service*** > enter ***Username*** and ***Password***.
   d. Select the ***Basic Service*** tab > ***Parameters*** > ***Gas Unit***.
   e. Start feeding calibration gas. Wait until the CO2 value in the Gases menu rises to approximately 5%.
   f. Open the zero valve to room air by selecting ***Zero Valve ctrl***.
   g. Check that the CO2 value in the menu drops back near to 0%.
   h. Stop feeding the calibration gas.
   i. Turn the zero valve back to the normal measurement position by selecting ***Zero Valve ctrl***.

4. Gas calibration *

   Perform gas calibration according to the instructions in “Gas calibration”.

5. Ambient pressure *

   Use a barometer to check the operation of the absolute pressure sensor.

   a. Check that the ambient pressure value shown in the Gas service menu does not differ more than ± 10 mmHg from the value shown by the barometer.

6. Occlusion detection *

   a. Block the tip of the sampling line by your finger.
   b. Check that message 'Sample line blocked' appears to the digit field within 30 seconds.

7. Air leak detection *
   a. Detach the Mini D-fend water trap.
   b. Check that message ***Check Water Trap*** appears to the digit field within 30 seconds.
8. Gas exhaust blockage *
   a. Block the gas exhaust connector with your finger.
   b. Check that the ***Sample gas out*** message appears in the digit field within 30 seconds.
9. Airway gases *
   a. Breathe a minimum of 5 times to the tip of the sampling line.
   b. Check that a normal CO_2 waveform appears to the waveform field and the $EtCO_2$ and $FiCO_2$ values are updated to the digit field.
10. Apnea detection
    a. Stop breathing to the gas sampling line.
    b. Check that an 'Apnea' alarm appears to the message field within 30 seconds.

Completing the check procedure

1. Select > ***Discharge*** tab > ***Discharge*** > ***YES*** to discard any changes made to the patient monitor configuration during checkout.
2. Disconnect the test setup.
3. Complete the check form.

Configuration

There is no service configuration for this module.

Calibration and adjustments

CAUTION Make sure the patient is disconnected from the monitor before performing any service on the device.

Sample flow rate adjustment

Sample flow rate shall be adjusted:

- if the sample flow rate check failed.

Required tools

- A mass flowmeter for measuring air flow, minimum measurement range 100-300 ml/min, accuracy 5% or better in the 100-300 ml/min range.
- 3 m / 10 ft gas sampling line

NOTE See the Supplies and accessories for compatible accessories.

NOTE Use only accurate, properly maintained, calibrated and traceable calibration tools for the parameter calibration to ensure measurement accuracy.

NOTE If the flowmeter unit is not ml/min, it shall be converted to ml/min according to the instructions of the flow meter manufacturer.

NOTE Refer to the flowmeter documentation for user instructions.

Making connections

1. Ensure that the module is connected to the monitor.
2. Ensure that you have a new water trap in use.
3. Connect a new gas sampling line to the sampling line connector in the water trap.
4. Connect the other end of the gas sampling line to the flow meter.

NOTE Before checking or adjusting the sample flow, make sure there is no leakage in the sampling system.

Adjusting sample flow rate

1. Select the > ***Service*** > enter ***Username*** and ***Password***.
2. Select the ***Basic Service*** tab > ***Parameters*** > ***Gas Unit***
3. Adjust the sample flow close to the nominal value 150 ml/min by using the ***Sample Flow Gain*** up-down spinner controls:
   a. To decrease the sample flow rate measured by the flow meter by approximately 7.5 ml / min, add gain value by 0.05.
   b. To decrease the sample flow rate measured by the flow meter by approximately 7.5 ml / min, add gain value by 0.05.
4. Select ***Confirm*** to check the effect of the gain adjustment. Wait until the sample flow value shown in the menu returns near to the nominal value 150 ml/min and then check the actual measured flow rate from the flow meter.
5. Repeat steps 3 and 4 until the flow meter shows a 150 ± 25 ml /min flow rate.

NOTE Adjust the flow rate according to the reading in the flow meter. The flow rate reading in the menu is measured by the internal electronics and settles always back to the nominal 150 ml /min independent on the real flow rate.

Gas calibration

WARNING A failure in zeroing or calibrating airway gases may cause inaccurate readings.

Gas calibration shall be performed:

- each time planned maintenance is performed.
- each time corrective maintenance is performed.

NOTE Gas calibration is a normal user action. Refer to the monitor's user's manual for the recommended gas calibration interval in clinical use.

Required tools

- P/N: 755534-HEL Calibration Gas Regulator
- P/N: M1006864, Calibration Gas Regulator, US only
- P/N: 755580 Calibration gas 5% CO2 and air, package of 4 cans
- 3 m / 10 ft Gas sampling line
- P/N 755587 QUICK CAL calibration gas, US only

NOTE Use only the specified GE Healthcare calibration gas for the gas calibration to ensure measurement accuracy. Do not use any other calibration gases. Check the calibration gas container's labeling to ensure that the calibration gas has not expired.

NOTE Ensure that the gas regulator is functioning properly before gas calibration. Refer to the gas regulator's Instructions for Use letter for the annual maintenance instructions.

Making connections

1. Ensure that the module is connected to the monitor.
2. Ensure that you have a new water trap in use.
3. Connect the gas regulator to the calibration gas container.
4. Connect a new gas sampling line to the sampling line connector in the water trap.
5. Connect the other end of the gas sampling line to the regulator on the gas container. Leave the regulator overflow port open to room air.

The following illustrates how to connect a gas regulator to the calibration gas container and a sampling line to the gas regulator:

Calibrating gases

NOTE Gas calibration is not available during the first five minutes after the module is connected. For maximum accuracy, let the monitor warm up for 30 minutes before starting calibration.

NOTE Gas calibration is not available during a ***Sample line blocked***, ***Check D-Fend*** and ***Check sample gas out*** alarm condition. Resolve the alarm condition before starting calibration.

1. Select the gas digit field.
2. Select ***Calibration*** tab.
3. The monitor will start automatic zeroing of the gas sensor. Wait until the message ***Zeroing*** is replaced by the ***Zero Ok*** message.
4. Open the regulator after the message ***Feed gas*** is shown. The measured gas concentration is shown in real-time in the gas calibration menu. Wait until the measured gas concentration is stabilized and the adjust menu is shown. Close the regulator.
5. Use the CO_2 up-down spinner controls to adjust the CO_2 reading shown in the calibration menu to match with the CO_2 reading in the labeling of the calibration gas container. Select ***Accept*** to accept the adjusted value when the two CO_2 readings match each other.
6. Wait until the message ***Ok*** is shown.

NOTE The message ***Zero Error*** is shown in case the zeroing fails.

NOTE The message ***Calibr. error*** is shown, if you do not start feeding gas within one minute after the automatic zeroing is completed, or if the calibration fails due to too large gain adjustment.

NOTE If zeroing or calibration failed, select ***Recalibrate*** to restart the calibration procedure from the beginning.

Troubleshooting guidelines

This chapter focuses on troubleshooting technical problems. Refer to the user's manual for troubleshooting monitoring problems and clinical configuration issues.

If a problem remains, contact technical support for service. To ensure accurate problem solving, please be prepared to provide the following information:

- Product name and serial number or UDI
- Hardware and software versions
- Detailed problem description
- Error messages, if any
- Configuration information (or settings file)
- Service Logs
- The troubleshooting you have done so far

Perform the specified corrective maintenance check after any corrective maintenance to the product.

Performing visual inspection for the module

Before any detailed troubleshooting, complete a thorough visual inspection for the module.

1. Remove the module and check that:
   a. The front cover is intact.
   b. All connectors are intact, clean and attached properly.
   c. The module casing and the latch are clean and intact.
   d. The patient cables are clean and intact.
2. If you doubt any loose parts or cable connections inside the module, remove the two screws from the back of the module to detach the module box, and check that:
   a. All the screws are tightened properly.
   b. All cables are connected properly.
   c. There are no loose objects inside the module.

Troubleshooting checklist

The following simple troubleshooting hints may help you to localize and isolate a functional problem to the correct unit. Ensure that the monitor is turned on and the module is connected:

- Check if there are any messages shown in the message field. Find the possible cause and solution.
- Check that the module in doubt is compatible with the monitor. Compatibility information can be found from the Supplemental Information Manual.
- Connect the accessories to the module in doubt. Check that the parameters measured by the module are configured to the display. (***Screen Setup***).
- Do a visual check to the accessories used with the module. If in doubt, replace the accessories with known good ones.

Gas sampling system troubleshooting

- Faults which can occur in the sampling system are: leaks or blockages in the tubing, failure of the sampling pump or the magnetic valves, or diminishing of the flow rates because of dirt or other matter accumulating in the internal tubing.
- Whenever suspecting the sampling system and always after having done any work on it, check the sampling system for leakages and check the flow rate.
- The Mini D-fend water trap should be replaced, when the ***Replace D-Fend*** appears.
- If any liquid has entered the IR sensor due to water trap filter failure, contact GE Healthcare service.
- If the sampling pump is noisy it indicates possible problems with motor bearing. In this case it is recommended to replace the noisy sampling pump with a new one.
- Check that the tubing inside the module is not contaminated. Any contamination inside the tubing may indicate that the valve or sensor is contaminated, too. This can increase a risk of faulty operation in valve or sensor. The gas sensor is not possible to clean in the field. Therefore, replace the whole miniCO2 assembly with a new one.

NOTE All internal tubes are mechanically fragile. Sharp bends may cause leaks and occlusions.

MiniC sensor troubleshooting

- The CPU contains factory calibration data for the miniC sensor. Thus, they can't be replaced separately in the field. In case of failure, the complete miniCO2 assembly should be replaced.

Messages related to gases measurement

For information regarding alarm priorities and escalation times, see the supplemental information manual.

Make sure you are familiar with the generic layout of the screen. This will help you identify where on screen the following messages appear. The message location is indicated with the following abbreviations:

- MF = message field
- WF = waveform field
- DF = digit field

Message	Location	Possible causes	Suggested actions
• ***Apnea deactivated***	• DF	A new patient has been admitted, or the measurement has been started and the apnea alarm is not active yet.	• Wait. The message disappears after the monitor detects 3 breaths during the last minute.
• ***Calibrating gas sensor***	• WF	Due to the module warm-up, CO_2 measurement is not available during the first minute after the module has been connected.	• Wait until the warm-up has been completed.
• ***Check sample gas out***	• MF, WF, DF	The sample gas outflow is blocked. Internal tubing is blocked. Pump failure.	• Check the sample gas out connector in the front panel and the exhaust line for gas return or scavenging for blockages. ▪ If the sample gas is returned to the patient circuit, check that there is no occlusion in the tubing. ▪ If the sample gas outlet is connected to a scavenging system, make sure that such an open system is used where gas is removed in room pressure. • Check the internal tubing for blockages. • Check sample pump operation by measuring the sample gas flow rate. Replace the pump if needed.

Message	Location	Possible causes	Suggested actions
	• WF • MF, WF, DF	Water trap is not connected. There is a leak inside the internal tubing.	• Connect the water trap and sampling line to the module. • Check the tubing for leakages.
• ***Sample line blocked***	• WF • MF, WF, DF	Gas sampling line is blocked. Water trap container is full. Water trap is occluded. Internal tubing is blocked.	• Check the external gas sampling line for blockages. Replace if needed. • Empty the water trap container. • Replace the water trap. • Check the tubing for leakages.
• ***CO2 over scale***	• WF	Gas signal exceeds the maximum waveform field.	• Check the patient status. • Select a larger scale for waveform.
• ***Gas measurements removed***	• MF	Acquisition module has been removed.	• Connect the module if you want to restart the measurement.
• ***Low gas sample flow***	• MF	Sample flow deviates to less than 80% of the module's specific nominal flow value. Gas sampling line, gas output, water trap, or internal tubing is blocked. Pump failure.	• Check sample flow rate. Adjust if needed. • Check or replace the gas sampling line, water trap, or internal tubing. • Replace the pump unit.
	• MF	Defective or contaminated D-Fend. Occlusion in internal tubing.	• Replace the water trap. • Check sample and reference flows. Perform a visual check for the internal tubing. Remove the cause for occlusion.
• ***Sensor INOP***	• WF	Ambient pressure is too high or too low. No response from the gas module, high temperature inside the module, or EEPROM checksum failure.	• Check the ambient pressure (gas calibration menu). • Replace the miniCO2 assembly. • Return the module to GE for service.

Disassembly and reassembly

Disassembly guidelines

Field repair of the device is limited to replacing field replaceable units (FRUs).

WARNING Attempting a field repair on a PCB or a factory sealed component or assembly could jeopardize the safe and effective operation of the module, and void the warranty.

WARNING Disconnect the module from any monitoring system before performing any repair.

WARNING Always perform gas sampling system leak test after the module cover is reassembled.

WARNING Always perform gas calibration after any planned or corrective maintenance.

NOTE Only qualified service personnel should perform field replacement procedures.

NOTE Perform the specified corrective maintenance check after any corrective maintenance to the product.

Serviceable parts

- MiniC assembly, including the following components (CPU board, miniC sensor, pump unit, tubing unit and zero valve and pressure transducers).
- Tubing unit.
- Pump unit.
- Zero valve.
- Air filter.
- Mini D-fend O-rings.
- Nafion tube.
- Mini D-fend.
- Mechanical parts listed in the service parts chapter.

Service limitations

The following parts are not serviceable:

- MiniC sensor and CPU board cannot be replaced separately.

NOTE: The CPU contains factory calibration data for the miniC sensor. In case of failure, replace the complete MiniC assembly. Attempts to repair or calibrate the unit elsewhere will adversely affect operation of the unit. The information provided in this document is for reference only.

ESD precautions

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

All external connectors of the device are designed with protection from ESD damage. However, if the device requires service, exposed components and assemblies inside are susceptible to ESD damage. This includes human hands, non-ESD protected work stations or improperly grounded test equipment. The following guidelines may not guarantee a 100% static-free workstation, but can greatly reduce the potential for failure of any electronic assemblies being serviced:

- Discharge any static charge you may have built up before handling semiconductors or assemblies containing semiconductors.

- Wear a grounded, antistatic wristband or heel strap at all times while handling or repairing assemblies containing semiconductors.
- Use properly grounded test equipment.
- Use a static-free work surface while handling or working on assemblies containing semiconductors.
- Do not remove semiconductors or assemblies containing semiconductors from antistatic containers until absolutely necessary.
- Do not slide semiconductors or electrical/electronic assemblies across any surface.
- Do not touch semiconductor leads unless absolutely necessary.
- Store the semiconductors and electronic assemblies only in antistatic bags or boxes.
- Handle all PCB assemblies by their edges.
- Do not flex or twist a circuit board.

Protection from dust

The gas sampling system must be protected from dust entering the tubes, valves and other components. In order to achieve this goal, the following measures must be taken:

- Always connect the mini D-fend water trap to the module.
- Have a clean and dust-free working environment during all service procedures.
- Minimize the times with any open connections in the gas sampling system.
- Always close the open tube connections of the sampling system when not working on the module.
- Remove the protective caps on the gas pump only immediately before assembling it to the module.
- The clothing of the service person must be such that the dust risk has been taken into account.

Before disassembly

- Note the positions of any wires or cables. Mark them if necessary to ensure that they are re-assembled correctly.
- Save and set aside all hardware for reassembly.

Required tools

- Flat blade screwdriver
- Pozidrive screwdriver
- Antistatic wristband

Disassembly procedures

For reference, see the exploded view in Service parts chapter.

Detaching the module casing

To disassemble the airway module (see the exploded view of the module in chapter Service parts):

1. Remove the two screws from the back of the module.

2. While pressing the release latch, pull the module casing slowly backwards and remove it from the main body.

Detaching the pump unit

1. Detach the front cover of the module by releasing the snaps that hold the front cover to he front chassis unit by using a small flat blade screwdriver. There are 2 snaps on both sides of the module and 1 snap on the top.
2. Remove the module casing.
3. Unplug the two tubes from the back of the front chassis.
4. Detach the front chassis from the metal frame by removing the two screws.
5. Unplug the hose of the pump.
6. Disconnect the pump's cable from the CPU board.
7. Remove the two screws that connect the pump unit to the board.

Detaching the MiniC assembly

1. Detach the front cover of the module by releasing the snaps that hold the front cover to he front chassis unit by using a small flat blade screwdriver. There are 2 snaps on both sides of the module and 1 snap on the top.
2. Remove the module casing.
3. Unplug the two tubes from the back of the front chassis.
4. Detach the front chassis from the metal frame by removing the two screws.
5. Detach the MiniC assembly from the metal frame by removing the three screws.
6. Disconnect the flex board from MiniC assembly.

Reassembling the module

1. Reassemble in reverse order. Make sure that:
   a. All screws are tightened properly.
   b. All cables are connected properly.
   c. Tubes are not pinched and there are no sharp ends on them.
   d. All tubes are connected properly.
   e. There are no loose objects inside the module.

Service parts

Perform the specified corrective maintenance check after any corrective maintenance to the product.

Ordering parts

To order parts, contact your local GE representative. Contact information is available at www.gehealthcare.com. Make sure you have all necessary information at hand.

Single-width Airway Module, E-miniC

List of FRUs for E-miniC

Item	Part number	Description
-	8002174	Mini D-Fend, 10 pieces of package
-	2083290-001/M1013204	MiniCO2 assembly, including the following components: • CPU board • Mini CO2 sensor with EMI cover • Pump unit (#15) • Tubing unit (#17) • Nafion tube (#11) • Magnetic valve, zero valve (#12) • Pressure transducer • Air filter (#16) • Air filter (#16) • 3 mounting screws (#19)

Item	Part number	Description
-	M1206392	FRU, E-Modules Hardware kit: • 2 mounting screws for metal frame (#14) • 2 mounting screws for front chassis unit (#18) • 2 mounting screws for module casing (#8) • Latch (#6) • Torsion spring (#7) • Membrane keypad (not used in this module)
1	M1021035	Module Casing, Single
2	M1027134	Front Chassis Unit, E-miniC NOTE: Excludes the latch (#6) and torsion spring (#7)
3	8002173	M-miniCO2, CONNECTOR FOR D-FEND, MINI CO2
4	656565	O-RING, O-RING, 2.5x1.6, VITON, SHORE70, BLACK
5	M1026941	Front Cover, USA, E-miniC
5	M1026943	Front Cover, E-miniC
6	M1021039	Latch
7	M1020935	Torsion Spring
8	*	Screw-cross rec. c/s h, stzn, m3x6
9	879184	Metal frame
10	M1024360	Frame, E-miniC
11	733382-HEL	Nafion tubing 300mm
12	585714	MAGN-VALVE, N.O. valve, 3/2, 5VDC, 0.55W, includes seal
13	M1027744	Module Connection Flex, E-miniC
14	*	Cross cylinder head screw M3x6
15	2083166-001/M1013716	Pump Unit, E-miniC
16	M1011471	Air filter, M-MiniC
17	M1013717	Tubing unit
18	*	Cross cylinder head screw M3x10
19	*	Screw-cross rec.c/s h,m3x8, acidproof

*Part is not available from GE. Source locally.

Required parts

Replace the following parts that wear in use at the recommended interval.

Part number	Description	Pieces	Replacement interval
733382-HEL	Nafion Tube (#11)	1	Once a year
656565	Mini D-fend™ O-ring (#4)	2	Once a year
M1011471	Zero valve air filter (#16)	1	Once every 3 years

GE recommends that you replace the Mini D-fend water trap and the gas sampling line as part of the planned maintenance procedure.

NOTE See the Supplies and accessories for compatible accessories.

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Product privacy and security

Introduction

This section describes Privacy & Security considerations of the use of device. This section describes the expected intended use, the Privacy & Security capabilities included, and how they are configured and used appropriately.

This section assumes that the reader understands the concepts of Privacy & Security. Privacy is the property of protecting the personal private interests of patients. Security protects both system and information from risks to confidentiality, integrity, and availability. Security protects Privacy but also protects more broadly against these risks. Privacy requires security. In Healthcare one must balance privacy, security, and safety. Most of the time there isn't a conflict between these three domains of risk. The healthcare provider organization is encouraged to use risk management procedures to assess and prioritize privacy, security, and safety risks. Through the use of risk management one can determine how to best leverage the capabilities provided in the device.

Privacy & Security relevant information can be found at http://productsecurity.gehealthcare.com.

Privacy & Security Environment

The device has been designed for an intended use with the following expectations of Privacy & Security protections included in the environment where this product will be used:

The monitor is a portable multi-parameter unit to be used for monitoring, recording, and to generate alarms for multiple physiological parameters of adult, pediatric, and neonatal patients in a hospital environment and during intra-hospital transport.

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

The monitor can be interfaced to other devices via network. The monitor shall reside on an isolated monitoring network (GE CARESCAPE network).

Privacy & Security capabilities

The device incorporates a broad assortment of capabilities to enable Privacy & Security. This section describes the capability and use of these Privacy & Security capabilities.

Access controls

The access control features of the device may be used to help control access to sensitive information. Access control includes user account creation, assigning privileges

Identity provisioning

The provisioning of user accounts includes the steps of account creation, maintenance, and suspension of the account when it is no longer needed. A user account is created for the use by a specific individual. This user account is associated with access rights, and is recorded in security audit logging.

The monitor is intended to be used on one patient at a time and always in emergency mode, so no need user accounts in normal operation in a hospital environment. Clinical or service users are pre-defined for advanced configurations and system maintenance only.

User authentication

This section covers the administration of the authentication system to be used.

Role based user

The monitor defined three role based users: clinical, basic service and advanced service, for access control of advanced functions. The users are authenticated by main application with local password.

There is an independent password for each role. the default password could be changed by user. Each user can only change the password of current role or the role with lower priority. For example, the basic service user can change the password for basic service and clinical access.

For more information about how to change or reset password, refer to “Configuration” chapter.

Assigning access rights

The Assigning of Access Rights is the administrative process to associate permissions with user accounts.

Username	Password	Access to
clinical	Change Me	***Clinical***
service	Wh1teF1sh	***Clinical***, ***Basic Service***

For advanced service password, please refer to the Service for Depot Instruction.

The user functions are defined as follow:

Functions	User level		
	Clinical	Basic Service	Advanced Service
Alarm Options	•	•	•
Snapshot	•	•	•
Units	•	•	•
Colors	•	•	•
Save Modes	•	•	•

Functions	User level		
	Clinical	Basic Service	Advanced Service
Time and Date	•	•	•
Time Zone	•	•	•
Parameter Settings	•	•	•
Parameters		•	•
Country Settings		•	•
Licenses		•	•
Service Log		•	•
Enter/Exit Demo Mode		•	•
Set/Test		•	•
Network		•	•
WLAN Config		•	•
WLAN Status		•	•
SW Management		•	•
Use configuration file			•

Patient privacy consent management

Patient privacy consent management is the process of supporting the patient expressing their privacy requirements. This is distinct from other forms of consent such as the consent to treat.

User can only view the authenticated information by different role.

Privacy & security audit logging and accountability controls

Privacy & security audit logging and accountability controls support security surveillance and privacy investigations and reporting.

System audit records include alarm logging, keyboard logging, service (system) logging and wireless logging.

These logs can be viewed through:

- The service menu: > ***Service*** > ***Basic Service*** tab > ***Service Log***.
- Downloading the logs from the device, and being viewed on PC.

Information protection

This section of the manual focuses on Privacy & Security operations, and contains information to guide in the preparation of a secure environment for the device.

Security operations is best implemented as part of an overall “defense in depth” information assurance strategy are used throughout an Information Technology system that addresses personnel, physical security and technology. The layered approach of defense in depth limits the risk that the failure of a single security safeguard will allow compromise of the system.

Network security

GE strongly recommends that medical devices are operated in a network environment that is separate from an organization's general purpose computing network. There are many effective techniques for isolating medical devices on a secure sub network, including implementing firewall protection, Virtual Local Area Networks (VLANs) and network enclaves.

To assist in secure network design, the following network profile outlines the required network services for the device.

Ports, protocols and services required by system:

Port	Protocol	Direction	Network service	Source/ Destination
2000, 7000, 7001	udp	outbound inbound	CARESCAPE (Unity) network	All trusted hosts
6000	tcp	outbound	HL7	All trusted hosts

Firewall integration:

- IP table in file system.

System supports NTP (Network Time Protocol) to synchronize time from time server via network.

Network diagram

CARESCAPE Network

- HL7 outbound from monitor though CNI V2 switch.

NOTE Need unity network and HL7 network license.

Hospital Network

- HL7 outbound from monitor though hospital switch.

NOTE Need HL7 network license.

Wireless Security

Due to the broadcast nature of wireless communication, wireless devices require special security consideration. There are effective techniques and tools for improving the security of wireless communication devices.

- Transmission methods
  - WiFi
- Use of Transport Controls
  - Mutually-Authenticated-TLS
- Network Transmission Encryption
  - WPA–Persional
  - WPA2–Persional
  - WPA–Enterprise
  - WPA2–Enterprise
- Access Controls
  - WPA2-PSK
  - WPA2-Enterprise
- SSID Broadcasting
- Transmission power/range
- MAC address filtering
- VPN over wireless

Removable media security

System supports removable USB storage device.

All functions of removable media need authentication by password. Sanity of removable media is supported in menu.

All the exported logs have been encrypted.

Boot, execute and auto-run from USB media have been disabled.

Serial port can only be used for S5 iCollect through multi-I/O adapter.

Data integrity capabilities

The device contains capabilities that ensure the system data are not modified accidently or maliciously.

System data integrity check is performed during device start-up and user will be alerted if there is any error.

During downloading device software or importing system settings, the related data integrity check will also be performed.

Use key log to confirm user operation.

De-identification capabilities

The device contains de-identification (anonymization and pseudonymization) capabilities to limit Privacy & Security risks to sensitive information.

Personal information is not included in data exported.

Business continuity

System watchdog is used to keep monitoring main application activity.

System will be automatically reset if main application stops response.

System can be recovered from the system upgrade failure through the backup of main application.

System can restore system settings and data after an outage within 2 hours.

System supports backup storage for all settings.

System protection

The system needs to be configured and maintained in a way that continually protects Privacy & Security.

Malicious software protection

The computing environment is increasingly hostile, and threats continue to grow from malicious software, including computer viruses, worms, Trojan horses, denial of service attacks, and other malware. Vigilant defense on many levels is required to keep systems free from compromise by malicious software. In most cases, effective protection requires cooperation and partnership between GE and our customers.

Commercial Anti-virus software is commonly used on general-purpose computers to detect the presence of malicious software (virus, Trojan horse, worm, etc). Anti-Virus software is useful on general-purpose computers as they typically cannot be sufficiently hardened against the attack vectors used by malicious software.

Medical Devices however are single purpose (dedicated) devices that have controlled intended use, and thus often can be well hardened. For medical devices, the patient safety risk introduced by using commercial Anti-virus software outweighs any security benefit. Such risks include:

- Real-time scanning affecting system performance.

- Introducing false positives
- Quarantining of clinical data that randomly appear to match a virus signature
- The Anti-virus software itself is another popular attack vector
- Support of the Anti-virus software throughout the life cycle of the medical device (Operating System support and virus signatures/libraries)

Due to the cited risks, the use of anti-virus software is not part of this product security strategy.

For more information on Malicious Software Protection, refer to the following two whitepapers by the Joint NEMA/COCIR/JIRA Security and Privacy Committee:

- "Defending Medical Information Systems Against Malicious Software", December 2003, http://www.medicalimaging.org/policy-and-positions/joint-security-and-privacy-committee-2/
- "Patching Off-the-Shelf Software Used in Medical Information Systems", October 2004, http://www.medicalimaging.org/policy-and-positions/joint-security-and-privacy-committee-2/

System (product) change management

System OS: Linux Kernel: linux3.18

File system: Buildroot 2015.05

System supports the following upgrade options:

- Main application
- Module software

Only service user is allowed to upgrade the main application and module software.

For Software Upgrade Procedure, refer to software upgrades instruction.

OS updates and release will be reviewed by GE Healthcare periodically. System patches will be released and upgraded if needed.

No additional software is allowed to be installed on system.

No files in system is allowed to be changed by unauthorized user.

FDA Guidance - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Document issued on: October 2, 2014

FDA guidance - Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software FDA-1553:2005, document issued on January 14, 2005

For more information on communication with GE, refer to the following URLs: http://ge.com

Personal information collected by the product

The device mainly collects patient demographics and health information, for intended use, which including:

- Patient ID
- Patient Name
- Patient Age

- Patient assigned Room/Bed
- Physiological information (e.g., ECG)
- Vital Signs
- Alerts (Type of patient related alert such as a code blue, etc.)

The device protects this information by technical safeguards like authentication, and retains this information.

The action of personal information collection will be recorded into audit logging.

For more information on IHE Integration statements, refer to the following URLs:

http://ge.com/ihe

http://ge.com/hl7

Additional privacy & security considerations

The device has been designed with Privacy & Security functionality integrated into the core design. However, there exist Privacy & Security residual risks that must be mitigated once the device is integrated into the work environment. This section contains some risks that should be imported into the Risk Assessment of the deployment of the device for proper mitigation.

- Users should be trained to use the data destruction feature of the device when returning it for service, or other Privacy & Security awareness training needs.
- If this product is used in an environment where robust authentication methods are an impediment to clinical workflow, physical access restrictions to the device are encouraged.
- If the device persists data beyond the clinical encounter, notify the customer of the default retention period for this data and whether the retention period should be configured.

MDS2

The MDS2 is provided as a statement of the security and privacy capabilities using a well-known standard disclosure format. The MDS2 and other information Privacy & Security relevant information can be found at http://productsecurity.gehealthcare.com

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Networking disclosure to facilitate network risk management

Purpose and scope

This disclosure is intended to satisfy the requirements of IEC 60601-1:2005 clause 14.13 and IEC/ISO 80001-1:2010 clause 3.5 for disclosure of network-related specifications, requirements, and residual risks in order to facilitate the responsible organization's risk management activities (e.g. pursuant to 80001-1) for their networks incorporating the monitor.

Purpose for B125/B105 monitor connection to network

The B125/B105 monitor is intended to be connected to a network in order to support the following functionality:

- Providing realtime patient data (i.e. parameters, waveforms and alarms) to compatible network devices such as central stations.
- Remote configuration (patient admission, alarm settings, etc.) from compatible network devices.

Network interface technical specifications

Connection Name	**Mission Critical (MC) network port**
Physical network connection type	IEEE 802.3-1998 10/100BaseT Ethernet
Speeds and duplex modes supported	100 Mbps half and full deplex
Default IP Address (from factory)	IP address: 172.16.X.X Subnet mask: 255.255.0.0 Gateway: 172.16.254.254
IP Addressing	IPV4 Static
QoS Support	IP layer DSCP tagging

Connection Name	WLAN
General WLAN Standards / Certifications	Protocols: 802.11a/b/g/n Radio RF standards: • USA: FCC Part 15.247, 15.407 • EU: EN300328, EN301893 EMI/EMS standards: • USA: FCC Part 15.207, 15.209 • EU: EN 301 489-1, EN 301 489-17 Safety Compliance: IEC 60950-1:2005 (2nd Edition)/EN 60950-1:2006
Antenna Gain	2.4 GHz: +2.2dBi Maximum 5 GHz: +4.5dBi Maximum
Supported Channel Range	2.4 GHz: 1-14 5 GHz: 36-165
RF Output Power Range	2.4 GHz EIRP: up to +18.83dBm 5 GHz EIRP: up to +16.42dBm NOTE: May be further restricted on some channels according to regulatory domain.
Supported Data Rates [Mbps] and Corresponding Receive Sensitivity [dBm, referenced to radiated output]	2.4 GHz (802.11 b): 11Mbps: Channel 1/ -79 dBm, Channel 6/ -81dBm , Channel 11/ -78 dBm (Sensitivity corresponds to 8% max packet error rate with 1024 byte MPDU)
	2.4 GHz (802.11 g): 54Mbps: Channel 1/ -68 dBm, Channel 6/ -67 dBm , Channel 11/ -66 dBm (Sensitivity corresponds to 10% max packet error rate with 1024 byte MPDU)
	5 GHz (802.11 a): 54Mbps: Channel 36/ -67 dBm, Channel 48/ -67 dBm , Channel 60/ -68 dBm, Channel 100/ -67 dBm, , Channel 140/ -68 dBm, Channel 165/ -69 dBm (Sensitivity corresponds to 10% max packet error rate with 1024 byte MPDU)
Minimum Expected RSSI in Coverage Area	-65dBm ±5dB
Dynamic Frequency Selection	802.11h DFS
Transmit Power Control	None
MAC-layer QoS and Power Save Support	802.11e WMM: Customizable DSCP settings
Data Encryption Support	Wi-Fi Protected Access with TKIP and AES-CCMP
Authentication Support	WPA-Personal, WPA2–Personal, WPA-Enterprise, and WPA2–Enterprise

Connection Name	WLAN
Over-the-air Configuration Support	None
Fast roaming Support	802.11 r
IP Addressing	IPv4 statically configured
IP Layer QoS	DSCP tagging per dataflow, 802.11e, WMM

Network information flows

Flow Name	Realtime patient data
Network Connection on device	MC network
Usage Type/Function/Purpose	Clinical/Waveforms, parameters, trends, alarms, admit/discharge patient/Transmit clinical data to other devices on the network
Licensed/optional/required	Licensed
Communication Partner Device/IP Address/Network	Unity Devices / MC Network
Middle Layer Protocols	UDP
Application Layer Protocol and Encoding	Unity
Ports	2000, 7000, 7001
Traffic characterization and Bandwidth Requirements	Outgoing unicast traffic is approximately 50 Kbps per patient view. Maximum of 10 views supported on wireless network. Maximum of 11 views supported on wired network.
Latency max	250 ms

Flow Name	Ping
Network Connection on device	MC network
Usage Type/Function/Purpose	Network troubleshooting
Licensed/optional/required	Required
Communication Partner Device/IP Address/Network	PC, Other Medical Devices / MC Network
Middle Layer Protocols	ICMP
Application Layer Protocol and Encoding	NA
Ports	NA
Traffic characterization and Bandwidth Requirements	On-demand, User-initiated

Flow Name	HL7
Network Connection on device	MC network
Usage Type/Function/Purpose	HL7 outbound to EMR system
Licensed/optional/required	Licensed
Communication Partner Device/IP Address/Network	HL7 Server
Middle Layer Protocols	TCP
Application Layer Protocol and Encoding	HL7
Ports	Customer defind, default port is 6000
Traffic characterization and Bandwidth Requirements	On-demand, 720 bps

Flow Name	Software Transfer
Network Connection on device	MC network
Usage Type/Function/Purpose	Performs software upgrades
Licensed/optional/required	Required
Communication Partner Device/IP Address/Network	PC
Middle Layer Protocols	TCP
Application Layer Protocol and Encoding	HTTP
Ports	10001
Traffic characterization and Bandwidth Requirements	10 Mbps

Required characteristics and configuration for support

- The network must meet the specific requirements above for all traffic flows associated with the subset of features, use cases and workflows required by the responsible organization's users.
- In addition, the network must be 'flat' (i.e. limited to a single IP broadcast domain).

Potential risks to safety, effectiveness or security resulting from failure of IT network to provide the required

Loss of network connectivity can result in the following hazardous situations:

- Missed alarm at a remote viewing station (bedside or display).
- Complete or partial loss or deterioration of remote monitoring of waveform and parameter data at remote viewing device.

Product mitigations:

- Low alarm volume is increased if network communication fails.
- Audio off, audio pause are interrupted if network communication fails.
- User is notified of network communication failure, message is displayed until user acknowledges it.
- User is notified if a duplicate IP address is detected.
- User is notified if a duplicate unit/bed name.

In addition to the hazardous situations identified above, connection of the monitor to a network that includes other equipment could result in other unidentified risks to patients, operators or third parties. The responsible organization should identify, analyze, evaluate and control these risks on an ongoing basis including after changes to the network, which could introduce new risks and require additional analysis.

- changes in network configuration
- connection of additional items to the network
- disconnecting items from the network
- update of equipment connected to the network
- upgrade of equipment connected to the network

A

Software download instruction

Introduction

This instruction describes how to upgrade the software to the B125/B105 patient monitor.

Their two method for software download.

- **For USB storage device**. Insert the USB storage device to the monitor directly to transfer software.
- **From PC**. Transfer software by GE Healthcare Software Transfer Utility (STU), which runs on a service PC. With this application, you can transfer new software to the patient monitor over the CARESCAPE Network or a crossover cable.

Contents of the USB storage device

- STU software package with all versions
- USB software package with all versions
- Download instruction: this document

Tools needed

- For USB: USB storage device (file system: FAT32) with related version of software.
- For PC:
  - Service PC with: Windows XP, 7 or 10, Ethernet network card, Internet Explorer v 6.0 or greater
  - Ethernet Cable
  - STU software package with related version

Installing software with PC

Connecting a service PC to a patient monitor or to the Network for multiple patient monitors

Connection method to be used	Procedure
Direct connection:	1. Connect a service PC to the monitor's Ethernet connector with an Ethernet cable.

Connection method to be used	Procedure
This connection method lets you transfer software to one patient monitor at the time.	2. Verify that the service PC can perform a network ping to the patient monitor.
Network connection: This connection method lets you transfer software to multiple patient monitors at a time.	1. Connect a service PC to the Network with an Ethernet cable. 2. Verify that the service PC can perform a network ping to the patient monitor.

Checking the network settings of the patient monitors

Check the Network settings of the patient monitors. Contact the biomed or hospital IT to obtain the network settings of the patient monitors, or check the settings from the patient monitors by following these instructions:

1. Turn on the patient monitor(s).
2. Select the > ***Service*** > enter ***Username*** and ***Password***.
3. Select the ***Basic Service*** tab > ***Network*** > ***TCP/IP*** tab.
4. Record the following information:
   - ***IP Address***: _____
   - ***Subnet Mask***: _____
   - ***Default Gateway***: _____

Checking and configuring the network settings of the service PC

Configure the service PC to communicate with the patient monitors in the same subnet. Use the information that you gathered about the network configuration of the patient monitors.

Refer to the Windows documentation to see how to verify and configure the network settings in your service PC.

NOTE It's recommended you to disable the firewall protection or networking services, such as Cisco Systems VPN, Sophos, McAfee on the service PC before you use Software Transfer Utility. Refer to Technical Bulletin DOC1397399 and DOC1020271 or contact IT support engineer for details.

1. Configure the service PC's network settings to operate in a manual configuration mode. Configure a unique IP address and a valid subnet mask.

   Use the same subnet that is in use in the patient monitors network.
2. If default gateway is in use in Network, configure also the default gateway address to the service PC.

Launching the Software Transfer Utility

Launch the GE Healthcare Software Transfer Utility (STU) to transfer software packages to target patient monitors.

1. Insert the software USB disk into the service PC.
2. Open the USB disk and the target STU software folder on the PC.
3. Double click the ***auto.bat*** file to run the STU.

The STU has an on-screen help. Select ***Help*** for more information about the use of the tool.

Specifying the IP addresses of the target patient monitors

Define the set of target patient monitors under the ***Add Target IP Addresses*** section. You have two options how to specify the IP addresses of the target patient monitors. You can either enter the IP addresses manually or import a text file that contains the IP addresses.

Entering the IP addresses manually

1. In the ***IP Address*** field, enter the IP address of the patient monitor where you want to transfer the software. For the IP address, use the X.X.X.X address format where X is a decimal number from 1 to 254. Any additional text added after a space following the IP address is treated as a comment.
2. Select the ***down arrow*** button to add the IP address to the list.
3. Repeat the steps 1. and 2. for each additional patient monitor.

NOTE To remove an incorrect IP address from the displayed list, select the IP address and click the ***up arrow*** button. To remove all IP addresses, select ***Clear all IP addresses***.

NOTE To save the list of displayed IP addresses into a text file (.txt) for future use, select ***File*** > ***Export IP File***. Specify the destination and file name of the .txt file and select ***Save***.

Uploading the IP addresses from text file

1. Select ***File*** > ***Import IP File***.
2. In the Open dialog box, browse and select the text file (*.txt) that contains the IP addresses of the patient monitors.
3. Select ***Open***.

NOTE IP addresses that are in incorrect format in the text file are not imported. The IP address must be in the X.X.X.X address format where X is a decimal number from 1 to 254. Any additional text added after a space following the IP address is treated as a comment. There must be one IP address per line. See the on-screen help for additional information.

4. Verify that the IP addresses are correctly listed in the ***Add Target IP Addresses*** list. Make sure that they are the IP addresses of the target patient monitors.

NOTE To remove an incorrect IP address from the displayed list, select the IP address and click the ***up arrow*** button. To remove all IP addresses, select ***Clear all IP addresses***.

Transferring the software

After the IP addresses of the target patient monitors are entered or imported, transfer the selected software packages to the inactive software storage of the target patient monitors.

1. Enable the software download mode from monitor.
   - For main software: > ***Service*** > enter and username and password > ***Basic Service*** tab > ***Page2*** vertical tab > ***SW Management*** > ***SW Download Enable:*** > ***Yes***
   - For firmware: ***SW Management*** > ***Module Upgrade*** tab > ***Module Download Enable:*** > ***Yes***

   NOTE The monitor will display ***Restart Needed*** message, please ignore this message. Restart the monitor(s) after the software has been successfully transferred.

2. On the STU, select the software package you want to transfer for ***Select Software Packages***.

   You can hold the **Control** key to select several software packages.

3. Select ***Transfer***.

   Software can only be transferred to a limited number of target monitors at a time. As a result, the software transfer may occur in sequential groupings.

   Transfer status is shown in the ***Transfer Status*** list at the bottom of the STU window. The transfer status can be:

   - ***Queued***: A submitted transfer that is not in progress yet.
   - ***Started***: Communicating with a target device and transfer is in progress.
   - ***Success***: A successfully completed transfer.
   - ***<Failure Message>***: A failed transfer that is detailed in a failure message.

   To cancel a software transfer, select ***Cancel***. Selecting ***Cancel*** only cancels the transfer of the queued software packages shown in the ***Transfer Status*** list. When a software package transfer starts, you cannot cancel it.

4. Verify that the transfer status of all selected software packages for all selected target patient monitors indicate ***Success***.
5. Select ***Exit***.
6. Restart the monitor(s).

Installing software with USB

Preparing the USB disk

If need to copy the electronic package to your own USB disk, should follow specific folder structure and naming rules.

1. Make sure the file system format for USB disk should be FAT32, if not, please format the disk.
2. Create the related folder in the root of the disk, the folder name as following:
   - “software”: for device main software
   - “NIBP”: for NIBP firmware
   - “ECG”: for ECG firmware
   - “RECX”: for recorder firmware
   - “STP”: for TP firmware
3. Copy the target version of software/firmware package to the above related folder, rename the target package name:
   - “VSP_x.x.x.x”: for device main software
   - “NIBP_x.xx”: for NIBP firmware
   - “ECG_x.xx”: for ECG firmware
   - “RECX_x.xx”: for recorder firmware
   - “TPMx.x”: for Masimo TP firmware
   - “TPNx.x”: for Nellcor TP firmware

   X is the version number.

For example:

```
/software/VSP_1.0.5.0/detailed files
/NIBP/NIBP_1.06/detailed files
/ECG/ECG_1.05/detailed files
/RECX/RECX_1.02/detailed files
/STP/TPM1.4/detailed files
/STP/TPN1.1/detailed files
```

Transferring the software with USB

1. Insert the USB disk with the target software to monitor.
2. Select the ⊕ > 🛠 ***Service*** > enter ***Username*** and ***Password***.
3. Select the ***Basic Service*** tab > ***Page 2*** vertical tab > ***SW Management*** > ***USB Disk Upgrade*** tab.
4. Select the version of each target software.
5. Select ***Download*** of each target software.
6. Restart the monitor.

Activating the software

Before you start:

- Verify the compatibility of the connected bedside and network devices with the new software version that you are activating.
- For traceability – Record the serial number of the monitor where the software is installed to your local service database.
- Contact GE Healthcare to get the latest version of the user and service documentation.

NOTE Loss of monitoring - Software is activated only when the patient monitor is in a patient discharged state. Normal patient monitoring is unavailable until the software activation is completed.

1. For main software: > ***Service*** > enter the username and password > ***Basic Service*** tab > ***Page2*** vertical tab > ***SW Management*** > ***SW Upgrade*** tab. Or,

   For firmware: ***SW Management*** > ***Module Upgrade*** tab > select ***Upgrade Module Type:***

   The software status displays.
2. Check that the software to be activated is listed in the status.
3. For main software: Select ***SW Activate Enable:*** > ***Yes*** to activate the new software.

   For firmware: Select ***Module Upgrade Enable:*** > ***Yes*** to activate the new software.
4. Wait until the software activation completes.
5. Restart the monitor.

Performing post software activation checkout

Verify that the software activation is successful and the patient monitor runs the activated software.

1. Select > ***Monitor Info***.
2. Select the related vertical tab, if needed.
3. Verify that the active software version is correct.

NOTE There is no need to do any electrical safety tests and maintenance checkout after software download.

B

Installation checkform

B125/B105 Patient Monitor installation check

Customer	Monitor type	S/N
Service record #	Software version	
Service engineer		

Prior to testing, verify that all equipment is calibrated via "Cal" labeling and record Cal Due Dates.

Measuring equipment / test gases used:				
Equipment / tool / gas	Manufacturer	Model / Type / Part No.	Serial number / ID	Calibration date

PASS = Test passed

NA = Test is not applicant, a component or a feature is not part of tested system.

FAIL = Test failed

Visual inspection (Acceptance criteria)	**Observed result**	**Pass**	**Fail**
The monitor and the connected peripheral devices are undamaged.			
The monitor is properly mounted with specified mounting solutions.			
The cables between the patient monitor and the connected devices are intact, properly connected and secured to the right connectors.			
The modules are properly connected and locked.			

Electrical safety tests	
The manufacturing week and year of the device:	
Is there less than 12 months since the device was manufactured?	

Electrical safety tests	
Yes	You do not have to perform the electrical safety tests. To continue the installation check, mark the electrical safety test completion N.A. and proceed to Functional check.
No	Refer to “Electrical safety tests checkform” to perform the electrical safety tests.

Functional check	Observed result	Acceptance criteria	Pass	N.A.	Fail
Start-up		Monitor starts up normally.			
Display: picture quality		Text is readable, images are clear and brightness is good.			
Display: touchscreen control		Touchscreen operates correctly.			
Time and date		Time and date is correct.			
Device information		Device information is correct.			
Parameters measurements					
ECG		***Leads off*** will display.			
SpO_2		SpO_2 sensor will lit.			
NIBP		***Adult/Pediatric*** or ***Neonatal*** will display.			
IBP		***InvBP's not Zeroed*** will display.			
Temperature		***Performing temp test*** will display.			
Gas		***Calibrating gas sensors*** will display.			
Recorder		Quality of the recording is acceptable.			
MC Network connection		Network symbol is correctly shown on the screen.			
Wireless LAN		WLAN network symbol is correctly shown on the screen.			
Test completion					

Wireless MC network infrastructure (WLAN configuration device only)
Refer to “Wireless MC Network infrastructure checkform” to perform the wireless network infrastructure verification.

Notes

Used service parts			

Signature	Date

C

Electrical safety tests checkform

Electrical safety tests

Customer	Monitor type	S/N
Service record #	Software version	
Service engineer		

Prior to testing, verify that all equipment is calibrated via "Cal" labeling and record Cal Due Dates.

Measuring equipment / test gases used:				
Equipment / tool / gas	Manufacturer	Model / Type / Part No.	Serial number / ID	Calibration date

PASS = Test passed

NA = Test is not applicant, a component or a feature is not part of tested system.

FAIL = Test failed

Electrical safety tests		**Observed result**	**Acceptance criteria**	**Pass**	**N.A.**	**Fail**
Power outlet is correctly wired.						
Power cord and plug are undamaged and all conductors are properly connected.						
Ground (earth) integrity						
Ground continuity test	without power cord		≤ 0.1 ohms			
	with power cord		≤ 0.2 ohms			
Impedance protective earth connection	without power cord		≤ 0.1 ohms			
	with power cord		≤ 0.2 ohms			
Earth leakage current test						
Normal Condition (NC)	Polarity: Normal		≤ 500 µA EN /IEC ≤ 300 µA UL			

Electrical safety tests		Observed result	Acceptance criteria	Pass	N.A.	Fail
Single Fault Condition (SFC)	Polarity: Normal		≤ 1 mA			
	Polarity: Reversed		≤ 1 mA			
Normal Condition (NC)	Polarity: Reversed		≤ 500 µA EN /IEC ≤ 300 µA UL			
Enclosure leakage current (touch current) test						
Normal Condition (NC)	Polarity: Normal		≤ 100 µA			
Single Fault Condition (SFC)	Ground closed (normal)		≤ 500 µA EN /IEC ≤ 300 µA UL			
	Ground open (normal)		≤ 500 µA EN /IEC ≤ 300 µA UL			
	Ground open (reverse)		≤ 500 µA EN /IEC ≤ 300 µA UL			
	Ground closed (reverse)		≤ 500 µA EN /IEC ≤ 300 µA UL			
Normal Condition (NC)	Polarity: Reversed		≤ 100 µA			
Patient (source) leakage current tests — ECG						
Normal Condition (NC)	Polarity: Normal		≤ 10 µA			
Single Fault Condition (SFC)	Ground closed (normal)		≤ 50 µA			
	Ground open (normal)		≤ 50 µA			
	Ground open (reverse)		≤ 50 µA			
	Ground closed (reverse)		≤ 50 µA			
Normal Condition (NC)	Polarity: Reversed		≤ 10 µA			
Patient (sink) leakage current test — ECG						
	Polarity: Normal		≤ 50 µA			
	Polarity: Reversed		≤ 50 µA			
Test completion						
Patient (source) leakage current tests — SpO_2/IP						
Normal Condition (NC)	Polarity: Normal		≤ 10 µA			

Electrical safety tests		Observed result	Acceptance criteria	Pass	N.A.	Fail
Single Fault Condition (SFC)	Ground closed (normal)		≤ 50 µA			
	Ground open (normal)		≤ 50 µA			
	Ground open (reverse)		≤ 50 µA			
	Ground closed (reverse)		≤ 50 µA			
Normal Condition (NC)	Polarity: Reversed		≤ 10 µA			
Patient (sink) leakage current test — SpO_2/IP						
	Polarity: Normal		≤ 50 µA			
	Polarity: Reversed		≤ 50 µA			
Test completion						

Notes

Used service parts			

Signature	Date

D

Maintenance checkform

B125/B105 Patient Monitor maintenance check

Customer	Monitor type	S/N
Service record #	Module type	S/N
Service engineer		Software version
Planned maintenance / Corrective maintenance		Start date

Prior to testing, verify that all equipment is calibrated via "Cal" labeling and record Cal Due Dates.

Measuring equipment / test gases used:				
Equipment / tool / gas	Manufacturer	Model / Type / Part No.	Serial number / ID	Calibration date

PASS = Test passed

NA = Test is not applicant, a component or a feature is not part of tested system.

FAIL = Test failed

Visual inspection (Acceptance criteria)	**Observed result**	**Pass**	**Fail**
The monitor and the connected peripheral devices are undamaged.			
The monitor is properly mounted with specified mounting solutions.			
The cables between the patient monitor and the connected devices are intact, properly connected and secured to the right connectors.			
The modules are properly connected and locked.			

Refer to "Electrical safety tests checkform" to perform the electrical safety tests.

Functional check	**Observed result**	**Acceptance criteria**	**Pass**	**N.A.**	**Fail**
Start-up		Monitor starts up normally.			
Display: picture quality		Text is readable, images are clear and brightness is good.			

Functional check	Observed result	Acceptance criteria	Pass	N.A.	Fail
Display: touchscreen control		Touchscreen operates correctly.			
Time and date		Time and date is correct.			
Device information		Device information is correct.			
ECG measurement					
1. Normal Sinus rhythm		Monitor displays the ECG leads II, V1 & aVL and the waveforms are noise-free.			
	bpm	***HR*** is 80 ± 5 bpm.			
		An audible QRS tone sounds with each QRS complex.			
2. Pacemaker detection		Pacemaker spikes are shown on the ECG waveform.			
3. Asystole detection		***Asystole*** alarm appears on the screen.			
4. Leads Off detection		***RA/R lead off***, ***Lead changed*** and ***Learning*** messages appear on screen one by one.			
		Lead III is replaced back to Lead II.			
Respiration measurement					
1. Respiration Rate		RESP waveform appears.			
	bpm	***RR*** value is 20 ±5 bpm.			
2. Apnea detection		***Apnea*** alarm appears on the screen.			
SpO_2 measurement					
1. Test measurement	%	90 - 100 %			
HR value calculation		HR is calculated from SpO2 when ECG and InvBP (ABP or Art) is not measured.			
Non Invasive Blood Pressure measurement					
1. NIBP calibration check	mmHg	NIBP is working properly, the pressure is stabile, not leak, and the pressure drops ≤ 1 mmHg.			
Invasive blood pressure measurement					
1. Zeroing		***Zeroing*** and ***Zeroed*** messages appear correctly on screen.			
2. Static Pressure	mmHg	200 ± 10 mmHg			

Functional check	Observed result	Acceptance criteria	Pass	N.A.	Fail
3. Pressure Waveforms		IBP waveform and Sys/Dia (Mean) pressure values are shown on the screen.			
Temperature measurement					
1. Temperature detection	°C	Temperature value is 37 ± 0.1 °C.			
		No error messages on the screen.			
MC Network		Network symbol is correctly shown on the screen.			
Wireless LAN		WLAN network symbol is correctly shown on the screen.			
Recorder		Quality of the recording is acceptable.			
Synchronization connector test		Marker Out signals are correct.			
Test completion					

Notes

Used service parts			

Signature	Date

E

Maintance checkform, E-miniC

Maintenance check form, E-miniC

Customer	Monitor type	S/N
Service record #	Module type	S/N
Service engineer		Software version
Planned maintenance / Corrective maintenance		Start date

Prior to testing, verify that all equipment is calibrated via "Cal" labeling and record Cal Due Dates.

Measuring equipment / test gases used:				
Equipment / tool / gas	Manufacturer	Model / Type / Part No.	Serial number / ID	Calibration date

PASS = Test passed

NA = Test is not applicant, a component or a feature is not part of tested system.

FAIL = Test failed

Replacement of planned maintenance parts	**Replaced**	**N.A.**
Zero valve air filter (every 3rd year)		
Nafion Tube		
Mini D-fend O-ring		

Visual inspection (Acceptance criteria)	**Observed result**	**Pass**	**Fail**
Module front cover is intact.			
All connectors are intact and attached properly.			
Module box and latch are intact.			
The metal D-fend connectors and D-fend O-rings are clean and intact.			
Module and the applied parts are clean.			

Functional check	Observed result	Acceptance criteria	Pass	N.A.	Fail
Gas sampling system leak test		The pressure reading does not drop more than 6 mmHg during 1 minute.			
Sample flow rate check		The flow rate within the specification limit 150 ±25 ml/min.			
Zero valve operation		The CO2 value drop back near 0%.			
Gas calibration		The gas calibration completed.			
Ambient pressure		The ambient pressure value in menu is differ from barometer within 10 mmHg.			
Occlusion detection		***Sample line blocked*** appears to the digit field within 30 seconds.			
Air leak detection		***Check Water Trap*** appears to the digit field within 30 seconds.			
Airway gases		A normal CO2 waveform and EtCO2, FiCO2 values are shown.			
Apnea detection		***Apnea*** appears to the message field within 30 seconds.			
Test completion					

Notes

Used service parts			

Signature	Date

F

Wireless network infrastructure checkform

Wireless MC Network infrastructure checkform

Observations				
Test point #	Time (hh:mm:ss)	RSSI (dBm)	Transmit rate (Mbps)	Observations

Test summary and recommended actions

Signature	Date

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