BIS module, E-BIS

Service Manual

Host software version 3
Module hardware version 01

BIS module, E-BIS
English
2nd edition
2098086-010

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

Covidien, BISx, Bispectral Index, and BIS are trademarks of a Medtronic company.

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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

BIS module introduction

This document provides information for the maintenance and service of the BIS module, E-BIS-01 and E-BIS-01-JA. The BIS measurement is based on electroencephalography (EEG) signals, which are processed as the BIS index.

Calculated parameters are:

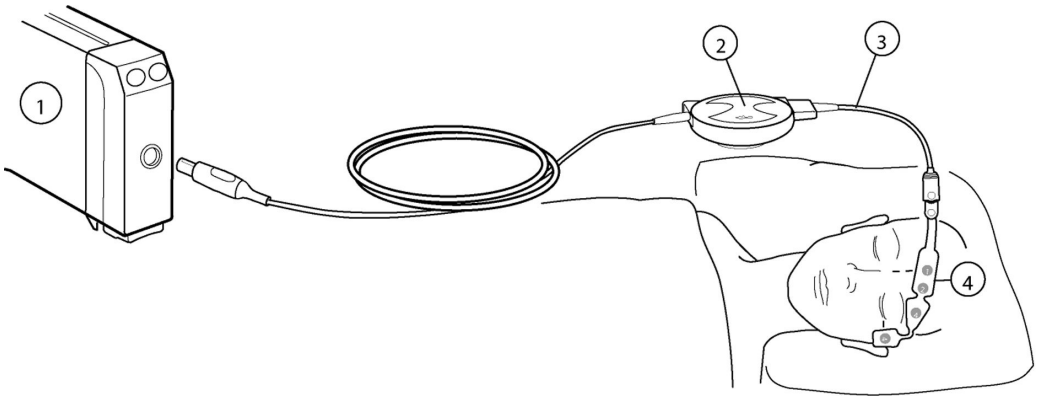
- Bispectral Index, BIS
- Suppression Ratio, SR
- Electromyograph EMG
- Signal Quality Index, SQI

The calculated parameters can be selected on the display, and trended (excluding SQI).

Module compatibility

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

BIS equipment to patient connection

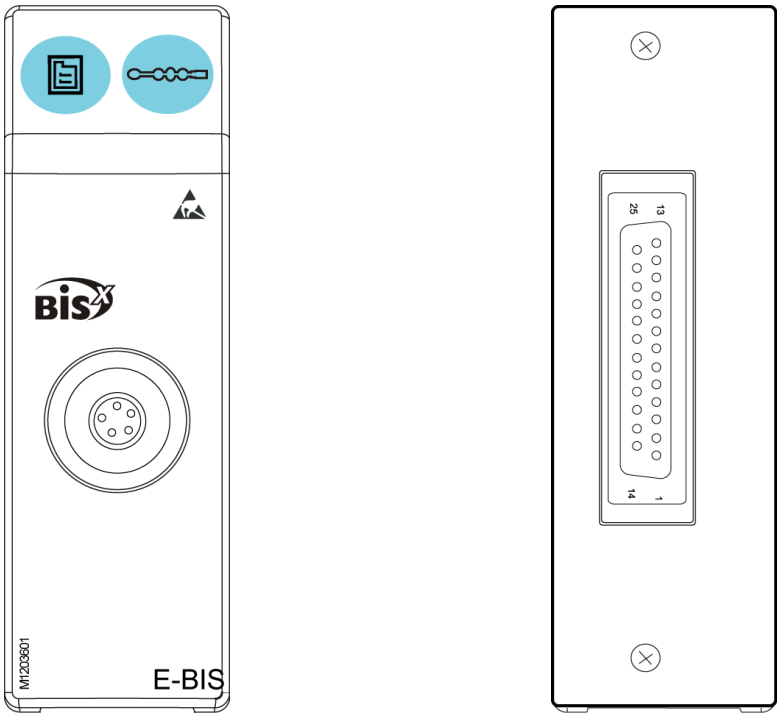


1. E-BIS module
2. BISx unit
3. Patient Interface Cable, PIC Plus
4. BIS sensor

NOTE BISx unit is also referred to as digital signal processing (DSC) unit in this document.

Controls and connectors

Front and back panels of BIS module:



There are two connectors on the module:

BIS	Connector for BISx unit
D25 connector	Module bus connector

BIS module keys

There are two keys on the module:

	Opens or closes the BIS menu on the screen.
	Starts the manual sensor check.

Measurement principle

The BIS measurement is based on EEG signals, these are processed as the BIS index. The BIS sensor is placed on the patient's forehead to acquire the high-resolution signals required. These EEG signals are transferred to the BISx unit that amplifies and digitizes the EEG signal. The BISx unit calculates the BIS index and sends the signal

and the index to the module. Then the module sends both the signal and the index to the monitor via module bus.

BIS measurement on the monitor screen

The waveform field shows the BIS EEG waveform. The following BIS related data appears in the parameter window and in graphical trends (except SQI):

BIS number indicates the patient's level of hypnosis, ranging from 100 for wide awake to 0 in the absence of brain activity.

Signal Quality Index (SQI) bar graph indicates the quality of the EEG signal in the range of 0 to 100.

Electromyograph (EMG) bar graph represents the absolute power in the 70 to 110 Hz frequency band and it ranges from 30 to 55 dB. This frequency band contains power from muscle activity (electromyograph). High frequency artifacts may contribute to the measured signal.

Suppression ratio (SR) number indicates the percentage of suppressed (flat line) EEG detected over the last 63 seconds. It ranges from 0 to 100%.

BIS sensor check

BIS sensor check is performed automatically at the beginning of each case when the sensor is attached to the patient interface cable. An initial ***Checking sensor*** message is shown in the parameter window with a picture of the sensor electrodes. The information on the passed or failed sensor check is shown in the parameter window for each electrode. The BIS measurement cannot continue if the first sensor check fails. In such a case the message ***Sensor check failed*** is shown in the parameter window and waveform field.

Continuous checking of the reference and signal electrodes and periodic checking of the ground electrode are performed by default. The automatic check can be switched off by selecting OFF in the BIS Setup menu, and the message ***Automatic check off*** appears on the screen. Sensor check can be started manually by pushing a module key or selecting the appropriate command from the menu. Manual sensor check can be useful e.g. when AEP's are being monitored at the same time, as continuous sensor check might disturb the AEP measurement.

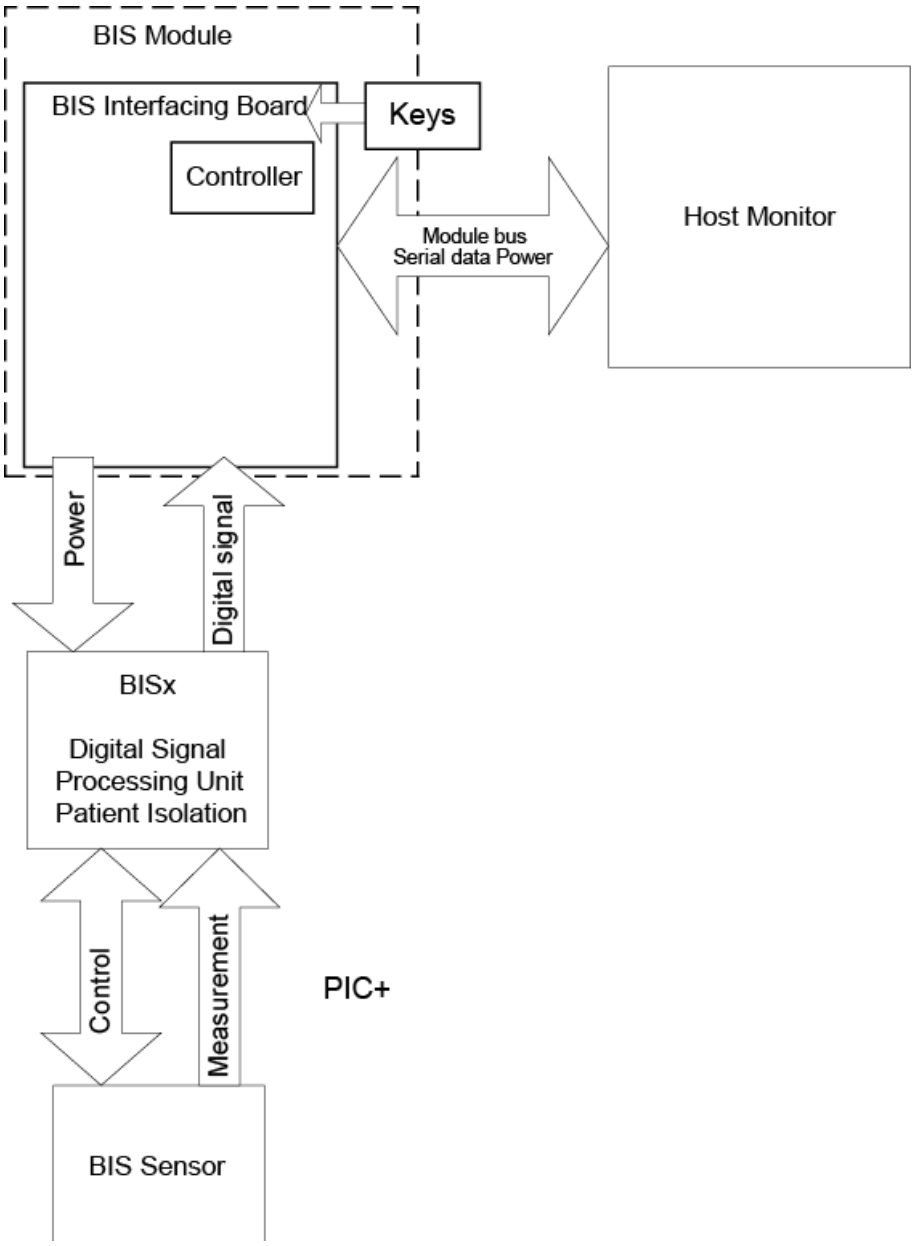
During a periodic ground electrode check, the signal disappears momentarily and the message ***Checking sensor*** is displayed in the parameter and waveform windows. The BIS calculation stops during this check, and no measurement values are shown.

CAUTION ERRONEOUS READINGS. Automatic sensor check may need to be disabled if the 1 nA 128 Hz impedance check signal interferes with other equipment, such as EEG module with evoked potentials measurement.

Main components

BIS measurement system block diagram

The BIS measurement chain is composed of a BIS sensor, BISx unit, BIS module containing an interfacing board, and a host monitor. A block diagram of the system is shown below.



BISx unit

BISx unit receives, amplifies and digitizes patient EEG signals. Then it processes the digitized EEG signals and communicates calculated BIS index and other supported parameters through an asynchronous serial connection to the BIS module.

The BISx unit is placed close to the patient's head where the EEG signal is less subject to interference from other medical equipment. The BISx unit is connected to the module with a 2.7 m long shielded cable and to the BIS sensor with a 1.2 m long patient interface cable.

For information about the BIS sensor, refer to the instructions for use in the accessory package.

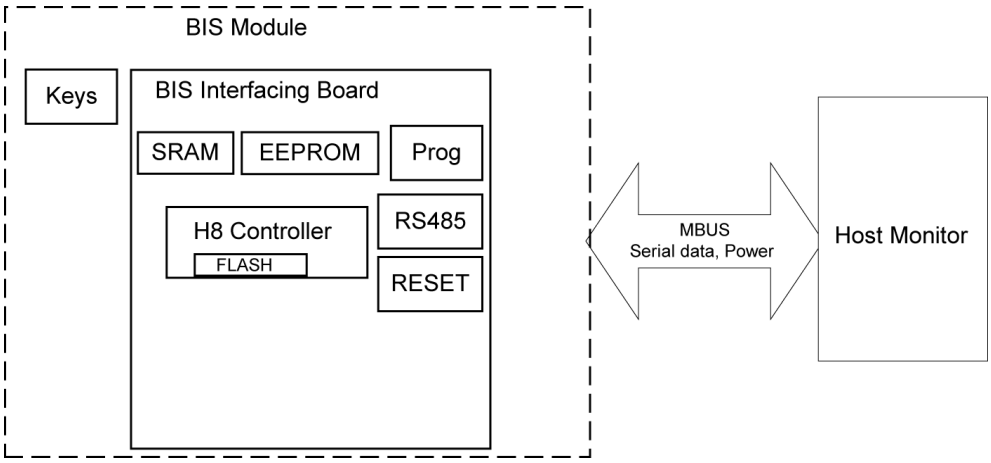
CAUTION ERRONEOUS READINGS. The BIS measurement based on measuring the EEG signal is inherently very sensitive. Radiated electromagnetic fields may cause erroneous measurements at various frequencies. Do not use electrical radiating equipment close to the BISx or DSC. Details regarding radiated field strengths are given in the technical specifications.

BIS interfacing board

The BIS interfacing board supplies data from the BISx unit to the monitor via a module bus. In addition, the module accepts commands from the monitor via the module bus. The module also provides supply voltages and all the required control signals to the BISx unit.

The controller has an on-chip RAM and FLASH ROM, external SRAM and EEPROM.

The following illustrates the setup block diagram:



3 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.
2. Check the BISx unit to ensure that:
   a. The cover and the panel stickers are intact.
   b. Cables and their connections are intact.
   c. The module and the applied parts are clean.

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 BIS module functional check

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

- BIS sensor simulator, P/N: 900508

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.

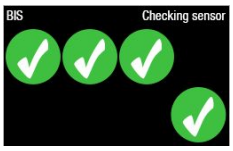
Configuring monitor for BIS module functional check

1. Configure the ***BIS EEG*** waveform to the screen with adequate priority.

Testing BIS measurement *

1. Check the module and BISx unit identification:
   a. Connect the BISx unit with the patient interface cable to the BIS module.
   b. Check that the BIS waveform field and the related information appear to the screen and a ***No sensor*** message is shown.
2. Check the BISx unit functionality:
   a. Connect the BIS sensor simulator to the PIC Plus cable
   b. Check that the ***Checking sensor*** message appears in the BIS parameter window and wait for a while until all electrodes are checked.

      The sensor check is passed if a green circle with a check mark appears on the screen for each tested electrode.

   c. Select ***BIS Setup*** > ***Test DSC*** to activate the BISx unit test.
   d. Wait for a while and check that the test result is ***PASS***.

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 and for the BISx unit.

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. Check the BISx unit to ensure that:
   a. The cover and the panel stickers are intact.
   b. The cables and their connections are intact.

3. 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 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. Select ***BIS Setup*** > ***Test DSC*** to activate the BISx unit test and wait until the test is completed.
   - If the test result is ***FAIL***, the BISx unit is defective.

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.

7. Press one of the module keys.

8. 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 BIS 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
• ***Apply sensor***	• param.	The sensor connection to the patient may be loose.	• Press the BIS sensor electrodes to improve connection.
• ***Artifact***	• param., wavef.	Signals contain noise or artifact. Non-EEG data, such as EMG, eye blinks, or shivering is present.	• Wait for good data.
• ***Automatic check off***	• param.	Automatic sensor check has been turned off.	• If required, activate the automatic check.
• ***BIS cable off*** Only with host software version 3.1 or earlier.	• al. area	Cable is disconnected from the module.	Connect the cable.
• ***BIS DSC error***	• al. area	The BISx is not communicating or operating properly. This may occur during the use of an electrocautery device.	• Replace the BISx unit.
• ***BIS measurement removed***	• al. area	The BIS module is disconnected from the module slot.	• Reconnect the BIS module to the module slot.
• ***BIS module error***	• al. area	BISx unit failure.	• Replace the BISx unit.
• ***BIS sensor check failed***	• al. area	Sensor check failed. One or more of the electroder impedances exceeds the threshold.	• Reattach the sensor to the patient according to the sensor instructions. • Replace the sensor. • Check the PIC+ cable and then the BISx unit.
• ***BIS sensor expired***	• al. area	The sensor date has expired, the sensor has been used too many times, or the validity time for the sensor cannot be determined. The sensor has been used for more than 24 hours.	• Replace the sensor.
• ***Cable off*** Only with host software version 3.1 or earlier.	• param., wavef.	Cable is disconnected from the module.	• Connect the cable.

Message	Location	Possible explanations	Suggested actions
• ***Checking sensor***	• param., wavef.	Sensor check is in progress. It can be either the initial sensor check, the manual check, or the periodic check.	• Wait until the check is over. Check results are displayed. • If the check fails, check electrode connections.
• ***Demo data***	• param., wavef.	BIS simulator is connected.	• Disconnect the BIS simulator.
• ***DSC error***	• param.	The BISx is not communicating or operating properly. This may occur during the use of an electrocautery device.	• Replace the BISx unit.
• ***High BIS impedance***	• al. area	Electrode impedance is too high. Sensor is not properly connected to the patient.	• Check the cable connections. • Reattach the sensor to the patient according to the sensor instructions.
• ***Identical BIS modules***	• al. area	There are two or more BIS modules in the system.	• Remove all but one BIS module.
• ***Incompatible device: BIS module*** Not available with host software version 3.1 or earlier.	• al. area	The module is not compatible.	• Replace with a compatible BIS module. For a list of compatible devices, refer to the supplemental information provided.
• ***Incompatible DSC*** Only with host software version 3.1 or earlier.	• param.	The hardware/ software is not compatible with the BISx.	• Connect a correct type of the BISx unit.
• ***Incompatible sensor***	• param., wavef.	The sensor used is not a BIS sensor. Sensor is not recognized.	• Make sure that you are using a Covidien BIS sensor. • Make sure that the PIC connector is clean and dry.
• ***Module error***	• param., wavef.	BISx unit failure.	• Replace the BISx unit.
• ***No BIS sensor*** • ***No sensor***	• al. area • param., wavef.	The sensor is not connected to the PIC+ cable, or the PIC+ cable is not connected to the BISx unit.	• Connect the sensor to the PIC+ cable. • Connect the PIC+ cable to the BISx unit. • Replace the sensor and then the PIC+ cable.
• ***Poor signal***	• param., wavef.	Artifacts or the level of EMG activity prevent calculating BIS, data excluded. SQI < 50.	• Check the sensor, then the PIC cable. • Reattach the sensor to the patient according to the sensor instructions.

Message	Location	Possible explanations	Suggested actions
• ***Replace sensor***	• param.	The sensor date has expired, the sensor has been used too many times, or the validity time for the sensor cannot be determined. The sensor has been used for more than 24 hours.	• Replace the sensor.
• ***Sensor check failed***	• param., wavef.	Sensor check failed. One or more of the electroder impedances exceeds the threshold.	• Reattach the sensor to the patient according to the sensor instructions. • Replace the sensor. • Check the PIC+ cable and then the BISx unit.
• ***Testing DSC***	• param., wavef.	BISx unit test has been manually activated from the BIS menu.	• Wait until the check is completed. • If the test result is FAIL, repeat the test. • If the problem persists, replace the BISx.

Troubleshooting BIS measurement

Problem	Possible cause	Recommended action
Checking sensor message stays longer than 2 minutes.	Sensor check fails. The sensor is not attached to the patient while connected to the PIC+ cable.	Attach the sensor to the patient, and press ***Check Sensor*** button on the module.
No BIS waveform on the screen.	BIS waveform is not selected on the screen, or the priority is too low.	Select ***Monitor Setup*** > ***Main Setup*** > ***Screen Setup***, and select BIS waveform to the screen with adequate priority.
Sensor impedance check is not available on menus.	• Sensor is not connected to the BISx unit. • BISx unit is not connected to the module.	Connect the sensor and the BISx unit.
Sensor impedance check fails.	Sensor is poorly attached.	Attach the sensor by following the instructions delivered with the sensor.

6

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 BIS interface board or the front chassis

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 interface board by removing the two screws located near the front chassis unit.
5. Disconnect the keypad cable and 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.

Replacing BISx Host cable and BISx bulkhead connector

1. The replacement instructions of the GE BISx Host Cable and BISx bulkhead connector are included in the FRU kits.

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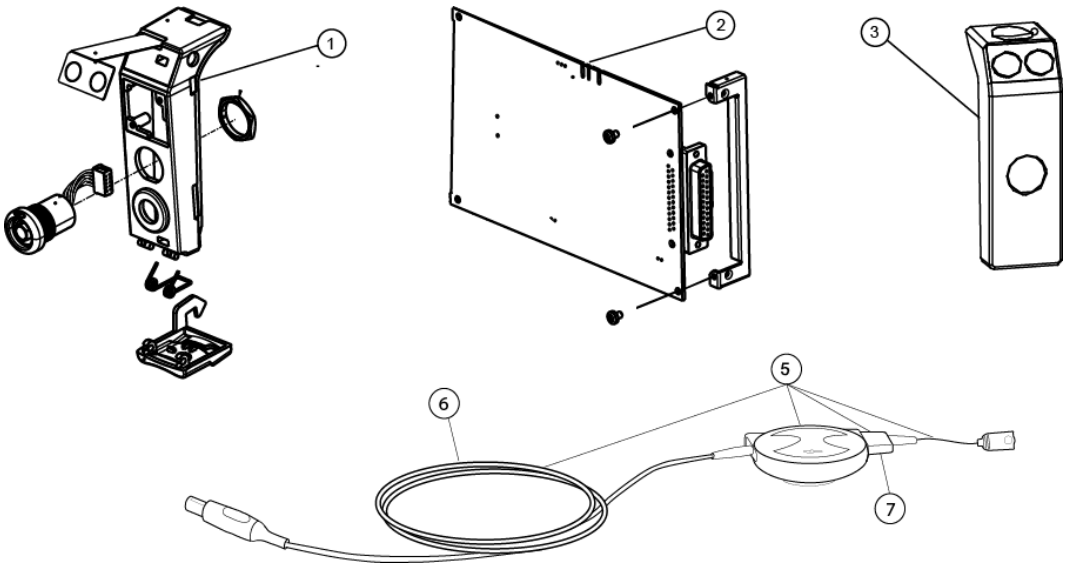
Service parts

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 BIS module



List of FRUs for E-BIS

Part number	Description
M1206390	FRU, Front Chassis Unit, E-BIS-01 (#1) • Front Chassis • Membrane Keyboard • Connector Unit • Latch • Torsion Spring
M1206391	FRU, Interface Board, E-BIS-01 (#2) • Interface Board

Part number	Description
	• Metal Frame • 2 mounting screws
M1233348	FRU, Interface Board, E-BIS-01-JA, (#2) • Interface Board (Japanese Version) • Metal Frame • 2 mounting screws
M1203601-S	FRU, Front Cover, E-BIS-01 (#3) • Front Cover
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 Keypad
M1206545	FRU, BISx unit (#5) • BISx unit • GE BISx Host Cable Kit • BISx Bulkhead Connector • Patient Interface Cable, PIC plus
2080644-001	FRU, GE BISx Host Cable Kit (#6)
2080645-001	FRU, BISx Bulkhead Connector (#7)

E-BIS module

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