Masimo module, E-MASIMO

Service Manual

Host software version 3
Module hardware version 00

Masimo module, E-MASIMO
English
3rd edition
2098086–004

Due to continuing product innovation, specifications in this manual are subject to change without notice.

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

Contents

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About this manual

Intended use of this manual

This manual contains instructions for the planned and corrective maintenance of the acquisition module. This manual must be used together with the monitor's service manual for important safety and installation information.

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

See the monitor's service manual for an overview of the patient monitoring system, information needed for system installation and for planned and corrective maintenance of the monitor.

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

See the monitor's user 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 maintain, troubleshoot, or repair this device.

Manual conventions

This manual uses the following styles to emphasize text or indicate an action. Also note the terminology conventions.

Item	Description
bold	Indicates hardware keys and connectors.
bold italic	Indicates menu options, software keys and messages.
italic	Indicates terms for emphasis.
>	Indicates menu options to select consecutively.
select	The word select means choosing and confirming.
supplemental information	In this manual, the phrase supplemental information refers to information that appears in the Supplemental Information Manual or supplements provided.
NOTE	Note statements provide application tips or other useful information.

Illustrations and names

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

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

Related documents

- CARESCAPE monitor's service manual
- CARESCAPE monitor's user manual
- CARESCAPE monitor's supplemental information manual
- Cleaning and Disinfecting Supplement
- Supplies and Accessories Supplement

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.

Trademarks

GE, GE Monogram, and CARESCAPE are trademarks of General Electric Company.

Third party trademarks

Masimo SET is a trademark of Masimo Corporation.

All third party product and company names are the property of their respective owners.

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.
- The equipment is installed, maintained and serviced in accordance with the instructions provided in the related service manuals.

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.

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Module introduction

E-MASIMO module introduction

This document provides information for the maintenance and service of the MASIMO compatible saturation module, E-MASIMO. The E-MASIMO module measures the following parameter:

- Pulse oximetry, SpO_2

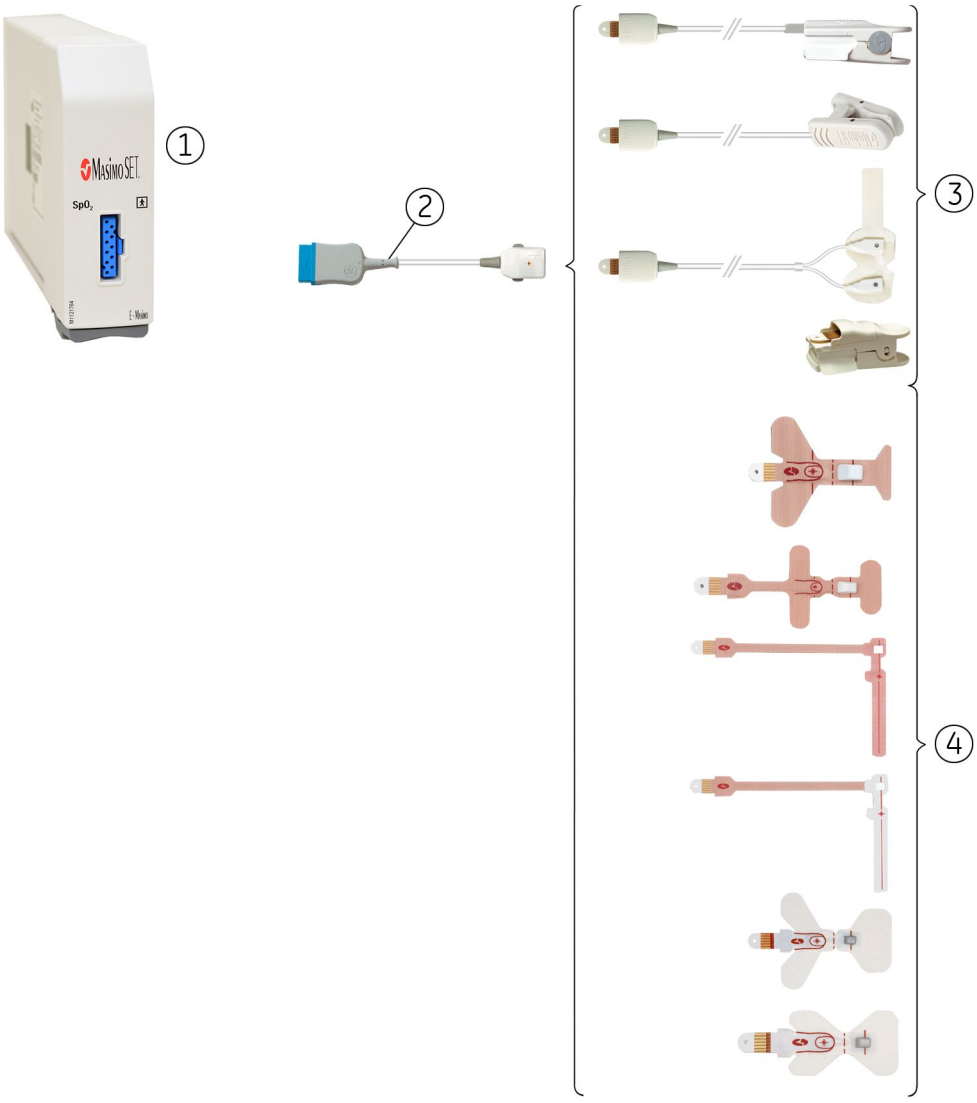
The E-MASIMO module uses the Masimo SET pulse oximetry technology.

Use only MASIMO SET sensors with the E-MASIMO module.

Module compatibility

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

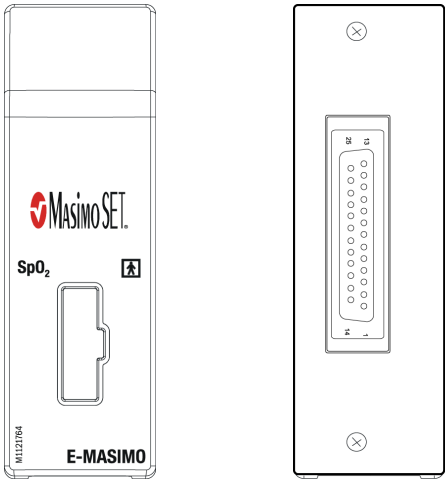
SpO_2 equipment to patient connection with Masimo SET technology



1. Acquisition module with SpO_2 measurement capability
2. Interconnect cable
3. Reusable sensors
4. Disposable sensors

Controls and connectors

Front of Masimo Compatible Saturation Module, E-MASIMO, and the back of the module:



Connector	Description
SpO_2	SpO_2 connector
D25 connector	Module bus connector

Sensors can be plugged into the E-MASIMO module by using the MasimoSAT(R) interconnect cable. Refer to the supplemental information provided for E-Masimo specific interconnect cables and sensors.

The interconnect cable is plugged into the SpO_2 connector on the front panel of the module.

Masimo SET technology and sensor measurement guidelines

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

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

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

- Refer to the cleaning instructions in the directions for use for reusable Masimo RD SET, M-LNCS, or LNCS sensors.

Main components of E-MASIMO

The E-MASIMO module consists of the following parts:

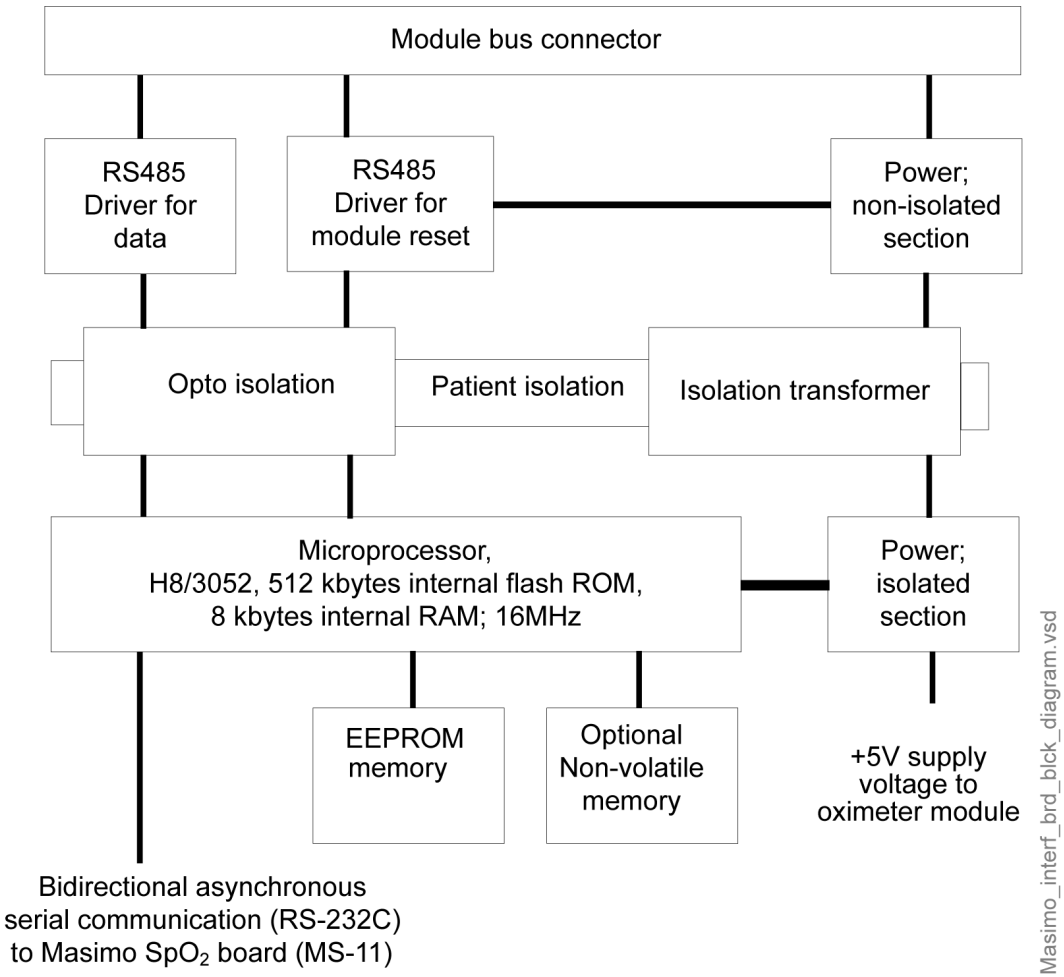
- Masimo SpO_2 board, MS-2011
- Masimo interface board
- Front chassis unit, including the connector, a ferrite and a flex cable

Masimo SpO_2 board

The Masimo SpO_2 board is a surface mounted PC board manufactured by Masimo. It contains the signal processing electronics and software that are based on Masimo stand-alone pulse oximeters. The measured SpO_2 and pulse rate values as well as status information are transferred from the Masimo SpO_2 board to the Masimo interface board. Communication between the Masimo SpO_2 board and the Masimo interface board is established through an RS232C serial interface. The Masimo interface board, in turn, transmits the measurement information to the module bus of the monitor through an RS485 serial interface.

Masimo interface board

The following illustrates the Masimo interface board block diagram:



RS485 drivers

There are drivers for data and for optional module reset functions. These drivers are used for driving the RS485 type serial communication bus between the module and the monitor. Data transmission speed of the bus is 500 kbps.

Power supply, non-isolated section

The power supply is a switched mode circuit where the driver circuit is controlled by a quartz oscillator. The voltage, +15 V received from the module bus, is used as the supply voltage of the switched mode circuit.

Power supply, isolated section

The secondary voltages of the isolation transformer are rectified, filtered, and regulated. Special attention is paid for the Masimo +5 V supply voltage where low noise regulator is used.

Opto isolation

The signals of the serial communication bus between the interface board and the monitor are transferred through the patient isolation by high speed opto couplers.

Microprocessor, optional non-volatile memory

The microprocessor with an on-chip memory is used for converting and transferring data from the Masimo SpO_2 board to the monitor. The communication between Masimo SpO_2 board and the CPU of Masimo interface board is realized with bi-directional asynchronous serial communication.

The non-volatile memory is used for storing identification information such as a serial number, control number, date, etc.

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Planned and corrective maintenance

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 manual or supplemental information provided.

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 PATIENT SAFETY. Planned maintenance must be carried out at the specified interval. Failure to implement the maintenance schedule may cause equipment failure and possible health hazards.

Perform the planned maintenance procedure completely every 2 years after installation. Perform the procedure in the following order:

1. Visual inspection
2. Electrical safety tests *
3. Functional check

Corrective maintenance

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

Performed service activity	Required checkout procedure		
	Visual inspection	Electrical safety test	Functional check
Product casing opened either for troubleshooting purpose or for replacing any of the internal parts.	All steps	All steps	All steps
Front cover, or an other external part, replaced.	All steps	Not applicable	Not applicable

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 patient cables are clean and intact.

Performing electrical safety tests *

Perform the electrical safety tests described in the monitor's service manual, Checkout procedures chapter. Perform the following tests:

1. Patient (source) leakage current test
2. Patient (sink) leakage current test

Performing functional check

Required tools for SpO_2 functional check

For a list of compatible accessories, see the supplemental information provided.

- SpO_2 interconnect cable
- SpO_2 finger sensor

Making connections for the functional check

1. Turn on or restart the monitor and wait until the normal screen appears.
2. Ensure that the module is connected to the monitor.
3. Connect the SpO_2 interconnect cable to the SpO_2 connector in the module.
4. Connect the SpO_2 finger sensor to the SpO_2 interconnect cable.

Configuring monitor for SpO_2 functional check

1. Configure ***SpO2*** waveform to the screen with adequate priority.

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 parameter window.
   - The plethysmographic waveform appears on the screen.

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

Completing the functional check

1. Select ***Discharge Patient*** or ***Reset Case*** to discard any changes made to the monitor configuration during the functional check.
2. Disconnect the test setup.

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Configuration and calibration

Configuration

There is no service configuration for this module.

Calibration and adjustments

No calibration or adjustments are needed for this module.

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Troubleshooting

Troubleshooting guidelines

This chapter focuses on troubleshooting technical problems. Refer to the user 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

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 the 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 suspect that there are 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 the cables are connected properly.
   c. There are no loose objects inside the module.
   d. The ferrite of the flex cable is attached properly.

Troubleshooting module functionality

Follow these instructions to identify the unit causing the functional problem.

Before you begin, ensure that the monitor is turned on, and all the modules are connected.

1. Check if there are any error messages shown in the message field.

   For a list of possible causes and solutions, see Messages related to the measurement.

2. Check the compatibility of each system component.

   For a list of the compatible monitors, modules, and accessories, see the supplemental information provided.

3. Check that there are no identical modules connected to the monitor.

   For a list of identical modules, see the supplemental information manual.

4. Check that:

   a. The module is identified as: channel 2 SpO_2

   b. The screen configuration is set correctly.

5. Visually check the accessories in use. Replace them, if necessary.

   For a list of compatible accessories, see the supplemental information provided.

6. Connect the accessories with a simulator to the module. Check that the parameters measured by the module are configured to the display with adequate priority.

Viewing device information

To view the hardware, software and configuration information of the monitor, modules and/or connected devices:

1. Ensure that the module is connected to the monitor.
2. Log in to the service interface.
3. Select ***Information***.
4. Select an item on the side navigation menu or scroll down the page to view the information.

Service log files

The monitor collects information about different system events, errors and alarms to log files to help troubleshoot equipment problems. The following service logs may contain related useful information:

- ***System Logs*** records different system events, messages, clinical alarms, user interactions and internal communication events.
- ***EMBC Logs*** records module communication events and errors for E-series acquisition modules.

Viewing log files

1. Log in to the service interface.
2. Select ***Diagnostics*** > ***View Logs***.
3. Select the log you want to view. The contents of the selected log file are shown on the screen.

Downloading log files

For security reasons, the contents of the log file(s) will be encrypted with a user-selectable password before the download. Provide the password in a secure way only for the authorized receiver of the log file. Use 7-Zip open-source file archiver (http://7-zip.org/) and the password to decrypt the downloaded log file.

1. Log in to the service interface.
2. Select ***Diagnostics*** > ***Download Logs***.
3. Select the log(s) you want to download.
4. Provide a password to encrypt the contents of the log file. This password is user-selectable.
5. Depending on your access to the service interface:
   a. If you are using a service PC, you can save the log file to any storage device connected to the service PC.
      i. Select ***Download***.
      ii. Save the log file according to the instructions provided by the web browser.

      The steps to download the log file to a service PC depend on the web browser used. The web browser may also notify you about security issues. Refer to the web browser documentation for details.
   b. If you are using the local, integrated service interface, you can save the log file to a USB flash drive that is connected to one of the monitor's USB ports:
      i. Select ***Save to USB storage*** to save the log file to the USB flash drive.

      The log file is saved always to the root directory of the USB flash drive.

      NOTE Do not disconnect the USB flash drive until downloading is complete.
6. Send the log file and the password in a secure way to GE Service for further investigation.

Messages related to SpO_2 measurement

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

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:

- al. area = alarm area
- param. = parameter window
- wavef. = waveform area

Message	Location	Possible causes	Suggested actions
• ***Check device*** • ***SpO2(2) malfunction***	• param. • al. area	The acquisition module has failed.	• Perform the planned maintenance check for the acquisition module. Repair the acquisition module, if needed.
• ***Check probe*** • ***Check SpO2(2) probe***	• param. • al. area	There is no detectable SpO_2 signal, the sensor is faulty or is detached from the patient.	• Check the sensor and connections. • Replace the sensor, if needed.
• ***Faulty probe*** • ***SpO2(2) faulty probe***	• param. • al. area	The sensor has failed.	• Replace the sensor.
• ***Identical SpO2(2) sources***	• al. area	E-module and UNID SpO_2 sources detected simultaneously.	• Remove one source.
• ***Identical SpO2(2) modules***	• al. area	There are two or more identical SpO_2 modules in the system.	• Remove one of the identical SpO_2 modules.
• ***Incompatible probe*** • ***Incompatible SpO2(2) probe***	• param. • al. area	The sensor is not compatible.	• Replace the sensor with a compatible one. See the supplemental information provided. • If the problem persists, contact qualified service personnel.
• ***Interference***	• param.	Interference is detected by the module.	• Check and remove any sources of interference.
• ***Low perfusion***	• param.	Low perfusion at the measurement point.	• Check the sensor and sensor positioning. • Relocate the sensor to a better measurement site, if possible.
• ***No probe*** • ***No SpO2(2) probe***	• param. • al. area	Sensor is not connected to the acquisition module.	• Check connection between the sensor and the acquisition module.
• ***PR(SpO2(2)) high*** / ***PR(SpO2(2)) low***	• al. area	Measurement values are equal to or outside the alarm limits.	• Adjust alarm limits if necessary.
• ***Probe off*** • ***SpO2(2) probe off***	• param. • al. area	The sensor may be defective or it is not connected to the patient.	• Reposition the SpO_2 sensor. • Replace the SpO_2 sensor.
• ***Pulse search***	• param.	The measurement is starting normally. Defective or damaged sensor or cable. Sensor is off of the patient. Detection of a repeatable pulse has stopped.	• Wait for waveforms and parameter values to display. • Check the sensor and cable. • Reposition or replace sensor.
• ***SpO2(2) high*** / ***SpO2(2) low***	• al. area	Measurement values are equal to or outside the alarm limits.	• Adjust alarm limits if necessary.
• ***SpO2(2) measurement removed***	• al. area	Acquisition module is disconnected.	• Connect the acquisition module to the monitor.

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Disassembly and reassembly

Disassembly guidelines

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

NOTE Only qualified service personnel should perform field replacement procedures.

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

ESD precautions

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.

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

- Torx screwdriver, T10
- Flat blade screwdriver
- Antistatic wristband

Disassembly procedures

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

Detaching the front cover

1. Detach the front cover of the module by releasing the snaps that hold the front cover to the 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.

Detaching the Masimo SpO_2 board

1. Remove the two screws (T10) 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.
3. Detach the screw and the three nylon posts that secure the Masimo SpO_2 board to the Masimo interface board. Detach the Masimo SpO_2 board.

Detaching the Masimo interface board or the front chassis unit

1. Detach the front cover of the module by releasing the snaps that hold the front cover to the 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 two screws (T10) from the back of the module.
3. While pressing the release latch, pull the module casing slowly backwards and remove it from the main body.
4. Detach the screw and the three nylon posts that secure the Masimo SpO_2 board to the Masimo interface board. Detach the Masimo SpO_2 board.
5. Detach the interface board by removing the two screws located near the front chassis unit.
6. Disconnect the flex cable from the interface board and pull out the front chassis unit.

Reassembling the module

NOTE When reassembling the module, make sure that the pin connector on the Masimo SpO_2 board connects properly to the connector on the Masimo interface board underneath.

1. Reassemble in reverse order. Make sure that:
   a. All screws are tightened properly.
   b. All cables are connected properly.
   c. There are no loose objects inside the module.
   d. The ferrite of the flex cable is attached properly.

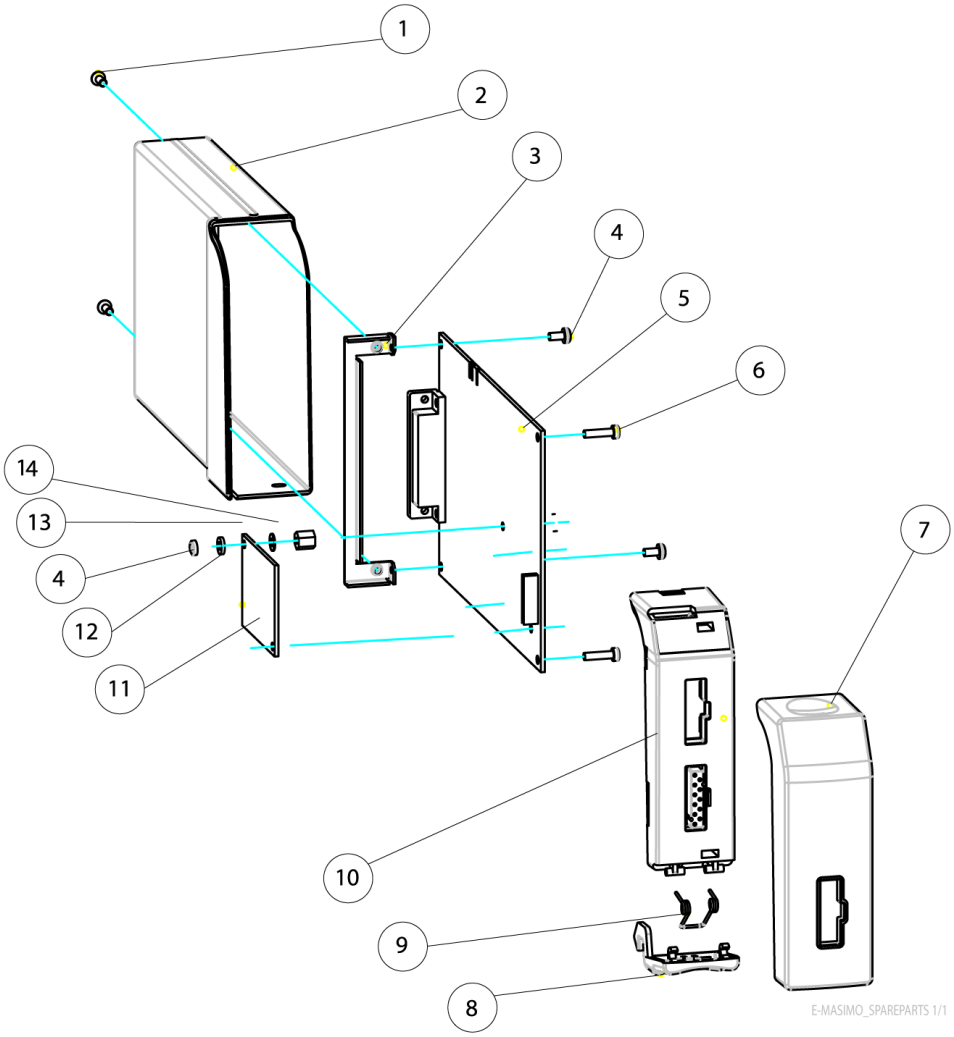
7

Service parts

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.

Exploded view of Masimo compatible Saturation Module, E-MASIMO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E-MASIMO_SPAREPARTS 1/1

List of FRUs for E-MASIMO

Part number	Description
2099530-001	FRU, Interface Board, E-Masimo • Masimo interface board (#5) • 4 mounting screws for metal frame & Masimo OEM board (#4) • Metal frame (#3) • 3 circuit board spacers, nylon (not shown on picture) • 1 spacer (#14) • 2 screws for Masimo SpO2 board (#4) • 2 washers (#12) • 1 washer (#13)
2081823-001	FRU, Masimo SpO2 Board (MS-2011SB), E-Masimo • OEM-ITEM, MS-2011 SB SPO2 BOARD (#11) • 3 circuit board spacers, nylon (not shown on picture) • 1 spacer (#14) • 2 screws for Masimo SpO2 board (#4) • 2 washers (#12) • 1 washer (#13)
M1121205	Front Cover, E-MASIMO (#7)
2081821-001	FRU, Front Chassis Unit, E-Masimo • Front chassis unit (#10), including also the connector, ferrite and cable. • Latch (#8) • Torsion spring (#9)
M1206392	FRU, E-Modules Hardware kit • 2 mounting screws for metal frame (#4) • 2 mounting screws for front chassis unit (#6) • 2 mounting screws for module casing (#1) • Latch (#8) • Torsion spring (#9) • Membrane keypad (not used in this module)

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