Entropy module, E-ENTROPY
Service Manual
Host software version 3
Module hardware version 01

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.

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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.
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

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

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Third party trademarks

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

Entropy module introduction

This document provides information for the maintenance and service of the Entropy module, E-Entropy-01.

The Entropy module uses an electroencephalography (EEG) signal, together with spontaneous facial muscular activity with a frontal electromyography (FEMG) signal to measure:

- Response Entropy (RE)
- State Entropy (SE)
- Burst Suppression Ratio (BSR)

The Entropy module provides EEG and FEMG signal acquisition, amplification, filtering and digitization, and electrode impedance measurement. All the calculated parameters can be selected on the display and trended.

Module compatibility

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

Entropy equipment to patient connection
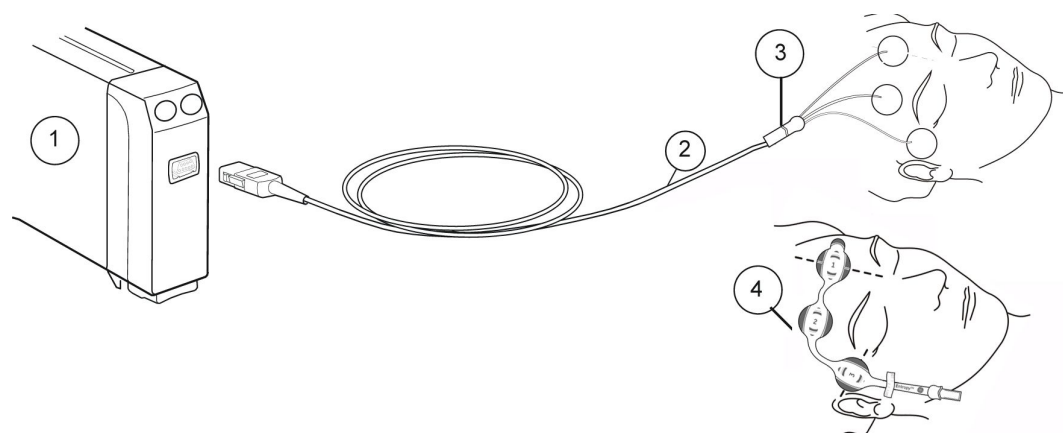
1. Module with Entropy measurement capability
2. GE Entropy cable
3. GE Entropy sensor

4.   Entropy EasyFit sensor

Controls and connectors

Front panel of Entropy Module, E-ENTROPY, and the back of the module:
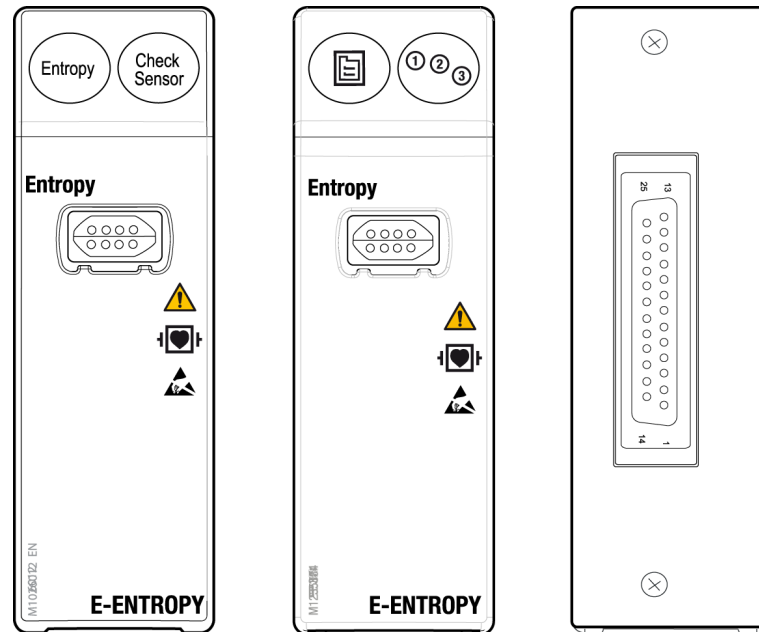
Connector	Description
Entropy	Entropy connector
D25 connector	Module bus connector

Entropy module keys

There are two keys on the module. Depending on the module version either the text only or symbol only appear on the keys, and the table below covers both versions.

or **Entropy**	Opens or closes the Entropy menu on the screen.
or **Check Sensor**	Starts the manual sensor check.

Measurement principle

Entropy is a measure of irregularity in any signal. During general anesthesia, EEG changes from irregular to more regular patterns when anesthesia deepens. Similarly, FEMG quiets down as the deeper parts of the brain are increasingly saturated with anesthetics. The Entropy Module measures these changes by quantifying the irregularity of EEG and FEMG signals.

Entropy parameters and BSR are calculated from EEG and FEMG signals acquired with a sensor which is attached to the patient's forehead. The sensor consists of three electrodes. This referential measurement yields one channel of raw EntrEEG.

The following is a general view of the cable connections:

EntrEEG measurement principle

EEG is a differential voltage signal measured from electrodes attached to the patient's skin. EEG measures the spontaneous electrical activity of the brain. This electrical activity reflects the state of the brain. In referential measurement, the referential electrode delivers its potential to every channel's minus-input. The signal is the potential difference between this 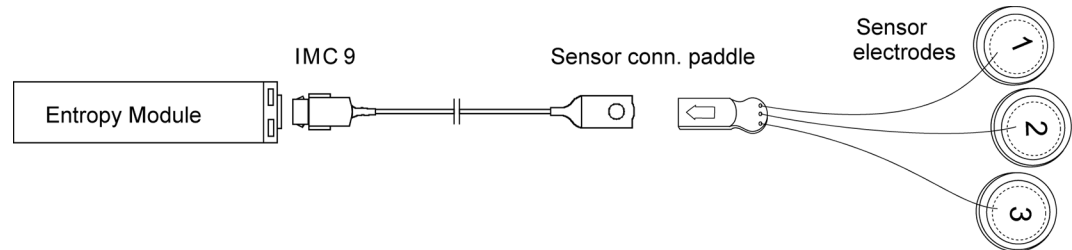common reference electrode (electrode #3) and the electrode connected to the plus input (electrode #1). The purpose of the ground electrode (electrode #2) is to reduce common mode noise.

The EntrEEG signal is amplified, antialias filtered, digitized, and software filtered. After that, the EntrEEG signal is shown on the screen and the RE, SE, and BSR characteristics are calculated from it.

FEMG measurement principle

FEMG is an electrical signal originating from facial muscles. The FEMG signal has much broader spectrum than EEG and it overlaps with EEG at low frequencies. The FEMG signal gives its contribution to the RE values. Mains power frequency and its harmonics are digitally filtered away to reject interference noise from power lines.

RE and SE measurement principle

Entropy numbers range from 100 to zero (RE 0 to 100, SE 0 to 91), correlating to the patient's anesthetic state. High values of Entropy indicate high irregularity of the signal, signifying that the patient is awake. There are two Entropy parameters: the fast-reacting Response Entropy and the more steady and robust State Entropy. State Entropy consists of the entropy of EEG signal calculated up to 32 Hz. Response Entropy includes additional high frequencies up to 47 Hz and, consequently, the fast frontalis EMG (FEMG) signals enable a fast response time.

Frequency ranges for Entropy calculation:

Response Entropy, RE	$0 < f < 47$ Hz
State Entropy, SE	$0 < f < 32$ Hz

Burst suppression ratio (BSR)

BSR is defined as the percentage of time of suppressed (isoelectric, flatline) EEG periods during the last minute of observation. Emergence of burst suppression pattern may indicate very deep anesthesia, hypothermia or ischemia.

Typically, during general anesthesia, in the absence of requirements for profound levels of anesthesia, BSR is 0%. Higher levels of burst suppression indicate very deep hypnosis/unconsciousness level. Burst suppression generally emerges with Entropy values below 40, but may not appear even with very low Entropy values.

Impedance measurement

The impedance measurement is performed for all leads at the same time and the EntrEEG is stopped for no longer than 5 seconds during the impedance measurement.

Differences in the electrode impedance of the electrodes cause common mode noise coupling to the measured signal. To minimize this, the electrode impedance is measured and a warning of an unsatisfactory impedance level is generated when necessary. The impedance of an electrode is measured by applying a known current through the electrode and measuring the voltage drop over the electrode. This way the impedance of a single electrode can be resolved.

Main components

Entropy board

The Entropy board consists of the following functional sections:

- Microprocessor for measurement control, and for processing the measurement signal

- Digital I/O circuit for smart chip communication (the chip is located in the entropy sensor)

- Serial communication driver for module bus communication

The serial bus speed to the monitor is 500 kbps and the bus itself is half duplex, i.e. data can be transferred to both directions but only one way at a time.

The following illustrates the Entropy measurement system block diagram:
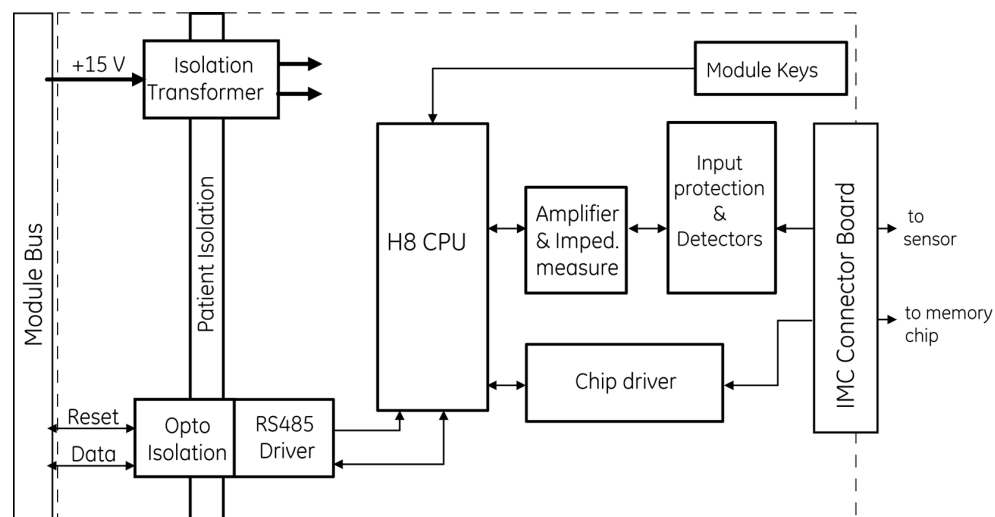
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Planned and corrective maintenance

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.

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 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 Entropy module functional check

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

*   Entropy simulator, P/N: N-ES

*   Entropy sensor cable

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.

Configuring monitor for Entropy module functional check

1. Configure Entropy waveform to the screen with adequate priority.

2. Press the *Entropy* module key to open the *Entropy setup* menu and select:

   - *Scale μV*: 250.
   - *Display format*: RE+SE
   - *Automatic sensor check*: ON

   CAUTION   Automatic sensor check may need to be disabled if the 70 Hz impedance check signal interferes with other equipment, such as EEG module with evoked potentials measurement.

Testing entropy measurement *

1. To check the module and sensor recognition:

   a. Connect the entropy sensor cable to the module.

   b. Check that the Entropy EEG waveform field and related information appears on the screen.

   c. Check that *No sensor* message appears in the Entropy parameter window.

2. To check the sensor:

   a. Connect the Entropy simulator to the Entropy sensor cable.

   b. Check that *Checking sensor* message appears in the Entropy parameter window after a while.

   c. Wait until all 3 electrodes are checked.

   d. Check that all 3 sensors pass the check successfully: there is a green circle with a check mark for each tested electrode.

   NOTE   The monitor may show *No Entropy sensor* and *Demo data* messages when using Entropy simulator.

3. To check the measurement:

   a. Wait about 30 seconds after the sensor check is completed and check that the EntrEEG waveform and RE & SE values appear on the screen.

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.

Planned and corrective maintenance

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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.

Entropy module, E-ENTROPY

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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.

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.

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 manual.

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

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

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

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

5. 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.

6. Press one of the module keys.

7. Check that the correct menu opens or the activity starts. If nothing happens, check if there is a loose keypad cable or other problem in the module.

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 Entropy 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 explanations	Suggested actions
• *Artifacts*	• param.	Signals contain noise or artifact. Patient movements, eye blinks, shivering, deep breathing, arrhythmia, or irregular beats may cause the measurement to fail.	• Wait for good data. • See the monitor user manual.
• *Automatic check off*	• param.	Automatic sensor check has been turned off.	• If required, activate the automatic check from the Entropy menu.
• *Cable off*	• param.	The Entropy sensor cable is not connected to the Entropy module.	• Connect the Entropy cable to the Entropy module.
• *Checking sensor*	• param., wavef.	Sensor check is in progress. This can be either the initial sensor check, manual check, or periodic check.	• Wait until the check is over. Check results are displayed.
• *Confirm electrode 1* • *Confirm electrode 2* • *Confirm electrode 3*	• param.	One of the sensor electrodes has poor contact. Automatic impedance check gets too high impedance values for one electrode only.	• Confirm proper sensor electrode 1, 2 or 3 contact as indicated in the message. • Ensure that the sensor has good skin contact, is positioned correctly, and is not dry. • Press the **Check sensor** key on the module to verify good contact.
• *Confirm electrodes*	• param.	More than one of the sensor electrodes have poor contact. Automatic impedance check gets too high impedance values.	• Reattach the sensor electrode to the patient according to the sensor instructions to ensure proper contact. • Ensure that the sensor has good skin contact, is positioned correctly, and is not dry. • Press the **Check sensor** key on the module to verify good contact.
• *Demo data*	• param., wavef.	Entropy simulator is connected instead of the Entropy sensor.	• Disconnect the Entropy simulator.
• *Entropy Cable off*	• al. area	The Entropy sensor cable is not connected to the Entropy module.	• Connect the Entropy cable to the Entropy module.
• *Entropy measurement removed*	• al. area	Entropy module has been disconnected from the module slot.	• Reconnect the module.

Message	Location	Possible explanations	Suggested actions
• *Entropy sensor check failed*	• al. area	The sensor has not passed the impedance check. One or more of the electrode impedances exceed the impedance threshold.	• Reattach the sensor to the patient according to the sensor instructions. • Ensure that the sensor has good skin contact, is positioned correctly, and is not dry. • Replace the sensor.
• *Entropy sensor off* • *Sensor off*	• al. area • param.	The sensor is connected to the sensor cable but not attached to the patient.	• Attach the sensor to the patient according to the sensor instructions.
• *Identical Entropy modules*	• al. area	There are two or more Entropy modules in the system.	• Remove all but one Entropy module.
• *Isoelectric EEG*	• param., wavef.	Isoelectric (flatline) EEG detected in Entropy measurement.	• See the monitor user manual.
• *Low signal*	• param.	The EEG amplitude is too low for reliable Entropy measurement.	• See the monitor user manual.
• *No Entropy sensor* • *No sensor*	• al. area • param.	The Entropy sensor is not connected to the Entropy sensor cable.	• Connect the Entropy sensor to the Entropy sensor cable.
• *Noise*	• wavef.	Unreliable Entropy calculation or distorted EEG waveform may appear during electrosurgery or other high frequency noise.	• See the monitor user manual.
• *Sensor check failed*	• param.	The sensor has not passed the impedance check. One or more of the electrode impedances exceed the impedance threshold.	• Reattach the sensor to the patient according to the sensor instructions. • Ensure that the sensor has good skin contact, is positioned correctly, and is not dry. • Replace the sensor.
• *Starting up*	• param.	The sensor check has been passed and the Entropy measurement is starting.	• Wait for about 30 seconds. Entropy values appear automatically.

Troubleshooting Entropy measurement

Problem	Possible causes	Suggested actions
No EntEEG waveform or Entropy parameter window on the screen.	Entropy module is not connected.	Connect the Entropy module to the monitor and the Entropy sensor cable to the module.
	EntEEG waveform or Entropy parameter window is not configured to the screen, or the parameter priority is set too low.	Configure EntEEG waveform or Entropy parameter to the screen, or increase the priority of the parameter information.

Problem	Possible causes	Suggested actions
	Entropy measurement is not supported by the active software package.	Entropy measurement is supported only by OR and PACU software packages.

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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

Disassemble the module in the order described in this section.

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 Entropy board or 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. Disconnect the front panel connector cable and the membrane keyboard cable from the Entropy board.

5. Detach the Entropy board by removing the two screws located near the front chassis unit. Pull out the front chassis unit.

Reassembling the module

1. Reassemble in reverse order. Make sure that you:

   a. Tighten all the screws properly.

   b. Connect all the cables properly.

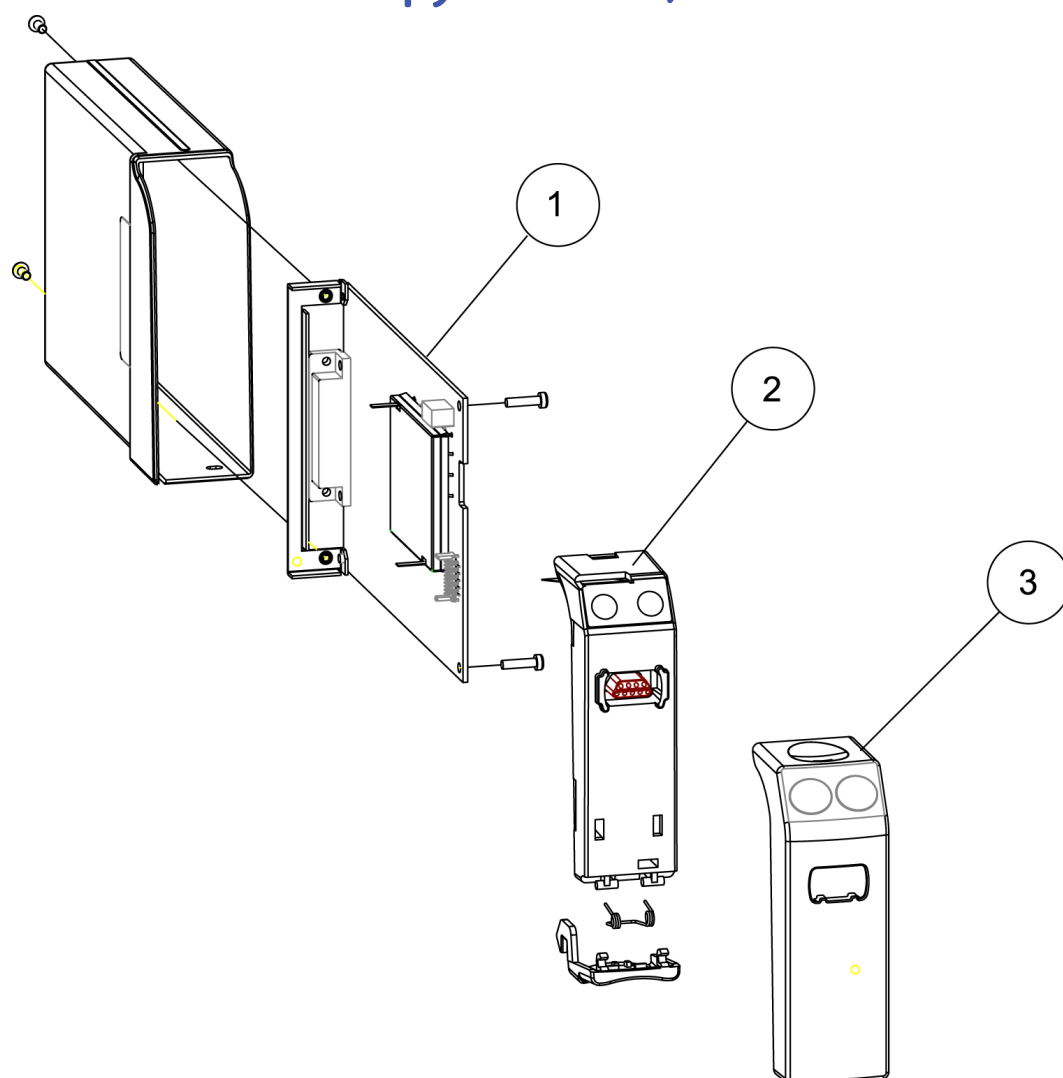   c. Check that there are no loose objects inside the module.

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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 Entropy Module, E-ENTROPY-01

List of FRUs for E-Entropy

Part number	Description
2099532-001	FRU, Entropy Board, E-ENTROPY-01 (#1) • Measurement board • Metal Frame • 2 mounting screws
M1235747	FRU, Front Chassis Kit, E-ENTROPY-01 (#2) • Front Chassis • Membrane keyboard • Connector unit • Latch • Torsion spring
M1236171	FRU, Front Cover, E-ENTROPY-01 (#3) • Front cover, English, US only
M1236170	FRU, Front Cover, E-ENTROPY-01 (#3) • Front cover, symbols
M1206392	FRU, E-Modules Hardware Kit • 2 mounting screws for Metal Frame • 2 mounting screws for Interface Board • 2 mounting screws for Module Casing • Latch • Torsion Spring • Membrane Keyboard
These parts are backwards compatible with E-ENTROPY-00.	

Entropy module, E-ENTROPY-01