BIS™ Advance Monitor

Operator's Manual

DRAFT

PN: PT00117631 Rev A

CE 0123

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1. Introduction

1.1. Introduction

Carefully read this operator's manual and the Directions for Use that accompany the BIS™ sensors in order to use the BIS™ Advance Monitor (henceforth referred to as the monitor) and the BIS™ BISx module or BIS™ BISx4 module (henceforth the term BISx will refer to both modules) correctly and safely. Use of the monitor requires full understanding and strict observance of these instructions, the precautionary information, and the specifications.

1.1.1. Safety Symbol Definitions

WARNING: A Warning is inserted to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal injury or death of the operator or patient.

Caution: A Caution is inserted to call attention to a procedure which, if not followed exactly, can lead to damage or destruction of the equipment.

Note: A Note is inserted to point out procedures or conditions which may otherwise be misinterpreted or overlooked and to clarify apparently contradictory or confusing situations.

1.2. Safety Information

1.2.1. General

WARNING: Fire hazard: do not use the BIS™ Advance monitor in a flammable environment or where concentrations of flammable anesthetics may occur.

WARNING: Be sure the monitor is mounted securely in place to avoid personal or patient injury.

WARNING: The BIS™ Advance monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration in which it will be used.

WARNING: To minimize the risk of patient strangulation, the patient interface cable (PIC) (which is an integral part of the BISx module) must be carefully placed and secured.

WARNING: Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Place contaminated materials in a container designated for regulated waste. The BISx module and the monitor should be cleaned using approved cleaning materials only.

WARNING: The monitor is not designed for use in MRI environment.

WARNING: The software shall reset all settings with defined default values to Institutional Defaults upon the end of each case, excluding Institutional Default Language settings. The software will also reset all settings (including language) to Institutional Defaults upon the restart of the monitor. However, if a sensor for which certain settings were set (as described in *3.15.3 Advanced User Settings* on page 131, and whether changes were performed by a user or administrator) is re-attached, the monitor will apply the settings that were in place when that sensor was used last time.

WARNING: When no longer in use, this electronic equipment must be recycled or disposed of properly. Follow local ordinances for the safe disposal of electronic equipment.

WARNING: No modification of this equipment or its accessories is allowed.

WARNING: BIS™ Advance monitoring technology is intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting BIS™ values in conjunction with other available clinical signs. Reliance on BIS™ values alone for intraoperative anesthetic management is not recommended. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS™ values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. BIS™ values should also be interpreted cautiously with certain anesthetic combinations, such as

those relying primarily on either ketamine or nitrous oxide/narcotics to produce unconsciousness. Due to limited clinical experience in the following applications, BIS™ values should be interpreted cautiously in patients with known neurological disorders and those taking other psychoactive medications.

Caution: Do not autoclave the BISx module or monitor. Autoclaving will seriously damage both components.

Caution: Avoid liquid ingress to the Patient Interface Cable (PIC), which is an integral part of the BISx module. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

1.2.2. Electrical Issues

WARNING: Use only the power cord and power supply supplied by the manufacturer. Never adapt the plug from the monitor to fit a non-standard outlet.

WARNING: U.S.A. requirement: For proper grounding, the power receptacle must be a three-wire grounded outlet. A hospital grade outlet is required. Never adapt the three-prong plug from the monitor to fit a two-slot outlet. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.

WARNING: To avoid the risk of electric shock, the BIS™ Advance monitor must only be connected to an AC power source with protective ground/earth.

WARNING: If the integrity of the AC power source with protective ground/earth is in doubt, the BIS™ Advance monitor shall be operated from its internal battery power source only.

WARNING: Electric Shock Hazard: Do not attempt to disconnect the power cord with wet hands. Make certain that your hands are clean and dry before touching the power cord.

WARNING: Electrical Shock Hazard: Do not remove battery compartment cover during operation or while power is connected to monitor.

WARNING: Electrical Shock Hazard: The manufacturer's inspection of this apparatus verified that the ground leakage current and the patient safety current were less than the specified limits established by the applicable safety standards. As a matter of safe practice, the institution should conduct periodic tests to verify these currents.

WARNING: Whenever an event such as spillage of blood or solutions occurs, re-test ground leakage current before further use.

WARNING: Power supply is internally fused. Replace power supply only with the power supply designated for this monitor, Medtronic PN PMB4000PWS.

WARNING: When connecting external equipment (e.g., data capture computer), the system leakage current must be checked and must be less than the IEC 60601-1-1 limit. Only approved medical devices which comply to 60601-1 (or USB flash drives) shall be connected to the monitor or docking station.

WARNING: Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS™ Advance monitor.

WARNING: 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:

oUse 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 60601-1-1 harmonized national standard.

Caution: Keep power cord, plug and socket clear in case an urgent power supply disconnection is required.

Caution: When connecting or disconnecting the BISx module, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

1.2.3. Battery Cautions

WARNING: Charge the monitor fully before your first use of the monitor, by attaching the monitor to AC power with the battery installed. See *3.3 Battery Operation* on page 60.

WARNING: The monitor should always be operated with the battery installed in order to provide back-up power in the event of a momentary or temporary power outage.

WARNING: Improper operation may cause damage to the battery or endanger the user.

WARNING: Do not place the battery near any heat source.

WARNING: Do not try to disassemble or short circuit the battery.

WARNING: Only the battery pack provided with this monitor should be used for the monitor. Use of another battery or a refurbished battery may cause damage to the monitor or endanger the user. Reference *Table 34. BIS™ Advance Accessories* on page 252 regarding the battery pack.

WARNING: The BIS™ Advance monitor contains an internal lithium ion battery. The battery must be disposed of or recycled based on national and local waste disposal legislation and requirements. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com**.**

WARNING: Never soak the battery in liquid such as water, drink, or oil.

WARNING: Use, store, and transport the battery only under the designated temperature conditions. Reference *7.6.4 Battery Specifications* on page 231.

WARNING: If the monitor is to be stored for three months or more, store the battery outside the monitor.

WARNING: If the battery has not been in use for an extended period, charge the battery before use to a level of at least 80% charge. Battery capacity indicators are described in *3.3.3 Battery and Power Usage* on page 63.

Caution: There should always be a battery installed in the device. If the battery is not installed, the monitor will operate properly on AC power, but if AC power is lost for any reason, the monitor will cease to function.

Caution: Replace the removable battery if an on-screen message informs you that this is required, or if more than seven years have passed since the production date marked on the battery, whichever comes first. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com**.**

Caution: Check the battery annually by operating a BIS™ Advance monitor that has been disconnected from the wall socket and that has been charged for 4 hours when the monitor is powered off or 8 hours when the monitor is functioning. The monitor should function for at least one hour on battery power only.

1.2.4. Burn Hazards

WARNING: Due to elevated surface temperature, do not place the BISx module in prolonged direct contact with patient's skin, as it may cause discomfort.

WARNING: The conductive parts of electrodes or sensor and connectors should not contact other conductive parts, including earth.

WARNING: To reduce the hazard of burns during use of high-frequency surgical equipment (in the event of a defect in the neutral electrode connection of the high frequency surgical equipment), the sensor or electrodes should not be located between the surgical site and the electro-surgical unit return electrode.

WARNING: To reduce the hazard of burns during use of brain-stimulating devices (e.g., transcranial electrical motor evoked potential), place stimulating electrodes as far as possible from the BIS sensor and make certain that sensor is placed according to package instructions. The sensor must not be located between defibrillator pads when a defibrillator is used on a patient connected to the BIS™ Advance monitor.

1.2.5. EMC Issues

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the BIS™ Advance monitoring system, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

WARNING: The proximity of an AC/DC power supply can significantly reduce the performance of the BISx module. All power supplies, including the dedicated power supply provided with the BIS™ Advance monitor, must be placed at least 30 cm away from the BISx module, the cables connected to the BISx module, the BIS™ sensor, and the patient.

WARNING: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment, especially during use with a defibrillator, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

1.2.6. Alarms

WARNING: Check Target Range alarm limits to ensure they are appropriate for the patient being monitored with each use. Ensure Target Range alarm limits do not exceed the standard thresholds set by the institution.

WARNING: If you plan to monitor the patient using alarms, do not set the Target Range alarm limits to extreme values that render the monitoring system ineffective. Ensure Target Range alarm limits are appropriate for each patient.

WARNING: If you plan to monitor the patient using alarms, do not pause, disable or decrease the audible alarm volume until you verify that the patient is being monitored by other means, such as direct observation, as this could compromise patient safety.

WARNING: If you plan to monitor the patient using alarms, do not decrease the adjustable alarm volume below ambient sound levels. Decreasing the alarm volume below ambient levels might impede operator recognition of the audible alarm, which might lead to patient harm during an alarm situation.

WARNING: BIS™ monitoring is intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting BIS™ in conjunction with other available clinical signs. Reliance on BIS™ alone for intraoperative anesthetic management is not recommended.

1.2.7. Sensors

WARNING: Please note that the sensors are consumable products with a defined lifetime and expiry date. An expired sensor or a sensor that has been used beyond its defined lifetime may pass the sensor check (depending on various use parameters), but it is strongly recommended to avoid use of expired sensors and replace sensors after 24 hours. Use of expired or over-used sensors may cause degraded performance.

WARNING: Use of the BIS Advance system with sensor during external defibrillation may lead to shunting of defibrillator energy, causing defibrillation to be ineffective. In emergency use when defibrillation is required to save a patient's life, ineffective defibrillation may result in death.

WARNING: The sensor is not intended to collect EEG, ECG, or other electrophysiological signals for interpretation; the signals collected are intended for use solely for calculating the BIS™ parameter.

WARNING: Use of the host system with sensor during electroconvulsive therapy (ECT) may result in a corrupted EEG signal.

Caution: Dispose of the sensor in accordance with current medical standards and applicable national regulations for biologically hazardous waste.

1.2.8. Cautions

Caution: Do not block inlet holes on the monitor as this may prevent ventilation constriction or affect the audio output of the monitor.

Caution: Do not open the BISx unit for any reason. The seal to prevent liquids from entering the BISx unit may be damaged if it is opened.

Caution: Service or repairs must be performed only by qualified biomedical technicians.

Caution: Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

Caution: The USB port on the monitor and the USB port on the docking station are intended only for the connection of a USB flash drive; do not use these ports for any other use.

Caution: The BIS™ Advance monitor has been validated for use only with the BIS™ sensor. The sensor is a silver/silver chloride electrode array that utilizes Covidien's connector and Zipprep™ technology. Electrodes or sensors that are not validated for use with the monitor may not work properly and may not produce the expected results. Also, electrodes or sensors that are not validated for use with the monitor have not undergone a data integrity analysis and may potentially pose a data security risk. For a list of sensors, reference *Table 33. BIS™ Advance Monitor Components and Sensors* on page 252.

Caution: To completely remove power from the monitor: disconnect power cord from the power receptacle of the monitor, then remove the battery from the monitor.

Caution: Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Caution: Considerations when using Electro-Convulsive Therapy (ECT) equipment during BIS™ monitoring: Place ECT electrodes as far as possible from the BIS™ sensor to minimize the effect of interference. Certain ECT

equipment may interfere with the proper function of the BIS™ Advance monitor. Check for compatibility of equipment during patient setup.

Caution: The BIS™ Advance monitor complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:
• Increase separation between devices.
• Re-orient device cabling.
• Plug devices into separate outlet circuit branches.
• Reference *7.7 Electromagnetic Compatibility Specifications* on page 237.

Caution: When connecting or disconnecting the BISx module, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

1.2.9. Notes

Note: Important: The BIS™ Advance monitor complies with the MDR- EU Medical Device Regulation 2017/745 and applicable regulatory requirements of the country distributed to and carry the CE Marking. Declarations of Conformity provided upon request where appropriate.

Note: Read this entire manual carefully before using the monitor in a clinical setting. The monitor shall be used only according to the instructions that appear in this manual.

Note: Use of the host system with sensor along with a neurostimulator may cause neurostimulator malfunction or diminished neurostimulator effectiveness.

Note: The system provides protection against defibrillation, without loss of any operator settings or stored data, and shall continue to perform its intended functions within 30 seconds after exposure to defibrillation voltage, as specified in IEC 80601-2-26 and IEC 60601-2-26.

Note: The battery pack supplied with this monitor should not be used with other devices.

Note: Since the case storage capacity of the monitor is limited, it is recommended to download cases when the case ends, to avoid accidental erasure of case data.

Note: Please select the date and time format in common use in your locality to enhance clarity for users of the monitor.

Note: Medtronic recommends use of the 24-hour clock option in all clinical settings, to avoid situations in which the current time may be misunderstood by users.

Note: The screenshots seen in this manual do not represent actual patient data and are provided for illustrative purposes only.

Note: FEDERAL COMMUNICATIONS COMMISSION INTERFERENCE STATEMENT:

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
• Reorient or relocate the receiving antenna.
• Increase the separation between the equipment and receiver.
• Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
• Consult the dealer or an experienced radio/ TV technician for help.

Note: RF Exposure Information (SAR):
This device meets the government's requirements for exposure to radio waves. This device is designed and manufactured not to exceed the emission limits for exposure to radio frequency (RF) energy set by the Federal Communications Commission of the U.S. Government.
The exposure standard employs a unit of measurement known as the Specific Absorption Rate, or SAR. The SAR limit set by the FCC is 1.6 W/kg. Tests for SAR are conducted using standard operating positions accepted by the FCC with the EUT transmitting at the specified power level in different channels.

Note: Canada, Industry Canada (IC) Notices:
This device complies with Canada licence-exempt RSS standard(s).
Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Note: Canada, avis d'Industry Canada (IC)
Cet appareil est conforme avec Industrie Canada exemptes de licence RSS standard(s).
Son fonctionnement est soumis aux deux conditions suivantes : (1) cet appareil ne doit pas causer d'interférence et (2) cet appareil doit accepter toute interférence, notamment les interférences qui peuvent affecter son fonctionnement.

Note: Radio Frequency (RF) Exposure Information
The radiated output power of the Wireless Device is below the Industry Canada (IC) radio frequency exposure limits. The Wireless Device should be used in such a manner such that the potential for human contact during normal operation is minimized.
This device has been evaluated for and shown compliant with the IC Specific Absorption Rate (“SAR”) limits when operated in portable exposure conditions.

Note: Informations concernant l'exposition aux fréquences radio (RF):
La puissance de sortie émise par l’appareil de sans fil est inférieure à la limite d'exposition aux fréquences radio d'Industry Canada (IC). Utilisez l’appareil de sans fil de façon à minimiser les contacts humains lors du fonctionnement normal.
Ce dispositif a été évalué pour et démontré conforme à la Taux IC d'absorption spécifique ("SAR") des limites lorsqu'il est utilisé dans des conditions d'exposition portatifs.

Note: This device complies with part 15 of the FCC rules. Operation is subject to the following conditions:
• The device may not cause harmful interference, and
• This device must accept any interference received, including interference that may cause undesired operation.

Note: This Class B digital apparatus meets all requirement of the Canadian Interference-Causing Equipment Regulations. Cet appareil numérique de la classe B respecte toutes les exigences de Règlement sur le matériel brouilleur du Canada.

1.3. Device Description

The BIS™ Advance monitor is a user-configurable patient monitoring system designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The monitor processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS™ value, which correlates with the

patient's level of hypnosis. The device is for use by medical personnel only. The monitor and the BISx unit are designed for use for multiple patients, multiple uses.

The BIS™ Advance monitor display consists of:

- The current BIS™ number
- Raw EEG waveforms in real time
- Various signal quality indicators (EMG, SQI)
- Trend graphs of processed EEG variables
- Processed EEG variables, including suppression ratio (SR), suppression time (ST), and burst count (the latter available when a 4-channel BIS™ system and a BIS™ bilateral sensor or an Extended sensor are in use)
- Alarm Indicators and Messages

The system shall perform computations on the acquired EEG signals in order to produce the following processed variables in addition to the BIS™ number:

- Electromyography (EMG)
- Signal Quality Index (SQI)
- Suppression Ratio (SR)
- Burst Count - for Extend Sensor and four-channel monitoring only (BURST)
- Suppression Time (ST)
- Spectral Edge Frequency (SEF)
- Median Frequency (MF)
- EEG Power Asymmetry Index (ASYM) (for four-channel monitoring only)

The BIS™ Advance monitor can work with a BISx module, which records and displays two channels of patient EEG information, or with a BISx4 module, which records and displays four channels of EEG, two from each side of the brain. For more information about the four-channel system, listing the unique aspects of four-channel monitoring, reference *3.8 Four-Channel Monitoring* on page 92.

For both the 2-channel and the 4-channel systems, BIS™ monitoring is implemented as follows: A sensor placed on the patient's head transmits EEG signals to the BISx module. The BISx module filters the data, analyzes it for artifacts and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording. A list of the processed variables and a description of each is provided in *Table 1. The BIS™ Advance Monitor Parameters,* on page 31. This data is displayed on the screen according to the preferences set by the user in the menu system.

1.4. Intended Purpose

The ELECTROENCEPHALOGRAPHY INSTRUMENTS are intended to monitor the state of the brain and may be used to guide anesthetic administration.

1.4.1. BIS™ Monitor

The ELECTROENCEPHALOGRAPHY INSTRUMENTS are intended to monitor the state of the brain and may be used to guide anesthetic administration.

1.4.2. BISx and BISx4 Modules

The ELECTROENCEPHALOGRAPHY INSTRUMENTS – HARDWARE ACCESSORIES calculate parameters which are used to support monitor functions.

1.4.3. BIS™ Sensors

The ELECTROENCEPHALOGRAPHY INSTRUMENTS – CONSUMABLES collects electrical signals which are used to support monitor functions.

1.4.4. BIS™ Cables

The ELECTROENCEPHALOGRAPHY INSTRUMENTS – HARDWARE ACCESSORIES transmits electrical signals which are used to support monitor functions.

1.5. BIS™ Advance Monitor System Indications and Contraindications

The BIS™ Advance monitor system is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The system, and all its associated parameters, is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS™ index, one of the BIS™ Advance monitor system output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS™ index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation. No known contraindications are listed in either the BIS™ Advance monitor operator's manual or in the BIS™ Sensor IFUs.

1.6. Patient Target Groups

The BIS™ Extend and Bilateral Sensors are intended for adult patients, while the BIS Pediatric Sensor is intended for pediatric patients. These sensors are designed for application to the frontal/temporal area to enable recordings of electrophysiological signals, such as EEG. They are low impedance, single patient use, disposable electrode sensors, intended to be used in conjunction with the rest of the BIS™ Advance monitor system.

1.7. Intended Users

The BIS™ Advance monitor and BISx and BISx4 modules are intended to be used under the direct supervision of a licensed healthcare practitioner, or by personnel trained in their proper use. The system (and all of its associated parameters) is intended for use on pediatric and adult patients within a hospital or medical facility. It provides patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS™ education site, www.biseducation.com, offers relevant information and published articles on the clinical use of the BIS™ Advance system. In addition, there is a “Monitoring Consciousness Using the Bispectral Index during Anesthesia” Clinician’s Pocket Guide in English available on the website and through your local Medtronic representative.

For more information and technical support, contact BISTechnicalsupport@medtronic.com.

1.8. Essential Performance

The essential performance of the monitor is the display of the BIS™ index and EEG in order to monitor a patient's level of consciousness.

In addition, the monitor meets the essential performance requirements per IEC 80601-2-26:2019, as listed below.

Requirement	Subclause	Results
Accuracy of signal reproduction	201.12.1.102	2-channel max variation of the output signal is -13% of the input signal 4-channel max variation of the output signal is -6.5% of the input signal
Input dynamic range and differential offset voltage	201.12.1.103	2-channel max deviation of the output signal with applied +300V DC (DC offset voltage) is 1.6% compared to the output signal without applied DC offset voltage 2-channel max deviation of the output signal with applied -300V DC (DC offset voltage) is 3.4% compared to the output signal without applied DC offset voltage 4-channel max deviation of the output signal with applied +300V DC (DC offset voltage) is 1.2% compared to the output signal without applied DC offset voltage 4-channel max deviation of the output signal with applied -300V DC (DC offset voltage) is 0.4% compared to the output signal without applied DC offset voltage
Input noise	201.12.1.104	4-channel: The max measured signal noise is: 3.5µV (peak-to-valley) 2-channel: The max measured signal noise is: 1.3µV (peak-to-valley)

Frequency response	201.12.1.105	The output at 0.5 Hz and 50 Hz is within 71 % to 110 % of the output obtained with a 5 Hz sine wave input signal: 4-channel: 101.7% at 0.5 Hz; 95.8% at 50 Hz 2-channel: 104.8% at 0.5 Hz; 90.4% at 50 Hz
Common mode rejection	201.12.1.106	4-channel: max output signal is 39 µv p-v (peak to valley) 2-channel: max output signal is 47 µv p-v (peak to valley)

1.8.1. EEG Particular Standard (IEC 60601-2-26, 3rd Edition)

With regard to immunity to electromagnetic interference, the standard states the following:

- May show temporary degradation during discharges
- Shall resume normal operation after ESD within 30 seconds. Within this context, normal operation for the BIS™ monitoring system means the EEG wave shall appear on the BIS™ monitor within 30 seconds.
- Shall not lose operator settings or stored data
- Shall continue to perform its intended purpose

It is possible, and acceptable per the standard, for the BIS™ monitoring system to experience a temporary loss of function, or degradation of behavior, due to an EMC Immunity, that could require operator intervention, provided that the system resumes normal operation (i.e., displays the EEG analog signal) within 30 seconds.

Depending on the type of error the BIS™ system detects if exposed to significant electromagnetic interference, the following are examples of operator intervention:

- Pressing a button on the touch-screen

- Disconnecting the Monitor Interface Cable of the BISx module from the BIS™ Advance monitor and then immediately reconnecting back to the BIS™ Advance monitor

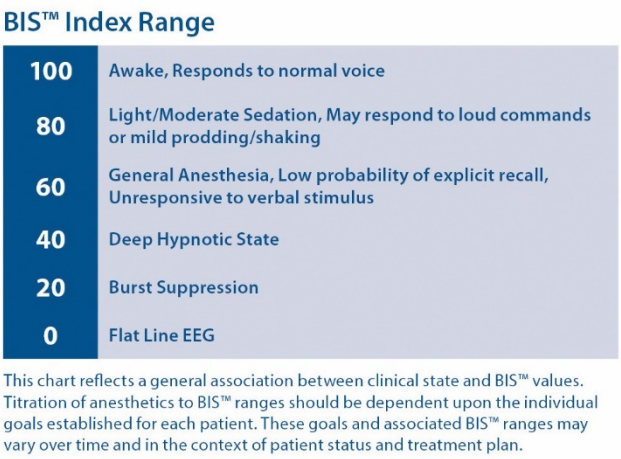
1.9. Adverse Events (Residual Risks)

Any serious incident that occurs in relation to the device or its accessories should be reported to Medtronic and to the national competent authority. Covidien is a Medtronic company.

1.10. The BIS™ Advance Parameters

The BIS™ value (Bispectral Index) is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100 = awake and 0 = flat line EEG. The BIS™ value was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain. The BIS™ value is displayed as a number in the upper left corner of the screen and is plotted over time on the BIS™ Trend Graph. When signal quality is too low to accurately calculate a BIS™ value, the BIS™ number is not displayed.

Figure 1. BIS Range Guidelines



This chart reflects a general association between clinical state and BIS™ values. Ranges are based on results from a multi-center study of the BIS™ monitor involving the administration of specific anesthetic agents. BIS™ values and ranges assume that the EEG is free of artifacts that can affect its performance. Titration of anesthetics to BIS™ range should be dependent upon the individual goals established for each patient. These goals and associated BIS™ ranges may vary over time and in the context of patient status and treatment plan.

For more detailed clinical information, reference the clinical quick guide cards supplied with your monitor. EEG data provides a real-time indication of brain status.

The EEG waveform data recorded by the system data is used to create the processed variables BIS, SQI, SR, ST, Burst Count, SEF, MF, DSA, and ASYM. In addition, the raw EEG data is provided as a trend waveform on the BIS™ Advance monitor home screen.

More details about the BIS™ Advance processed variables are listed in *Table 1. The BIS™ Advance Monitor Parameters,* below. For display of these variables, reference *3.9 Home Screen Trend Graphs* on page 96 and *3.10 Home Screen Numeric Section* on page 104.

Table 1. The BIS™ Advance Monitor Parameters

Processed Parameter	Description
Bispectral Index (BIS™ number)	The BIS™ number is a processed EEG value representing the depth of sedation. It is a continuously processed EEG parameter that correlates to the patient's level of hypnosis, where 100 = awake and 0 = flat line EEG. BIS™ was designed to correlate with "hypnotic" clinical endpoints and to track changes in the effects of anesthetics of the brain. This value is computed based on computations on the acquired 2 or 4 EEG channels. For the standard system with 2-channel sensors, the system shall produce one BIS™ value; for 4-channel sensors, the system shall produce 2 BIS™ values, one for each brain hemisphere. The EEG number of channels feature enables the user to view the primary measured electrodes of each brain hemisphere, only one brain hemisphere, or all of them. A BIS™ value above 90 typically represents an awake state. As the drugs cause deeper sedation, this value will decrease. You can set the BIS™ value limits to cause an alarm if the level of consciousness exceeds the desired limits. A BIS™ value below 60 indicates a high probability of drug-induced unconsciousness. A BIS™ value below 30 indicates an increasing level of EEG suppression. Both the BIS™ number and the BIS™ trend are displayed on the Home screen. For more details, reference *3.7 Home Screen* on page 88.
BIS™ Smoothing Rate	Smoothing rate is the time over which the BIS™ value is averaged. The smoothing rate can be adjusted by the user; for the Extend sensor it is automatically 30 seconds. A shorter smoothing rate provides increased responsiveness to state changes, such as induction or awakening. A longer

	smoothing rate provides a smoother trend with decreased variability and sensitivity to artifact.
EEG (Electroencephalogram)	A visual representation of the rhythmic fluctuations of electric potential between parts of the brain (brain waves).
EEG (Electroencephalogram) Amplitude	The maximum absolute voltage of the waveform. The EEG waveform amplitude is typically conveyed in microvolts (µV).
EMG (electromyogram)	A measurement technique indicating forehead muscle activity and other high-frequency artifacts. The EMG numeric indicates the absolute power in the 70-110 Hz range. This frequency range contains power from muscle activity as well as power from other high-frequency artifacts. It is conveyed in decibels (dB) relative to 0.0001µV2. Significant forehead muscle activity may cause the BIS™ value to increase, so when EMG is high, the BIS™ value should be interpreted with caution.
SQI (Signal Quality Indicator)	SQI measures the signal quality of the EEG. It represents the percentage of good epochs and suppressed epochs in the last 120 (61.5 seconds) that could be used in the BIS™ calculation. It is calculated based on impedance, artifact presence, and other variables. An icon with 5 green bars represents the optimal SQI.
Burst Count	The number of EEG bursts per minute, where a "burst" is defined as a short period of EEG activity preceded and followed by periods of inactivity (suppression). Burst count represents the number of bursts in the last minute. Burst count is displayed as a trend and as a numeric value. This type of electroencephalography (EEG) pattern, which is characterized by periods of high-voltage electrical activity alternating with periods of no activity in the brain, is a pattern found in patients with inactivated brain states, due to

	factors such as general anesthesia, coma, or hypothermia. Burst count is activated by connection of an Extend Sensor or Bilateral Sensor. Thus, the burst count parameter will appear on the screen only when an Extend and Bilateral sensor is used.
SR (Suppression Ratio)	The percentage of time during the last 63 seconds in a state of isoelectric EEG. For example, SR=10% represents 6.3 seconds of the last 63 seconds. When set, the SR limit appears as a purple dashed line on the SR trend.
ST (Suppression Time)	The accumulated time in this case that the patient was in a state of suppressed (isoelectric) EEG. It is provided in hours, minutes and seconds as HH:MM:SS.
DSA (Density Spectral Array)	A graphic display of the EEG power at each frequency over time. The amplitudes of the power spectrum are represented by varying colors. Red indicates high power, and blue indicates low power.
MF (Median Frequency)	The frequency below which 50% of the total EEG power lies. It is displayed as a purple line on the DSA graph. The MF Number shall be displayed on the main monitoring screen in 2-channel mode; for the 4-channel mode, the Left MF Number or Right MF Number shall be displayed, according to the user's selection of the brain hemisphere side.
SEF (Spectral Edge Frequency)	The frequency below which 95% of the total EEG power lies. It is displayed as a white line on the DSA graph.

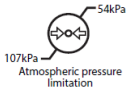
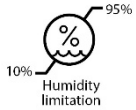
ASYM (Asymmetry)	The difference in EEG power between the left and right hemispheres of the brain over time. ASYM is displayed as a value between 20% and 100%. It represents the ratio of EEG power present in one hemisphere to the total EEG power (total power = left power + right power). ASYM is displayed only during four-channel monitoring.

1.11. Symbols

The following symbols appear on the body of the monitor and on its packaging (including labels).

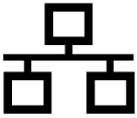
Table 2. Symbols that Appear on the Monitor and its Packaging

Symbol	Description	Location
	For prescription use only	Packaging
	Consult instructions for use	Packaging
	Consult instructions for use	Packaging
	Caution, consult accompanying documents for warnings and precautions	Packaging

	Caution, consult accompanying documents for warnings and precautions	Packaging
	Follow Instructions for Use (in blue on device)	Packaging
	MR Unsafe	Packaging
	Atmospheric pressure limit for storage and transport for monitor and docking station; values for BISx unit seen in *7.6.1 General Specifications* on page 227	Packaging
	Humidity limit for storage and transport, for monitor, docking station and BISx unit	Packaging
	Temperature limit for storage and transport, for monitor, docking station and BISx unit	Packaging
	This side up	Packaging
	Keep dry	Packaging

	Fragile	Packaging
	China ROHS CB symbol (for BISx unit only)	Packaging
	China RoHS symbol (indicating no hazardous substances above restriction limits)	Packaging
	China RoHS symbol (indicating Environment Friendly Use Period of 50 years)	Packaging
	Directive on waste from electrical and electronic equipment	Packaging
	UL recognized component certification symbol for Canada and the USA (on BISx unit and adapter cable)	Packaging
	Defibrillation-proof type BF applied part (on BISx unit)	Packaging
IPX2	IP (liquid ingress) level	Packaging
	Non-ionizing electromagnetic radiation on packaging; Wireless functionality on device	Packaging and device
	Direct current	Packaging

	Caution, hot surface (on BISx unit)	Packaging
	Latex free (on BISx unit only)	Packaging
	Medical Device	Packaging
	UL registration mark. Complies with 21CFR 1040.10 and 10410.11 except for deviation pursuant to Laser Notice No.50, dated June 24 2007. MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 6061-1 (2005) + AMD (2012) and CAN/CSA-C22.2 No.6060-1 (2014)	Packaging
	Federal Communications Commission certification mark. Contains: FCC ID: PX9-AC9260NGW Contains: IC: 9911A-AC9260NGW	Packaging
	Australia wireless symbol	Packaging

CE0123	CE mark	Packaging
EC REP	Authorized representative in the European Community	Packaging
REF	Catalog number	Packaging
	Manufacturer	Packaging
	Importer	Packaging
SN	Serial number	Packaging
	Date of manufacture	Packaging
	Battery charging icon	Device
	USB port indicator on docking station and monitor	Device
	Network port indicator on docking station	Device
	On/Off button and On/Off indicator	Device

	Battery compartment cover locked	Device
	Battery compartment cover unlocked	Device
	Home button	Device
Fn	Function button	Device
	Earphones/microphone port indicator on monitor	Device
R	Reset button on monitor (Not for user/operator use)	Device
HDMI	HDMI port indicator on monitor (Not for user/operator use)	Device
DCin	DC power port indicator on monitor	Device
RS-232	RS-232 port indicator on docking station	Device
VGA	VGA port indicator on docking station	Device

2. The BIS™ Advance Monitor — Equipment and Supplies

2.1. The BIS™ Advance System

All of the items listed below are required in order to operate the BIS™ system:

BIS™ monitor: The monitor processes collected data and provides an interface for the user, in which results are displayed, settings are inputted, and data is recorded for download. The monitor is supplied with a removable battery.

Docking station: The docking station provides power and communication for the monitor. It is required for mounting the monitor and thus is strongly recommended for all use cases of the monitor. The docking station is provided with the monitor and is also sold separately. It uses the power supply and power cord supplied with the monitor.

Adapter cable: Connects between the tablet and the BISx module integral cable (MIC). The adapter cable is sold separately, and should be connected to the monitor before use.

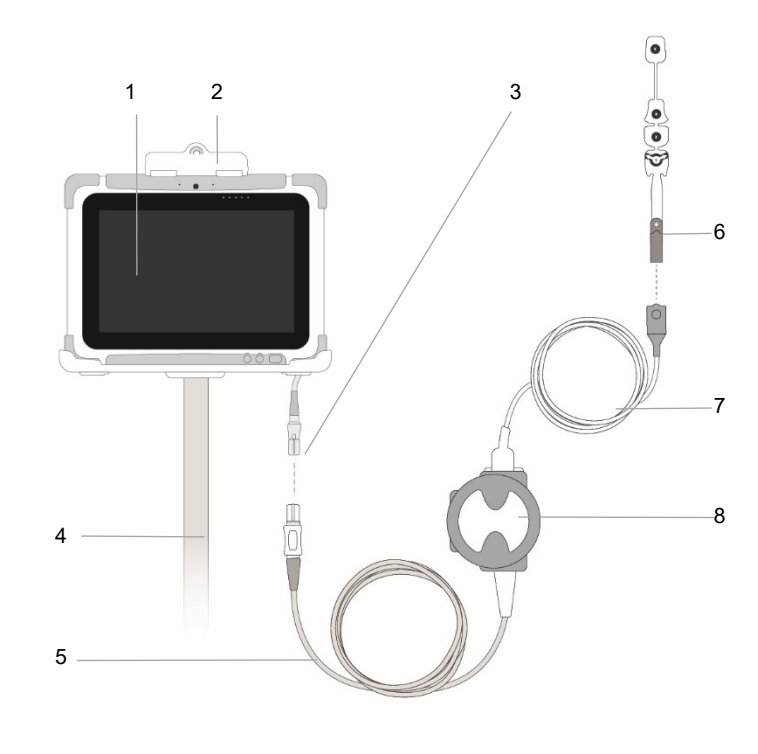
BISx or BISx4 module: The BISx module acquires and processes EEG signals and processes collected data. Monitoring with BIS™ system requires both the tablet and the BISx module. The BISx module includes an integral cable to connect to the adapter cable on one side (the MIC), and connects to the patient (via a cable – the PIC - and a sensor) on the other side. The BISx module is sold separately.

Monitor Interface Cable (MIC): Connects between the BISx module and the monitor. The monitor interface cable is an integral part of the BISx module.

Patient Interface Cable (PIC): Connects between the BISx module and the sensor. The patient interface cable is an integral part of the BISx module.

BIS™ sensor: The appropriate BIS™ sensor is used to connect the system to the patient and acquire patient data for analysis.

Figure 2. BIS™ Advance Monitor Components



Number	Component
1	Monitor
2	Docking station
3	Adapter cable
4	GCX mounting accessory (the selected accessory will depend on the use case)
5	MIC
6	Sensor
7	PIC
8	BISx module/BISx4 module

For a list of these parts and their part numbers, reference *Table 3. BIS™ Advance Monitor Components*, below.

A list of sensors for use with the BIS™ Advance monitor appears in *Table 34. BIS™ Advance Accessories* on page 252.

Table 3. BIS™ Advance Monitor Components

Product Name	Legacy Product Name	Description or Application	Part Number of BIS Advance Product
BIS™ Advance Monitor	BIS Vista Monitor or BIS Complete Monitor	BIS™ monitor that can be used with either a BISx or BISx4 module.	PMB4000 (in some cases, an additional suffix will denote region)
BIS™ Advance docking station	NA	Docking station to permit easy mounting of monitor	PMB4000DOC

Product Name	Legacy Product Name	Description or Application	Part Number of BIS Advance Product
BIS™ Advance Adaptor cable	NA	Adapter cable used to connect monitor to BISx module	PMB4000ACBL
BISx module	LoC 2 Channel	Processes 2 channels of EEG information (one brain hemisphere) to work with BIS™ Advance Monitor. The MIC (monitor interface cable) and PIC (patient interface cable) are integral to this module. The monitor can work with a BISx module or a BISx4 module.	186-1095-xxx
BISx4 module	LoC 4 Channel	Processes 4 channels of EEG information (both hemispheres of the brain) to work with BIS™ Advance Monitor. The MIC (monitor interface cable) and PIC (patient interface cable) are integral to this module.	186-0224-xxx

2.2. Parts of the System

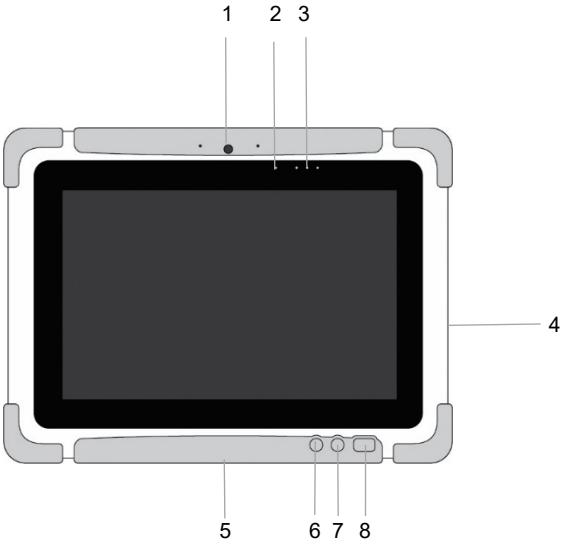
2.2.1. BIS™ Monitor

The tablet processes collected data and provides an interface for the user, in which results are displayed, settings are inputted, and data is recorded for download.

It includes three hard keys, three LEDs, a brightness sensor, a touch screen for display and interface, a camera (which is disabled), and a series of connectors as described below.

The BIS™ monitor does not have wireless functionality.

Figure 3. The BIS™ Monitor



Number	Item	Description
1	Camera	The camera is disabled and is not used for BIS™ monitor functionality.
2	Brightness sensor	Senses ambient level of brightness
3	Indicator LEDs	Indicates status of various connectivity functions. Reference *Figure 5. BIS Tablet LEDs* on page 47.
4	Power and connectivity connectors (on	Ports for (from left to right when seen with the bottom edge of the monitor at the left): power, microphone/

Number	Item	Description
	monitor's right edge, not seen)	earphones, USB, mini USB, reset button, HDMI. Only the USB port is intended for end-user use.
5	Docking station connector (on monitor's bottom edge, not seen)	Used to connect the monitor to the docking station in order to provide power and connectivity to the monitor via the docking station.
6	Function button	Will open the main menu when pressed
7	Home button	Will open the home screen when pressed
8	Power On/Off button	Will turn on and off the monitor when pressed

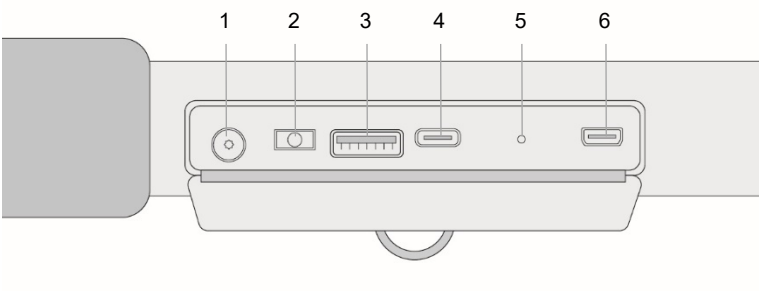
The monitor includes a series of power and connectivity connection ports on its right side, behind a door. Reference *Figure 4. BIS Monitor Connectors* on page 46. These are connection ports for (from left to right when seen with the bottom edge of the monitor at the left): power, microphone/audio connection, USB, mini USB, reset button, and HDMI. The microphone is disabled.

The power and USB connection ports on the monitor are provided for power connection and attachment of a USB flash drive for download of data. These ports can be used at any time; however, they are intended for a use case in which the monitor is used without a docking station, when the power and USB ports on the docking station are not available to the user. The USB port is intended only for the connection of a USB flash drive; do not use it for any other use. The other ports behind the door on the right side of the monitor are not for user/operator use. The power and USB connection ports on the monitor are not intended for use during monitoring.

The monitor is shipped with a power supply for use with the monitor.

WARNING: Use only the power cord and power supply supplied by the manufacturer. Never adapt the plug from the monitor to fit a non-standard outlet.

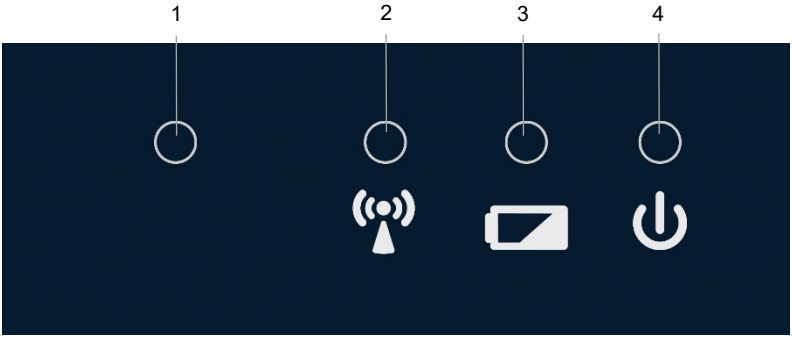
Figure 4. BIS Monitor Connectors



Number	Item	Description
1	Power connector	Used to connect monitor directly to power (when used without a docking station)
2	Microphone/audio connection	Not for user/operator use
3	USB	Used for downloading data
4	Mini USB	Not for user/operator use
5	Reset button	Not for user/operator use
6	HDMI	Not for user/operator use

The tablet includes three LEDs at the top right of the screen, as well as a brightness sensor, as seen in *Figure 5. BIS Tablet LEDs*, below. The meaning of these LEDs are described in the table below, listed from left to right.

Figure 5. BIS Tablet LEDs



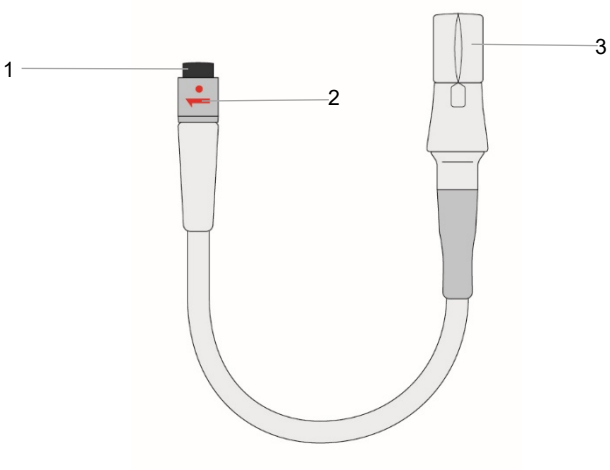
Number	LED	Description	Functioning
1	Brightness	Brightness sensor	Detects ambient brightness
2	Wireless reception	Green LED	Wireless reception detected; as the BIS™ Advance monitor does not have wireless functionality, this will always be off.
3	Charging	Yellow/green LED	Will appear yellow when the monitor is attached to mains power and the tablet battery pack is charging, will appear green when battery pack is fully charged. If the monitor is not attached to mains power, a blinking yellow LED will be displayed if the battery charge level is under 10%.
4	Power	Blue LED	Will appear blue when the monitor is turned on

The monitor can be viewed from any viewing angle up to 140 degrees from either side and up to 120 degrees from above or below the tablet. The BIS value is visible at up to 4 meters from the monitor, the EMG data at up to one meter, and graphs and status data at up to 45 cm from the monitor.

2.2.2. Adapter Cable

The adapter cable is seen in *Figure 6. BIS™ Advance Adapter Cable,* below.

Figure 6. BIS™ Advance Adapter Cable



Number	Description
1	Connector to monitor
2	Adapter cable marking
3	Connector to BISx module

The adapter cable must be connected to the monitor for use. Attach the adapter cable to the back of the monitor as follows:

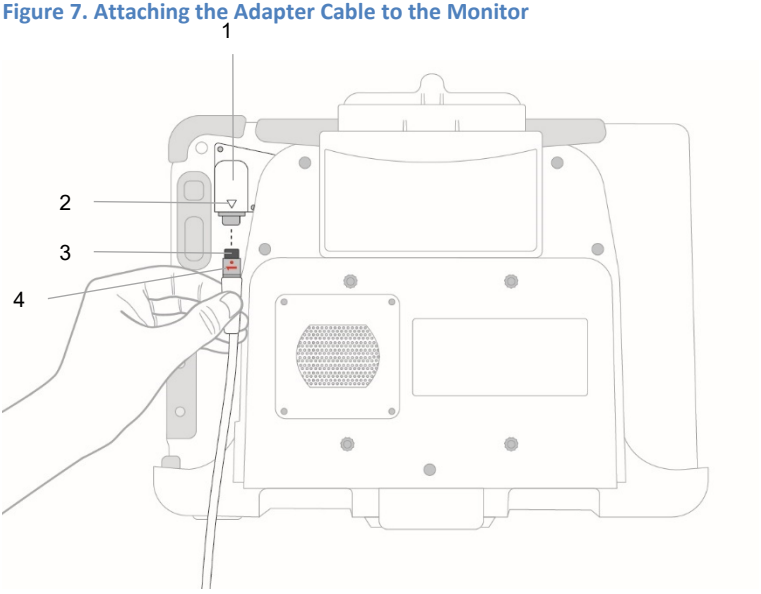
Place the adapter cable in place at the back of the monitor, lining up the arrow on the cable port and the red dot on the adapter cable.

Push the cable into the port. Reference *Figure 7. Attaching the Adapter Cable to the Monitor* on page 49.

Once this connection is made, the adapter cable can stay connected to the monitor, whether the monitor remains on or is turned off between uses.

To remove the adapter cable from the monitor, grasp the metal part of the adapter cable connector and twist it to the left (towards the closer outer edge of the tablet), in the direction of the red arrow, and pull out the cable. Reference *Figure 8. Detaching the Adapter Cable from the Monitor* on page 50.

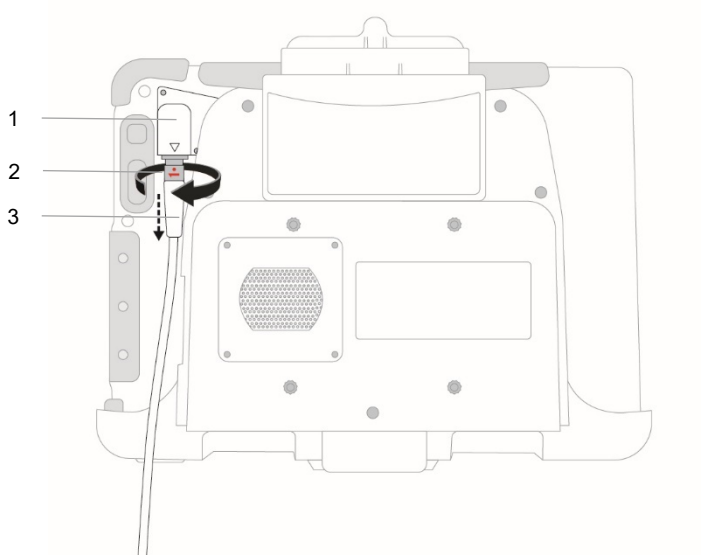
Figure 7. Attaching the Adapter Cable to the Monitor



Number	Description
1	Adapter cable port on monitor
2	Adapter cable port marking

3	Adapter cable connector to monitor
4	Adapter cable marking (appears on metal part of adapter cable)

Figure 8. Detaching the Adapter Cable from the Monitor



Number	Description
1	Adapter cable port on monitor
2	Adapter cable marking (appears on metal part of adapter cable)
3	Adapter cable

2.2.3. Docking Station

A docking station is provided in order to permit the mounting of the monitor on a variety of surfaces, as required by user preference. For a list of operating configurations, reference *7.6.2 Operating Environments* on page 229.

The docking station is provided with the monitor and is also sold separately. It uses the power supply and power cord supplied with the monitor.

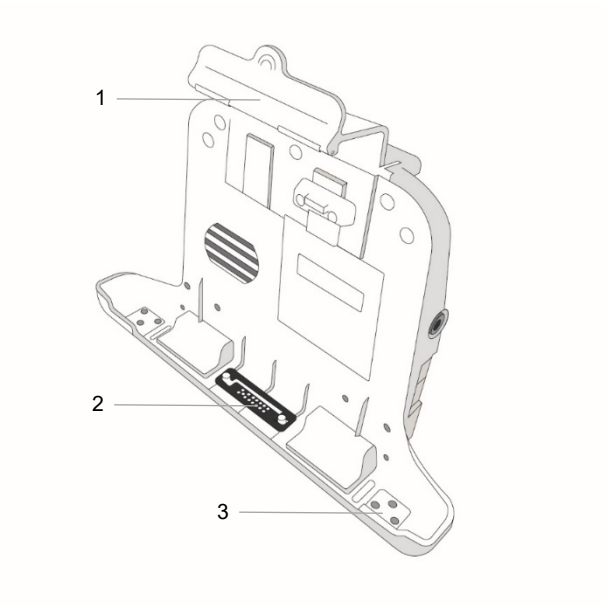
WARNING: Use only the power cord and power supply supplied by the manufacturer. Never adapt the plug from the monitor to fit a non-standard outlet.

To attach the monitor to the docking station, reference *3.5 Preparing the Docking Station* on page 68.

The docking station includes a series of connectors used to connect the docking station to power and communications. These are located at the bottom of the docking station and are not seen in either of the docking station views in the figures below. For an illustration and description of the docking station connectors, reference *Figure* 11. BIS™ Advance Docking Station Connectors on page 54.

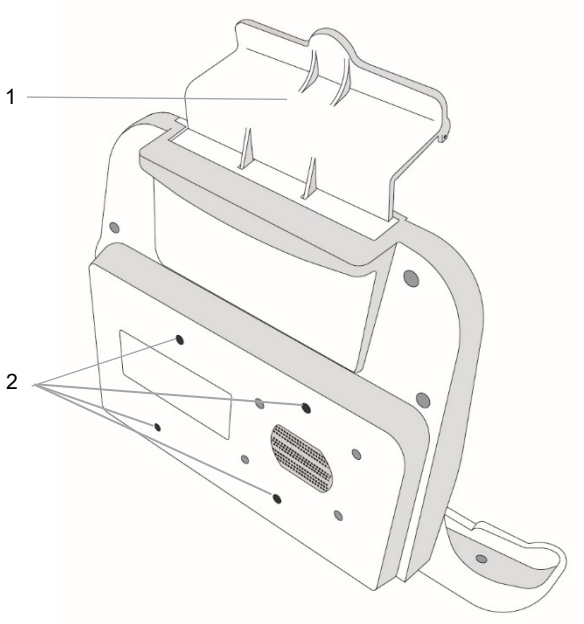
Note: Please note that the network connector on the docking station is for development, production and service use only. It is not intended for use for any other purpose.

Figure 9. BIS™ Advance Docking Station, Front View



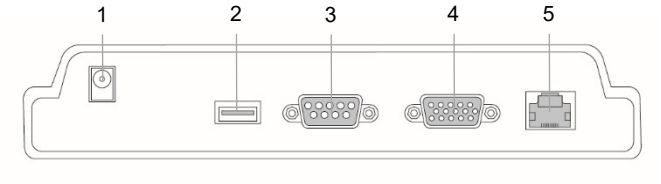
Number	Feature	Description
1	Clasp for top edge of tablet	The clasp, when pushed into place, holds the monitor in place in the docking station
2	Connection pins	Docking station connection pins, which connect with pins at the bottom edge of the monitor to provide power and communication to the monitor via the docking station
3	Monitor groove	Groove in which to place the monitor when docking the monitor in the docking station

Figure 10. BIS™ Advance Docking Station, Back View



Number	Feature	Description
1	Clasp for top edge of tablet	The clasp, when pushed into place, holds the monitor in place in the docking station
2	Docking station mounting connectors	Used to attach the docking station to the required mounting solution

Figure 11. BIS™ Advance Docking Station Connectors



Number	Feature	Description
1	Power	For connecting docking station to AC power
2	USB	For data download only
3	RS-232 (serial) port	For connection to monitoring systems, including hospital data systems. Only approved medical devices may be connected.
4	VGA	For connection to display data on an additional screen
5	Network	For development, production and service use only

2.2.4. BISx Module

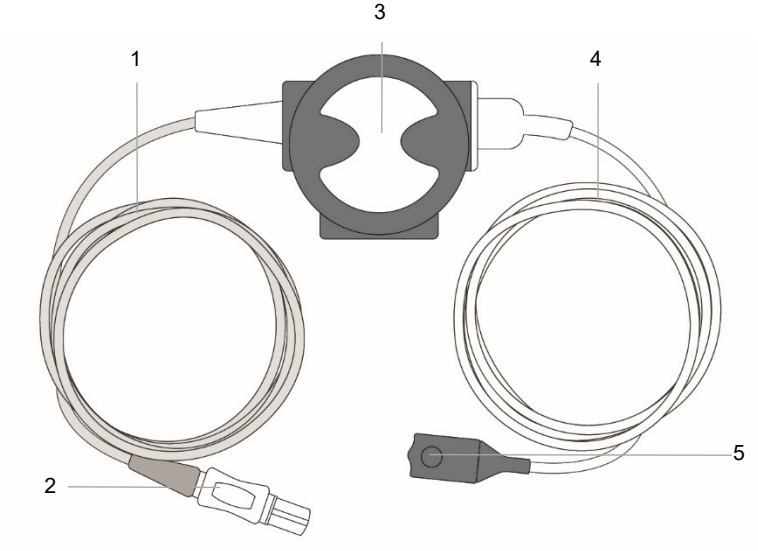
There are two versions of this module, the BISx module for use with two-channel monitoring, and the BISx4 module for use with four-channel monitoring (for both hemispheres of the brain). The designation for two-channel or four-channel monitoring appears on the BISx module. In this document, when the term BISx module is used, it refers to both modules; use the correct module for your monitoring situation.

If using a BISx4 module for four-channel monitoring, please note that the appropriate sensor must also be used in order to enable four-channel monitoring.

The BISx module receives, filters, and processes patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment.

Its integral Monitor Interface Cable (MIC) connects to the interface cable which should be attached to the monitor. Its integral Patient Interface Cable (PIC) connects the BIS™ sensor to the BISx module. (It is possible to remove the PIC from the BISx module without special tools, by pulling the parts apart, but it is supplied securely attached to the BISx module.) The attachment clip on the BISx module is used to secure it in a convenient location near the patient's head.

Figure 12. BISx Module with Integral Cables



Number	Feature	Description
1	MIC cable	Connects between the BISx module and the monitor
2	Monitor connector	This end of the MIC cable connects to the monitor adapter cable

Number	Feature	Description
3	BISx module	Unit which collects, processes and stores data as part of the functionality of the BIS™ Advance monitoring system.
4	PIC cable	Connects between the BISx module and the patient sensor
5	Sensor connector	This end of the PIC cable connects to the sensor. Note the button on the connector; when connected, press this button to release the sensor.
NA	Clip (not seen)	This clip at the back of the BISx module permits the mounting of the BISx module on a pole or other item as required.

WARNING: Due to elevated surface temperature, do not place the BISx module in prolonged direct contact with patient's skin, as it may cause discomfort.

Caution: Do not open the BISx module for any reason. The seal to prevent liquids from entering the BISx module may be damaged if opened.

Caution: Service or repairs must be performed only by qualified biomedical technicians.

2.2.5. BIS Sensors

WARNING: Please note that the sensors are consumable products with a defined lifetime and expiry date. An expired sensor or a sensor that has been used beyond its defined lifetime may pass the sensor check (depending on various use parameters), but it is strongly recommended to avoid use of expired sensors and replace sensors after 24 hours. Use of expired or over-used sensors may cause degraded performance.

WARNING: Use of the BIS Advance system with sensor during external defibrillation may lead to shunting of defibrillator energy, causing

defibrillation to be ineffective. In emergency use when defibrillation is required to save a patient's life, ineffective defibrillation may result in death.

WARNING: The sensor is not intended to collect EEG, ECG, or other electrophysiological signals for interpretation; the signals collected are intended for use solely for calculating the BIS™ parameter.

WARNING: Use of the host system with sensor during electroconvulsive therapy (ECT) may result in a corrupted EEG signal.

Caution: Dispose of the sensor in accordance with current medical standards and applicable national regulations for biologically hazardous waste.

Note: Use of the host system with sensor along with a neurostimulator may cause neurostimulator malfunction or diminished neurostimulator effectiveness.

Select the appropriate sensor.

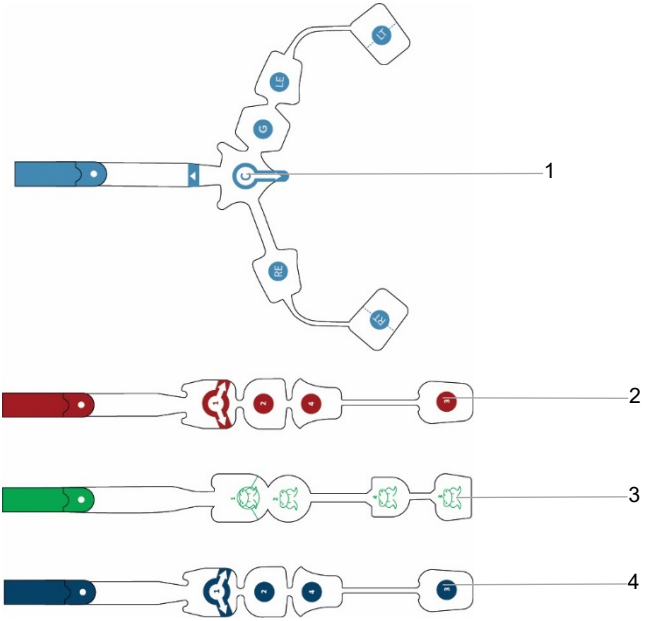
A list of sensors appears in *Table 34. BIS™ Advance Accessories* on page 252. The sensors are also seen in *Figure 13. BIS™ Advance Sensors* on page 58. It is important to use the correct sensor for your current patient and monitoring situation; a Quatro, Extend or Pediatric sensor for use with a BISx module or a BISx4 to monitor patients on two channels, or a Bilateral sensor for use with a BISx4 module to monitor patients on 4 channels (in both hemispheres of the brain).

The patient sensor is intended for single patient use.

The sensors are consumable products with a defined lifetime and expiry date. An expired sensor or a sensor that has been used beyond its defined lifetime may pass the sensor check (depending on various use parameters), but it is strongly recommended to avoid use of expired sensors and replace sensors after 24 hours. Use of expired or over-used sensors may cause degraded performance.

When a sensor is attached to the system, the system will automatically perform a sensor check. All of the sensor's electrodes must receive a pass grade in order for the sensor check to pass and measurement to proceed.

Figure 13. BIS™ Advance Sensors



Number	Description	Part Number
1	Bilateral sensor	186-0212
2	Extend sensor	186-0160
3	Pediatric sensor	186-0200
4	Quatro sensor	186-0106

2.2.6. The BIS™ Sensor Simulator

In addition to patient sensors, the BIS™ Sensor Simulator is also available. It is a service tool that allows for the verification of proper impedance values being detected by the BIS™ Advance monitor during the sensor check. This sensor is used for testing purposes only.

If the sensor does not pass the sensor check process, check the following:

1. Ascertain if the PIC cable is functioning properly by running the sensor check with the Sensor Simulator attached to the patient end of the PIC cable instead of a sensor.

2. If the PIC cable functions correctly with the Sensor Simulator, and the Sensor Simulator passes the sensor check process, replace the sensor.

3. If the Sensor Simulator does not pass the sensor check process, replace the PIC and/or the entire BISx module.

For more information about the sensor check process, reference *3.6.3 Sensor Check* on page 82.

3. Installation and Preparation for Use

3.1. Operating Environment

The system is designed for use in operating rooms and in transit following procedures. For more details regarding specific operating environments and the recommended mounting options, reference *7.6.2 Operating Environments* on page 229.

3.2. Power Requirements and Battery Use

The BIS™ Advance monitor should always be operated with a battery installed, to permit for continued use following interruption of supply mains. Following interruption of power supply, including interruptions exceeding 30 seconds, the monitor will continue to function, drawing power from the battery.

3.3. Battery Operation

3.3.1. Battery Pack General Information

The monitor includes one lithium-ion battery pack.

When fully charged, the battery pack will provide power to the tablet for use for at least one hour, if the tablet is not receiving power from wall power via the docking station.

WARNING: Charge the monitor fully before your first use of the monitor, by attaching the monitor to AC power with the battery installed. See *3.3 Battery Operation* on page 60 for more information.

WARNING: The monitor should always be operated with the battery installed in order to provide back-up power in the event of a momentary or temporary power outage.

WARNING: Improper operation may cause damage to the battery or endanger the user.

WARNING: Do not place the battery near any heat source.

WARNING: Do not try to disassemble or short circuit the battery.

WARNING: The BIS™ Advance monitor contains an internal lithium ion battery. The battery must be disposed of or recycled with national and local waste disposal legislation and requirements. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com.

WARNING: Never soak the battery in liquid such as water, drink, or oil.

WARNING: Use, store and transport the battery only under the designated temperature conditions. Reference *7.6.4 Battery Specifications* on page 231.

WARNING: If the monitor is to be stored for three months or more, store the battery outside the monitor.

WARNING: If the battery has not been in use three months or longer, charge the battery before use to a level of at least 80% charge. Battery capacity indicators are described in *3.3.3 Battery and Power Usage* on page 63.

3.3.2. Battery Pack Removal and Installation

Remove or install the battery pack as follows:

1. The device is shipped with a battery that is not fully charged. Before first use, charge the battery in the monitor until the battery indicator indicates that it is fully charged (as described in in *3.3.3 Battery and Power Usage* on page 63).

2. To remove or switch the battery pack (#2 in *Figure 14,* below) , open the battery pack compartment of the monitor as follows:

3. Pushing the lower lock lever at the back of the tablet (#5 in *Figure 14,* below) towards the lower edge of the tablet. Note that this lock lever is indicated by locked and unlocked symbols above the lever. The lower lock will remain in the open position until moved again to the center of the tablet to close the lock.

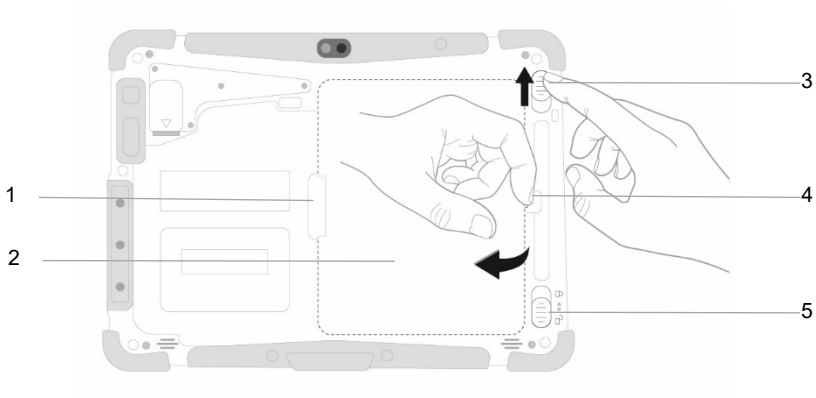
4. Push the upper lock (#3 in *Figure 14*, below) into the open position and hold it in this position while you perform the next step.

5. With the lock open, pull the tab (#4 in *Figure 14*, below) to remove the battery pack.

6. To put a battery pack in the tablet, place the bottom edge of the battery pack, which fits in the center of the back of the monitor into the battery connector pins (#1 in *Figure 14*, below), into position. Push the top of the battery pack into the battery compartment and the battery pack will click into place.

7. Re-lock the battery compartment completely by moving the lower battery lock into the locked position, towards the center of the tablet; the locked position is marked by a lock icon on the tablet.

Figure 14. Battery Assembly/Disassembly



Label	Function	Description
1	Connector pins area	Battery connector pins are located under this panel
2	Battery pack	Removable battery pack
3	Upper Battery pack lock	This lock must be held in the open position while removing the battery.
4	Tab to open battery pack	Pull this tab out to remove the battery pack
5	Lower Battery pack lock	Slide this lock to the open position; it will remain in the open position until moved again to the center of the tablet to close the lock.

WARNING: Only the battery pack provided with this monitor should be used for the monitor. Do not use another battery or a refurbished battery. Use of another battery or a refurbished battery may cause damage to the monitor or endanger the user. Reference *Table 32. BIS™ Advance Accessories* on page 250 regarding the battery pack.

Caution: There should always be a battery installed in the device. If the battery is not installed, the module will operate properly on AC power, but if AC power is lost for any reason, the monitor will cease to function.

Note: The battery pack supplied with this monitor should not be used with other devices.

The battery icons indicate the charge level of the batteries. Reference *Table 5. Home Screen Indicators* on page 114 for more details.

3.3.3. Battery and Power Usage

If power is lost when the monitor is operating from AC power, the monitor will automatically switch to the battery pack for power. If the battery pack is empty and the device is not connected to AC power, the device will shut down.

Therefore, ensure that a battery is always installed in the device, to ensure that the monitor maintains power and can continue to function when disconnected from an AC power source.

A low priority battery alarm (BATTERY LOW) will be triggered when the battery reaches a level below 30% state of charge (state of charge is current capacity/maximum capacity) and the battery is not charging (that is, if the monitor is not connected with a cable to AC power or charging is faulty). A medium priority battery alarm (BATTERY IS CRITICALLY LOW) will be triggered when the change level falls to a critical charge level. In both cases, attach the device to AC power to begin charging or replace the battery. For the critical alarm, do so immediately to avoid a loss in coverage.

Battery change status is indicated by the indicators described in *Table 5. Home Screen Indicators* on page 114.

The battery will charge when the monitor is attached to AC power, either directly through a power cable from the monitor to AC power, or through a power cable from the docking station to AC power, when the monitor is docked in the docking station. Charging time is up to 8 hours when the tablet is powered on, and up to 4 hours when the tablet is powered off.

The monitor's battery indicators are shown in *Table 5. Home Screen Indicators* on page 114.

For additional battery specifications, reference *7.6.4 Battery Specifications* on page 231.

3.4. Mounting the Docking Station

A number of mounting options are available for mounting the docking station. The caregiver should select the mounting option that best fits his desired location. For more information about selecting the most appropriate option, reference *7.6.2 Operating Environments* on page 229.

Before mounting the docking station, ensure that you have the following components ready:

1. Monitor with adapter cable connected, ready for placement in the docking station. The docking station may be mounted (on a GCX clamp mount or a

GCX desktop mount) before or after you place the monitor in the docking station.

2. GCX clamp mount or GCX desktop mount with required screws (screws are packaged with the mount)

3. If desired, IV pole, anesthesia mount, or other hardware for mounting medical devices for use

To set up the monitor with the GCX clamp mount:

1. Place the docking station on a stable surface.

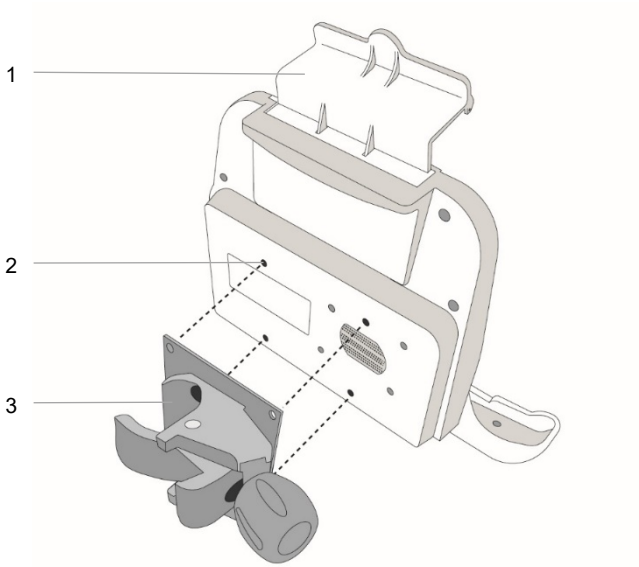
2. If your docking station has four round black supports attached to its back (to the four screw holes seen in *Figure 15. Setup with GCX Clamp* Mount on page 66), remove these supports and set them aside in case you need them in the future for other mounting solutions.

3. Locate the four screws supplied with the GCX clamp mount. Using a standard screwdriver, attach the GCX clamp mount to the back of the docking station using these four screws, by inserting the screws through the four holes in the GCX clamp mount and into the four screw holes on the back of the docking station (from which the four supports were removed). Reference *Figure 15. Setup with GCX Clamp* Mount, below.

4. Once the GCX clamp mount and the docking station are firmly attached, mount the GCX clamp mount to an IV pole, anesthesia mount or other hardware, following the instructions supplied with that hardware.

5. The monitor can now be placed in the docking station and attached to a BISx module and sensor to begin monitoring.

Figure 15. Setup with GCX Clamp Mount



Label	Description
1	Docking station
2	Screw holes for attaching clamp mount to docking station
3	Clamp mount

To set up the monitor with the GCX desktop mount:

1. Stand the GCX desktop mount on a stable surface.

2. Prepare the docking station. If your docking station has four round black supports attached to its back (to the four screw holes seen in *Figure 16. Setup with GCX Desktop* Mount on page 67), remove these supports and set

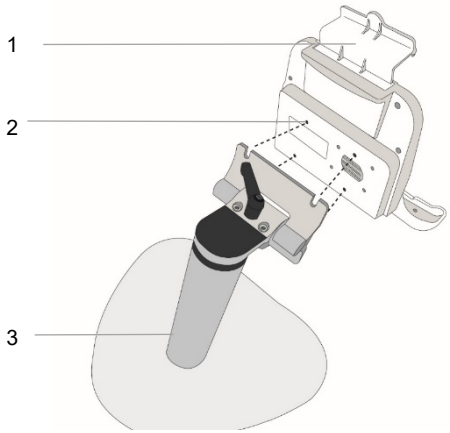
them aside in case you need them in the future for other mounting solutions.

3. Locate the four screws supplied with the desktop mount. Using a standard screwdriver, attach the GCX desktop mount to the back of the docking station using these four screws, by inserting the screws through the four holes or indentations in the desktop mount and into the four screwholes on the back of the docking station (from which the four supports were removed). Reference *Figure 16. Setup with GCX Desktop* Mount on page 67.

4. Once the GCX desktop mount and the docking station are firmly attached, place the GCX desktop mount on the work surface.

5. The monitor can now be placed in the docking station and attached to a BISx module and sensor to begin monitoring.

Figure 16. Setup with GCX Desktop Mount



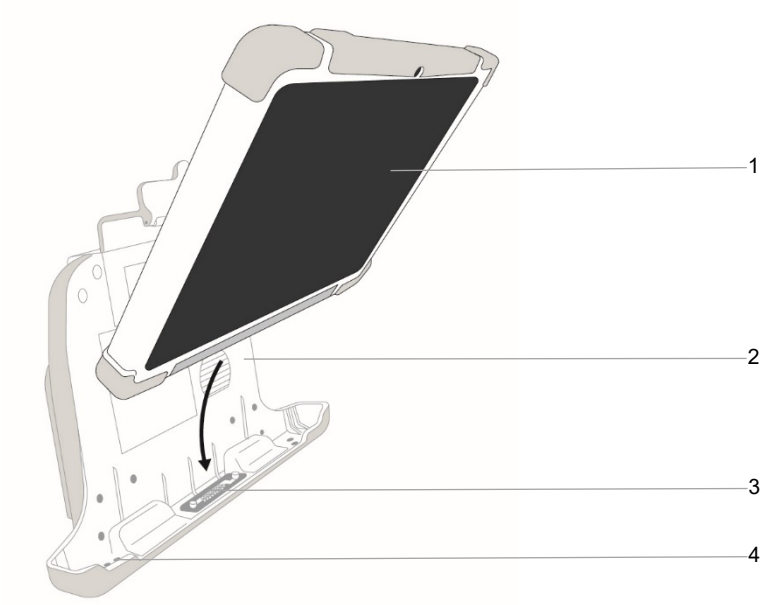
Label	Description
1	Docking station
2	Screw holes for attaching desktop mount to docking station
3	Desktop mount

3.5. Preparing the Docking Station

Follow the instructions below to place the monitor in the docking station:

1. Place the monitor in the docking station so that the connectors on the monitor's bottom edge fit into the connectors in the groove at the inside of the bottom of the docking station (#3 in *Figure 17*). Reference *Figure 17. Docking Station Installation Step 1* on page 68.

Figure 17. Docking Station Installation Step 1

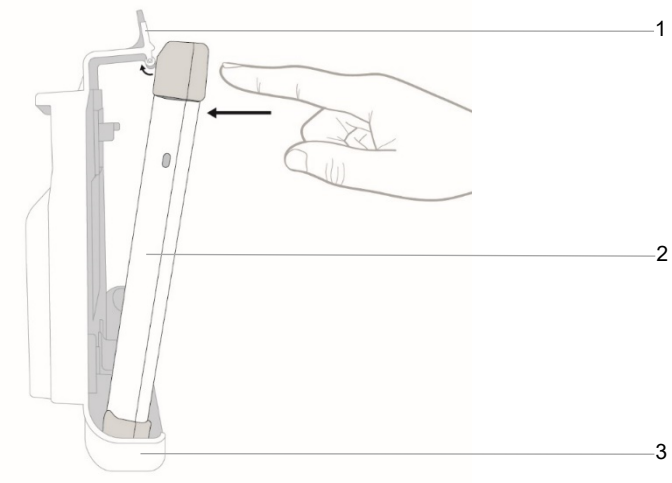


Number	Description
1	Monitor
2	Docking station

3	Connector pins in docking station groove
4	Docking station groove to hold monitor

2. Push the top edge of the monitor inwards to fit it into the docking station. Reference *Figure 18. Docking Station Installation Step 2* on page 69.

Figure 18. Docking Station Installation Step 2



Number	Description
1	Top edge clasp
2	Monitor
3	Docking station

3. The top edge clasp will now click into place and hold the monitor in place inside the docking station.

4. If required, use the four supports connected to the back of the docking station to attach the docking station to the required mounting solution. For more information, reference *3.4 Mounting the Docking Station* on page 64.

5. Attach the power supply connector to the power port on the docking station and to mains AC power. Attach your selected communications cable to provide communication with the docking station. Options include an RS-232 cable, a network cable, a VGA cable, and a USB flash drive. The docking station connectors are located at the bottom of the docking station. The docking station connectors are seen in *Figure* 11. BIS™ Advance Docking Station Connectors on page 54.

WARNING: Use only the power cord and power supply supplied by the manufacturer. Never adapt the plug from the monitor to fit a non-standard outlet.

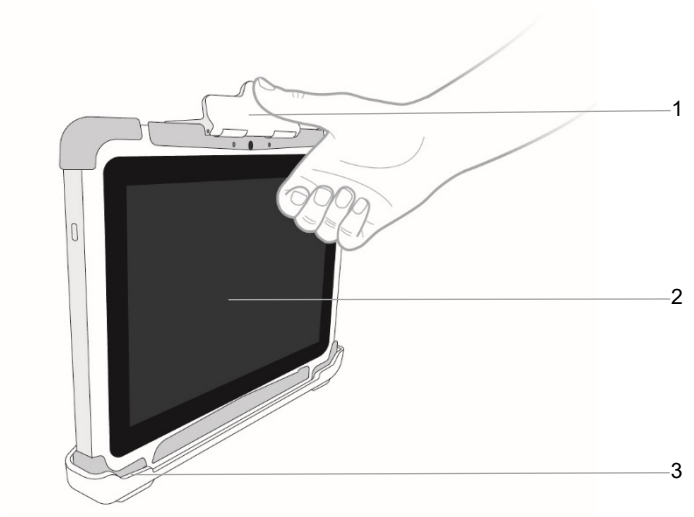
Once the docking station is connected as required and the BIS™ Advance Monitor is placed into the docking station, the monitor will receive both power and communication via the docking station.

To position the docking station for use after placing the monitor in the docking station and connecting as required, mount the docking station using your selected mounting accessory, as described in *3.4 Mounting the Docking Station* on page 64.

The available accessories are listed in *Table 34. BIS™ Advance Accessories* on page 252.

To remove the monitor from the docking station, push top edge clasp lever at the top of the docking station (as seen in *Figure 19. Docking Station Removal* on page 71); this will release the connectors. Grasping the monitor from its top edge, pull it towards you and up to remove the monitor from the docking station.

Figure 19. Docking Station Removal



Number	Description
1	Top edge clasp
2	Monitor
3	Docking station

3.6. Preparing the Monitor

Follow the steps described below to prepare the monitor for use.

3.6.1. Connecting the Monitor

Ensure that you have all of the required components, as described in *2.1 The BIS™ Advance System* on page 40.

The adapter cable should already be connected to the monitor, as described in *2.2.2 Adapter Cable* on page 48.

If you want to mount the docking station, do so now. Follow the instructions in *3.4 Mounting the Docking Station* on page 64.

Connect the docking station and the monitor as described in *3.5 Preparing the Docking Station* on page 68.

The BIS™ Advance monitor may be used without the docking station, but use of the docking station with an appropriate mount is strongly suggested in order to suit the device to the requirements of the monitoring environment. If you are required to use the monitor without the docking station, a power cable may be connected to the monitor at its right side; reference *Figure 3. The BIS™ Monitor* on page 44.

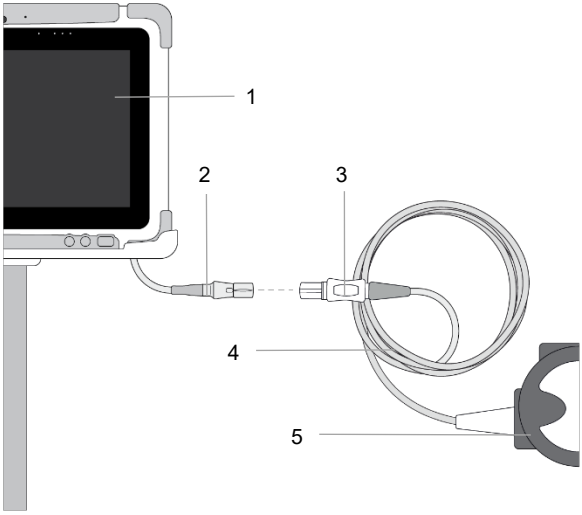
Power on the device as described in *3.6.5 Start Procedure* on page 87. Connect the BISx or BISx4 module to the monitor, as follows:

1. Locate the monitor end of the MIC, which is an integral part of the BISx module.

2. Connect the monitor end of the MIC to the adapter cable which is connected to the BIS™ Advance monitor. Once connected, the BISx module need not be disconnected again.

3. If you wish to disconnect the BISx cable from the monitor, carefully grasp the BISx module connector, push the button on the BISx module MIC connector (#3 in Figure 20, below), and pull the adapter cable connector and the BISx module connector apart. DO NOT pull on the cable.

Figure 20. Attaching the BISx Module to the BIS Advance Monitor



Label	Description
1	Monitor
2	Adapter cable
3	MIC push button (used to disconnect MIC and adapter cable)
4	MIC (monitor interface cable, an integral part of the BISx module)
5	BISx module

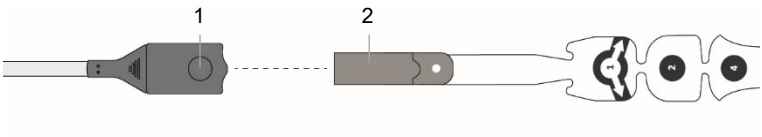
If the BIS™ Advance initialization is completed before the BISx or BISx4 module is connected, an on-screen message will indicate **Connect BISx to start monitoring**. Connect the BISx or BISx4 module, and an on-screen message will indicate **Initializing BISx**.

If the BISx or BISx4 module is connected but no sensor is connected, an on-screen message will indicate **Connect sensor to start monitoring**.

Ensure that you are using a BISx module or a BISx4 module with a Quatro, Extend or Pediatric sensor to conduct two-channel monitoring, or a BISx4 module with a Bilateral sensor to conduct four-channel monitoring.

Connect the appropriate sensor (reference *Figure 21. Connecting the sensor to the BISx module*, below) to the PIC on the BISx module to begin sensor initialization. To insert the sensor into the PIC, line up as shown and insert the sensor tab into the PIC sensor connector without pausing, until an audible "click" is heard. The blank side of the sensor tab (i.e. the side without the visible computer chip) should be facing up. Reference *Figure 21. Connecting the sensor to the BISx module*, below.

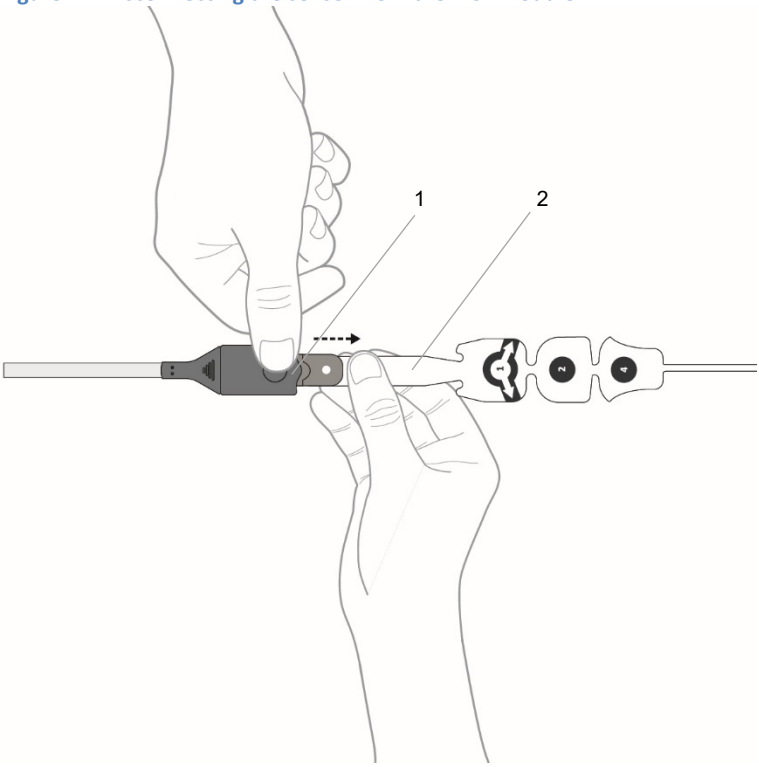
Figure 21. Connecting the sensor to the BISx module



Label	Description
1	PIC (patient interface cable, connected to BISx module) connector
2	Sensor connector

To disconnect a sensor from the BISx module, grasp the sensor and the PIC (patient interface cable) which is attached to the BISx module. Press the button on the PIC as seen in *Figure 22. Disconnecting the sensor from the BISx module* on page 75, and, while pressing the button, pull apart the two connectors.

Figure 22. Disconnecting the sensor from the BISx module



Label	Description
1	PIC (patient interface cable, connected to BISx module) connector
2	Sensor connector

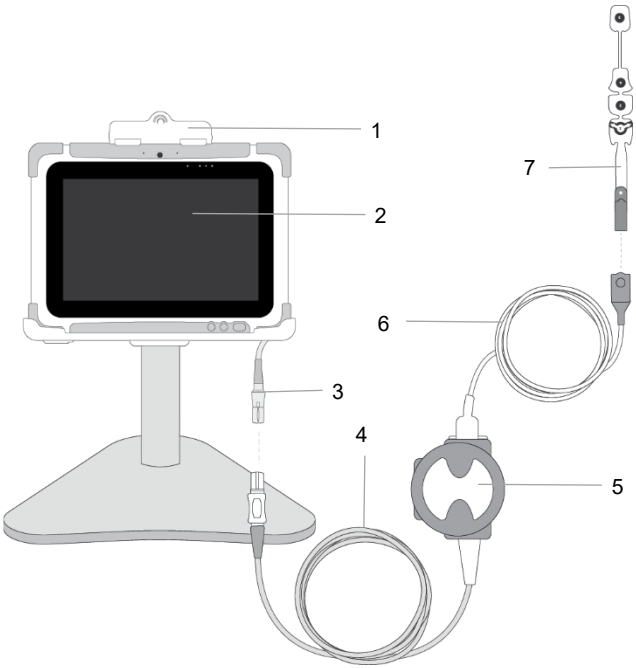
To begin monitoring, connect the sensor to the patient; reference *3.6.2 Connecting a Sensor to a Patient*, below.

When the system identifies that a sensor has been connected to the BISx module, the system will perform Sensor Initialization to check that the sensor is supported and that impedance values are in the acceptable range.

The automatic sensor check is described in *3.6.3 Sensor Check* on page 82.

The BIS Advance monitor setup should now appear as seen in *Figure 23. BIS Advance Monitor Setup* and *Figure 24. BIS Advance Monitor Setup - Back*, both below.

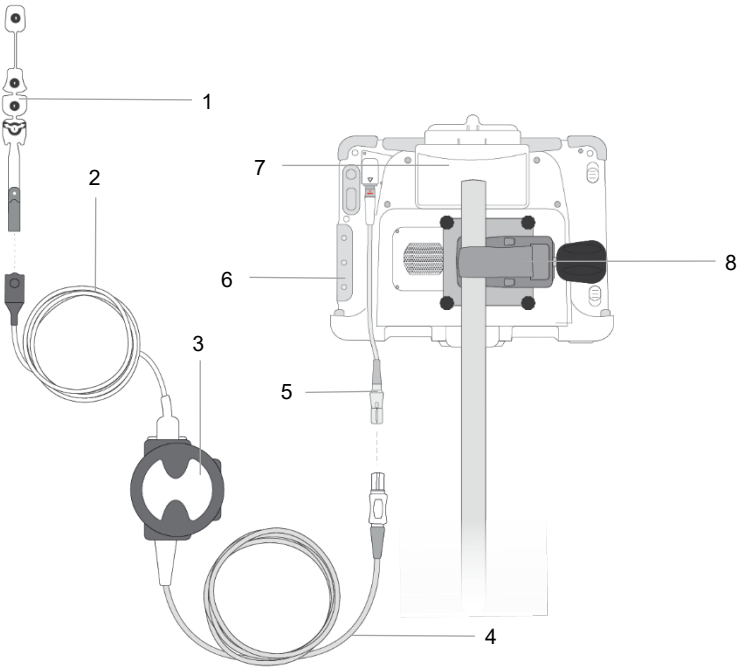
Figure 23. BIS Advance Monitor Setup



Label	Description
1	Docking station
2	Monitor
3	Adapter cable
4	MIC (monitor interface cable, an integral part of BISx module)
5	BISx module

Label	Description
6	PIC (patient interface cable, attached to BISx module)
7	BIS™ sensor

Figure 24. BIS Advance Monitor Setup - Back



Number	Description
1	Sensor
2	PIC
3	BISx module
4	MIC
5	Adapter cable
6	Monitor
7	Docking station
8	GCX mounting accessory (the selected accessory will depend on the use case)

3.6.2. Connecting a Sensor to a Patient

Select the appropriate sensor. A list of sensors appears in *Table 34. BIS™ Advance Accessories* on page 252. It is important to use the correct sensor for your current patient and monitoring situation, as follows:

Table 4. Sensor/BISx/Use Case Matrix

Sensor	BISx module	Monitoring Type
Quatro, Extend or Pediatric sensor	BISx module or a BISx4 module	Two-channel monitoring (in one hemisphere of the brain)
Bilateral sensor	BISx4 module	Four-channel monitoring (in both hemispheres of the brain).

Before applying the sensor to the patient, view the sensor application animation video. To open the video, click **Sensor Application Guide** on the **Connect sensor to begin monitoring** screen. Apply the sensor to the patient as described in the video.

Please note that this video, the instructions, and the sketch below describe applying the sensor to the left side of the patient's head; the sensor may also be applied to the right side of the patient's head. To apply to the right side of the patient's head, follow the instructions below, starting to apply the sensor from the middle of the patient's forehead, and following the instructions in reverse, applying the sensor towards the right side of the patient's face.

Note the sequence of the application of the sensor the patient's forehead, as follows:

1. Clean the patient's forehead with a disinfectant wipe.

2. Hold the sensor over the patient's forehead to ascertain where to place the sensor. Note that the section labeled with a target circle and the number 1 should be placed on the forehead directly above the bridge of the nose, and the other sections of the sensor should be located in succession towards the left side of the patient's face, so that the last section of the sensor, labeled with a target circle and the number 4, will be placed on the left side of the patient's face at the level of his eye. See the sketch below. (For the pediatric sensor, the sections of the sensor are marked by numbered sketches rather than by circles.) If preferred, the sensor may be placed on the right side of the patient's forehead, by simply following these instructions in reverse.

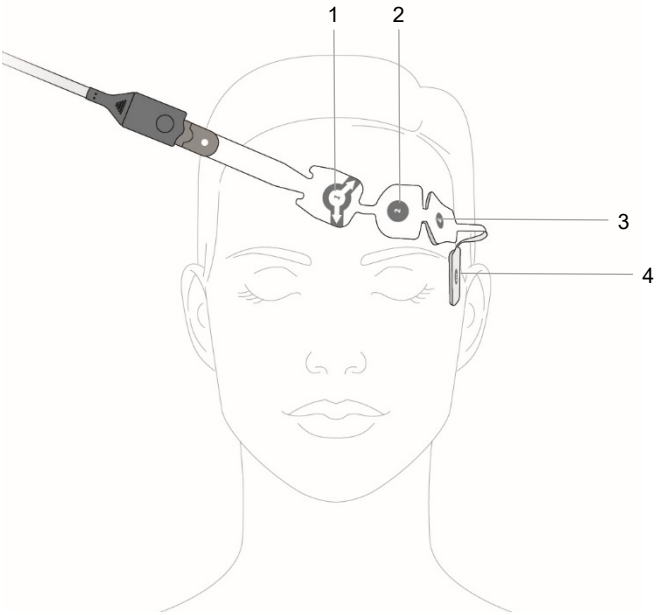
3. Each sensor section contains both adhesive (in the ring of the target circle) and conductive gel (in the center of the target circle). For each section of the sensor, place it in its proper position on the patient's forehead and press the white ring around the target circle to seal the adhesive to the skin. Repeat with each section of the sensor.

4. Once the adhesive portion of all of the sensor's sections has been firmly adhered to the patient's forehead, press the center of each target circle and hold for 5 seconds to push the conducting gel into position.

5. For a 4-channel system using a Bilateral sensor, position the sections of the sensor on the patient's face as seen on the sensor packaging, with the target circle marked with the letter C above the bridge of the patient's nose, and seal the adhesive and push the conductive gel into position for each section of the sensor as described above.

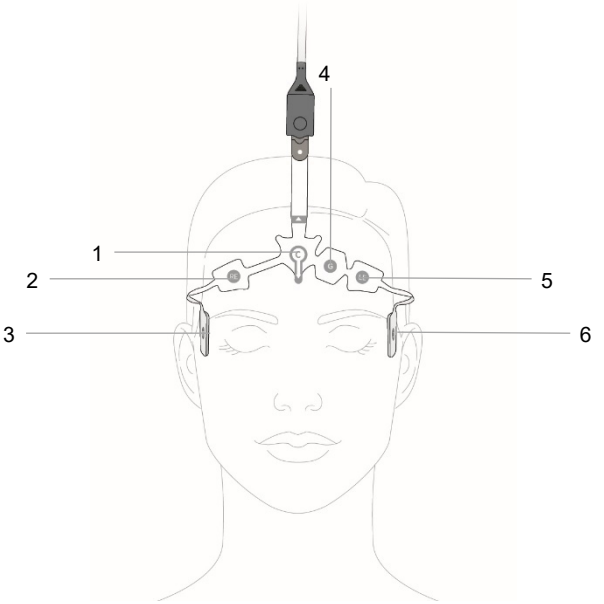
6. Sketches displaying sensor placement for both two-channel monitoring and four-channel monitoring appear below.

Figure 25. Sensor Positioning for Two-channel Sensor



Label	Function	Description
1	Electrode 1	Place lined up to bridge of nose
2	Electrode 2	Place as seen in sketch
3	Electrode 3	Place as seen in sketch
4	Electrode 4	Place aligned with left eye (or right eye, if placing the sensor on the right side of the patient's forehead)

Figure 26. Sensor Positioning for Four-channel Sensor



Label	Function	Description
1	Electrode C	Place lined up to bridge of nose
2	Electrode RE	Place above right eyebrow
3	Electrode RT	Place aligned with right eye
4	Electrode G	Place as seen in sketch
5	Electrode LE	Place above left eyebrow
6	Electrode LT	Place aligned with left eye

3.6.3. Sensor Check

Ensure that the BISx or BISx4 module is connected to the monitor, as described in *3.6.1 Connecting the Monitor* on page 71. Attach the selected sensor to the BISx or BISx4 module. Please note that the sensors are consumable products with a defined lifetime and expiry date. An expired sensor or a sensor that has been used beyond its defined lifetime may pass the sensor check (depending on various use parameters), but it is strongly recommended to avoid use of expired sensors and replace sensors after 24 hours. Use of expired or over-used sensors may cause degraded performance.

Connect the sensor to the patient as described in *3.6.2 Connecting a Sensor to a Patient* on page 78.

The device will begin an automatic sensor check when a sensor is connected to the BISx module. The sensor check process tests impedance at each sensor section; it is designed to assess the functionality of the sensor and the quality of the contact (to the patient) and connection (to the monitor) of the sensor, to determine whether the sensor can be used in patient monitoring.

The sensor check will then begin. Reference *Figure 27. Sensor Check Window: In progress and Completed* on page 85 for the appearance of the sensor check window. The auto sensor check process, during which the system checks that the sensor is connected properly to the patient, takes a few seconds. The system provides an indication for this process: **Sensor check in progress**. The automatic sensor check will detect any sensor problems.

The sensor check window will show the status of the sensor check. If **Display Sensor Check Values** is selected (at the top left of the window) the impendence value of each electrode will be displayed. (For more information, reference *3.15.3.4 Sensor Check Values* on page 134.) If it is not selected, **PASS**, **NOISE**, **HIGH** or **POOR CONTACT** labels for each electrode will be displayed. The sensor check window will indicate **Sensor check completed successfully** and then automatically close.

If the sensor check result is **PASS** (whether the sensor check was manual or automatic), the system shall exit the manual sensor check mode and begin monitoring. If the sensor check does not pass the test, i.e., at least one of the electrodes is not within the defined impedance range, the sensor check results will display the resulting icons and/or values, and you will not be able to begin monitoring with that sensor.

The system will display the sensor check test result for each electrode as follows:

Result	Icon	Value color in sensor check screen	Description
PASS		Green	An electrode PASSES the sensor check if the impedance for that electrode is less than 7.5 kiloohms. The ground electrode (electrode 2 for a two-channel sensor and electrode G for a four-channel sensor) must be less than 30 kiloohms to pass.
HIGH		Red	An electrode is labeled HIGH if its impedance value is above 7.5 kiloohms (30 kiloohms for the ground electrode). If the sensor check displays this result for a particular electrode, pushing the electrode to create better contact between the electrode and the patient's skin may help the electrode pass the sensor check.
NOISE		Gray	If the signal from the electrode goes beyond the measurable range, NOISE will be displayed. This notification may appear if pressing sensor during check or in the presence of large external stimulus.
POOR CONTACT		Red	If the impedance check indicates that the electrode is not in contact with the patient, the sensor check will indicate that that electrode is in POOR CONTACT. If the sensor check displays this result for a particular electrode, pushing the electrode to create better contact between the electrode and the

			patient's skin may help the electrode pass the sensor check.

The sensor check will determine if the sensor will pass the sensor check based on the impedance of the electrodes and the ground electrode.

If the sensor passes the sensor check, monitoring will begin automatically. If the sensor fails, monitoring will not begin. If the sensor does not pass the sensor check process, check the functionality of the PIC cable by running a sensor check using a Sensor Simulator. If the sensor check does not pass with the Sensor Simulator, replace the PIC or the BISx module. If the sensor check passes with the Sensor Simulator, replace the sensor with a new appropriate sensor. That sensor will then undergo an automatic sensor check upon attachment. If it passes the sensor check, monitoring will commence.

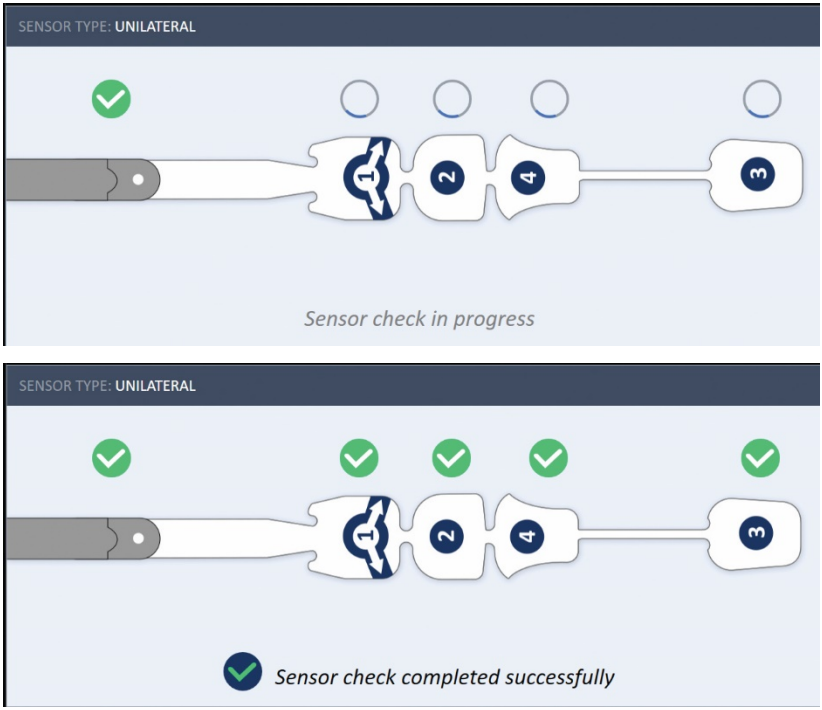
For the 2-channel system, the electrodes will be labeled as follows, starting from the left-most electrode when viewing the sensor from the front: 1,2,4,3.

For the 4-channel system, the electrodes shall be labeled as follows, starting from the left-most electrode when viewing the sensor from the front: LT, LE, G, C, RE, RT.

The user can determine if he wants to display the sensor check values or just a PASS, HIGH, NOISE or POOR CONTACT indicator. By default, Display Sensor Check Values is disabled, so PASS, HIGH, NOISE or POOR CONTACT will appear for each sensor section. To enable sensor check values, reference *3.15.3.4 Sensor Check Values* on page 134.

If the sensor is supported and impedance values are in the acceptable range, the system shall display patient data based on the information collected by the sensor. If there are issues that prevent the system from reading information from this sensor, an on-screen message will display this information.

Figure 27. Sensor Check Window: In progress and Completed



3.6.3.1.Manual Sensor Check

The user can start a sensor check manually when a sensor is already connected to the monitor, if desired, perhaps because the user is actively monitoring a patient, but no BIS™ value is displayed, or if the clinician suspects that the BIS™ value does not align with the clinical assessment of the patient. This option is available only when a BISx module and a sensor are connected to the monitor or when the monitor is in DEMO mode. (In the latter case, this is just for demonstration purposes.)

Click the **Sensor Check** button in the left bar menu (on the left side of the screen) to begin a sensor check. The sensor check will proceed as described in *3.6.3 Sensor Check* on page 82.

As with the automatic sensor check, if the sensor passes the sensor check, monitoring will begin automatically. If the sensor fails, monitoring will not begin, and the sensor should be replaced. An on-screen message will display this information.

3.6.3.2.Ground Check and Combined Sensor Check

The monitor automatically performs a ground check every ten minutes during monitoring, to ensure that the sensor is positioned correctly on the patient. During the ground check (duration approximately 5 seconds), EEG values will not be collected, but the BIS™ value will continue to be displayed. If the results of the ground check indicate a problem with the sensor, an on-screen message will display this information; if there is no issue, monitoring will resume automatically.

Combined sensor check mode is the performance of ground check and sensor check at the same time. The monitor automatically performs this combined check during monitoring. If the results of the ground check indicate a problem with a specific electrode on the sensor, an on-screen message will display this information (so that this can be corrected, perhaps by adhering that sensor section better to the patient); if there is no issue, monitoring will resume automatically.

3.6.4. Case ID

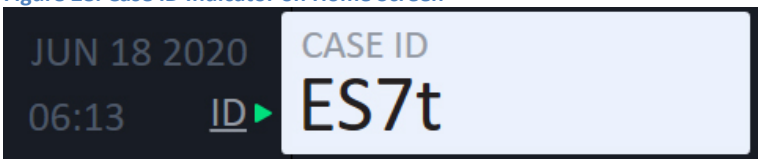
A unique Case ID will be generated automatically by the BISx module when a sensor is attached to the system and passes the sensor check.

To view the current Case ID, click on the ID icon or the small arrow to its right; it appears just to the right of the time on the upper right side of the screen. The ID window will open, displaying the Case ID. If required, record the Case ID in your institutional records. This window will automatically close in one minute. In *Figure 28. Case ID Indicator on Home Screen*, below, the ID window is seen next the ID icon.

If there is no sensor connected to the BIS™ system, no Case ID is assigned and the ID window is disabled and cannot be viewed.

If a sensor is attached to the system, and then detached and re-attached, the monitor will automatically resume the case with the same Case ID.

Figure 28. Case ID Indicator on Home Screen



3.6.5. Start Procedure

To start the monitor, press and hold the ON/OFF button at the lower right side of the monitor for up to 3 seconds. The system will indicate that it is initializing.

If no BISx module is connected to the monitor, the monitor will indicate **Connect BISx to start monitoring**. In this case, the operator can enter Demo mode or review recorded case data in Case Review mode. Monitoring cannot take place without a BISx module. If a BISx module is connected without a sensor, the system will indicate **Connect sensor to start monitoring**.

In a case where the system identifies that a BISx module and a sensor have been connected, the system shall perform sensor initialization and a sensor check. If the sensor is supported (reference *Table 33. BIS™ Advance Monitor Components and Sensors* on page 252) and impedance values are in the acceptable range, the system shall display patient data based on the information collected by the sensor. If there are issues that prevent the system from reading information from this sensor, an on-screen message will display this information.

Monitoring will now commence. After the sensor has been connected, make any desired changes in settings, such as setting alarm limits. Reference *4.3.7 Changing Alarms Settings* on page 168 for alarm settings or *3.15 Settings and Maintenance* on page 128 for other settings. The settings set when a sensor is connected will remain valid for that sensor (i.e., that case), but the system will revert to institutional defaults when another sensor is connected and another case starts.

3.6.6. Terminating Monitoring with the Monitor

In most use case scenarios, the caregiver will terminate monitoring with the BIS™ system when BIS™ monitoring is no longer needed for the patient, as the patient starts to awaken.

If the patient is no longer sedated, the parameters will indicate that status. To end the case and terminate monitoring, remove the sensor from the patient and disconnect the sensor from the monitor.

Record the Case ID and download any relevant patient data (reference *5.4 Types of Exported Data* on page 188) to ensure that your documentation is complete.

Press the ON/OFF button at the front of the monitor. (Reference *Figure 3. The BIS™ Monitor* on page 44 for the location of this button.) If you press the button for 1.5 seconds, a dialog box will ask if you want to shut down, restart or cancel the action.

Click **Shutdown** to shut down the monitor. If you press the ON/OFF button for 4 seconds, the monitor will shut down without requiring a response in the dialog box.

3.7. Home Screen

The BIS™ standard graphical home screen includes four main screen sections, as follows:

1. Trend Section: The screen may display one trend that covers most of the screen, or display two or three trends on the screen at the same time. For the two-channel system, the default display is a two-trend display in which the upper trend section will display the BIS trend, and the lower trend section will display the EEG waveforms. Selection of other options for this section can be done via **Main Menu**>**Display Settings**>Select desired trend>**Apply**>close window. Reference *3.12 Home Screen Options* on page 121 for more information. The trend section is generally viewed in graph format as described in *3.9 Home Screen Trend Graphs* on page 96 . The trend section of the screen may also be viewed in chart format; for more information, reference *4.4 Chart Data* on page 173.

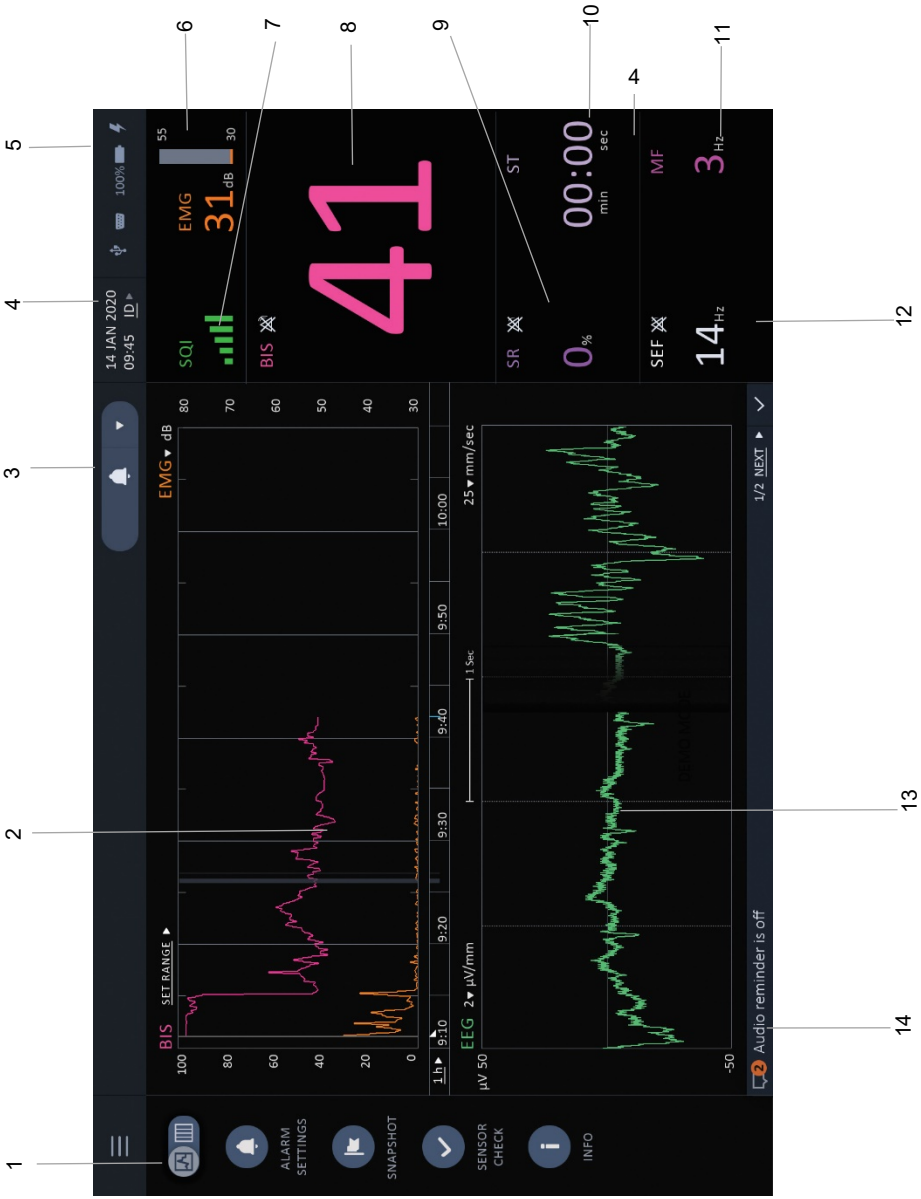
2. Numeric section: The numeric section, which always appears at the right side of the screen, will differ based on the type of monitoring taking place; the display will appear as seen in Figure *29. Sample 2-channel BIS™ Screen* on page 90 for 2-channel monitoring, and will appear as seen in *Figure 30. Sample 4-channel BIS™ Screen* on page 94 for 4-channel monitoring. This section will show real-time BIS parameters, indicating parameter name, number and alarm range numbers (alarm range will be seen only if an alarm has been set) for each parameter. For two-channel monitoring, the values shown will be BIS, SQI, EMG, SR, ST, SEF and MF, as well as BURST count if using an Extend sensor. For 4-channel monitoring, BIS, SQI, EMG, SR, ST, SEF, MF, BURST count and ASYM data will also be shown. For more information about these values and their meaning, reference *1.10 The BIS™ Advance Parameters* on page 29.

3. Title/top bar section: The title/top bar section will indicate the date and time, the Case ID, and alarm and connections status. Reference *3.14 Home Screen Audio Alarm Settings* on page 126 and *3.10.9 Home Screen Indicators and Messages* on page 114 for more information about alarms and connections indicators.

4. Bottom message bar: The bottom message bar will show one or more messages initiated by user activity and or displayed by the system. If there

is more than one message, they will appear in succession, and a message count will appear at the right side of the message bar. To view the next message more quickly, click the **NEXT** button on the right side of the message bar. For a list of messages that may appear in this section of the screen, reference *Table 13. Information Messages* on page 153.

Figure 29. Sample 2-channel BIS™ Screen



Label	Function	Description
1	Left menu bar	Reference *3.11.2 Left Bar Menu* on page 118
2	BIS™ graph	Reference *3.9.1 BIS Trend Graph* on page 96
3	Audio alarm indicators area	Reference *3.14 Home Screen Audio Alarm Settings* on page 126
4	Case ID information	Reference *4.2 Cases* on page 138
5	Indicators area	Reference *3.10.9 Home Screen Indicators and Messages* on page 114
6	EMG numeric	Reference *3.10.2 EMG* on page 107
7	SQI indicator	Reference *3.10.3 SQI (Signal Quality Indicator)* on page 108
8	BIS™ numeric	Reference *3.10.1 BIS™ Number* on page 106
9	SR numeric	Reference *3.10.5 SR (Suppression Ratio)* on page 110
10	ST numeric	Reference *3.10.6 ST (Suppression Time)* on page 111
11	MF numeric	Reference *3.10.8 MF* on page 113
12	SEF numeric	Reference *3.10.7 SEF* on page 112
13	EEG graph	Reference *3.9.3 EEG* on page 98
14	Message bar	Reference *4.3.3 Messages* on page 152
Not seen	Burst count (not seen; appears only when	Reference *3.10.4 Burst Count* on page 109

Label	Function	Description
	using an Extend sensor or monitoring with four-channel monitoring)	

3.8. Four-Channel Monitoring

The monitor provides the option of monitoring both hemispheres of the brain, using a Bilateral sensor. This is known as four-channel or bilateral monitoring. The option may provide useful information to the clinician.

The bilateral system consists of the BIS™ Advance monitor, the BISx4 module, the PIC-4 (which is an integral part of the BISx4 module) and a BIS™ Bilateral Sensor. This section describes the additional features and options available when performing four-channel monitoring.

During four-channel monitoring, the BIS™ Advance monitor acquires four channels of EEG data, calculates BIS numbers and other variables for the left and right sides of the brain, and reports them to the monitor for display. The user selects which side of the brain is shown most prominently on the screen.

The designation '**L**' (left) or '**R**' (right) denotes which side of the brain is displayed. In addition, data from the left side of the brain display in pink, while data from the right side display in blue. BIS is calculated the same way as for the two-channel sensors (e.g. Quatro), using two EEG channels from the left side of the brain for BIS L and two EEG channels from the right side for BIS R.

If a Bilateral sensor and a BISx4 module are connected to the monitor, the monitor will detect the sensor and automatically move to four-channel monitoring mode. The four-channel (bilateral) screen (reference *Figure 30. Sample 4-channel BIS™ Screen* on page 94) will provide information on both hemispheres of the brain, as follows:

A **L/R** button (

) enabling the selection of the hemisphere which will be displayed more prominently will appear on the upper left side of the screen under the menu button. Some data will appear for both hemispheres no matter which hemisphere is selected with this button, while other information will appear only for the selected hemisphere. By default, the left hemisphere is selected for more prominent display.

The BIS graph will display the left hemisphere by default; if the right hemisphere is selected with the **L/R** button, it will display the right hemisphere.

If selected, the ASYM graph will display the left side at the top of the graph and the right side at the bottom of the graph.

The EEG graph will display the left side at the top of the graph and the right side at the bottom of the graph.

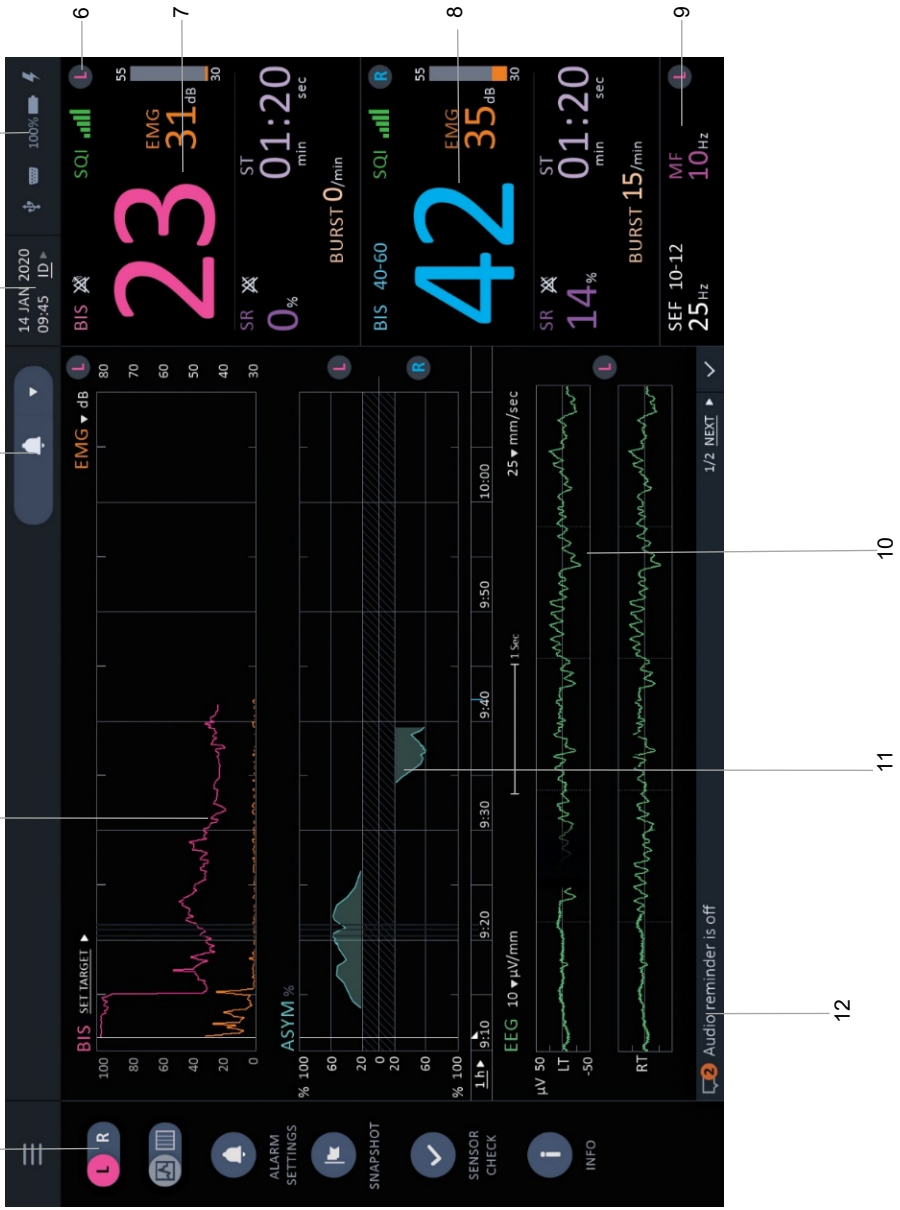
The upper numeric panel (BIS, EMG, SR and ST) will display data from the left hemisphere.

The middle numeric panel (BIS, EMG, SR and ST) will display data from the right hemisphere.

The lower numeric panel (SEF and MF) will display left or right hemisphere data, depending on the selection of hemisphere in the L/R button at the top left side of the screen (under the main menu button).

Note the L and R indicators in the numeric panel next to the numeric values, indicating the hemisphere to which these values refer.

Figure 30. Sample 4-channel BIS™ Screen



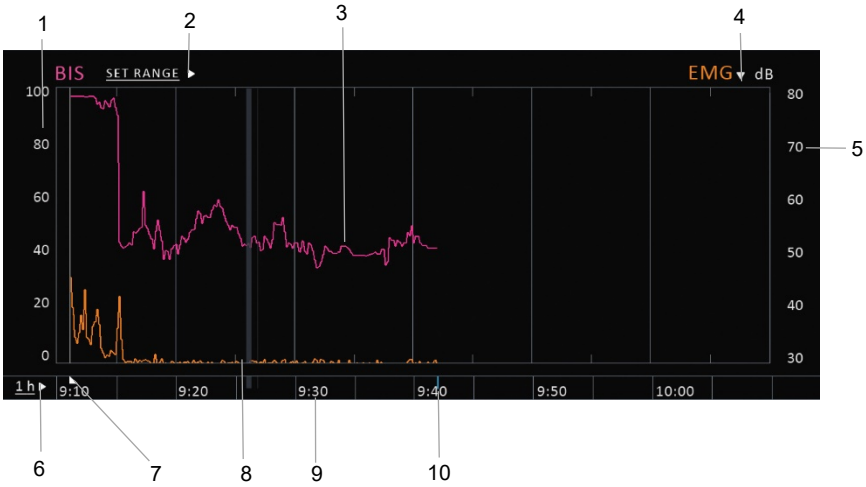
Label	Function	Description
1	Left menu bar	Reference *3.11.2 Left Bar Menu* on page 118. Note the L/R icon at the top of the menu bar, just under the Main Menu icon.
2	BIS™ graph	Reference *3.9.1 BIS Trend Graph* on page 96
3	Audio alarm indicators area	Reference *3.14 Home Screen Audio Alarm Settings* on page 126
4	Case ID information	Reference *4.2 Cases* on page 138
5	Indicators area	Reference *3.10.9 Home Screen Indicators and Messages* on page 114
6	Hemisphere indicator	L hemisphere indicator, indicating that the data in this section is derived from the left hemisphere
7	Upper numeric panel	BIS, EMG, SR and ST data from the left hemisphere. Note L hemisphere indicator.
8	Middle numeric panel	BIS, EMG, SR and ST data from the right hemisphere. Note R hemisphere indicator.
9	Lower numeric panel	SEF and MF data from left or right hemisphere (depending on user selection). Note L hemisphere indicator.
10	EEG graph	Reference *3.9.3 EEG* on page 98
11	ASYM graph	Reference *3.9.5 ASYM Graph* on page 102
12	Message bar	Reference *4.3.3 Messages* on page 152

3.9. Home Screen Trend Graphs

3.9.1. BIS Trend Graph

The BIS trend graph is provided as a default graph on the monitor main screen, both in the 2-channel and 4-channel systems. This graph enables the user to view changes in the BIS value for the patient over time, which is useful in patient monitoring. This information provides added value for the caregiver, beyond the BIS number that appears on right side of the screen.

Figure 31. BIS Trend Graph



Label	Function	Description
1	BIS scale	Left side vertical Y axis showing BIS scale, from 0 to 100
2	BIS SET RANGE selection arrow	Selection arrow to select BIS alarm limit range (will open the same window as the **ALARMS>BIS** selection opens)
3	BIS trend line	BIS value at each point of time on the graph

Label	Function	Description
4	Secondary variable drop-down arrow	Selection drop-down arrow to select secondary variable to appear on BIS graph (will open the same window as the **Display Settings**>**BIS** graphs> **Secondary** section opens); see description below
5	Secondary variable scale	Right side vertical Y axis indicating the scale of the secondary variable, in this case EMG in orange
6	Display time scale selection	Indication of time scale in current use and drop-down arrow for selection of scale; options are 1hr, 6hr, 12hr, and 24hr. When the time scale is changed, this affects all graphs on the screen (for example, BIS, DSA and ASYM). The EEG display is not affected by a time scale change.
7	Monitoring start indicator	Indicator showing the time of monitoring start
8	Secondary variable trend line	Secondary trend value at each point of time on the graph (will be seen if a secondary value is selected). This graph shows the EMG trend line in orange.
9	Time scale	Horizontal X axis showing time scale
10	Current time cursor	Small blue vertical line on the horizontal axis indicates the current time of monitoring

3.9.2. Secondary Variables

One of the following secondary variables can be overlaid onto the BIS trend graph. When this is done, the BIS trend graph shows both the BIS™ trend and the secondary variable trend. The secondary variable options are:

- EMG
- Suppression ratio (SR)
- Signal quality (SQI)
- Burst count (for bilateral and Extend sensors only) (BURST)
- BIS number of the non-selected hemisphere (for 4-channel mode only)

The user can also choose **NONE** for the secondary variable; in this case, no secondary variable will be shown on the BIS™ trend graph, and no secondary variable scale will be seen on the right Y axis of the graph. Reference *Figure 48. Secondary Trend Selection* on page 126.

When a secondary variable is displayed on the BIS trend, the vertical Y axis scale for the secondary variable is displayed on the right side of the graph, while the BIS scale is displayed on the left side. The color of the secondary variable trend line on the graph and its vertical Y axis scale will match, and will differ from the BIS trend graph and scale color, to enhance clarity.

To select a secondary variable, open the secondary variable drop-down menu that can be reached by the following methods:

- **Main Menu**>**Display Settings**>select a trend display that includes the BIS graph>**Secondary** drop-down menu>select your preferred secondary variable>click **APPLY**.
- **BIS trend** graph on home screen>**EMG** (or currently selected secondary variable) drop-down menu>select your preferred secondary variable

Any change made with either of these methods will be reflected in all BIS trend screens.

For an example of a secondary variable on the BIS graph, reference *3.9.1 BIS Trend Graph* on page 96.

3.9.3. EEG Display

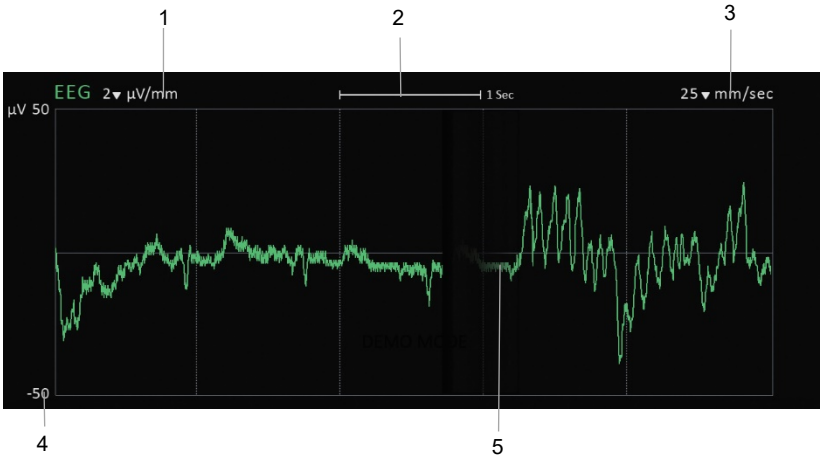
The EEG display is provided to enable the caregiver to view raw EEG data.

On the home screen, the user can select one of the following EEG scales: 2, 5, and 10 [µV/mm]. When a 2 µV/mm scale is used, only one EEG channel is seen on the graph; with other scales, 2 channels are seen. Not all scales are available in all screen layouts.

By default, the graph's default display will show EEG amplitude of up to 50 microVolt (µV); in full screen EEG layout (when only the EEG display is seen on the home screen) the display can show an EEG amplitude of up to 100 microVolt (µV).

The scale and amplitude can also be adjusted in the **Settings and Maintenance**>**Settings**>**Advanced**>**EEG Trends** section.

Figure 32. EEG Display



Label	Function	Description
1	EEG scale	Display of EEG scale in use on display
2	Area of one second on trend graph	Indicates the width of 1 second of data on the displayed graph
3	EEG sweep speed indicator and drop-down arrow	Indicator of current EEG sweep speed and selection arrow to select

Label	Function	Description
4	Y axis	Y axis showing the EEG amplitude
5	EEG trend line/s	One EEG trend line is seen if scale is 2µV/mm; with other scales, one graph will be displayed for each channel

3.9.4. DSA Display

To display DSA on the home screen, select a display option that includes DSA as described in *3.12 Home Screen Options* on page 121.

The DSA reflects the EEG as a function of frequency (in Hz, on the Y vertical axis), time (on the X horizontal axis), and power (indicated by color).

Blue shading indicates low EEG power and red shading indicates high EEG power. The color guide at the top of the DSA graph provides detailed shading information. Power indicates the strength of a particular frequency in the EEG signal, so, for example, if the DSA graph shows red shading at a specific frequency, say at the Delta wave frequency, it would mean that the EEG signal is largely composed of Delta waves at those points that show red (that is, high power) shading.

The frequency range (bandwidth) indicated by the DSA graph on the Y axis is 0.5 - 30 Hz, with each vertical line corresponding to frequencies for Delta (0.5-4Hz), Theta (4-8Hz), Alpha (8-13Hz) and Beta (13-30 Hz) waves respectively. For the 4-channel system, the graph is shown for each brain hemisphere.

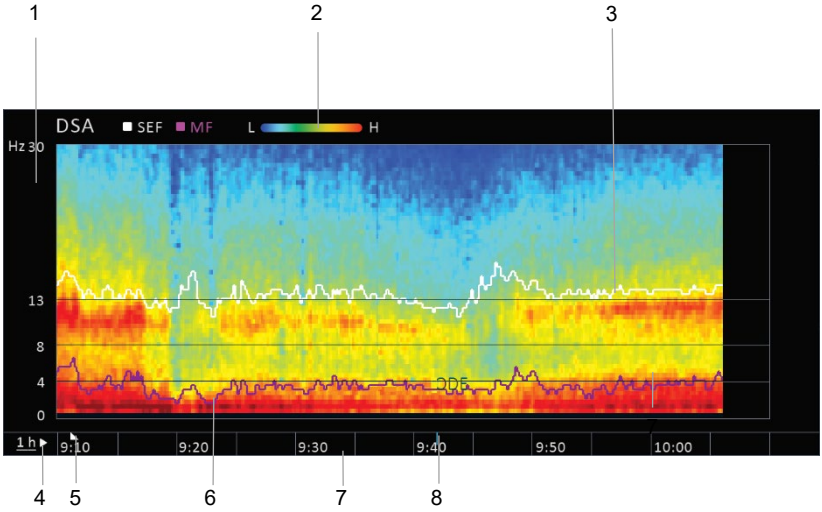
The DSA graph also displays the MF and SEF trend lines:

MF is the line under which 50% of the EEG power lies. This information helps identify the frequency of the EEG signal.

SEF is the line under which 95% of the EEG power lies. This information helps identify the dominant frequency/s of the EEG signal.

In four-channel monitoring, a DSA graph is displayed for each hemisphere.

Figure 33. DSA Trend Display



Label	Function	Description
1	Y vertical axis - frequency	The vertical axis indicates the frequency of the EEG signal in Hz.
2	Power legend	Legend explaining the colors demonstrating the level of power; blue indicates lower power and red lighter power.
3	Spectral Edge Frequency (SEF)	The white line on the graph indicates the SEF, the line under which 95% of the EEG power lies.
4	Time scale drop-down menu	Use the small arrow next to the time scale indicator to change the time scale of the graph. Options are 1 hours, 6 hours, 12 hours, and 24 hours. When the time scale is changed, this affects all graphs on the screen (for example, BIS, DSA and ASYM).

Label	Function	Description
		The EEG display is not affected by a time scale change.
5	Case start indicator	The small grey triangle on the horizontal axis time line indicates the case start, if the case start occurred during the period seen on the screen
6	Median Frequency (MF)	The purple line on the graph indicates the MF, the line under which 50% of the EEG power lies.
7	X horizontal axis - time	The horizontal axis indicates the time at each point on of the DSA graph
8	Current time indicator	Small blue vertical line on the horizontal axis indicates the current time of monitoring

3.9.5. ASYM Graph

To display ASYM on the home screen, select a display option that includes ASYM as described in *3.12 Home Screen Options* on page 121.

ASYM is the asymmetry between EEG power between the left and right hemispheres of the brain, over time. The value provided is calculated as EEG power present in the one hemisphere as compared to total (left and right) EEG power.

ASYM is displayed on the graph as a value between 100 left and 100 right. Asymmetry data less than 20% are not displayed on the graph, but are available in the Chart Data screen.

In a situation in which EEG power is equivalent in both hemispheres of the brain, ASYM = 0. A value with the indicator LEFT, for example, 70% LEFT, indicates that the left hemisphere has more power, and a value with the indicator RIGHT indicates that the right hemisphere has more power.

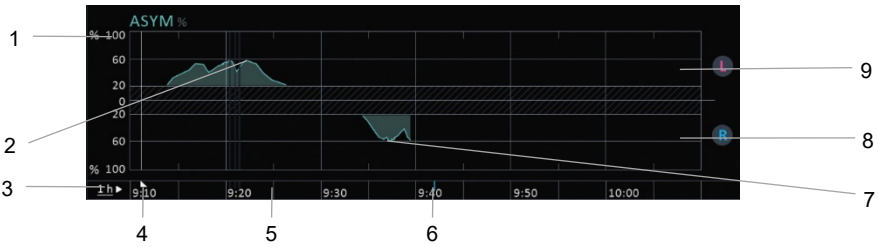
In the graph, ASYM values are shown at each point in time. Thus, the ASYM value can appear either in the upper (left) part of the graph, indicating that most of the EEG power resides in the left hemisphere, or in the lower (right) part of the graph, indicating that most of the power resides in the right hemisphere.

ASYM is displayed only for four-channel monitoring.

Two examples are show in *Figure 34. ASYM Graph* on page 103:

- A value of 60 LEFT for ASYM at a certain point in time would mean that the EEG power in the left hemisphere is 60% higher than it is in the right hemisphere at that point in time. On the graph, it would be displayed as a peak at the line representing the level of 60 in the upper part of the graph; the upper part of the graph is indicated by an L icon, representing the left side of the brain.
- A value of 32 RIGHT for ASYM (at a different point in time) would mean that the EEG power present in the right hemisphere is 32% higher than it is in the left hemisphere at that point in time. On the graph, it would be displayed as a trough at the line representing the level of 32 in the lower part of the graph; the lower part of the graph is indicated by a R icon, representing the right side of the brain.

Figure 34. ASYM Graph



Label	Function	Description
1	Y vertical axis - percent	The Y vertical axis indicates the power of the EEG signal, with lines indicating levels for power in each hemisphere. The ASYM value can appear either in the upper (left) part of the graph, indicating that most of the EEG power resides in the left hemisphere, or in the lower (right) part of the graph, indicating that most of the power resides in the right hemisphere.
2	60 LEFT indicator	Indicates a point at which the EEG power in the left hemisphere is 60% higher than the EEG power in the right hemisphere

3	Time scale drop-down menu	Use the small arrow next to the time scale indicator to change the time scale of the graph. Options are 1 hours, 6 hours, 12 hours, and 24 hours. When the time scale is changed, this affects all graphs on the screen (for example, BIS, DSA and ASYM). The EEG display is not affected by a time scale change.
4	Case start indicator	The small grey triangle on the horizontal axis indicates the case start (not seen on this screen)
5	X horizontal axis - time	The horizontal axis indicates the time at each point on the ASYM graph
6	Current time indicator	The small blue vertical line on the horizontal axis indicates the current time
7	60 RIGHT indicator	Indicates a point at which the EEG power in the right hemisphere is 60% higher than the EEG power in the left hemisphere
8	Right hemisphere data	ASYM data for the right hemisphere. The waveform will appear in this section when the EEG power in the left hemisphere is at least 20% higher than the EEG power in the left hemisphere.
9	Left hemisphere data	ASYM data for the left hemisphere. The waveform will appear in this section when the EEG power in the left hemisphere is at least 20% higher than the EEG power in the right hemisphere.

3.10. Home Screen Numeric Section

The home screen numeric section, seen in *Figure 35. Home Screen Numeric Section*, below, displays the parameters listed in this section.

Figure 35. Home Screen Numeric Section

Label	Function	Description
1	SQI data	Reference *3.10.3 SQI (Signal Quality Indicator)* on page 108
2	EMG data	Reference *3.10.2 EMG* on page 107
3	BIS data	Reference *3.10.1 BIS™ Number* on page 106
4	SR data	Reference *3.10.5 SR (Suppression Ratio)* on page 110
5	ST data	Reference *3.10.6 ST (Suppression Time)* on page 111
6	SEF data	Reference *3.10.7 SEF* on page 112
7	MF data	Reference *3.10.8 MF* on page 113
8 (not seen)	Burst Count data	Not seen; only seen in use with an Extend sensor. Reference *3.10.4 Burst Count* on page 109.

3.10.1. BIS™ Number

The BIS™ number is a processed EEG value representing the depth of sedation.

The current BIS™ number is displayed in the numeric section of the home screen, as one number for the 2 channel mode, and as two numbers, for the left and right hemispheres, for the 4-channel mode.

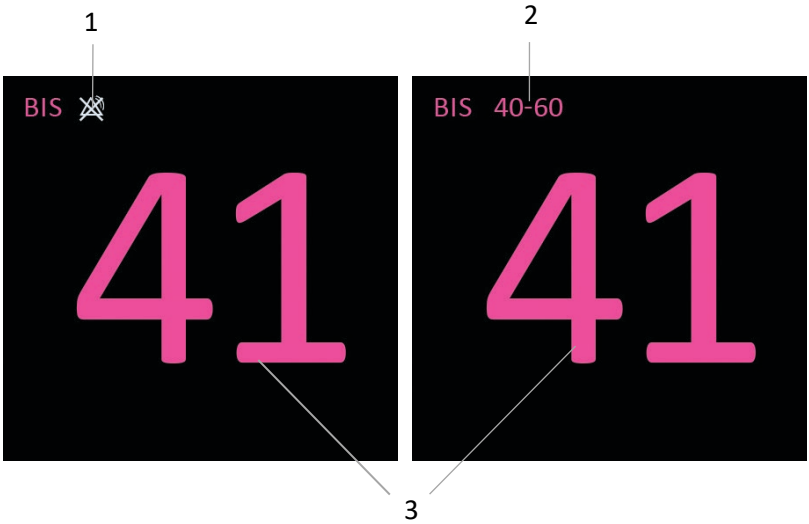
The user may set a BIS range alarm, which sets the system to alarm if the patient's BIS™ value falls below or exceeds the set range. For example, if the range is set at 40-60, a BIS™ value of 35 or of 70 will trigger the BIS range alarm.

To set this alarm, reference *4.3.7 Changing Alarms Settings* on page 168.

If the BIS™ target range alarm is enabled, the BIS™ target range will appear next to the numeric. If the alarm is disabled, the alarm disabled icon will appear instead of the target range.

If measuring with a 4-channel system, the BIS display will appear for each hemisphere.

Figure 36. BIS Numeric



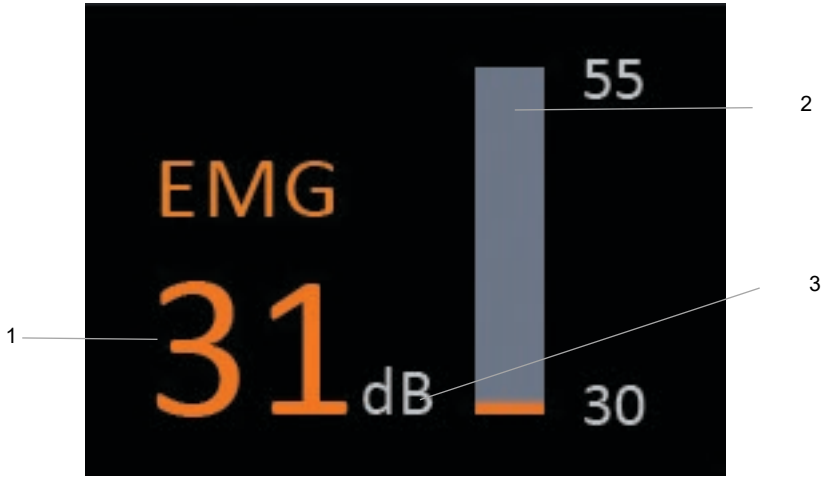
Label	Function	Description
1	BIS disabled icon	If range alarm is disabled, the Alarm Disabled icon will be displayed
2	BIS range	Current BIS range; this will be displayed only if BIS range alarm has been enabled
3	BIS numeric	Current BIS value of patient

3.10.2. EMG

EMG is displayed with three indicators: as a numerical value, as a bar (30-55 dB), and, if selected as a secondary trend on the BIS graph, as a trend (30-80 dB) in the form of a solid orange line.

To view the EMG trend line, see *3.9.1 BIS Trend Graph* on page 96.

Figure 37. EMG Display on Home Screen



Label	Function	Description
1	EMG numeric	EMG numeric
2	EMG bar	Displays EMG in graphic format
3	EMG units	Units in which EMG is measured

If measuring with a 4-channel system, the EEG display, including both the numeric and the bar, will appear for each hemisphere.

3.10.3. SQI (Signal Quality Indicator)

SQI appears on the home screen on the main monitoring screen, as a graphical indicator, displayed as one SQI indicator for 2 channel mode, and as two SQI indicators, for the left and right hemispheres, for 4-channel mode. SQI is indicated in graphic format and can range from 0-100 percent. It can also be displayed as a solid green line on the BIS trend graph (0-1000 dB), if selected as a secondary trend on the BIS trend graph.

Figure 38. SQI Indicator

A high SQI will be indicated by five complete green bars, as seen in the figure above. Lower values will be indicated by fewer green bars, two orange bars (denoting excessive artifacts in the EEG signal), or one red bar only (denoting a very low SQI value).

If measuring with a 4-channel system, the SQI display will appear for each hemisphere.

3.10.4. Burst Count

Burst count is displayed with two indicators: as a numerical value, and as a trend, if selected as a secondary trend on the BIS graph.

Burst count is activated by connection of an Extend Sensor or Bilateral Sensor. Thus, the burst count will appear as a numeric and become available as an option for a secondary trend on the BIS graph only when an Extend or Bilateral sensor is used.

If measuring with a 4-channel system, the Burst Count display will appear for each hemisphere.

Figure 39. Burst Count Numeric

Label	Function	Description
1	Burst Count numeric	Burst Count numeric
2	Burst units	Units in which Burst Count is displayed

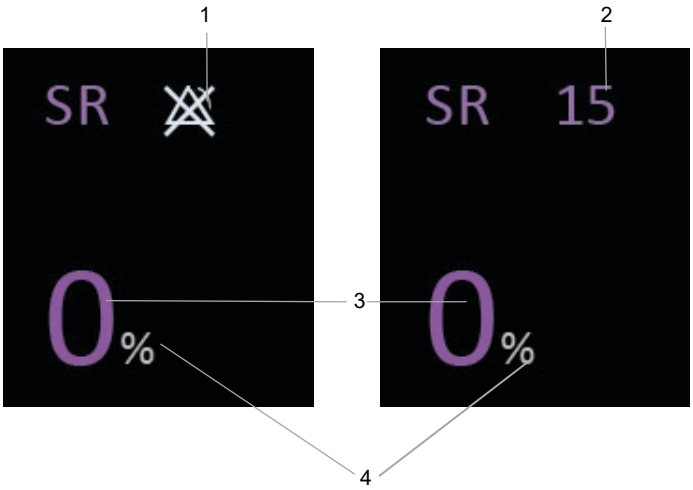
3.10.5. SR (Suppression Ratio)

SR is displayed as a numeric in percent units, and, if selected as a secondary trend on the BIS trend graph, also as a solid purple line on the BIS trend graph (0-100%).

If an SR alarm limit is set, the SR limit will be displayed as a dashed purple line on the BIS trend graph, and the SR limit will be displayed near the SR Label. The SR limit is an SR high limit; if SR surpasses the level set in the alarm limit, an alarm will be triggered.

For 4-channel monitoring, two SR Numbers, for the left and right hemispheres, will be displayed.

Figure 40. SR Display on Home Screen



Label	Function	Description
1	SR alarm disabled indicator	When the SR alarm is disabled, the alarm disabled icon will be displayed
2	SR alarm level	When the SR alarm is enabled, its level will be displayed
3	SR numeric	SR numeric
4	SR units	Units for SR (percent)

3.10.6. ST (Suppression Time)

ST is displayed as a time value in units of seconds and minutes (or sec, min, hr if ST time exceeds 59 minutes and 59 seconds).

The ST Number shall be displayed as a numeric on the home screen, with two ST Numbers displayed, for left and right hemispheres, for the 4-channel mode.

The ST Number value will begin at 00:00 [MM:SS] at the start of each case and move to 0:00:00 [H:MM:SS] if the case exceeds 59:59. The maximum ST that can be displayed is 9:59:59.

Figure 41. ST Display on Home Screen

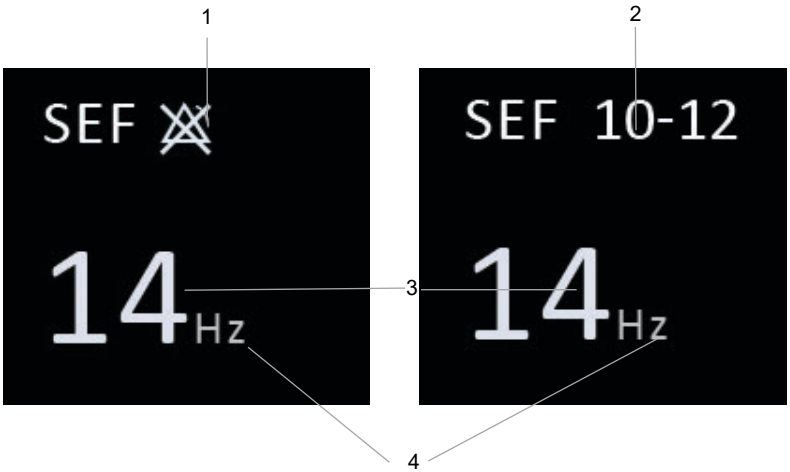
Label	Function	Description
1	ST numeric	ST numeric in minutes and seconds (and hours, if required)
2	ST unit markers	If ST is over 59 minutes and 59 seconds, an hour section will appear as well

3.10.7. SEF (Spectral Edge Frequency)

SEF, the Spectral Edge Frequency (indicated in Hz) , is displayed as a numeric in the numeric section and as a white line on the DSA graph. If no SEF range is set, the alarm disabled icon will appear; if an SF range is set, the alarm range will appear and an alarm will be triggered if the SEF is too high or too low.

For 4-channel mode, the Left SEF Number or Right SEF Number shall be displayed, according to the user's selection of the brain hemisphere side.

Figure 42. SEF Display on Home Screen



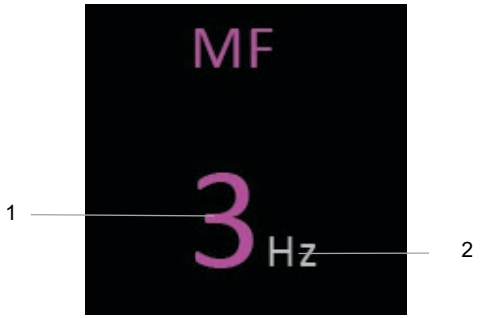
Label	Function	Description
1	Alarm disabled icon	Since no alarm is set, an alarm disabled icon will appear
2	SEF alarm range	Alarm range will display when an alarm is set
3	SEF numeric	SEF numeric in Hz
4	SEF units	SEF unit is Hz

3.10.8. MF (Median Frequency)

MF (Median Frequency) (indicated in Hz) represents the frequency below which 50% of the total EEG power lies. It is displayed as a purple line on the DSA graph.

The MF Number is displayed at the bottom of the numeric section of the home screen in 2-channel mode; for the 4-channel mode, the Left MF Number or Right MF Number shall be displayed at the bottom of the numeric section, according to the selected brain hemisphere.

Figure 43. MF Numeric



Label	Function	Description
1	MF numeric	MF numeric in Hz
2	MF units	MF unit is Hz

3.10.9. Home Screen Indicators and Messages

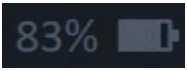
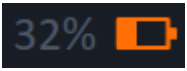
The monitor provides a number of power and connectivity indicators on the top bar of the home screen, as described in *Table 5. Home Screen Indicators*, below.

At the bottom of the home screen, monitor messages are displayed. If more than one message is active, the messages will appear consecutively, with an indicator on the icon and at the right that another message is also available.

Both the top bar and the monitor messages can be seen in the home screens displayed in *Figure 29. Sample 2-channel BIS™ Screen* on page 90 and *Figure 30. Sample 4-channel BIS™ Screen* on page 94.

Table 5. Home Screen Indicators

Icon	Description
Icons on indicators bar at the top of the screen	
	USB flash drive is connected
	Monitor is connected to the docking station and communicating via the RS-232 (serial) port
	RS-232 (serial) port connection not identified by monitor; either tablet is not docked in the docking station, or tablet is docked in docking station but the monitor does not identify RS-232 port connection

	Power cable is connected
	Current battery capacity
	Battery is charging
	Battery is installed, but not charging; charge is over 50%
	Battery is installed, but not charging; charge is 25% to 50%
	Battery is installed, but not charging; charge is under 25%
	The monitor is currently recording a live case
Icons on message bar at the bottom of the screen	
	Message active (in this case, 2 messages are active)

3.11. Home Screen Menus

3.11.1. Main Menu Settings

To access the main menu, click on the Main Menu icon at the top left side of the touch screen.

Figure 44. Main Menu Icon

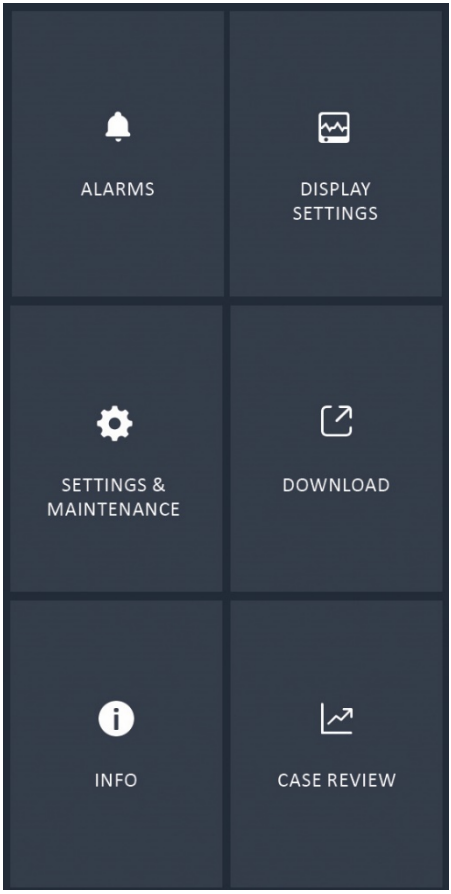
The main menu will open a drop-down menu, with options as described in *Table 6. Main Menu Selections*, below.

Using the touch screen, select the desired sub-menu.

Table 6. Main Menu Selections

Menu Button	Description
ALARMS	Set alarm settings, including alarm enabling and disabling, alarm limits, alarm volume, and audio off reminder. For a description of alarms options, reference *4.3.7 Changing Alarms Settings* on page 168.
DISPLAY SETTINGS	Select desired display setting; reference *3.15.3.5 Display Settings* on page 134 for more information.
SETTINGS & MAINTENANCE	Set various settings and maintenance options; for a full list of options, reference *3.15 Settings and Maintenance* on page 128.
DOWNLOAD	Download using **Live Case** recording, **Monitor Saved Cases**, or **BISx Saved Cases** download options. Download options are described in *5 Data Storage, Transfer, and Export* on page 186.
INFO	Permits opening of Demo Mode and describes various BIS parameters. For more information, reference *3.16 Info Options* on page 135.
CASE REVIEW	Permits Case Review; for more information, reference *4.2.2 Case Review* on page 139.

Figure 45. Main Menu on Home Screen



If no sensor is connected to the BISx module connected to the monitor, or if no BISx module is connected, all of these options are available.

In monitoring mode, that is, when a BISx module and a sensor are attached to the system, the Alarms and Case Review sub-menus are disabled.

In Demo Mode, the Download and Case Review sub-menus are disabled.

3.11.2. Left Bar Menu

The left menu bar provides quick access to some important features directly from the home screen. It includes the options listed in *Table 7. Home Screen Left Menu Bar Icons*, below:

Figure 46. Left Bar Menu

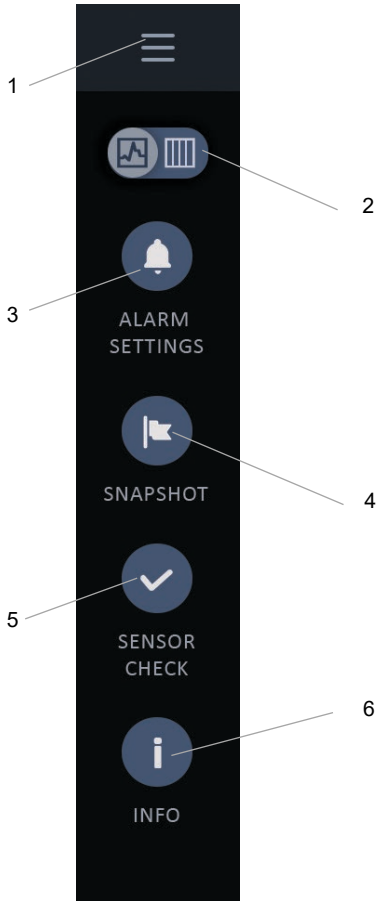


Table 7. Home Screen Left Menu Bar Icons

Label	Function	Description
1	Main Menu button	Opens the main menu, described in *3.11.1 Main Menu Settings* on page 115
2	Trend view toggle button	Toggles the screen view from graph view to a data chart view
3	ALARMS	Opens the Alarm setting window; for more information, reference *4.3.7 Changing Alarms Settings* on page 168.
4	SNAPSHOT	Enables recording of a Snapshot; for more information, reference *5.7 Recording a Snapshot* on page 195. Note that the SNAPSHOT option is not available in Demo Mode.
5	SENSOR CHECK	Starts the sensor check process; for more information about sensor check, reference *3.6.3 Sensor Check* on page 82.
6	INFO	Opens the **INFO** window; for more information, reference *3.16 Info Options* on page 135.
7	EXIT DEMO MODE (not seen)	This button will appear only if the monitor is in Demo Mode; in that case, use this button to exit Demo Mode.

3.11.3. Alarm Status Displayed on Home Screen

On the home screen, an indicator will provide the alarm status, as follows:

Parameter	Indicator	Meaning
Alarm Enabled		
BIS target range	BIS target range seen in numeric section. Message shown when alarm range exceeded.	BIS target range alarm is enabled; target range is as shown; target range stripe seen on BIS graph; message indicates that the alarm has been triggered
SR parameter	Alarm limit seen in numeric section. Message shown when alarm range exceeded.	SR alarm is enabled; SR alarm limit is as shown; message indicates that the alarm has been triggered
SEF	Alarm range seen in numeric section. Message shown when alarm range exceeded.	SEF alarm is enabled; SEF alarm range is as shown; message indicates that the alarm has been triggered
Alarm Disabled		
Alarm Disabled Indicator	 The appearance of the indicator will differ depending on the priority level of the alarm. A high priority alarm will appear with two lines to the right of the triangle and a medium priority alarm will appear with one line to the right of the triangle.	
BIS parameter range	Alarm Disabled icon seen in numeric section	BIS target range alarm is disabled
SR parameter	Alarm Disabled icon seen in numeric section	SR alarm is disabled

Parameter	Indicator	Meaning
SEF	Alarm Disabled icon seen in numeric section	SEF alarm is disabled

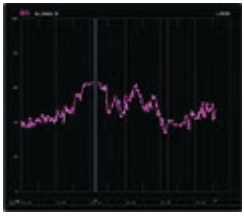
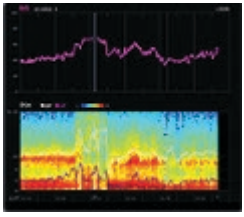
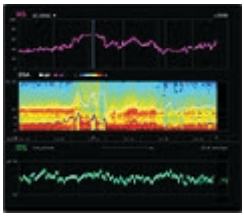
3.12. Home Screen Options

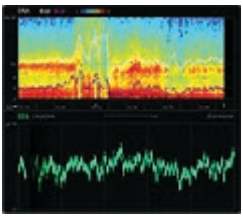
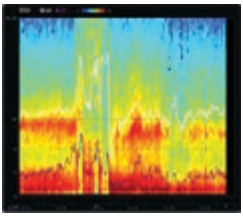
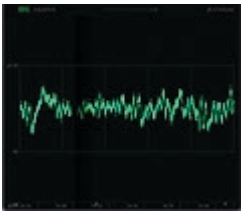
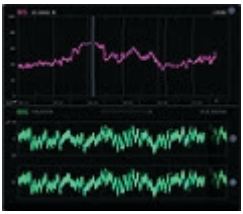
By default, the home screen will appear as seen in *Figure 29. Sample 2-channel BIS™ Screen* on page 90 or as seen in *Figure 30. Sample 4-channel BIS™ Screen* on page 94, depending on the selected type of monitoring (two-channel or four-channel). The software also provides the option to set a different layout and different parameter display for the home screen.

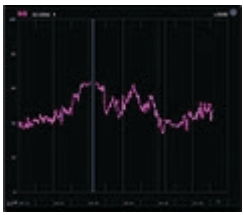
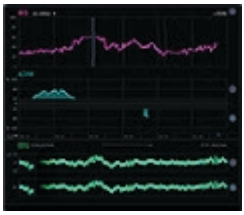
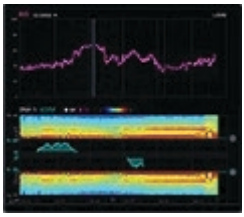
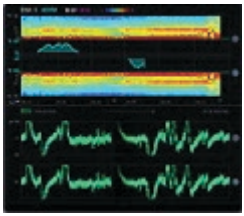
To set a different layout and parameter display, select Main Menu>**Display Settings**>select desired setting option.

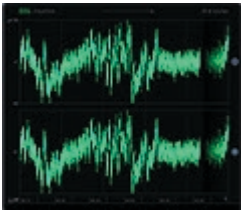
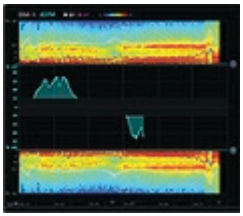
Figure 47. Display Settings Selection

Table 8. Home Screen Display Settings Options

Symbol	Display Icon	Description
Layouts for 2-channel mode:		
BIS, EEG (default layout)		The BIS and EEG trends occupy the graph/trend area, with each occupying half of the area
BIS only		The BIS trend occupies the whole graph/trend area
BIS, DSA		The BIS and DSA trends occupy the graph/trend area, with each occupying half of the area
BIS, DSA, EEG		The BIS, DSA and EEG trends occupy the graph/trend area, with each occupying a third of the area

Symbol	Display Icon	Description
DSA, EEG		The DSA and EEG trends occupy the graph/trend area, with each occupying half of the area
DSA only		The DSA trend occupies the whole graph/trend area
EEG only		The EEG trend occupies the whole graph/trend area; sometimes referred to as full screen EEG layout
Layouts for 4-channel mode:		
BIS, EEG		The BIS and EEG trends occupy the graph/trend area, with each occupying half of the area. The BIS L (left) trend will be shown by default; this can be changed to show the BIS R (right) trend. Both EEG L (left) and EEG R (right) trends are shown.

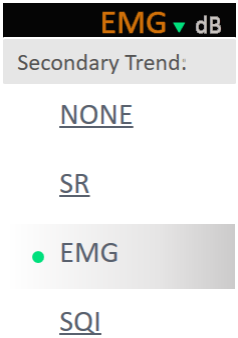
Symbol	Display Icon	Description
BIS only		The BIS trend occupies the whole graph/trend area. The BIS L (left) trend will be shown by default; this can be changed to show the BIS R (right) trend.
BIS, ASYM, EEG		The BIS, ASYM and EEG trends occupy the graph/trend area, with each occupying a third of the area. The BIS and EEG L (left) trends will be shown by default; this can be changed to show the R (right) trends.
BIS, DSA, ASYM		The BIS and DSA+ASYM trends occupy the graph/trend area, with each occupying half of the area. The ASYM graph is shown between the two DSA graphs. The BIS L (left) trend will be shown by default; this can be changed to show the BIS R (right) trend.
DSA, ASYM, EEG		The EEG and DSA+ASYM trends occupy the graph/trend area, with each occupying half of the area. The ASYM graph is shown between the two DSA graphs. Both EEG L (left) and EEG R (right) trends are shown.

Symbol	Display Icon	Description
EEG only		The EEG trend occupies the whole graph/trend area. Both EEG L (left) and EEG R (right) trends are shown.
DSA,ASYM		Two DSA graphs, one for each hemisphere, and the ASYM trend occupies the graph/trend area, with each occupying approximately one third of the area

3.13. Secondary Trend Selection

In screens that display the BIS™ trend, a secondary trend may also be shown on the BIS™ trend graph, so that both trend lines , the BIS™ trend line and the secondary trend line, appear on the same graph. Selection of the secondary trend is done on the Display Settings screen, by selecting **Menu>Display Settings**>select the BIS trend or, in a trend display that includes the BIS trend: Select **Secondary Trend**>click **Apply**.

Figure 48. Secondary Trend Selection



The options for the secondary trend on the BIS trend graph are **None**, **SR**, **EMG**, **SQI** or **Burst Count** (the latter only when using an Extend Sensor). For four-channel monitoring, the **BIS** value for the hemisphere not shown on the graph (R or L) or **Burst Count** can also be selected as a secondary trend.

When a secondary trend is shown on the BIS™ trend screen, the scale for that variable appears on the right side Y axis of the BIS™ trend graph, in the same color as the secondary trend. Reference *Figure 31. BIS Trend Graph* on page 96 for an example of a BIS™ trend graph displaying a secondary variable.

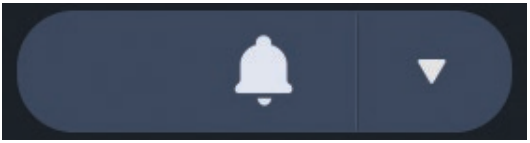
3.14. Home Screen Audio Alarm Settings

The home screen allows easy access to alarm controls, with two easy options, alarm control and expanded alarm control, both seen in figures below.

The default alarm setting is an alarm that sounds for all audio alarms.

Clicking on the bell seen in *Figure 49. Alarm Control,* below, will activate temporary alarm silence (for 120 seconds, with a count-down) with one click and permanent alarm silence with an additional click. The icons that will appear for temporary and permanent alarm silence are shown in *Table 9. Expanded Alarm Control* on page 127.

Figure 49. Alarm Control

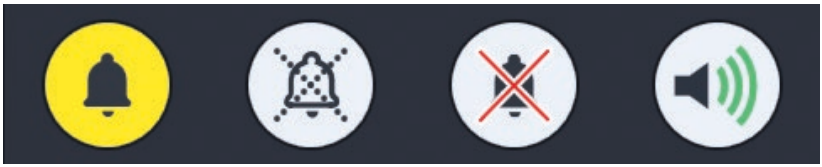


To open the expanded alarm control window, click the drop-down arrow on the right side of the window in *Figure 49. Alarm Control*, above. The options seen in *Figure 50. Expanded Alarm Control with Alarm Volume*, below, will appear. Select your desired option and click to activate.

With both methods of setting alarm silence, alarms will still continue to occur during temporary and permanent alarm silence, but an audible alarm indicator will not sound. The alarms for which the audible indicator is paused or silenced will continue to occur and will continue to be indicated by visual indicators and recorded in case records.

In the expanded alarm control window, the current audio status of the alarms will appear with a yellow background, and the other status options will appear with a white background. In the example seen in *Figure 50. Expanded Alarm Control with Alarm Volume*, below, the audio alarm status is On.

Figure 50. Expanded Alarm Control with Alarm Volume



The expanded alarm control options are as described in *Table 9. Expanded Alarm Control* , below.

Table 9. Expanded Alarm Control Icons

Symbol	Description	Details
	Alarm Audio Active	Default state with active audio alarm

	Alarm Pause (Temporary Alarm Silence)	Pauses the audio alarm for default time of 120 seconds, with countdown
	Alarm Off (Permanent Alarm Silence)	Turns off the audio alarm, until it is turned on again or device is restarted
	Alarm Volume adjustment	Opens window in which alarm volume can be adjusted

For more information about alarm settings, reference *4.3 Alarms* on page 143.

3.15. Settings and Maintenance

The monitor provides a number of settings adjustments that can be performed in the Settings and Maintenance screen by the user. Please note that these changes will be in force only for the current case or until restart of the monitor (whichever comes first). Once the monitor is shut down and restarted or a new case is started, the monitor will default to institutional Defaults.

To change institutional Settings on a more permanent basis, reference *7.3 Administrator Mode* on page 218.

WARNING: The software will reset all settings with defined default values to Institutional Defaults upon the end of each case, excluding Institutional Default Language settings. The software will also reset all settings (including language) to Institutional Defaults upon the restart of the monitor. However, if a sensor for which certain settings were set (as described in *3.15.3 Advanced User Settings* on page 131, and whether changes were performed by a user or

administrator) is re-attached, the monitor will apply the settings that were in place when that sensor was used last time.

Please note that all display settings will affect the display only, and will not affect the resolution of the patient data saved in the monitor.

3.15.1. Setting up Language, Date and Time

Enter **Main Menu**>**Settings and Maintenance**>**Settings**>**Global**>**Time and Language**.

The options that can be changed are as follows:

Feature	Options	Factory Default Option
Language	Bulgarian, Chinese, Croatian, Danish, Dutch, English, French, German, Greek, Hungarian, Italian, Japanese, Macedonian, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovenian, Spanish, Swedish	English
Date	Selection via calendar (October 26 2020 to October 26 2099) (but not before the monitor manufacture date). Available only when a BISx module is not connected.	NA
Time (hours)	0-23 or 0-11, depending on time format (available only when a BISx module is not connected)	NA
Time (minutes)	0-59 (available only when a BISx module is not connected)	NA

Date format	DD MMM YYYY, MMM DD YYYY	MMM DD YYYY
Time format	24 hours, 12 hours (AM/PM) Medtronic recommends use of the 24-hour clock option in all clinical settings, to avoid situations in which the current time may be misunderstood by users.	24 hours

Select the desired choice for each option and click **Apply**.

Please select the date and time format in common use in your locality to enhance clarity for users of the monitor.

Date and Time cannot be modified when a BISx module is connected (during active case monitoring) or during Demo Mode.

If time and/or date is changed after a case ends and the same case is resumed afterwards, an extended Case with the same Case ID and a different suffix will be created instead of a new case.

Time and Date will remain in force even when institutional defaults are restored.

3.15.2. MPM Configuration

MPM (Multi-parameter Monitor) Configuration setup can be accessed by clicking **Main Menu**>**Settings and Maintenance**>**Settings**>**Global**>**MPM Configuration**.

Under MPM Configuration Setup, the user can choose between the following serial communication port protocols:

- Binary
- ASCII
- Legacy binary

If MPM configuration is changed during a case to a configuration which is different from the factory default setting, the change will be valid only for the current active case. The factory default setting is Binary.

MPM Configuration cannot be adjusted during Demo Mode..

3.15.3. Advanced User Settings

The advanced user settings are described in the section below.

3.15.3.1. BIS Smoothing Rate Setup

This option permits the user to adjust the BIS Smoothing Rate. The factory default value is 15.

To access the BIS Smoothing Rate screen, click **Main Menu**>**Settings and Maintenance**>**Settings**>**Advanced**>**BIS Smoothing Rate**. To make changes to the BIS Smoothing Rate, make the desired changes and click **Apply** to apply the changes.

Option	Description
10	Sets BIS Smoothing Rate to 10
15	Sets BIS Smoothing Rate to 15 (default level)
30	Sets BIS Smoothing Rate to 30

When an Extend Sensor is connected to the system, the software shall automatically set the BIS Smoothing Rate to 30.

3.15.3.2. EEG Display

This option permits the user to adjust a number of parameters related to the EEG Trends graphical display, as listed below.

The EEG Trends graphical display is seen in *Figure 32. EEG* on page 99. The EEG trend parameters that can be set on the EEG Trends screen relate to this graph.

To access the EEG Trends screen, click **Main Menu**>**Settings and Maintenance**>**Settings**>**Advanced**>**EEG Trends**. To make changes to the EEG

Trends graphical display, make the desired changes on this screen and click **APPLY** to apply the changes.

The EEG Trends Graphical Display may be changed only when a sensor is attached to the monitor and the current display settings include an EEG waveform display.

Parameter	Options	Default
EEG Amplitude	+/- 50 [µV] +/- 100 [µV] (only when full screen EEG layout is selected as described in 3.12 Home Screen Options on page 121)	+/- 50 [µV]
EEG Scale	See *Table 10. EEG Display Scale Options* on page 132	See *Table 10. EEG Display Scale Options* on page 132
Number (#) of Channels	1,2,4	Depends on EEG scale and selection of 2-channel or 4-channel monitoring
EEG Filters	On/Off, using slide button to toggle	On

The software shall allow the user to choose the EEG display scale per number of channels, according to the details seen in *Table 10. EEG Display Scale Options*, below.

Table 10. EEG Display Scale Options

Display Scale	Full Screen (1:1)	Half Screen (1:2)	One Third Screen (1:3)
2 Channel Display Scale			
2 µV/mm	1 (no. of channels)	1	NA
5 µV/mm	1,2	1,2	1

Display Scale	Full Screen (1:1)	Half Screen (1:2)	One Third Screen (1:3)
10 µV/mm	1,2	1,2	1,2
4 Channel Display Scale			
2 µV/mm	1,2	1	NA
5 µV/mm	1,2,4	1,2	1
10 µV/mm	1,2,4	1,2,4	1,2

When the user applies a change to the EEG scale from the Home Screen, the same change will be displayed in the EEG scale as accessed from the Settings menu.

If filters are set, the values will be as follows:

- 2 (2.0 [Hz]) for the high pass filter
- 3 (70 [Hz]) for the low pass filter
- 3 (50 [Hz] and 60 [Hz]) for the notch filter

If the filters are OFF, no filtering shall take place.

Filter setting is set to ON each time the monitor starts up, a case ends, the user resets the monitor to Institutional Defaults (using the RESET SETTINGS button as described in *4.6 Institutional Settings* on page 180) or an administrator resets the monitor to Factory Defaults (using the RESET SETTINGS button as described in *4.6 Institutional Settings* on page 180).

3.15.3.3. Impedance

An automatic impedance check is performed by the monitor each time a sensor is connected (during auto sensor check) or during a manual sensor check. For more information, reference *7.1.3 Impedance Checking* on page 213.

The Impedance option in the Settings>Advanced menu (described in *4.6 Institutional Settings* on page 180) will permit the user to turn the automatic impedance check off or on. Impedance setting is set to ON each time the monitor starts up, a case ends,

the user resets the monitor to Institutional Defaults (using the RESET SETTINGS button as described in *4.6 Institutional Settings* on page 180) or an administrator resets the monitor to Factory Defaults (using the RESET SETTINGS button as described in *4.6 Institutional Settings* on page 180).

To enter the screen, click **Main Menu**>**Settings and Maintenance**> **Settings**>**Advanced**>**Impedance**. To change the status of this option, slide the switch left to turn **OFF** (switch will then appear grey) or to the right to turn **ON** (switch will then appear green) and click **APPLY**.

This option is available only when a sensor is attached to the monitor.

3.15.3.4. Sensor Check Values

The Sensor Check Values screen will permit the user to turn the display of sensor check values on the sensor check screen off or on. By default, display of the values is off.

To enter the screen, click **Main Menu**>**Settings and Maintenance**>**Settings**>**Advanced**>**Sensor Check Values**. To change the status of this option, slide the switch left to turn **OFF** (switch will then appear grey) or to the right to turn **ON** (switch will then appear green) and click **APPLY**.

This option is available whether or not a sensor is connected to the monitor.

3.15.3.5. Display Settings

The Display Settings screen will permit the user to select a particular trend display layout. By default, the layout for a 2-channel system is a 2-trend layout with BIS and EEG. For a 4-channel system, the default layout is a 3-trend layout with BIS, ASYM and EEG shown. The defaults can be adjusted in the Administrator Mode; reference *4.6 Institutional Settings* on page 180.

To enter the screen, click **Main Menu**>**Settings and Maintenance**> **Settings**>**Advanced**>**Display Settings**. To change the layout, click **Change**. This will open the Display Settings screen (also accessible by clicking **Main Menu**>**Display Settings**). To change the display , select a layout from the bar at left, and click **Apply**.

For a description of available layouts, reference *3.12 Home Screen Options* on page 121.

When a BIS™ trend is selected, the default secondary variable (EMG) will appear in all layouts. For more information about secondary variables, reference *3.12 Home Screen Options* on page 121.

If enabled in Administrator mode (reference *7.3.2 Administrator Mode Actions* on page 221), EEG Test layout will be an additional option available for display. This will display two EEG trends on the screen at the same time in 2-channel mode and four EEG trends in four-channel mode. The EEG Test layout will only be available until a new case is started or the monitor is turned off and restarted. While test layout is the selected display, EEG settings cannot be changed by the user.

Each trend graph can be viewed with a choice of time ranges. The selected time range of the trend display will not affect the resolution of the saved data.

3.15.3.6. Administrator Mode Login

The user can log in to the Administrator Mode in the Settings and Maintenance window, by clicking on Administrator Mode. For more information, reference *7.3 Administrator Mode* on page 218.

3.15.4. Maintenance

Enter **Main Menu**>**Settings and Maintenance**>**Maintenance**.

The available options are as follows:

- Logs: reference *5.9 Logs Export* on page 199 for more information
- Configuration: reference *6.5.2 Configuration Data on Monitor* on page 210 for more information.
- DSC Self-Test: reference *7.1.1 DSC Self-Test* on page 212 for more information.

For Administrator options under Maintenance, reference *7.3 Administrator Mode* on page 218.

3.16. Info Options

The **INFO** button on the main menu and the **INFO** button on the left menu bar both open the same window, which provides the options listed in Table 11. Info Window Options, below.

Table 11. Info Window Options

Button	Description
Demo Mode	Opens Two-channel or Four-channel Demo Mode, per user selection. For more information about Demo Mode, reference *7.3.2.2 7.4 Demo Mode* on page 223.
BIS, EMG, SQI, BURST, SR, ST, EEG, DSA, SEF, MF, ASYM	Describes each parameter and provides graphical display of each parameter's display on BIS™ Advance monitor screens. For description of the parameters, reference *1.10 The BIS™ Advance Parameters* on page 29.

3.17. Quick Reference Checklist

This "Quick Reference Checklist" is intended only as an operating checklist for users already familiar with the BIS™ Advance monitor. Do not proceed unless you have read *1.2 Safety Information* on page 13.

You may print out this Quick Reference Checklist for caregiver use.

Step 1: Basic Operation

If the BIS™ Advance system has already been installed, proceed as follows:

- Verify that all power and other cables are connected properly.
- Ensure that the BISx MIC cable is connected to the BISx adapter cable connector on the monitor.

Step 2: Turn On

Press the button in the bottom right corner of the monitor to turn the monitor and BISx module on. The system will initiate a self-test to ensure that all equipment is operating properly. The monitor home screen will appear.

Step 3: Attach sensor to patient

- Prepare sensor site and place BIS™ sensor on the patient in accordance with the sensor instructions.

Step 4: Set up the BISx module and connect the sensor to the BISx module

- Using the attachment clip, secure the BISx module to a convenient location near the patient's head.
- Insert the BIS™ sensor tab into the PIC connector on the BISx module until fully engaged.

Step 5: If you want to make any changes to monitoring parameters, such as setting an alarm limit, do so now.

You are now ready to begin monitoring. For detailed operating instructions and software configuration, read *4 Operating the BIS™ Advance Monitoring System* on page 138. Current settings may be viewed at any time by viewing the appropriate menu.

4. Operating the BIS™ Advance Monitoring System

4.1. Preparing for Operation

Ensure that the system, including the monitor, docking station, BISx module, sensor, and all connecting cables are set up as described in *3.5 Preparing the Docking Station* on page 68 and *3.6 Preparing the Monitor* on page 71. If you want to mount the monitor, do so before operation, following the instructions in *3.4 Mounting the Docking Station* on page 64. The BIS™ parameters and their meaning appears in *Table 1. The BIS™ Advance Monitor Parameters* on page 31.

4.2. Cases

A new case will be created automatically by the BISx module when a BISx module and a sensor are attached to the system. Once a sensor is connected, a sensor check will take place, the case will begin, and its **CASE ID** will appear on the screen as seen in *Figure 28. Case ID* on page 86. If the sensor is briefly removed and reattached to the BISx module, the same case will continue.

4.2.1. Case Storage

The monitor will store a maximum of 50 cases which will be available for Case Review. When the maximum number of saved cases has been stored, any new case will delete the oldest case in the monitor's memory.

The software shall store a maximum of 30 snapshots per case, and a maximum of 24 hours of Case Review data per case data file. When a case exceeds 24 hours, a new case data file shall be created, with the same file name and a different suffix. (The suffix is an integer indicating 1, 2, etc.)

Note: Since the case storage capacity of the monitor is limited, it is recommended to download case data when a case ends, to avoid accidental erasure of case data.

4.2.2. Case Review

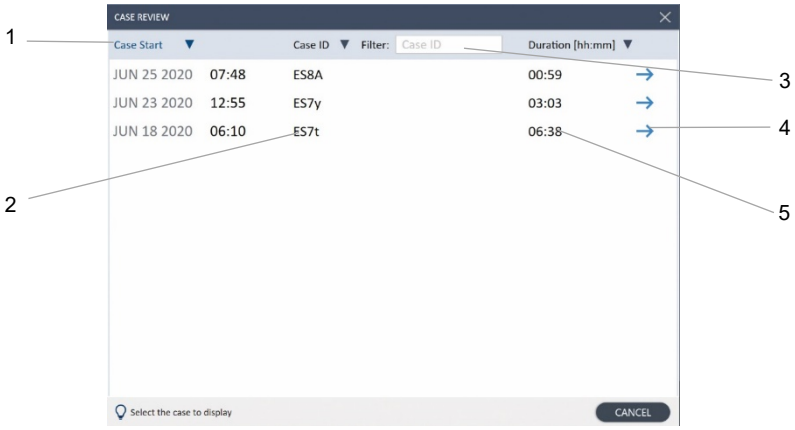
Case Review is available only when no sensor is attached to the monitor. If a sensor is connected, the option is greyed out. A BISx module may be connected during Case Review.

To select a case for review, click **Main Menu**>**Case Review**.

A list of saved cases will appear, by their date and time of creation, where the first case in the selection menu shall be the most recently created. The arrows at the top of the chart next to Case Start, Case ID and Duration can be used to reverse the order of the case list.

Cases may be filtered by Case ID. When filtering, the desired Case ID may be inputted without differentiation between upper and lower case letters; the software will still be able to find the correct case.

Figure 51. Case List Window

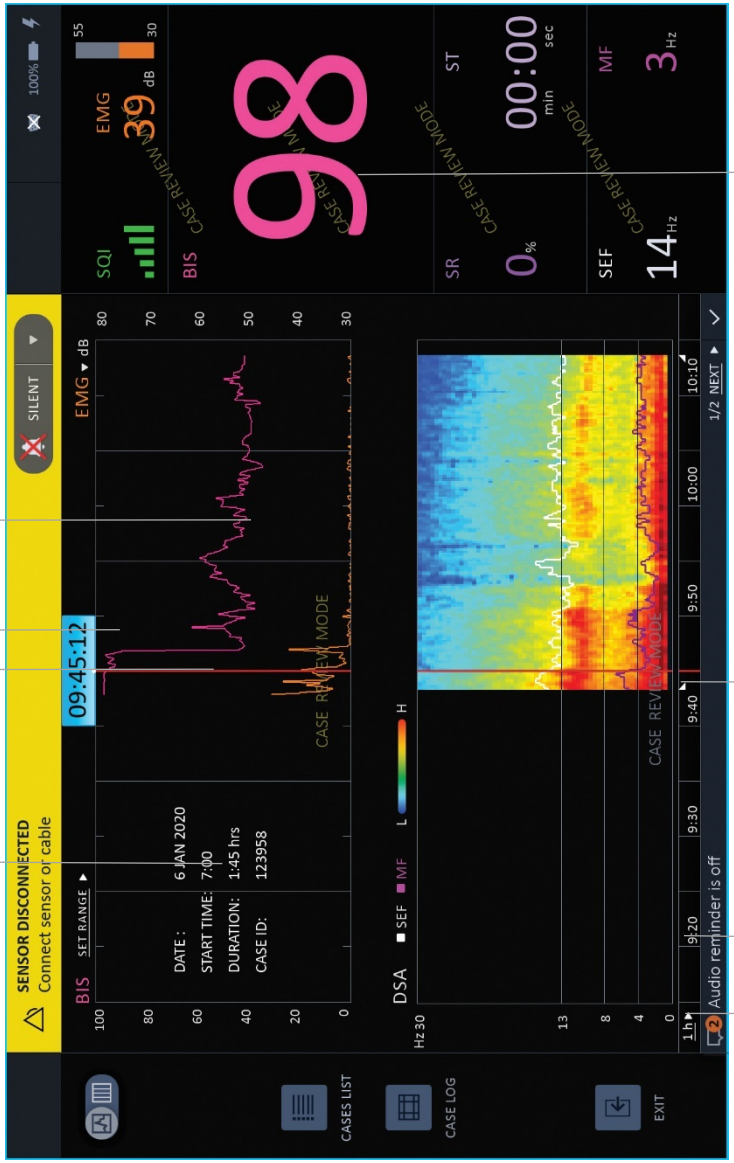


Label	Function	Description
1	Case Start	Date and time of case start
2	Case ID	Case ID assigned by system
3	Filter	Cases may be filtered by Case ID; when a valid Case ID is inputted, only cases with that Case ID will appear on the case list
4	Blue arrow	Clicking on the blue arrow will open the selected case
5	Duration	Duration of case in hours and minutes

Select a case and open the case review screen by clicking on its Case ID or on the blue arrow at the right side of each row. A Case Review graphical trend screen will appear, displaying the data saved for that case in trend format, and, in the numeric section, the data for that case at the point in time indicated by the cursor.

A sample Case Review screen is shown below.

Figure 52. Case Review Screen



Label	Function	Description
1	Case data	Indicates date, start time, duration and Case ID of displayed case
2	Cursor	Red line indicates point on graph for which numerical data is displayed at the right side of the screen
3	Cursor time indicator	Indicates time at cursor location
4	Graphical data	Graphical data for displayed case
5	Numeric Data	Numeric data of case in review, at the point in time represented by the cursor
6	Case start time indicator	Small grey triangle indicator indicates the point on the graph at which the currently displayed case started
7	Horizontal (time) axis	Time axis for graph, with scale as determined by displayed time scale on graph
8	Resolution display drop-down menu	Select desired resolution for graphs using this arrow

The Case Review display for a 2-channel case will be a layout with the BIS graph with EMG as a secondary variable in the top graph, and DSA in the bottom graph.

The Case Review display for a 4-channel case will be a layout with the BIS graph with EMG as a secondary variable in the top graph, and DSA with ASYM as a secondary variable in the bottom graph. The user can select a display of either Right BIS or Left BIS data (using the R/L toggle switch at the upper left side of the screen).

Case Review can also be displayed in Chart format, using the graph/chart toggle button at the upper left side of the screen.

While viewing a case in Case Review, the user can select a different secondary variable for the BIS graph, from the standard list of available secondary variables on this graph (reference *3.12 Home Screen Options* on page 121.)

During Case Review, the user can scroll through the trend in the displayed Trend window through a specific case time, by swiping the monitor's touch screen left or right to scroll through the available data. A cursor indicates the point in time on the graph for which the data appears in the numeric window.

During Case Review, Alarms which were active during the specific case being reviewed will not be displayed and will not sound. However, if a real-time alarm (not connected to monitoring, since no monitoring takes place during Case Review) occurs during case review, it will be displayed and will sound.

To save data from Case Review in a format for printing, reference *5.10 Viewing and Printing Saved Data* on page 203.

The monitor also provides an option to view a Case Log, by clicking the **Case Log** button at the middle of the left bar of the Case Review screen seen in *Figure 52. Case Review Screen* on page 141. This case log will list all events that occurred during the case, with the time, Event ID, type of event (such as **Alarm** or **Info** [message]) and a description of that event.

4.3. Alarms and Messages

4.3.1. Alarm and Message Types

A full list of alarm messages appears in *Table 12. Alarm Messages* on page 145..

By default, the BIS, SR, SEF and SQI alarms are off. To set an alarm, reference *4.3.7 Changing Alarms Settings* on page 168.

To change audio settings for alarms, reference *3.14 Home Screen Audio Alarm Settings* on page 126.

The alarms are categorized as High Priority, Medium Priority and Low Priority alarms. High Priority alarms will be indicated by a flashing red background for the alarming parameter (if the alarm refers to a parameter) and a red background in the alarm bar. Medium Priority and Low Priority alarms will be indicated by a yellow background for the alarming parameter (if the alarm refers to a parameter) and a yellow background in the alarm bar. For Medium Priority alarms, the yellow background for the alarming parameter will flash. The Priority status of an alarm also defines its appearance in the alarm bar and alarm list; reference *4.3.4 Alarm Display* on page 162 for more details.

The alarms and messages are also defined by categories both in terms of their audible status and their appearance in the message area, as follows:

Alarm/Message Categories

1. Periodic alarms will sound and be displayed continuously as long as the alarm condition continues to exist. If the alarm condition is cleared, the alarms will cease to sound and display. All alarms are periodic.

2. Once information messages will sound and display once for approximately 5 seconds, whether or not the condition continues to exist.

Message Area Display Categories

1. Non-latching items can be Periodic alarms or information messages; these items will appear on the screen continuously, but will disappear once the condition is cleared.

2. Latching information messages will continue to appear until the user acknowledges the alarm. Once the user acknowledges a latching information message, it will no longer appear. Alarms are never latching.

In addition to the display of Non-latching and Latching information messages, both Non-latching and Latching messages will also sound once when they first occur.

WARNING: Check Target Range alarm limits to ensure they are appropriate for the patient being monitored with each use. Ensure Target Range alarm limits do not exceed the standard thresholds set by the institution.

WARNING: If you plan to monitor the patient using alarms, do not set the Target Range alarm limits to extreme values that render the monitoring system ineffective. Ensure Target Range alarm limits are appropriate for each patient.

WARNING: If you plan to monitor the patient using alarms, do not pause, disable or decrease the audible alarm volume until you verify that the patient is being monitored by other means, such as direct observation, as this could compromise patient safety.

WARNING: If you plan to monitor the patient using alarms, do not decrease the adjustable alarm volume below ambient sound levels. Decreasing the alarm volume below ambient levels might impede operator recognition of the audible alarm, which might lead to patient harm during an alarm situation.

4.3.2. Alarms

The monitor's alarm messages are listed in *Table 12. Alarm Messages*, below. All alarms listed in this table are Periodic and Non-latching.

Table 12. Alarm Messages

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
BIS ALARM BIS below defined range	The BIS has fallen below the target range set by the user.	1. Check patient. 2. Take note of BIS limit set by user.	HIGH
BIS ALARM BIS above defined range	The BIS has risen above the target range set by the user.	1. Check patient. 2. Take note of BIS limit set by user.	HIGH
ISOELECTRIC EEG	No discernible EEG activity is detected for sixty-three seconds; SR = 100. Note: This message notifies user of a flatline EEG. This is a normal condition when sensor simulator is connected.	If unintended: 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self-test passes. 5. Verify PIC, using the sensor simulator and Sensor Check.	HIGH
LEFT ISOELECTRIC EEG	No discernible EEG activity is detected for sixty-three seconds; SR = 100. Note: This message notifies	If unintended: 1. Check patient vital signs, dosage, etc.	HIGH

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
	user of a flatline EEG. This is a normal condition when sensor simulator is connected.	2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self-test passes. 5. Verify PIC, using the sensor simulator and Sensor Check.	
RIGHT ISOELECTRIC EEG	No discernible EEG activity is detected for sixty-three seconds; SR = 100. Note: This message notifies user of a flatline EEG. This is a normal condition when sensor simulator is connected.	If unintended: 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self-test passes. 5. Verify PIC, using the sensor simulator and Sensor Check.	HIGH
SENSOR OVERCURRENT	Sensor is using too much current.	1. Disconnect and examine sensor connection. Clean any contamination. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.	HIGH

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
SENSOR GROUND FAULT	Problem is detected relating to sensor ground element. A continuous ground fault has occurred for longer than 8 seconds.	1. Disconnect and examine sensor connection. Clean any contamination present. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.	HIGH
MONITOR TEMPERATURE LIMIT EXCEEDED If the problem persists, consider replacing monitor	Monitor temperature limit has been exceeded.	If the problem persists, the monitor may need to be replaced. Contact technical support.	MEDIUM
BATTERY IS CRITICALLY LOW Monitor may shut down at any time	There are only a few minutes of battery usage time left. Monitor may shut down at any time.	Restore AC power to avoid automatic shutdown and continue working.	MEDIUM
SR ALARM SR above defined threshold	SR value is above the defined threshold.	Check patient status.	LOW
SEF ALARM SEF above defined range	SEF value is above the defined range.	Check patient status.	LOW
SEF ALARM SEF below defined range	SEF value is below the defined range.	Check patient status.	LOW

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
SENSOR DISCONNECTED Connect sensor or cable	o Disconnected sensor. o Poor or contaminated connection between sensor and PIC. o Disconnected PIC. o Defective PIC. o Defective BISx.	1. Connect the sensor. 2. Connect/clean connection between sensor and PIC. 3. Connect the PIC. 4. Replace the PIC. 5. Replace the BISx.	LOW
BATTERY TEMPERATURE LIMIT EXCEEDED If the problem persists, consider replacing monitor	Battery temperature limit has been exceeded.	If the problem persists, the monitor may need to be replaced. Contact technical support.	LOW
SENSOR EXPIRED Replace the sensor	Sensor is past its normal usability date, based upon date of manufacture.	Replace sensor.	LOW
SENSOR MAXIMUM USES EXCEEDED Replace the sensor	Sensor has been connected and disconnected too many times.	Replace sensor.	LOW
SENSOR USED MORE THAN 24 HOURS	Sensor was attached to	Replace sensor.	LOW

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
Replace the sensor	system for more than 24 hours.		
UNRECOVERABLE MONITOR ERROR Restart the monitor	A system error has occurred. The monitor may stop operating.	1. Follow on-screen instructions (if any). 2. Turn the monitor off, then on again. 3. Replace monitor.	LOW
BISx UNRECOVERABLE ERROR Disconnect and reconnect BISx	o Poor connection between BISx module monitor cable and monitor. o Defective BISx module. o Defective monitor.	1. Disconnect and reconnect the host cable. Unplug and connect the host cable. 2. Follow on-screen instructions. If necessary, power OFF and unplug power cord to shut down monitor completely. Then plug in and restart monitor. 3. Replace the BISx. 4. Replace the monitor.	LOW
SQI MEDIUM Excessive artifacts in signal	SQI value is medium, indicating that there are excessive artifacts in the EEG signal.	1. Attempt to identify and eliminate artifact source. 2. Verify Sensor Check passes. If not, replace PIC. 3. Replace BISX.	LOW
SQI LOW Due to poor signal quality some parameters are not available	SQI value is low, indicating that no data is available due to poor EEG signal quality.	1. Attempt to identify and eliminate source of poor signal quality. 2. Verify Sensor Check passes. If not, replace PIC. 3. Replace BISX.	LOW

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
BATTERY LOW Connect to power supply	There is only a short amount of battery usage time remaining.	Restore AC power to avoid automatic shutdown.	LOW
DSC SELF-TEST FAILED Replace BISx	The DSC Self-Test process failed.	Replace the BISx module.	LOW
BISx INITIALIZATION ERROR Disconnect and reconnect BISx	o Poor connection between BISx module monitor cable (MIC) and monitor. o Defective BISx. o Defective monitor.	1. Disconnect and reconnect the adapter cable. Unplug and connect the adapter cable. 2. Follow on-screen instructions. If necessary, power OFF and unplug power cord to shut down monitor completely. Then plug in and restart monitor. 3. Replace the BISx. 4. Replace the monitor.	LOW
UNABLE TO READ SENSOR Replace the sensor	The monitor is unable to read data from the BIS™ sensor.	Replace the sensor.	LOW
UNSUPPORTED SENSOR TYPE Replace the sensor	The sensor is not compatible with the monitor configuration.	Replace sensor. Reference *Table 33. BIS™ Advance Monitor Components and Sensors* on page 252 for a list of approved sensors. Ensure that the sensor used is compatible with the monitor configuration.	LOW

Alarm Message	Possible Causes	Corrective Actions	Alarm Priority
PRESS CENTER OF ELECTRODES {0} TO ENABLE MONITORING	One (or more) of the sensor electrodes is not in contact. The relevant electrode number will appear instead of the parentheses.	Press the center of the electrode listed on the BIS sensor to initiate contact and enable monitoring.	LOW
TEMPORARILY UNABLE TO MEASURE ELECTRODES {0}	The system is temporarily unable to measure data from one of the electrodes on the sensor. The relevant electrode number will appear instead of the parentheses.	If the issue does not correct itself, replace the sensor.	LOW
POSSIBLE PIC PROBLEM Replace PIC or check cable using sensor simulator	Ground electrode impedance is high and impedance of other electrodes is low. • Defective PIC.	1. Test another PIC with sensor simulator. 2. If failure persists, replace simulator and retest. 3. If failure persists, replace PIC.	LOW
POSSIBLE PIC PROBLEM Replace PIC	One of the electrodes (other than ground) has high impedance. • Defective PIC. • Defective sensor simulator.	1. Test another PIC with sensor simulator. 2. If failure persists, replace simulator and retest. 3. If failure persists, replace PIC.	LOW

4.3.3. Messages

All information messages will sound once and be displayed in the information message section at the bottom of the home screen. For an example of this display, reference *Figure 54. Home Screen with Active Alarm* on page 165.

The information messages displayed on the message bar at the bottom of the screen are described in *Table 13. Information Messages* on page 153.

Figure 53. Message Bar

Label	Function	Description
1	Number of messages	Number of current messages
2	Current message	Text of message currently displaying
3	Message number	Number of message currently displaying / total number of messages
4	Next button	Click to view next message in list
5	Check mark	Click to dismiss currently displaying message, if it is a Latching message

If more than one message is active, the messages will be displayed in succession. To view the messages more rapidly, click the **NEXT** button or the arrow to its right. To dismiss a Latching message (so that it will no longer appear), click the check mark.

Information messages are listed in Table 13. Information Messages, below. The message display types are described in *4.3.1 Alarm and Message Types* on page 143.

Table 13. Information Messages

Message	Meaning	Message Display Type	Suggested Action
This is the last time this sensor can be used	The sensor attached to the monitor has already been used, and the current use is the last use for this sensor.	Non-latching	Replace the sensor
AC power disconnected	The monitor is not connected to AC power and therefore is running on battery power	Non-latching	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 60 minutes (when the battery is fully charged). 1. Restore the AC power. 2. Verify power cord. 3. Replace power supply.
Testing alarm volume	Currently testing alarm volume	Once	None. Informational message only.
Date and time changed	Date and time have been changed	Once	None. Informational message only.
Smoothing rate changed to 10 seconds	Smoothing rate was changed to 10 seconds, based upon the type of sensor connected, or the user changed the smoothing rate.	Once	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Smoothing rate changed to 15 seconds	Smoothing rate was changed to 15 seconds, based upon the type of sensor connected, or the user changed the smoothing rate.	Once	None. Informational message only.
Smoothing rate changed to 30 seconds	Smoothing rate was changed to 30 seconds, based upon the type of sensor connected, or the user changed the smoothing rate.	Once	None. Informational message only.
Number of channels for EEG changed to 1	Monitor has adjusted the number of EEG channels to 1 based upon the sensor connected.	Once	None. Informational message only.
Number of channels for EEG changed to 2	Monitor has adjusted the number of EEG channels to 2 based upon the sensor connected.	Once	None. Informational message only.
Number of channels for EEG changed to 4	Monitor has adjusted the number of EEG channels to 4 based upon the sensor connected.	Once	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Alarm Silent Mode On	Audio Alarm Silent Mode is on	Once	None. Informational message only.
Alarm Silent Mode Off	Audio Alarm Silent Mode is off	Once	None. Informational message only.
Audio Reminder is On	Audio Off alarm reminder signal is on	Once	None. Informational message only.
Audio Reminder is Off	Audio Off alarm reminder signal is off	Non-latching	None. Informational message only.
Alarm Pause Mode On	Alarm Pause Mode is on	Once	None. Informational message only.
Export failed - USB drive removed	Removable drive was removed from USB port during download	Latching	Place USB flash drive in USB port and try again, do not remove drive until a message indicating that the download is completed appears. For Live Case download, stop live data recording and then remove drive. Reference *5.5 Live Case Export* on page 188 for more information regarding Live Case download.
Export failed - USB drive full	Drive is full.	Latching	1. Check connection. 2. Replace drive.
Snapshot created	Snapshot was created	Once	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
EEG Filtering On	EEG filters are on	Once	None. Informational message only.
EEG Filtering Off	EEG filter are off	Latching	None. Informational message only.
Live data export in progress	Live data export is in progress	Non-latching	None. Informational message only.
Live data export stopped	Live data export has been stopped	Once	None. Informational message only.
Monitor Saved Cases export in progress	Monitor case history export is in progress	Non-latching	None. Informational message only.
Monitor Saved Cases export completed	Monitor case history export has been completed	Once	None. Informational message only.
Monitor Saved Cases export failed	Monitor case history export has failed	Latching	Same as other export failed
BISx Saved Cases export in progress	BISx module history export is in progress	Non-latching	None. Informational message only.
BISx Saved Cases export completed	BISx module history export has been completed	Once	USB flash drive may be removed.
BISx Saved Cases export failed	BISx module history export was not successful. • Removable drive is not connected	Latching	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position.

Message	Meaning	Message Display Type	Suggested Action
	properly to USB port. • Drive "write protect" is locked. • Drive is incompatible or defective. • Drive is full.		3. Replace drive. .
BISx connection history export completed	BISx module connection history export has been completed	Once	USB flash drive may be removed.
BISx connection history export failed	BISx module connection history export was not successful. • Removable drive is not connected properly to USB port. • Drive "write protect" is locked. • Drive is incompatible or defective. • Drive is full.	Latching	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive.
Sensor connection history export in progress	Sensor connection history export is in progress	Non-latching	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Sensor connection history export completed	Sensor connection history export has been completed	Once	USB flash drive may be removed.
Sensor connection history export failed	Sensor connection history export was not successful. • Removable drive is not connected properly to USB port. • Drive "write protect" is locked. • Drive is incompatible or defective. • Drive is full.	Latching	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive.
Monitor log export completed	Monitor log export has been completed	Once	USB flash drive may be removed.
Monitor log export in progress	Monitor log export is in progress	Non-latching	None. Informational message only.
Monitor log export failed	Monitor log export was not successful. • Removable drive is not connected properly to USB port.	Latching	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive.

Message	Meaning	Message Display Type	Suggested Action
	• Drive "write protect" is locked. • Drive is incompatible or defective. • Drive is full.		
System log export completed	System log export has been completed	Once	USB flash drive may be removed.
System log export in progress	System log export is in progress	Non-latching	None. Informational message only.
System log export failed	System log export was not successful. • Removable drive is not connected properly to USB port. • Drive "write protect" is locked. • Drive is incompatible or defective. • Drive is full.	Latching	1. Check connection. 2. Verify "write protect" switch on the drive is set to "unlock" position. 3. Replace drive.
DSC Self-Test in progress	DSC Self-Test is in progress	Non-latching	None. Informational message only.
BISx connection history export in progress	BISx module connection history export is in progress	Non-latching	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Factory settings restored	Factory settings have been restored	Latching	Message appears at each power-up after a normal shutdown. No action, informational message.
Impedance Checking Off	User has disabled impedance checking.	Non-latching	None. Informational message only.
Last case resumed - User settings restored	Case resumed - settings previously set for that case have been restored	Once	None. Informational message only.
System recovered from unexpected shutdown	System has recovered from an unexpected shutdown	Latching	None. Informational message only.
Sensor simulator connected	Sensor simulator is connected	Non-latching	None. Informational message only.
Replace battery	Battery does not charge completely after a full charge session, or has reached the maximum amount of charging cycles.	Non-latching	Replace battery
DSC Self-Test timeout	DSC Self-Test timeout	Once	None. Informational message only.
DSC Self-Test passed	Monitor has passed DSC Self-Test	Once	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Institutional settings restored	Institutional settings have been restored	Once	None. Informational message only.
Monitor software update failed	Monitor software update has failed	Latching	Contact technical support
Monitor software update complete	Monitor software update is complete	Latching	USB flash drive may be removed.
BIS alarm enabled	BIS alarm has been enabled by user	Once	None. Informational message only.
BIS alarm disabled	BIS alarm has been disabled by user	Once	None. Informational message only.
SR alarm enabled	SR alarm has been enabled by user	Once	None. Informational message only.
SR alarm disabled	SR alarm has been disabled by user	Once	None. Informational message only.
SEF alarm enabled	SEF alarm has been enabled by user	Once	None. Informational message only.
SEF alarm disabled	SEF alarm has been disabled by user	Once	None. Informational message only.
Testing PIC with sensor simulator	Testing PIC with sensor simulator	Non-latching	None. Informational message only.
PIC test successful	PIC test was successful	Once	None. Informational message only.

Message	Meaning	Message Display Type	Suggested Action
Fan malfunction - replace docking station	Fan malfunction has occurred.	Non-latching	Replace the docking station.
Battery not installed	Battery is not installed.	Non-latching	Install a battery in the monitor.
System is in Demo Mode	The monitor is currently running a demo case.	Non-latching	None. Informational message only.
Monitor Overheat - Recovered	The monitor has recovered from an overheat scenario.	Latching	None. Informational message only.
System recovery - System trying to restore communication between BISx and monitor	The system identified disconnection between BISx module and the monitor and is trying to reconnect.	Once	None. Informational message only.
System Recovery – system identified lack of communication between BISx and monitor and is trying to restore communication.	The system identified a lack of communication between BISx module and the monitor and is trying to restore communication.	Once	None. Informational message only.

4.3.4. Alarm Display

The system displays alarms using the following indicators:

Table 14. Alarm Indicators

Parameter	Alarm Indicators
BIS	Alarm Red square indication in numeric panel (since BIS is a High Priority alarm), alarm message
SR	Alarm yellow square indication in numeric panel (since SR is a Low Priority alarm), alarm message
SEF	Alarm yellow square indication in numeric panel (since SEF is a Low Priority alarm), alarm message
SQI	SQI display color (orange or red depending on SQI level) and number of bars in numeric panel, alarm message will appear.
Technical alarms	Technical alarm messages in the alarm message area at the top of the screen

The system uses the following enabled/disabled indicators to indicate the status of the alarms. When an alarm is marked as disabled, this means that it is completely disabled, and will not display audio or visual indicators. Therefore, when an alarm is disabled, no alarm indicators will be seen or heard and no alarm will be recorded in the record of the case.

In addition, please note that an enabled alarm can be silenced using the audio alarms pause and silence options described in *4.3.6 Audio Alarms Pause and Silence* on page 167. In such a case, visual alarm indicators will appear on the screen, as well as the enabled indicator seen in the table below, but audible alarm indicators will not occur.

Table 15. Alarm Enabled and Alarm Disabled Indicators

Indicator	Meaning
	High Priority alarm is enabled and will provide audible and visual indicators. If all alarms are silenced, an enabled alarm will still show visual indicators and be recorded in the case records, but will not provide an audible indicator.
	High Priority alarm is disabled. There will be no record of alarms in case records, and neither audible nor visual indicators will be provided.

Indicator	Meaning
	Medium Priority alarm is enabled and will provide audible and visual indicators. If all alarms are silenced, an enabled alarm will still show visual indicators and be recorded in the case records, but will not provide an audible indicator.
	Medium Priority alarm is disabled. There will be no record of alarms in case records, and neither audible nor visual indicators will be provided.

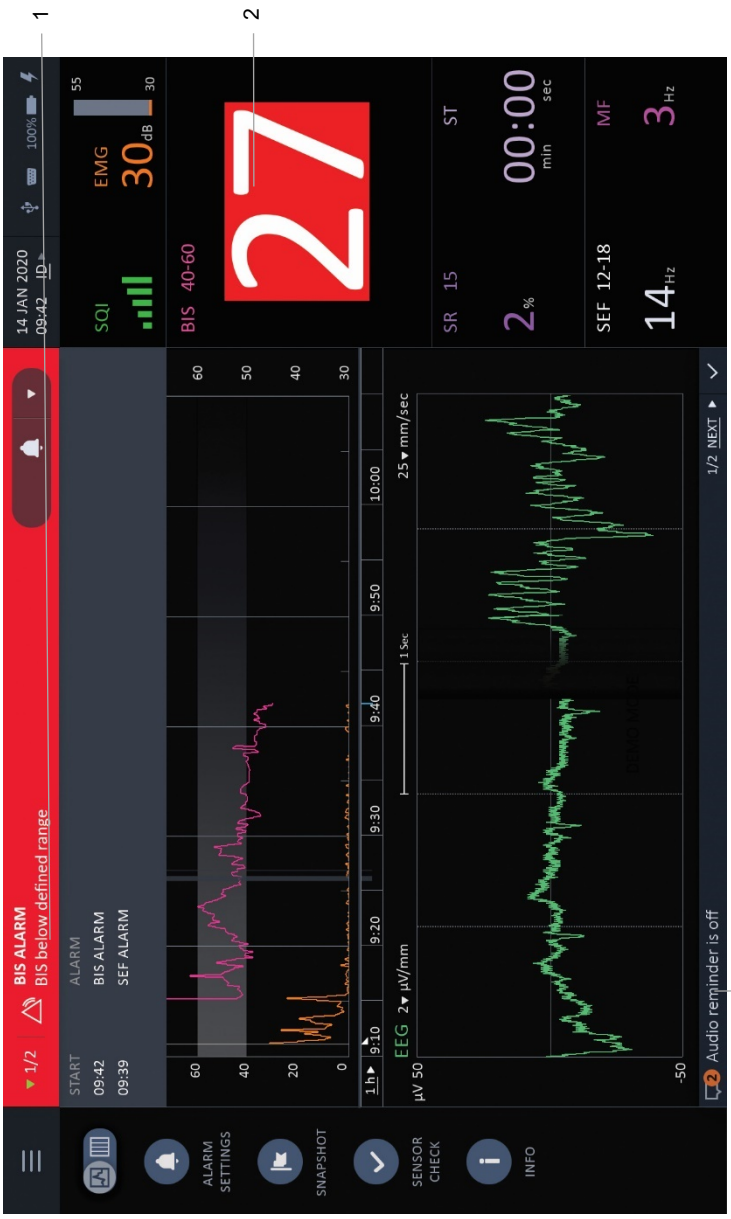
In addition to the numeric panel display for the BIS, SR, SEF and SQI alarms, all alarm messages (both alarms that warrant a display in the numeric panel and those that do not) will appear in the alarm message bar at the top of the screen as long as they are active (all alarms are periodic alarms) with the appropriate alarm indicator (High Priority Enabled or Medium Priority Enabled, as relevant). If there is more than one alarm occurring at the same time, the system will display the highest priority level alarm message in the alarm message bar.

In case of multiple alarms in the highest priority level, the system shall toggle between all the alarms in that level, displaying each message in turn. If there are multiple alarms in high, medium and low levels, the system shall toggle only the high alarms; the medium and low alarms can be viewed using the alarms list.

The alarms list is a list of current alarms (of all priority levels) that will appear if more than one alarm is currently active. To view the alarms list, click on the arrow at the left side of the alarm bar. Reference *Figure 55. Alarms List* on page 166.

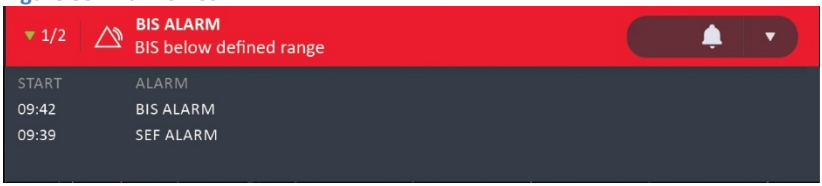
An example of a screen with an active alarm appears in *Figure 54. Home Screen with Active Alarm*, below.

Figure 54. Home Screen with Active Alarm



Label	Function	Description
1	Alarm message	BIS range alarm in alarm message bar
2	Alarm numeric	BIS range alarm as seen in numeric section
3	Information message	Information message in information message area

Figure 55. Alarms List



4.3.5. Alarm Limits

An alarm limit is a target level or target range within which the patient's value for that parameter should ideally remain at all points during monitoring. If the patient's value for that parameter exceeds or falls below the target level or target range, that patient may be at risk and should be checked by a caregiver. An alarm may be enabled to indicate this situation. Thus, these alarms can alert the caregiver to possible patient risk.

By default, all of these alarms are off. To set an alarm, reference *4.3.7 Changing Alarms Settings* on page 168.

The monitor proposes a target alarm range for the BIS™ parameter only. Target alarm ranges or limits may be set by the user for the other alarms, as described below. As soon as the user sets a range for an alarm, it is automatically enabled.

The proposed BIS™ target range is as follows:

Parameter	Recommended Target Range
BIS	40-60

For other alarms, there is no recommended target range, but the user can set the limit in the available range, as follows:

Parameter	Available Range
SR	SR High: 1 to 100, in increments of 1
SEF	0 to 29 for Low SEF limit, 1 to 30 for High SEF limit (there must be a gap of at least 1 between the Low and High limits)

In order to verify operator-set alarm limits, attach a sensor to the system (as described in *3.6.2 Connecting a Sensor to a Patient* on page 78) and make a note of the SEF value shown on the screen during monitoring. Then, remove the sensor and set the SEF target range (as described in *4.3.7 Changing Alarms Settings* on page 168) to a range that excludes that number. For example, if the sensor is showing SEF numbers between 27 and 28, set SEF High at 20. Re-attach the sensor and start monitoring. If the system is working correctly, an SEF High alarm should sound. This will verify that the monitor's alarm limits function is working correctly. Remove the sensor.

Once you have finished verifying the alarm limits, set the alarms as desired, or inactivate the alarms if desired, and begin monitoring.

4.3.6. Audio Alarms Pause and Silence

Alarms may be paused or turned off in one of two ways:

- Temporary Audio Alarm Paused
- Permanent Audio Alarm Off

In both cases, alarm paused or off affects only the audible alarms. Visual alarms are not affected.

Temporary audio alarm paused may be set for the device using the alarm keys. Temporary alarm silence will be for a period of 120 seconds; a countdown until the return of the alarm will appear in the Alarm area on the Home screen.

Audio volume can be set in the Alarm window, accessible using **Main Menu**>**ALARMS** or Left Menu bar>**ALARMS** on the home screen.

Reference *3.11.3 Alarm Status Displayed on Home Screen* on page 119 for the appearance of the home screen alarm touch keys.

If the alarms are silenced using the Permanent Audio Alarm Off option, it is recommended that the Audio Off Reminder be implemented. The Audio Off Reminder must be enabled in Administrator Mode in order for it to be available; by default, it is not available to the user.

The Audio Off reminder sounds every 180 seconds, reminding the user that auditory alarms are silenced. To implement the Audio Off Reminder, open the Alarm window, accessible using **Main Menu**>**ALARMS** or Left Menu bar>**ALARMS** on the home screen. Click **Audio Off Reminder** and slide the switch left to the right to turn the Audio Off option **ON** (switch will then appear green) and click **APPLY**. This will turn on the reminder which will sound every three minutes when the alarm audio is silenced.

The on screen message may indicate **NOTE: Audio OFF Reminder is currently disabled. To enable it, contact your administrator**. In this case, contact the administrator in your institution to turn on this option.

WARNING: If you plan to monitor the patient using alarms, do not pause, disable or decrease the audible alarm volume until you verify that the patient is being monitored by other means, such as direct observation, as this could compromise patient safety.

WARNING: If you plan to monitor the patient using alarms, do not decrease the adjustable alarm volume below ambient sound levels. Decreasing the alarm volume below ambient levels might impede operator recognition of the audible alarm, which might lead to patient harm during an alarm situation.

4.3.7. Changing Alarms Settings

Alarms Settings can be accessed using one of four methods:

1. **Main Menu**>**Alarm Settings**

2. Left Menu bar>**Alarms** button

3. **Alarm Settings** button that appears when a BISx module but not a sensor is connected to the monitor, on the **Connect sensor to start monitoring** window

4. The BIS target range can also be set using Home Screen>BIS Graph, Set **Range**>**BIS Range**

In the first three cases, the same Alarm Settings window will open. The BIS range setting choice will open a window that shows BIS range choices only.

Table 16. Alarm Limits Options

Alarm	Range	Factory Default Alarm Level
BIS range	None Low: 5 -95 High: 10-100	None; suggested level is 40-60
SR	None, 1-100	None
SEF	None Low: 1-29 High: 2-30	None

Follow the steps listed below to change alarm settings:

1. By factory default, set when the monitor leaves the factory, all alarms are set to **OFF**. If the alarms have been changed by the administrator in your institution, some or all of the alarms may already be set to **ON**. You can still change the alarm settings for your current monitoring session, but the monitor will revert to its institutional default settings (or factory default settings if institutional defaults have not been set) when a new case is started or when the monitor is turned off and turned on again.

2. Attach the BISx module to the monitor.

3. Open the Alarms Settings screen. The Alarm Settings screen can be reached via the options described above.

4. To enable an alarm, select a parameter at the left. Set limit by dragging alarm setting handle to the desired level. Once you make any change to the limit, the alarm will become enabled. Alternatively, you can slide the Alarm Disabled slider from the left side (Alarm Disabled) to the right side (Alarm Enabled) and then change the limit. Once this is done, the alarm indicators in this window (the **ON** or **OFF** text next to the alarm name and the slider in the middle of the window) will automatically indicate that the alarm is **ON**. Note that you will not be able to apply the enabling of the alarm limit until a limit is set.

5. Click **APPLY** to save these changes.

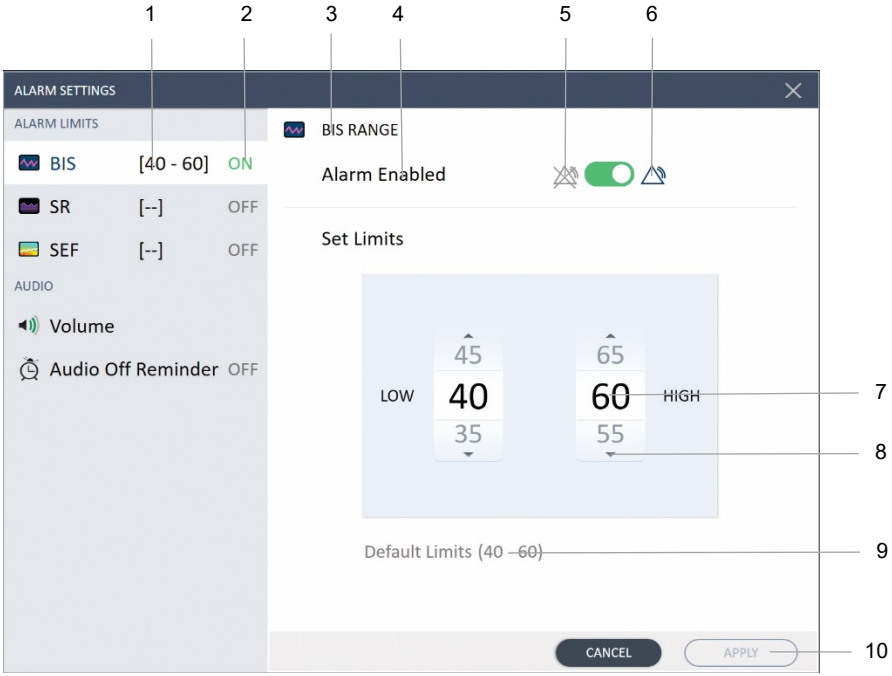
6. Attach a sensor to begin monitoring. Once a new sensor is attached to the monitor, a new case with a unique case ID will begin. This case will use the alarm settings that you have just set.

7. Alternatively, a sensor can be attached first, and then the alarm adjustment can be made. However, for recording purposes, best practice would be to set all alarms and then begin monitoring.

Once a sensor is attached to the monitor, the settings valid at the time the sensor was attached (if changes were made before attaching the sensor), or the changes made while the sensor was attached (if changes were made after attaching the sensor) will remain valid for that sensor. This will hold true even if the sensor is removed and replaced.

If alarm changes are made when no sensor is attached to the monitor, the alarm changes that have just been made will be valid until the monitor Is turned off. They will be valid for all sensors attached to the monitor, except for the following situation: If a sensor was previously attached to the monitor at a point when the settings were different, the sensor and its case will retain the previous settings.

Figure 56. Alarm Settings Screen



Label	Function	Description
1	Parameters	Parameters for which alarms can be set; if an alarm limit has been set (even if it has been set in the past and is not currently enabled, but the Reset to Default button has not yet been pressed) that limit will appear on this line.
2	ON/OFF indicator	This text indicates if the specific alarm is currently ON or OFF

3	BIS RANGE text and icon	Indicates the alarm which is currently displayed in this window
4	Alarm Enabled text	Indicates if the alarm is currently enabled; if the alarm being displayed is disabled, this text will indicate Alarm Disabled.
5	Alarm Disabled icon	If black, indicates that the alarm highlighted with a white background on the list at left and displayed at the top of the screen is disabled. If grey, indicates that the alarm is enabled. When the alarm is disabled, the slider section between the disabled and enabled icons will be grey.
6	Alarm Enabled icon	If black, indicates that the alarm the alarm highlighted with a white background on the list at left and displayed at the top of the screen is enabled. If grey, indicates that the alarm is disabled. When the alarm is enabled, the slider section between the disabled and enabled icons will be green.
7	Alarm Limits setting section	Set the desired limits in this section. The numbers seen in the middle of the section in black are the current limits (if the alarm in enabled) or the limits that will be set when APPLY is pressed (if you are now setting limits).
8	Down alarm setting handle	The up and down handles are used to set desired alarm limits
9	Reset to Defaults	Resets the alarm limits to institutional defaults, or, if no institutional defaults have been set, to factory defaults.
10	APPLY button	Click to apply limits that have been set. When active, the button will be blue.

An example of the alarm settings screen is seen in *Figure 56. Alarm Settings Screen* on page 171. The other alarms are set using the same procedure.

If an alarm is enabled, its range will display on the numeric panel of the home screen, next to the parameter name. If an alarm is disabled, the disabled icon will show on the numeric panel of the home screen, next to the parameter name. Reference *Figure 36. BIS Numeric* on page 107 for an example.

Audio alarm options are as seen in *Table 17. Audio Alarm Options*, below. Both alarm volume and the Audio Off reminder can be set in the alarm limits screen. The alarm volume can also be set on the Home screen; reference *3.14 Home Screen Audio Alarm Settings* on page 126.

Table 17. Audio Alarm Options

Feature	Options	Factory Default Option
Audio Alarm Volume	7 audio levels, from very low to very high	Level 4
Audio Off Reminder	ON, OFF	OFF

4.4. Chart Data

The monitor provides the option of viewing data in the form of a chart rather than as graphs. In both chart and graphical display, live data in numerical format will appear at the right side of the screen.

To view chart data, click the chart icon at the top left of the home screen. The chart icon appears in *Figure 57. Graph/Chart Toggle Icon*, below, at the right. If you are currently viewing chart data, click the graph icon to return to the graphical display.

Figure 57. Graph/Chart Toggle Icon

Chart data of the live current case, or chart data of a past case in Case Review, can be selected for viewing instead of graphical data.

Chart data can be seen at a selection of intervals: 1 minute, 5 minutes, 10 minutes, 15 minutes, 30 minutes, 60 minutes. The default interval is 15 minutes. To adjust the interval, click the **CHANGE** button next to the Interval text at the top of the chart and select the desired interval.

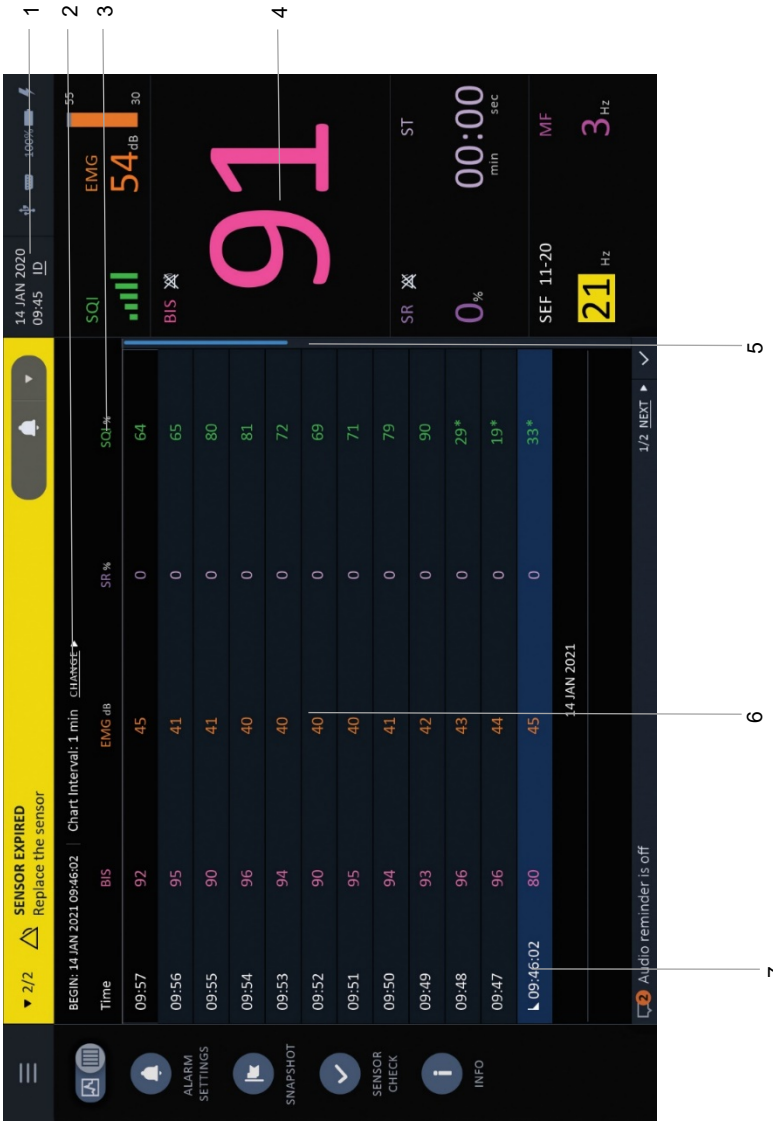
If there is no active case and the system is not in Case Review mode, chart data will not be available.

The information available on the Chart Data screen is listed below.

Table 18. Information on Chart Data Screen

Parameter	Description
2-channel system	
Time	Time of indicated row of chart
BIS	BIS at selected time
EMG	EMG in dB at selected time
SR	SR in % at selected time
SQI	SQI in % at selected time
4-channel system	
Time	Time of indicated row of chart
BIS L and BIS R	BIS left and right at selected time
EMG L and EMG R	EMG left and right at selected time
SR L and SR R	SR left and right in % at selected time
ASYM	ASYM at selected time
SQI L and SQI R	SQI left and right in % at selected time

Figure 58. Chart Data Screen for 2-Channel Monitor



Label	Function	Description
1	Case ID display	Click to see Case ID of current case
2	Interval display and selection	Displays interval used for table, or click to change interval displayed
3	Table headings	Displays headings of each column in table
4	Current numeric data	Numeric data at current point in time
5	Scroll bar	Scroll up or down to see other lines of data
6	Table data	Table data for displayed case
7	Start case icon	Icon indicating start date and time of current case

The top area also includes start date and time and the chart interval selected, along with a drop-down menu that can be used to change the chart interval.

The start case icon on the bottom row, which is the earliest row of the chart, will indicate that this is the first time period shown on the chart. Each additional row of chart data shall push the other rows down, so the most recent time period is always seen at the top of the chart. If the chart exceeds the space on the screen, scroll down to see earlier data.

If a chart data view is used to view a case in case review, the chart will show case review data and the numeric section will show the case review data at the cursor point.

4.5. Menu Map

For clarity, the menu map is provided in three sections:

1. Map of the menu items accessible from the main home screen

2. Map of the menu items available upon pressing the main menu button (at the top left of the main screen)

3. Map of the menu items available in the Administrator Mode (which is password-protected)

All three are seen in *Figure 59, Figure 60*, and *Figure 61*.

Figure 59. Home Screen Main Section Menu Map

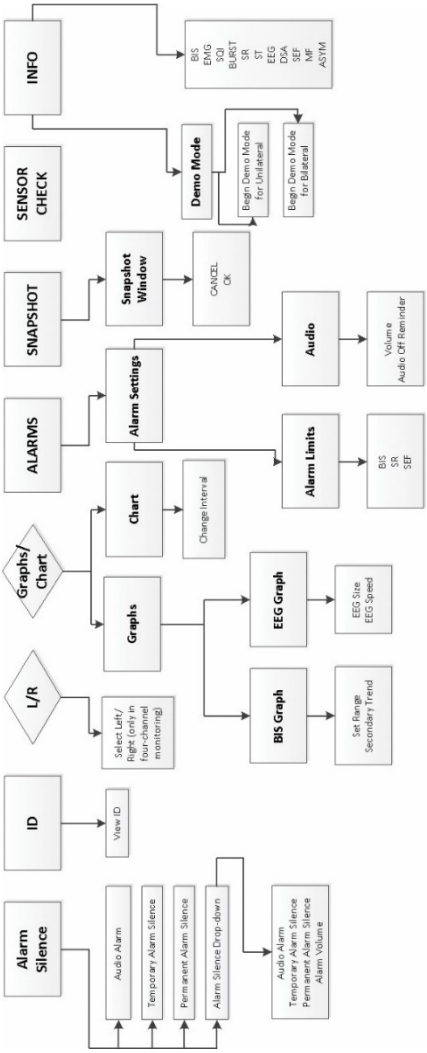


Figure 60. Main Menu - Menu Map

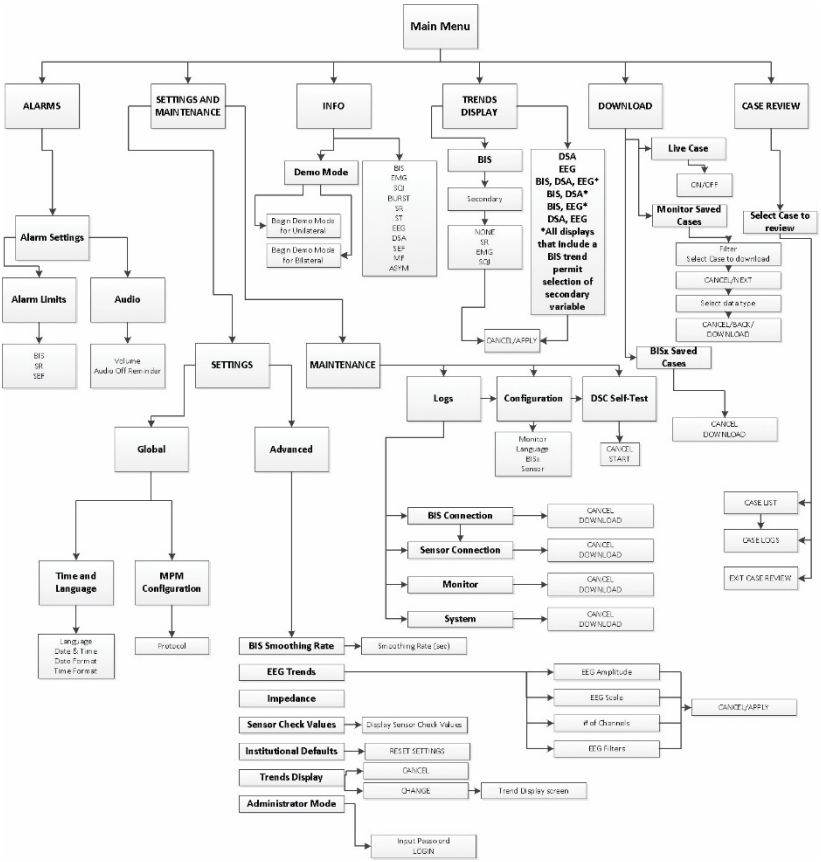
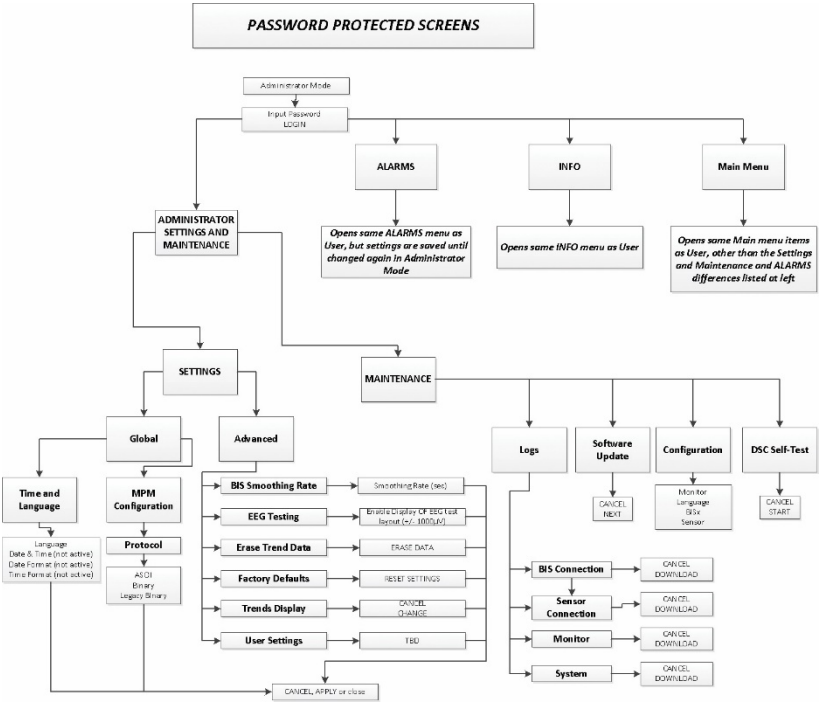

Main Menu
ALARMS
SETTINGS AND MAINTENANCE
INFO
TRENDS DISPLAY
DOWNLOAD
CASE REVIEW
Alarm Settings
Alarm Limits
Audio
BIS
SR
SEF
Volume
Audio Off Reminder
Demo Mode
Begin Demo Mode for Unilateral
Begin Demo Mode for Bilateral
BIS
EMG
SQI
BURST
SR
ST
EEG
DSA
SEF
V/F
ASYM
BIS
Secondary
NONE
SR
EMG
SQI
DSA
EEG
BIS, DSA, EEG*
BIS, DSA*
BIS, EEG*
DSA, EEG
*All displays that include a BIS trend permit selection of secondary variable
CANCEL/APPLY
Live Case
ON/OFF
Monitor Saved Cases
Filter
Select Case to download
CANCEL/NEXT
Select data type
CANCEL/BACK/ DOWNLOAD
Select Case to review
BISx Saved Cases
CANCEL DOWNLOAD
SETTINGS
MAINTENANCE
Global
Advanced
Logs
Configuration
DSC Self-Test
Monitor
Language
BISx
Sensor
CANCEL START
CASE LIST
CASE LOGS
EXIT CASE REVIEW
Time and Language
MPM Configuration
Language
Date & Time
Date Format
Time Format
Protocol
BIS Connection
Sensor Connection
Monitor
System
CANCEL DOWNLOAD
BIS Smoothing Rate
Smoothing Rate (sec)
EEG Trends
Impedance
Sensor Check Values
Display Sensor Check Values
Institutional Defaults
RESET SETTINGS
Trends Display
CANCEL
CHANGE
Trend Display screen
Administrator Mode
Input Password
LOGIN
EEG Amplitude
EEG Scale
# of Channels
EEG Filters
CANCEL/APPLY

Figure 61. Administrator Section Menu Map



4.6. Institutional Settings

The monitor is provided to the users with a defined set of factory defaults for various settings and alarms.

These defaults will remain in force unless:

1. The user adjusts one or more settings for the current use of the monitor; in this case the new adjusted settings will remain in force until a new case is started, or the monitor is shut down and then restarted.

2. The Administrator adjusts one or more settings in the Administrator Mode. In this case, the new settings will remain in force until the Administrator changes the settings or resets the monitor to factory defaults. The settings set by the Administrator for a particular monitor are called the Institutional

settings, and they shall appear as default settings to the regular (non-Administrator) user. If the user clicks **Reset to Default** in any Alarm Settings screen, the settings will return to the Institutional Default settings, not the Factory Default settings. The institutional default settings will remain in force even after the monitor is shut down and then restarted.

If the monitor loses power for any reason, settings that have been set for the current sensor (including alarm settings) will remain active when the monitor is turned on again, as long as the same sensor is attached to the monitor. If a different sensor is attached to the monitor, the monitor will use the default settings when it is turned on again.

Note: Note that changes can be made to the System Default settings by the user only when a BISx module and sensor are connected to the monitor.

Exceptions to these rules are as follows:

After monitor restart, the Chart Data time interval will revert to its last value before the monitor restarted.

After monitor restart, **Live Data Recording** setting (**On/Off**) shall revert to its last value before the monitor restarted. When sensor is disconnected while recording and then reconnected, the recording is not resumed automatically.

If a user applies changes to a System Default (e.g. Filters are set to **Off**) during a case, the new settings will remain for the current case. At the start of the following case, the user will be notified that these settings do not match the Institutional Defaults. The System Default settings are not accessible when no monitoring is taking place.

To adjust Institutional settings, enter Administrator mode, and then click **Main Menu**>**Settings and Maintenance**>**Settings**. Select the desired setting and make changes as required.

Table 19. Institutional Settings

Feature	Options	Factory Default Option
Language	Bulgarian, Chinese, Croatian, Danish, Dutch, English, French, German, Greek, Hungarian, Italian, Japanese, Macedonian,	English

	Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovenian, Spanish Swedish	
Date	Selection via calendar (October 26 2020 to October 26 2099) (but not before the monitor manufacture date). Available only when a BISx module is not connected. Not adjustable in Administrator Mode	NA
Date & Time Options	Not adjustable in Administrator Mode	
MPM/Partner Configuration	ASCII, Binary and Legacy Binary	Binary
Advanced User Settings		
BIS Smoothing Rate (excluding Extend sensor)	10, 15, 30	15
EEG Display Amplitude	+/-50 µV, +/-100 µV (+/-100 µV available only in full-screen EEG layout). Not adjustable in Administrator Mode	+/-50 µV
EEG Filters	On, Off Not adjustable in Administrator Mode	On

EEG Sweep speed	6.25 mm/sec, 12.50 mm/sec, 25 mm/sec, 50 mm/sec Not adjustable in Administrator Mode	25 mm/sec
EEG scale	2 µV/mm, 5 µV/mm, 10 µV/mm Not adjustable in Administrator Mode	2 µV/mm for 2 channels 10 µV/mm for 4 channels
EEG number of channels	1, 2, 4 Not adjustable in Administrator Mode	1 for 2 channels at 2 µV/mm 2 for 2 channels at 5 µV/mm and 10 µV/mm, 4 for 4 channels
EEG Testing (if enabled in Administrator Mode)	Enable/Disable display of EEG test layout (+/- 1000 µV)	Disabled
Impedance check (not available in Administrator Mode)	On, Off	On
Sensor Check Values (not available in Administrator Mode)	Enabled/Disabled	Disabled
Institutional Defaults (in User Mode)	RESET SETTINGS	
Factory Defaults (in Administrator Mode)	RESET SETTINGS	
Display Settings		
Click CHANGE to select the default layout		

2-Channel Default Layout	BIS, EEG; BIS; BIS, DSA; BIS, DSA, EEG; DSA, EEG; DSA; EEG	BIS, EEG
4-Channel Default Layout	BIS, EEG; BIS; BIS, ASYM, EEG; BIS, DSA, ASYM; DSA, ASYM, EEG; EEG; DSA, ASYM;	BIS, ASYM, EEG
Alarms Settings (accessible from **ALARMS** window)		
Alarm Limits		
BIS Target Range Alarm Enable	Enabled, Disabled	Disabled
BIS Target Range	Low – 5 to 95 High – 10-100	40-60
SR Limit Alarm Enable	Enabled, Disabled	Disabled
SR Limit	1 - 100	NA
SEF Target Range Alarm Enable	Enabled, Disabled	Disabled
SEF Target Range	Low – 1 to 29	NA

	High – 2 to 30	
Audio		
Alarm Volume	1-7	Level 4 of 7
Audio Off Reminder Access On/Off	Enabled, Disabled (OFF)	Off (can be changed only in Administrator Mode)
Other Settings		
Live Data recording (accessible on DOWNLOAD window)	On, Off	On
Chart Data time interval (accessible on Home Screen)	1, 5, 10, 15, 30, 60 minutes	15 minutes
BIS graph display scale (accessible on Home Screen)	1 hour, 6 hours, 12 h, 24 hours	1 hour

5. Data Storage, Transfer, and Export

5.1. Cybersecurity and Data Integrity

Caution: Do not connect any device to RS-232 (serial) port on the docking station (reference *2.2.3 Docking Station* on page 51) other than an approved RS-232 cable. RS-232 cable is supplied by the customer.

Caution: Do not connect any USB cables to the USB port on the monitor (reference *2.2.1 BIS™ Monitor* on page 43) or to the USB port on the docking station (reference *2.2.3 Docking Station* on page 51). The USB ports are intended only for the connection of a USB flash drive. USB flash drives that can be used with the monitor must have a capacity of at least 0.5 GB.

Caution: The BIS™ Advance monitor has been validated for use only with the BIS™ sensor. Electrodes or sensors that are not validated for use with the monitor have not undergone a data integrity analysis and may potentially impose a data security risk. For a list of sensors, reference *Table 33. BIS™ Advance Monitor Components and Sensors* on page 252.

Caution: For software updates, only use Medtronic's authorized software.

5.2. Monitor Data Memory

The following events are continuously logged in the monitor data memory with a unique ID for easy identification. This data is used to generate the various logs available for export, as described in *5.9 Logs Export* on page 199.

1. Alarm Messages (messages displayed in alarm bar)
2. Modal Messages (messages displayed in message windows, i.e., **Connect BISx to start monitoring**)
3. Information messages (messages displayed in message bar)
4. User Event Marking
5. System Events
6. BISx module Errors
7. Monitor Errors
8. User GUI Events (events in which user performed a GUI-related action)

The system log can hold up to 1,000,000 records or up to 50 cases, whichever is smaller. (The system log differs from the monitor log in that it includes data about the system as well as data about the patient.) If the log reaches a capacity of 50 cases, the earliest complete case will be deleted upon the opening of a new case. If the log reaches a capacity of 1,000,000 records, records (but not a complete case) will be deleted upon the addition of new records.

Data recorded in the log will be retained even if the monitor battery has been discharged and will be retained when the monitor and BISx are powered off.

5.3. BISx Data Memory

The BISx stores processed EEG parameters, including the BIS value, with time and date of acquisition. History data saved in the BISx can be accessed by exporting it to a removable drive using the **Download** function. The duration of BISx data saved is approximately 1200 hours. To view BISx history for a specific case, the user must first identify which BISx was in use during the case by looking up the BISx serial number, as follows: **Main Menu**>**Settings and Maintenance**>**Maintenance**>**Logs**>**BISx Connection log**. The appropriate serial number BISx can then be connected to any monitor to export its History Data.

To download BISx history, connect the relevant BISx unit, but do not connect a sensor. Attach a USB flash drive to the monitor. Select **Main Menu>Download>BISx Saved Cases>Download**. The BISx memory will be downloaded.

When the BISx memory is full, the oldest data are automatically erased as new data are saved. Memory will be retained even if the monitor battery has been discharged and will be retained when the monitor and BISx are powered off.

5.4. Types of Exported Data

The types of data that can be exported from the monitor include the following:

1. Live Case Data
2. Saved Cases on the monitor
3. Saved Data on the BISx module
4. Snapshot (if recorded, a Snapshot is exported as part of Monitor Saved Data)

To enable any data export from the monitor, insert a USB flash drive. USB flash drives that can be used with the monitor must have a capacity of at least 0.5 GB.

To export data, see the descriptions for export of each type of data.

In each case, an export will create a folder with a series of files on the USB flash drive to which the data has been exported. Some of the files are pdf files or txt files which are easily viewable. For a better understanding of the files that cannot be viewed easily, consult the BIS™ Advance Monitor Export Data Technical Specification document, available via BISTechnicalsupport@medtronic.com.

5.5. Live Case Export

Live recordings of data, including unfiltered EEG waveforms, may be downloaded to a USB flash drive during monitoring. Live Case data cannot be downloaded from a Demo Case.

To export Live Case data:

1. Attach a USB flash drive to the USB flash drive port on the monitor or the docking station. (For location of the ports, reference *Figure 3. The BIS™* on page 44 and *Figure 9. BIS™ Advance Docking Station, Front View* on page 52.)

Download of Live Case data cannot commence unless a USB flash drive is connected to the monitor or the docking station.

2. Live Case data can be exported during monitoring only, only when a USB flash drive is connected to the monitor (either directly to the monitor or via the docking station). Commence monitoring.

3. Click **Main Menu**>**DOWNLOAD**. Select **Live Case**. The left button in the middle of the screen will display a grey circle. Click this button , so that it will display a red circle and the word **REC** in red will appear next to **Live Case** at the left side of the window.

4. When Live Case recording is on, and a flash drive is connected to receive the Live Case recording, the Live Case icon will appear at the top right side of the home screen (reference *3.10.9 Home Screen Indicators and Messages* on page 114).

5. Live Case data will begin recording onto the USB flash drive. The Live Case icon at the top right side of the home screen (reference *3.10.9 Home Screen Indicators and Messages* on page 114) will indicate that Live Case recording is on.

6. Live Case data download will continue until one of the following occurs:

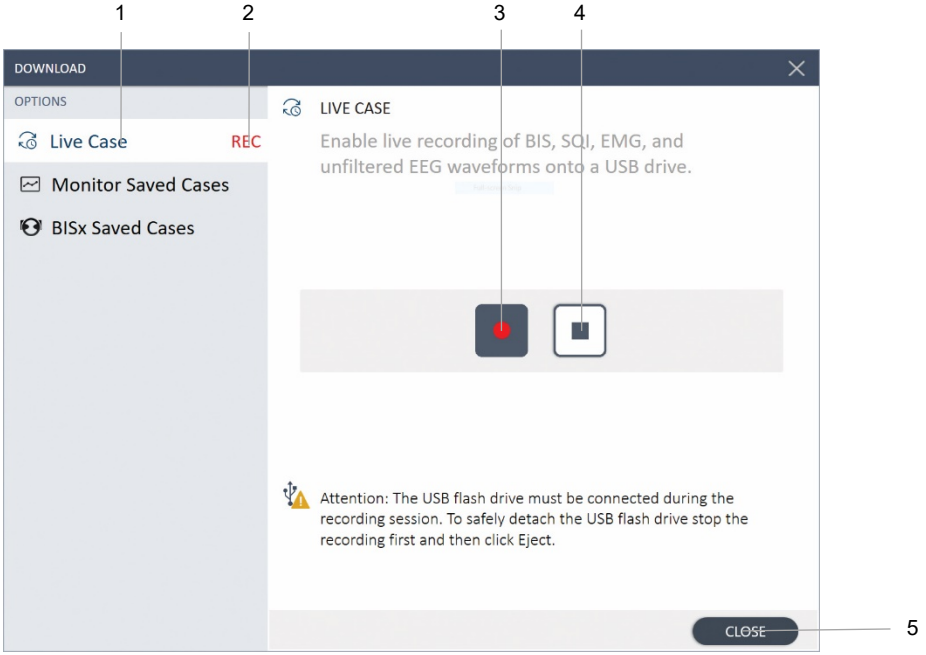
   - The monitor is shut down
   - The USB flash drive is removed
   - Live Case data download is stopped by turning **Live Recording** off by clicking the right square in the Live Case **DOWNLOAD** window.
   - The case ends
   - The operator removes and reinserts or switches the sensor or the BISx module (which will start a new case).

7. If the operator removes and reinserts or switches the sensor or the BISx module (which will start a new case), **Live Recording** must be set to **ON** again before download can commence.

8. The **Live Recording** default setting is **OFF**. **Live Recording** should be set to **ON** as described above before each new case.

9. To terminate Live Case Recording, best practice is to first terminate the case by removing the sensor from the patient, and then to remove the USB flash drive from USB flash drive port on the monitor or the docking station.

Figure 62. Live Case Recording Screen



Label	Function	Description
1	Download Options	List of download options. In this case, Live Case is the selected option
2	Recording indicator text	The word REC in red indicates that Live Case recording is going on

3	Live Case main recording indicator	The Live Case icon in the middle of the screen indicates that Live Case recording is going on
4	Not-recording indicator	Click this icon to turn off Live Case recording
5	CLOSE button	Click this button to close this window. Closing this window will not affect downloading.

Upon Live Case download, a folder with the name LMMDDHHMM (for description of file name, reference *Table 20. Live Data Export File Names Conventions*, below) will be created in the root folder of the USB flash drive. The folder will contain 9 files for each live export, as listed in the table below.

Table 20. Live Data Export File Names Conventions

Variable in File Name	Explanation
L	Live Data
MM	Month of recording
DD	Day of recording
HH	Hour of recording
MM	Minute of recording
.ar .e .f .h .m .o .r2 .sp .t	Fixed suffix, depending on file type. Each file in the folder will have its relevant suffix.
a	The last letter of the file name extension ('a') is the default option. If a file with the same base name exists, "a" will be changed to the next available letter.

The Live Data Export file will include the information described in *Table 22. Data Export Files* on page 197.

5.6. Saved Cases Export

Both the monitor and the BISx module will contain saved data, and both types of saved data may be downloaded. To download either type of data, monitoring must not be taking place. Thus, to download data from the monitor, remove the sensor from the BISx unit or remove the BISx unit from the monitor. To download saved data from the BISx module, ensure that the BISx module is connected to the monitor (but no sensor is connected to the BISx module). For information on the data that is available in saved cases export, reference *5.8 BIS™ Saved Data Files* on page 197.

To export saved cases:

1. Ensure that the monitor is not currently monitoring a patient - that is, there is no current open case. If there is an open case, remove the sensor or the BISx module to end the case.

2. Attach a USB flash drive to the USB flash drive port on the monitor or the docking station. (For location of the ports, reference *Figure 3. The BIS™* on page 44 and *Figure 9. BIS™ Advance Docking Station, Front View* on page 52.)

3. If you want to download data from the BISx module, connect the BISx module to the monitor.

4. Click **Main Menu**>**DOWNLOAD**.

5. Select **Monitor Saved Cases** or **BISx Saved Cases**, as desired. Download from the monitor or the BISx module is disabled during monitoring.

6. To download **Monitor Saved Cases**, select the desired case by checking the check box next to the desired **Case ID** on the **Monitor Saved Cases** screen that will open. The list of cases can also be searched by **Date & Time** or **Case ID**, using the **Filter** function. Click **Next**. Select the desired data types to download by clicking in the checkboxes to display check marks in the checkboxes for the selected data types. Click **DOWNLOAD** and the download will begin. Please note that the USB flash drive must remain connected during download.

7. To download BISx module saved cases, attach a BISx module to the monitor, but do not attach a sensor. Select the **BISx SAVED CASES** option. Click **DOWNLOAD** to download all data on the BISx module.

8. When the download is complete, the **Monitor Saved Cases** or **BISx Saved Cases** window will display a message indicating that the download has been successfully completed.

9. At this point the USB flash drive may be removed from the USB flash drive port on the monitor or the docking station.

The data types which can be exported for Monitor Saved Cases are listed in *Table 21. Monitor Saved Cases Export*, below.

Monitor saved cases folder names are created according to the following convention:

Folder name is M-CCCC-MMDDHHmm

- M = Monitor
- CCCC = case ID
- MM = month (01-12)
- DD = day (01-31)
- HHmm = hour (00-23) and the minute (00-59) (Date and time info refer to the case start time, except for Snapshot folders, for which the refenced time is the snapshot event time.)

For BISx module saved cases, the following folder name conventions are used:

Folder name is HMMDDHHmm_SNXXXXXXX

- H = BISx module
- MM = month (01-12)
- DD = day (01-31)
- HHmm = hour (00-23) and the minute (00-59) (All date and time info refer to the download time)
- SN = Serial number

XXXXXXX = serial number of BISx module

Table 21. Monitor Saved Cases Export Options

Option	Description	Folder Name
Case History data	A folder containing 9 files with case history data. The types of files are described in *Table 22. Data Export Files* on page 197. (For a better understanding of the files, consult the BIS™ Advance Monitor Export Data Technical Specification document, available via BISTechnicalsupport@medtronic.com.)	DHMMDDHHmm
Snapshot	A snapshot file will only be created if a snapshot event is created during the case. For description of the snapshot file, reference *5.7 Recording a Snapshot* on page 195.	ScrCap_CCCC_DDMMYYYHHmmSS.pdf (CCCC is a four character case ID, DD is a day [1-31], MM is a month [01-12], YYYY is a four digit year, mm is 2 digit minute [00-59], and SS is a 2 digit second [00-59]. The timestamp represents the time of the snapshot event.)
Table	A BIS report in pdf format showing BIS graphical and tabular data for the period covered in the export. The report also provides SQI and EMG data for each point in time alongside the BIS data in the table, as well as ASYM data for a report covers 4-channel monitoring. The data in the table shall be displayed in 1-minute intervals.	BIS_CCCC_DDMMYYYY_N-M (CCCC is a 4-character case ID, DD is a day [1-31], MM is a month [01-12], YYYY is a four digit year, N is the first page [1], M is the last page [2])

DSA Report	A DSA report in pdf format showing DSA chart data and BIS data for the period covered in the export. The data included in this report include: 1. SEF, MF 2. Frequency band scale labels 3. For 2-channel monitoring: DSA and BIS Trend 4. for 4-channel monitoring: ASYM, DSA left and right, and BIS trend	DSA_CCCC_DDMMYYYY_N-M.pdf (CCCC is a 4-character case ID, DD is a day [1-31], MM is a month [01-12], YYYY is a four digit year, N is the first page [1], M is the last page [2])

All date and time info refer to the case start time.

Download of BISx module Saved Cases will download all data saved in the BISx module at once.

The BISx module Saved Cases export will include the following files:

- HMMDDHHmm_SNXXXXXX.m_a
- MMDDHHmm_SNXXXXXX.spa

The data includes data saved in the BISx module: BIS values, SQI, EMG, and other related data at one-minute intervals. Data is identified by date and time (not by case IDs). For an explanation of the file types, reference *5.8 BIS™ Saved Data Files* on page 197. For a better understanding of the files, consult the BIS™ Advance Monitor Export Data Technical Specification document, available via BISTechnicalsupport@medtronic.com.

5.7. Recording a Snapshot Event

The Snapshot feature is used to capture a current screen shot as well as the preceding 10 minutes of case data, at any time during a case. The Snapshot feature is

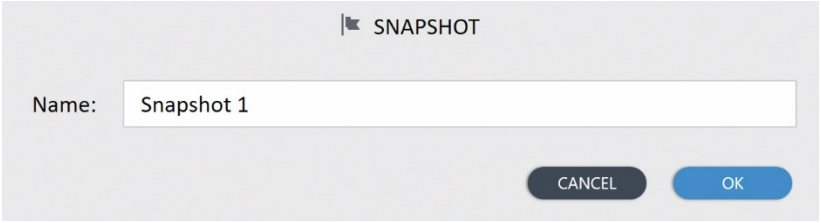
available only during a currently running case. A Snapshot cannot be recorded during Demo Mode.

If a snapshot is recorded as described in this section, the snapshot files will become part of the record for that case. Thus, if you download case data for a case for which a Snapshot has been recorded as described, the downloaded case data will include a Snapshot folder. To create a Snapshot event:

1. Create a Snapshot from a currently running case by clicking the **SNAPSHOT** button in the left Menu bar.

2. Click **OK** to save the data with the automatically generated Snapshot name, or change the Snapshot name and then click **OK** to save the snapshot with a file name of your choice. If you select a name, please note that, as the monitor uses an English keyboard only, all inputted letters must be available on the English keyboard.

Figure 63. Snapshot Window



When the user presses **OK in the SNAPSHOT window**, the system will create a separate sub folder for every Snapshot, named SNAP_EVENT_ID-MMDDHHmmss, in the Monitor's Saved Cases folder.

For each Snapshot event, it will create three folders, as follows:

1. A screen capture of the BIS home screen at the time of the snapshot event (in pdf format)

2. A page displaying EEG charts from the 10 minutes preceding the snapshot event (in pdf format) named "EEG_CCCC_DDMMYYYYHHmmSS" where CCCC is case ID, YYYY is a four digit year, MM is 2 digit month (01-12), DD is a 2 digit day (1-31), HH is 2 digit hour, mm is 2 digit minute and SS is 2 digit second. (e.g., EEG_Wv2I_19062007141744). The timestamp represents the earliest time of the EEG snapshot.

3. A Snapshot data sub-folder named SMMDDHHMM with BIS™ data files as described in *5.8 BIS™ Saved Data Files* on page 197.

The records are written from the earliest time to the latest time.

5.8. BIS™ Saved Data Files

Each type of export will create a folder with a series of files on the USB flash drive to which the data has been exported. The folders will include pdf files (described in the relevant sections) and a series of data files. For a more detailed explanation, consult the BIS™ Advance Monitor Export Data Technical Specification document, available via BISTechnicalsupport@medtronic.com.

Table 22. Data Export Files

File Type	File Suffix	Explanation
Artifact	ar	The Artifact binary file contains all the artifact flags from the period covered by the Processed Data file, and a Marker file, containing data regarding the monitor upon which the data was recorded, including its serial number, revisions, etc., as well as impedance messages and sensor check messages.
Error	e	The Error file lists errors that may occur during the case, including the following: Alarms Messages, Information Messages, System Event - Raw EEG missing packets (ID=25003), System Event - ProcVars missing packets (ID=25004), drop in RAW EEG or ProcVars data packets.
Spectra	f	The Spectra file is a readable text file displaying raw spectra values for 2 or 4 channels. It includes: "S_HDR3", Platform name, Software version, "Time", "Spectra"- for 2 channels or "Left Spectra","Right Spectra" - for bilateral, and time.
Header	h	The Header binary file includes the following data: Hours, minutes and seconds of Monitor current time, software revision 4 numbers followed by -1, Raw EEG data file size, current time in Epoch/Unix time.

		• Date - Month Day Year • Time - HH:MM:SS - in 24-hour format • Log type - ALARM or CLEAR • Name of Event • User Initialed event unique ID
Marker file	m	The Marker file will include the following data: BIS R2 Revision Information, BIS R2 Serial Number, Application revision, Platform revision, Serial protocol revision, Hardware revision, BISx module Revision Information, BISx module serial number, BISx module Software revision, BISx module Hardware revision, BISx module Serial protocol revision, Algorithm revision, Case ID, and current time for each line in marker file.
Offset	o	The Offset File will include the following data: BIS R2 Revision, SAD, Delimiter Tab, NaN, SAD, and Time
Raw EEG	r2 or r4	A Raw EEG data file (named LMMDDHHMM.r4a for the 4-channel system and LMMDDHHMM.r2a if using a 2-channel system). For snapshots, raw EEG data records are included in the Raw EEG file for 10 minutes preceding the Snapshot, or less than 10 minutes if less than 10 minutes have between the start of the case and the Snapshot.
Processed variables file	sp	Processed data file, listing the BIS™ system processed variables, including (but not limited to): Spectral Edge Frequency (SEF 95), SEF 50, Bispectral Index , Alternate BIS Value , Second Alternate BIS Value, EMG, Signal Quality Index (SQI), IMPEDANCE, Second artifact, BURST

		count, and, for 4-channel monitoring, ASYM, Standard BIS, and Standard EMG.
Time	t	The Time File includes current monitor time.

5.9. Logs Export

The user can download various logs to aid in troubleshooting and other analysis. The logs that are available for download are listed in the sections below. The BISx module Connection, Sensor connection, and System logs are provided in English only. The Monitor log will be in the current monitor GUI language.

To download any of these logs, click **Main Menu**>**Settings and Maintenance**> **Maintenance**>**Logs**. Download of the logs is not available during monitoring. Thus, disconnect the sensor from the BISx unit or disconnect the BISx module from the monitor before log download. However, note that the sensor connection log can be downloaded only with a BISx module (without a sensor) connected to the monitor.

Any of the four logs listed in the sections below can be selected. The logs can be accessed both in User mode and in Administrator Mode.

The monitor data memory is used to generate the various logs available for export. If the monitor data memory is full, the records of the earliest case will be deleted. Memory will be retained even if the monitor battery has been discharged and will be retained when the monitor and BISx are powered off.

5.9.1. BISx Module Connection History

The BISx Connection History log provides a list of BISx modules that have been connected to the monitor (including the monitor currently connected, if a BISx unit is currently connected), with the following details for BISx connection events:

- Date and time of connection
- BISx module/BISx4 module Serial number
- BISx module/BISx4 module Serial software version
- Date and time of start case

- "Demo Case," if this display was display of a demo case

The file name of the BISx connection history file will be as follows: nx_bisxcDDMMYYYYHHMMSS_SNNNNNNNNN.log, on the basis of the same variables used in the system log file name, except that "nx_bisxc" for "BISx Connection" will replace "s."

5.9.2. Sensor Connection History

The sensor connection history log provides information about all sensors that have been connected to the BISx module. Sensor Connection History may be downloaded only when a BISx module is connected to the monitor but not sensor is connected.

The log will be created in a folder named SDMMDDHHmm_SNXXXXXXXX in the root of the connected USB drive, on the basis of the same variables used in the system log file name, except that "SD" for "Sensor Connection" will replace "s."

The downloaded information will include:

- BISx module serial number
- BISx software revision
- Number of data records expected
- Log date/time
- Sensor LOT CODE
- Shelf life
- Usage count
- Sensor type
- Time in seconds, minutes, hour, day, month, year
- Checksum

5.9.3. Monitor Log

The Monitor Log includes the serial number of the monitor, SW Revision Number, and all saved events on the monitor, displayed in tabular format. The listed events include:

1. Alarm Messages (messages displayed in alarm bar)
2. Modal Messages (messages displayed in message windows, i.e., **Connect BISx to start monitoring**)
3. Information messages (messages displayed in message bar)
4. User Event Marking

For each line, the following data is provided:

1. Date - in the format DD MM YYYY (day month year)
2. Time - HH:MM:SS - using 24 hour clock format
3. Message ID
4. Message
5. Message status for alarms only (initiated, cleared)

The file is named m_logDDMMYYYYHHmmSS_SN_NNNNNNNN.log, based on the following:

- m – preset, denotes monitor
- _log – preset
- DD – Download day
- MM – Download month
- YYYY – Download year
- HH – Download hours
- mm – Download minutes

- SS – Download seconds
- SN – preset, denotes serial number
- NNNNNNNNNN – monitor serial number

The data in the Monitor Log is included in the System Log.

5.9.4. System Log

The System Log include identifying data (serial number of monitor and software revision number), as well as the records listed below. It differs from the monitor log in that it includes data about the system as well as data about the patient.

The System Log includes the following data:

1. Alarm Messages (messages displayed in alarm bar)
2. Modal Messages (messages displayed in message windows, i.e., **Connect BISx to start monitoring**)
3. Information messages (messages displayed in message bar)
4. Message status for alarms only (initiated, cleared)
5. User Event Marking
6. System Events
7. BISx module Errors
8. Monitor Errors
9. User GUI Events (events in which user performed a GUI-related action)

The System Log file is named s_logDDMMYYYYHHmmSS_SN_NNNNNNNN.log., on the basis of the same variables used in the monitor log file name, except that "s" for "system" will replace "m." This file will appear in a folder that will be created, titled: System_DDMMYYYYHHMMSS_SN_XXXXXXXXXX (where DD=day, MM=month, YYYY=year, HH=hour, MM=minute, SS=second, XXXXXXXXXX=serial number).

5.10. Viewing and Printing Saved Data in PDF Format

Some of the reports downloaded in the process described in *5.5 Live Case Export* on page 188 and *5.6 Saved Cases Export* on page 192 can be viewed in pdf format (with no need for additional processing). For a better understanding of the files that cannot be viewed with a pdf viewer, consult the BIS™ Advance Monitor Export Data Technical Specification document, available via BISTechnicalsupport@medtronic.com.

The reports in pdf format are listed and described in *Table 23. BIS™ Advance Reports in PDF format*, below.

Table 23. BIS™ Advance Reports in PDF format

Option	Description	Download Options
Snapshot: folder name SNAP_X_CCCC_ DDMMHHmmss (X is a consecutive number numbering the snapshot and mmss denotes the minutes and seconds of the snapshot time) Snapshot screen capture pdf file name is : ScrCap_CCCC_ DDMMYYYYHHmmss	Screen shot of BIS™ Advance home screen at the time the Snapshot was recorded, along with identifying data, including Serial number of the monitor, Monitor software version, BISx module software version, and case ID identifying data, date in which the report is generated, Case ID, Event ID - # of snapshot event, and Snapshot time - date and time.	As part of the Snapshot folder in a download of a Monitor Saved Case, if a Snapshot event was created during monitoring
Snapshot EEG report in the EEG Report sub-folder in the Snapshot folder: named "EEG_CCCC_YYYYMMDD_N-M.pdf" where CCCC is a case ID, YYYY is a four digit year, MM is 2 digit month (01-12), and DD is a 2	Each pdf 2-Channel EEG graph displays 10 seconds of EEG data, and includes 2 EEG sub graphs (channel #1 EEG sub-graph and channel #2 EEG sub-graph) for 2-channel monitoring and 4	As part of the Snapshot folder in a download of a Monitor Saved Case, if a Snapshot event was

Option	Description	Download Options
digit day (1-31), N is the first page (1), M is the last page(2).	EEG sub-graphs for 4-channel monitoring mode. Each 2-channel EEG PDF page includes 3 EEG graphs with different time slots, all of which will display time labels at 1 second spacing. The pdf includes identifying data, including date in which the report is generated, Case ID, Start and end date and time, Serial number of the monitor, Monitor software version, and BISx module software version.	created during monitoring
Table (in Monitor Saved Cases) Upon activation of Chart and Table export, the software shall create sub folder named "BIS_CCCC _ DDMMYYYYHHmmSS" in the Case History folder. For the 2-channel system: the PDF report is named "BIS_CCCC_YYYYMMDD_N-M.pdf" For the 4-channel system, the Chart/Trend PDF reports, are named "BIS_L_CCCC_YYYYMMDD_N-M.pdf" and "BIS_R_CCCC_YYYYMMDD_N-M.pdf" for the left and right hemispheres respectively.	A BIS report in pdf format showing BIS graphical and tabular data for the period covered in the export. The report also provides SQI and EMG data for each point in time alongside the BIS data in the table, as well as ASYM data for a report covers 4-channel monitoring. The data in the table shall be displayed in 1-minute intervals. For 4-channel monitoring, the pdf displays two side-by-side charts for the left and right hemispheres respectively. Data in the chart and table PDF report will include: Date in which the report is	As part of Monitor Saved Cases

Option	Description	Download Options
	generated, Case ID, Case start - date and time, Case end - date and time, Serial number of the monitor, Monitor software version, Copyright data and copyright symbol , BISx module software version.	
DSA Report The DSA report is named "DSA_CCCC_YYYYMMDD_N-M.pdf"	A DSA report in pdf format showing DSA chart data and BIS data for the period covered in the export. The data included in this report include: 1. SEF, MF trend lines (on DSA graph) 2. Frequency band scale labels 3. DSA and BIS Trend for 2-channel monitoring 3. ASYM (for 4-channel monitoring) 4. DSA left and right (for 4-channel monitoring) 6. BIS trend for 4-channel monitoring	As part of Monitor Saved Cases

6. Service and Maintenance

6.1. Introduction

This section describes the steps required for service and maintenance of the monitor.

6.2. Servicing the BIS™ Advance Monitor

Any type of service other than battery replacement may be performed only by authorized service technicians. Information regarding service is provided to service technicians in a separate service manual. For more information regarding servicing the monitor, contact BISTechnicalsupport@medtronic.com.

For battery replacement, reference *6.3 Battery Handling*, below.

WARNING: When no longer in use, this electronic equipment must be recycled or disposed of properly. Follow local ordinances for the safe disposal of electronic equipment. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com.

Note: Do not service the device when it is attached to a patient.

6.3. Battery Handling

Check the battery annually by operating a BIS™ Advance monitor that has been disconnected from the wall socket and that has been charging the battery for at least 4 hours when the monitor is powered off or 8 hours when the monitor is functioning. If the monitor fails to operate reliably from the battery for at least one hour, battery replacement is required.

After storage for three months or longer, charge the battery until it reaches at least an 80% charge level; battery charge will be indicated by the battery indicators. Battery capacity indicators are described in *3.3.3 Battery and Power Usage* on page 63. If the monitor fails to operate reliably from the battery for at least one hour when fully charged, battery replacement is required.

To charge the battery, place the battery in the monitor battery compartment as seen in *3.3.2 Battery Pack Removal* and Installation on page 61, and attach the device to AC power, either directly or via the docking station, via the power connectors described in *2.2.1 BIS™ Monitor* on page 43 and *2.2.3 Docking Station* on page 51. To provide battery power sufficient to power the monitor for at least 1 hour, charging time is up to 4 hours when the monitor is powered off and up to 8 hours when the monitor is functioning.

Note: It is recommended to use a protected ESD environment when replacing the battery pack.

The battery can be replaced by the user, as follows:

1. Remove the monitor from the docking station.

2. Obtain a replacement battery, as listed in *Table 34. BIS™ Advance Accessories* on page 252.

3. Remove the battery in the tablet, as described in *3.3.2 Battery Pack Removal* and Installation on page 61.

4. Place the new battery in the monitor, as described in *3.3.2 Battery Pack Removal* and Installation on page 61.

5. If your institution maintains an equipment log, record the replacement of the battery and the identifying data of the new battery in this log.

6. Dispose of the original battery in accordance with national and local waste disposal legislation and requirements.

WARNING: Electrical Shock Hazard: Do not remove battery compartment cover during operation or while power is connected to monitor.

WARNING: Only the battery pack provided with this monitor should be used for the monitor. Do not use another battery or a refurbished battery. Use of another battery or a refurbished battery may cause damage to the monitor or

endanger the user. Reference *Table 34. BIS™ Advance Accessories* on page 252 regarding the battery pack.

Caution: Check the battery annually by operating a BIS™ Advance monitor that has been disconnected from the wall socket and that has been charged for 4 hours when the monitor is powered off or 8 hours when the monitor is functioning. The monitor should function for at least one hour on battery power only.

Caution: The BIS™ Advance monitor contains an internal lithium ion battery. The battery must be disposed of or recycled with national and local waste disposal legislation and requirements. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com**.**

Caution: Replace the removable battery if an on-screen message informs you that this is required, or if more than seven years have passed since the production date marked on the battery, whichever comes first. To obtain a new removable battery, contact BISTechnicalsupport@medtronic.com**.**

The manufacture date of the battery can be identified as follows:

The battery's serial number appears on a label that is affixed to the battery just above the main label on the right side. The first three alphanumeric characters in the serial number are letters. The next four characters are numerals which make up the date code, in which the first two numerals indicate the year of manufacture (22 for 2022, for example) and the next two numerals indicate the week of manufacture (01 for the first week of the year, for example).

6.4. Cleaning the BIS™ Advance Monitor

6.4.1. Cleaning the BIS™ Advance Monitor and BISx Module

WARNING: Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Contaminated materials should be disposed of in accordance with national and local waste disposal legislation and requirements. The BISx module and the monitor should be cleaned using approved cleaning materials only.

Clean any spillage of blood or solutions on the surfaces of the monitor, docking station, adapter cable or BISx module as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISx module performance.

The surfaces of the tablet, docking station, adapter cable, and power supply may also be cleaned using the following materials:

- Lint-free cloths for use with cleaning agent
- Appropriate cleaning agent, as follows:
    - Ethanol 70%
    - Isopropanol 70%
    - Hydrogen Peroxide solution 0.5-1% concentration
    - Sodium Hypochlorite solution 6500 ppm (household bleach diluted approximately 1:10)

6.4.2. Disinfecting the BIS™ Advance System

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g., Lysol™* Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes) to clean the surfaces of the monitor, docking station, adapter cable and BISx module. After cleaning, dry all areas except the monitor display screen (see *6.4.3 Cleaning the Monitor Display* on page 210) with a lint-free absorbent paper towel. Wipe the BISx module and PIC connector ends with alcohol and allow to dry completely.

WARNING: Whenever an event such as spillage of blood or solutions occurs, re-test leakage current before further use.

Caution: Do not autoclave the BISx module or monitor. Autoclaving will seriously damage both components.

Caution: Avoid liquid ingress to the Patient Interface Cable (PIC), which is an integral part of the BISx module. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

6.4.3. Cleaning the Monitor Display

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaning materials.

6.5. Instrument Identification

6.5.1. Permanent Identification Marking

The BIS™ Advance monitor identification information is permanently marked on the rear panel of the monitor. The information includes instrument model, GTIN, serial number, and date of manufacture.

The BISx module identification information is permanently marked on the rear panel of the BISx module. The information includes instrument model and serial numbers and year of production.

6.5.2. Configuration Data on Monitor

Configuration data regarding the monitor, BISx module, and sensor is available on the monitor. BISx configuration data will appear on screen only if a BISx module is connected, and the **SENSOR CONFIGURATION** screen will display information about the currently connected sensor only if a sensor is connected to the monitor.

Take the following steps to access the Configuration Information screens:

1. Click the Main Menu button and select the **Settings and Maintenance** option.

2. Select **Maintenance**>**Configuration**. Select either **Monitor Configuration**, **Language**, **BISx Configuration**, or **Sensor Configuration**. The data listed in *Table 24. Monitor Configuration Data* on page 211 will appear.

Table 24. Monitor Configuration Data

Configuration Type	Available Data
Monitor Configuration	Monitor software, BIOS, OS, OS image version, Monitor serial no., Demo file, Serial port (MPM) protocol revision, BISx protocol revision, Hardware revision, Splash screen revision
Language Configuration	Displays Version of language pack for each installed language
BISx Configuration	BISx/BISx4, Serial Number, Software Revision, Software Checksum, FPGA Revision, SIC Revision, Hardware Revision, Protocol Revision, Algorithm Revision
Sensor Configuration	Lot Code, Serial Number, Sensor Type

7. Diagnostics and Troubleshooting

7.1. Diagnostics

7.1.1. DSC Self-Test

The Digital Signal Conversion (DSC) Self-Test verifies the signal acquisition and conversion functions of the BISx module, and tests the entire signal processing chain inside the BISx module.

It does not test the PIC or the sensor.

The BISx module must be connected to perform DSC self-test; a sensor may be connected but is not required.

The DSC Self-Test analyzes Noise, High-Pass Blocked, High Pass Normal, and Gain data from two channels or four channels, depending on the type of system (two-channel or four-channel). All results are in microvolts.

The DSC Self-Test will return a PASS result if all channels pass the test, and a FAIL result if one or more channels fails the test. The numerical values for any channel that passes the DC self-test shall be displayed.

To perform the DSC Self-Test, follow the steps listed below:

1. Click Main Menu>**Settings and Maintenance**>**Maintenance**>**DSC Self-Test**.

2. Click **START**.

3. The DSC Self-Test will proceed; an on-screen message will indicate **DSC Self-Test is in progress**. The DSC Self-Test cannot be stopped during the process.

4. When the process is complete, the screen will either indicate **DSC Self-Test – PASS** or **DSC Self-Test Failed** at the bottom of the screen. If the

monitor fails the DSC Self-Test, consult BISTechnicalsupport@medtronic.com for the next steps to take to continue working with the monitor.

7.1.2. EEG Filters

The monitor automatically turns on EEG filters in order to filter out undesirable interference from the raw EEG signals.

The notch filter handles both 50 and 60 Hz interference. The EEG filters for the display support the following modes: ON: 2 - 70 [Hz]; OFF: 0.25-100 [Hz]. The EEG filters also include high and low pass filters.

The user may want to view the EEG signals without filters, to aid in troubleshooting in case of problems. If so, the filters may be turned off by the user. For instructions on how to turn off the filters, reference *3.15.3.2 EEG Display* on page 131.

7.1.3. Impedance Checking

When a BISx module and sensor are connected to the monitor, the BIS™ Advance monitor continually checks impedance levels automatically by generating a 128 Hz test signal.

If the user is actively monitoring a patient, but is experiencing interference from other equipment, the user may want to turn off this 128 Hz impedance test signal to reduce the interference. For instructions on how to turn off the automatic impedance check, reference *3.15.3.3 Impedance* on page 133.

For additional information about impedance , reference *7.5 Glossary* on page 223.

7.1.4. Artifact Detection

The BIS™ Advance monitor automatically performs artifact detection. There are no user-changeable settings regarding artifact detection.

If no artifacts are detected, monitoring will proceed. If the monitor detects an artifact, a message indicating **Excessive artifacts in signal** will appear on the message bar at the bottom of the screen. For four-channel monitoring, the message shall appear if artifacts are found in data from at least one of the hemispheres.

7.2. Troubleshooting

In order to perform troubleshooting for issues that occur with use of the monitor, the following steps are recommended:

1. If a message appears on the monitor screen, locate that message in *4.3 Alarms and Messages* on page 143, and follow the relevant instructions in that section.

2. Check the list of issues in *Table 25. BIS™ Advance Monitor Troubleshooting Scenarios*, below, which covers issues which are not listed in the manual sections covering alarms and information messages (reference *4.3 Alarms and Messages* on page 143). If the problem occuring on your monitor appears in this table, follow the relevant instructions in the table.

3. If these steps do not resolve the problem, or if a problem which is not listed appears, contact BISTechnicalsupport@medtronic.com.

Table 25. BIS™ Advance Monitor Troubleshooting Scenarios

Scenario	Possible Cause	Recommended Action
Sensor does not fit into PIC.	The sensor may have been inserted into the PIC in the wrong direction.	Turn the sensor over and reinsert the sensor. Reference illustration in manual. If the sensor still does not fit, contact BISTechnicalsupport@medtronic.com.
Monitor does not turn on.	The monitor may not be receiving power, or battery may not be charged.	Check cable, socket power status, power status of docking station, and charge level of battery. If needed, contact BISTechnicalsupport@medtronic.com.
Monitor does not turn on when placed in docking station.	Power supply may not be attached to docking station, or monitor may not be securely	Check that power supply is attached to docking station and that monitor is securely placed in docking station. Reference *3.5 Preparing the Docking Station* on page 68. If needed, contact BISTechnicalsupport@medtronic.com.

	placed in docking station.	
	Pins may need cleaning.	Do not attempt to clean the pins. If needed, contact BISTechnicalsupport@medtronic.com.
Monitor is not monitoring even though all components are connected.	Sensor may not be compatible with the BIS™ Advance monitor and the BISx module.	Use only sensors supplied by Medtronic. Use the correct sensor for the specific patient and BISx module. For more information about sensors, reference *2.2.5 BIS Sensors* on page 56.
	Sensor may be expired or used up.	Replace sensor.
	Sensor may not be adhered correctly to patient.	Ensure all electrodes are securely fixed on patient and perform sensor check. If sensor does not pass the sensor check, replace sensor.
	PIC (the end of the BISx module that connects to the sensor) may be disconnected or faulty.	If replacing the sensor does not solve the issue, disconnect and reconnect the PIC. If this does not solve the issue, replace the PIC and the entire BISx module. If needed, contact BISTechnicalsupport@medtronic.com.
	MIC (the end of the BISx module that connects to the monitor) may be disconnected or faulty.	If replacing the sensor and/or the PIC does not solve the issue, ensure that the MIC is connected correctly to the monitor. If it is connected properly, replace the entire BISx module (the MIC is an integral part of the BISx module). If needed, contact BISTechnicalsupport@medtronic.com.

Adapter cable does not connect to monitor	The connection may have been performed incorrectly.	Arrow on monitor and red dot on adapter cable must be lined up in order to connect. Reference *Figure 7. Attaching the Adapter Cable to the Monitor* on page 49.
Touch screen not functioning properly: Screen does not respond at all; discernable delay in use of touch screen; touch screen is mis-aligned.	Touch screen problem.	Clean the touch screen with an approved cleaning solution. Restart the monitor. If needed, contact BISTechnicalsupport@medtronic.com.
Download not working	USB flash drive is full.	Try to download using another USB flash drive. USB flash drives that can be used with the monitor must have a capacity of at least 0.5 GB.
	USB flash drive does not fit into the USB port.	Try to download using another USB flash drive.
	LIVE DATA download option is not turned on.	Check that live download is turned on (reference *5.5 Live Case Export* on page 188).
	Monitor is placed in docking station but connected to power via the power port on the monitor ; in this case a USB flash drive attached to the docking station will not work.	Disconnect the monitor power connector, place the monitor securely in the docking station, and connect the docking station to AC power in order to use a USB flash drive in the docking station USB port.

Sensor check fails, even after the sensor has been replaced	EMC interference	Read EMC guidance in manual (reference *7.7 Electromagnetic Compatibility Specifications* on page 237) and readjust monitor and nearby appliances.
Sensor check fails, even after the sensor has been replaced	Faulty PIC	1. Ascertain if the PIC cable is functioning properly by running the sensor check with the sensor simulator attached to the patient end of the PIC cable instead of a sensor. 2. If the PIC cable functions correctly with the sensor simulator, and the sensor simulator passes the sensor check process, replace the sensor. 3. If the sensor simulator does not pass the sensor check process, replace the PIC and/or the entire BISx module.
Information from monitor does not appear on MPM, even though physical setup is correct	The incorrect protocol is being used, or the docking station is not receiving power.	Check that serial communication port protocol in use is correct for the MPM (reference *3.15.2 MPM Configuration* on page 130). Check that the docking station (to which the MPM cable is connected) is receiving power. (Data transfer to an MPM will not work when the docking station is not connected to AC power.) For docking station setup, reference *3.5 Preparing the Docking Station* on page 68.
Screen is dark and difficult to read	Screen is in "sleep mode"	Touch the screen or one of the hard keys to revert to a brighter screen. If needed, contact BISTechnicalsupport@medtronic.com.
Unexpected shutdown during operation	Device port door is open and liquid has entered the device via this door	IPX2 status is retained only if the monitor port door is closed. Ensure that monitor port door remains closed at all times.

Audio output is not clear	Stickers may be covering the device speakers.	Remove any stickers covering the device speakers. Stickers should be placed only on the battery area at the back of the monitor or on the docking station. If needed, contact BISTechnicalsupport@medtronic.com.
Software update failed	Flash drive not connected correctly, flash drive not readable by monitor, incorrect file on flash drive	If you are an administrator performing a software update, ensure that you have the correct files loaded onto a USB flash drive that is readable by the monitor and that the flash drive is connected to the docking station USB port or the monitor USB port; the location of these ports is described in *2.2.3 Docking Station* on page 51 and *2.2.1 BIS™ Monitor* on page 43. If needed, contact BISTechnicalsupport@medtronic.com.

For any questions regarding service or troubleshooting, please contact BISTechnicalsupport@medtronic.com.

7.3. Administrator Mode

7.3.1. Accessing Administrator Mode

To enter the Administrator Mode screen, click **Main Menu**>**Settings and Maintenance**>**Administrator Mode**. There must be no sensor attached to the monitor in order to enter Administrator Mode.

An Administrator password is required. Upon your first entry to the Administrator Mode, you will be asked to create an Administrator password.

The selected password shall include eight to ten (8-10) characters, including at least one character from each of the following types: Upper case English letters, lower case English letter, and digits (0-9). An underscore symbol may also be used in the password. As the monitor uses an English keyboard only, all inputted letters must be available on the English keyboard.

Record the selected password in a safe place. Input the selected password twice as requested by the software. Click **SET PASSWORD** and then **CLOSE**. The new password has now been set. Use this password for future entry to the Administrator section of the software.

Record the selected password in a safe place; reset of the Administrator password will require a service technician. For more information, contact BISTechnicalsupport@medtronic.com.

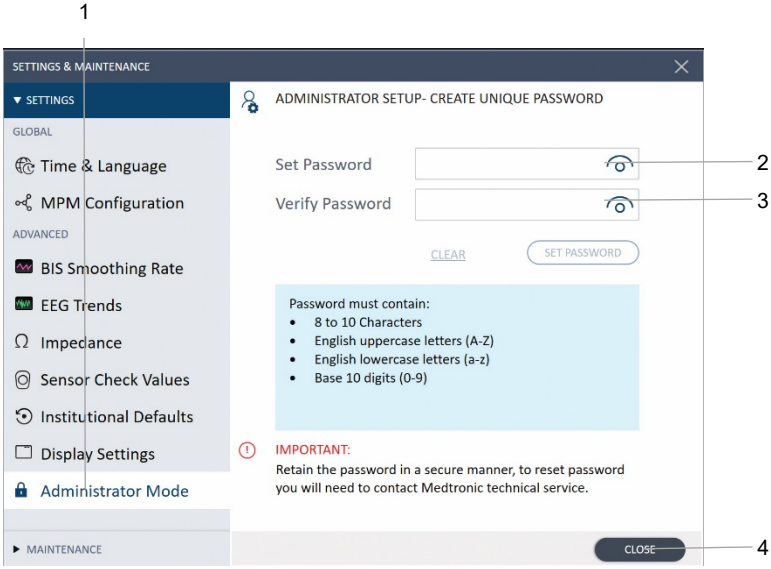
The Administrator Mode cannot be accessed when a sensor is connected. If a sensor is connected while the monitor is in Administrator Mode, the software shall exit Administrator mode and begin initializing the sensor for monitoring. In this case, the software shall automatically save all changed settings to Institutional Defaults and only then exit Administrator Mode. (If settings were changed but the **Apply** button was not clicked, the setting changes will not be saved.)

If the Administrator user sets changes to the Institutional Default settings, the software shall set the new values as Institutional Default values. The Institutional Default settings will now replace the factory default settings, and appear as defaults at the start of each case, until they are changed again in Administrator mode.

To exit Administrator Mode, click LOGOUT in the left bar menu. Please note that the monitor will also automatically exit the Administrator mode after 180 seconds of inactivity while in Administrator mode. A warning will appear after first 90 seconds of inactivity with a countdown.

WARNING: The software shall reset all settings with defined default values, to Institutional Defaults upon the end of each case, excluding Institutional Default Language settings. The software will also reset all settings (including language) to Institutional Defaults upon the restart of the monitor. However, if a sensor for which certain settings were set (as described in *3.15.3 Advanced User Settings* on 131, and whether changes were performed by a user or administrator) is re-attached, the monitor will apply the settings that were in place when that sensor was used last time.

Figure 64. Administrator Mode Login Screen



Label	Function	Description
1	Administrator Mode	Select Main Menu>**Settings and Maintenance**>**Administrator Mode** to enter this screen
2	Set Password field	Input desired unique password into this field
3	Verify Password field	Re-input desired unique password into this field
4	Close button	Select **Close** (or select the X at the top right of the window) to close this window and work in Administrator Mode.

7.3.2. Administrator Mode Actions

After the user enters a valid password and applies it, the software shall open the Administrator Settings and Maintenance menu and enable the Administrator user to perform the functions listed in this section.

7.3.2.1. Administrator Mode Settings

The user can modify defaults for the parameters listed in *Table 19. Institutional Settings* on page 181 while in Administrator Mode (except for those items listed in that table as not available in Administrator Mode).

To adjust Institutional settings, enter Administrator mode, and then click **Main Menu**>**Settings and Maintenance**>**Settings**. Select the desired setting and make changes as required.

The same settings can be adjusted by the user in standard mode, but in that case the settings will revert to defaults when a new case is started or when the monitor is turned off and on again. If changes are made and applied while in Administrator Mode, the changes will remain as active defaults on the monitor (that is, the institutional defaults) unless Factory Defaults are restored or changes are made in Administrator mode, even if the monitor is turned off and on again.

In addition, some settings can be adjusted in Administrator Mode only. The settings and actions that are available only in Administrator Mode are listed below. For other settings, reference *4.6 Institutional Settings* on page 180.

Table 26. Administrator Mode Settings

Feature	Options	Factory Default Option
Settings		
EEG Testing (enable display of EEG test layout for EEG testing) (when ON, EEG Testing will appear in Display Settings list, until the current case ends or the currently used	Enabled, disabled	Disabled

sensor is disconnected)		

Table 27. Administrator Mode Actions

Screen Text	Action	Result
Actions		
Erase Case Data	Erase Data: Cancel/Erase Data	Will permanently clear all previous case data
Factory Defaults	Reset Settings: Cancel/Apply	Will reset all settings to factory defaults
Audio Off Reminder (in ALARM SETTINGS screen if entered while in Administrator Mode)	Checkbox: check the checkbox to **Allow users to disable/enable this reminder for their own sessions**. Leave unchecked so that users cannot enable this reminder.	Users cannot enable/disable the Audio Off Reminder

7.3.2.2. Administrator Mode Maintenance

In the Administrator Mode, the administrator can perform the same maintenance activities as the user, as described in *3.15.3.6 Administrator Mode Login* on page 135. In additional, the Administrator can perform a software update, as follows;

1. Enter the Administrator Mode as described in *7.3.1 Accessing Administrator Mode* on page 218.

2. Select **Settings and Maintenance**>**Maintenance**>**Software Update**.

3. A USB flash drive that fits the device and contains the required software update files should be prepared. Fit this flash drive into the USB port on the docking station.

4. Click **NEXT** and follow the instructions on the screen to update your monitor software.

Caution: Do not disconnect the BISX™ unit during a software update.

For more information regarding software updates, contact BISTechnicalsupport@medtronic.com.

7.4. Demo Mode

The user can view either a 2-channel or a 4-channel Demo case. Demo cases can be viewed only if there is no BISx module connected to the monitor. In addition, please note that Demo Mode cannot be accessed while in Administration Mode. To view a Demo case, enter Demo Mode as follows: Click **Main Menu**>**INFO**>**Demo Mode** or **INFO** on left menu bar>**Demo Mode**. Select **Initiate Demo – 2-Channel** or **Initiate Demo – 4-Channel**, as desired.

To exit Demo Mode, click the **Exit Demo Mode** button at the bottom of the left bar on the screen. Alternatively, connect a BISx module with a sensor connected to exit the Demo Mode.

7.5. Glossary

Term	Definition
Administrator	Institutional support personnel who perform BIS monitor configuration and sets Institutional Defaults. Administrator is responsible to configure Global Settings, User Advanced Settings, Alarms Settings and User Defined Layouts for an institute or a department.
Anesthesia	A temporary induced state with one or more of: analgesia, paralysis, amnesia and/or unconsciousness. A patient under the effects of anesthetic drugs is referred to as being anesthetized. Anesthesia enables the painless performance of medical procedures that

	would cause severe or intolerable pain to an un-anesthetized patient.
Asymmetry	The percentage of total EEG power that resides in the left hemisphere of the brain. Available only with BISx4 and Bilateral Sensor. Calculated by BISx4 as: (Total Power Left / (Total Power Left + Total Power Right)) * 1000. The same calculation is performed for the right side of the brain, with (Total Power Right / (Total Power Right + Total Power Left)) * 1000.
Bilateral Sensor	The brand name for the 4-channel sensor used with the BIS Monitoring system, used to monitor both sides of the brain hemisphere ("bilateral" = 2 sides).
BISx module	The small module that attaches to the BIS™ Advance monitor via its own monitor cable and to a BIS™ sensor via the Patient Interface Cable (PIC). It acquires and processes EEG information and sends it to the monitor for display.
BISx4	A module similar to BISx module that is used during 4-channel monitoring with BIS Bilateral Sensor. It can be used in place of a BISx module with other sensors as long as it is used with the PIC-4.
BIS™ Bilateral Sensor	A single patient use, disposable, pre-gelled 6-electrode array that is applied directly to the patient's forehead and temple to record and display four channels of EEG, two from each side of the brain. The BIS sensor tab contains an electric smart card memory device that stores configuration and Identification information.

BIS™ Sensor	A single patient use, disposable, pre-gelled 4-electrode array that is applied directly to the patient's forehead to record electrophysiological signals. The BIS sensor tab contains an electric smart card memory device that stores configuration and Identification information.
BIS Complete Monitor, BIS Vista Monitor	Previous versions of the BIS™ Advance monitor
Extend Sensor	The brand name for the 2-channel (unilateral) sensor for use in the ICU. It is the same sensor as Quatro, but has space for time/date to be written on it, is smart chip detected, automatically sets smoothing rate to 30 seconds, and displays burst count.
Factory Defaults	Default settings values defined by manufacturer. Factory Defaults are loaded as Institutional Defaults on the first system boot or when restored through Administrator Mode.
Impedance	The measure of the quality of the sensor electrodes' contact; the amount of resistance that the electrical current encounters. Impedance is continuously monitored to ensure adequate signal quality.
Institutional Defaults	The default values for various settings which are defined by the Administrator for an institution or a certain department according to its requirements and policies.
Isoelectric EEG	Electrocerebral silence (flat EEG) or no significant electrical activity in the brain. Specifically, periods

	>240 msecs during which the electroencephalographic voltage did not exceed 5 μV.
Level of Consciousness (LoC)	Level of consciousness (LoC) is a measurement of a person's ability to be aroused and responsiveness to stimuli from the environment.
Monitor Interface Cable (MIC)	The portion of the cable the connects the BISx module to the Monitor. It is integral to the BISx module.
Patient Interface Cable (PIC)	The cable that connects the BIS™ sensor to the BISx module. It is integral to the BISx module.
Patient Interface Cable-4 (PIC-4)	A Patient Interface Cable that must be used when using the BISx4 module. It connects the BISx4 module to the BIS sensor.
Pediatric Sensor	The brand name for the 2-channel (unilateral) sensor used with the BIS™ Advance monitor for pediatric patients. The Pediatric sensor is suited for pediatric patients ages 4 and above.
Quatro Sensor	The brand name for the 2-channel (unilateral) sensor used with the BIS™ Advance monitor
Sensor Simulator	The BIS™ Sensor Simulator is a service tool that allows for the verification of proper impedance values being detected by the BIS™ Monitoring System during the sensor check. This sensor is used for testing purposes only.

7.6. Specifications

Specifications listed below are current for the time of manual printing. To obtain the most recent specifications, consult BISTechnicalsupport@medtronic.com. In case of any discrepancy, the data in the product specification to be supplied by BISTechnicalsupport@medtronic.com is considered authoritative.

7.6.1. General Specifications

Item	Value
Unit Dimensions	Monitor: 27.6cm (w) x 20.1cm (h) x 4.6cm (d) Docking station: 28.4 cm (w) x 23.8 cm (h) x 7.3 cm (d)
Unit Weight	Monitor: 1.2kg (2.6 lb) (1212g) Docking station: 0.7 kg (1.5 lb) (743g)
Packaged Dimensions	Monitor: 32.6 cm (w) x 24.9cm (l) x 10.5cm (h) [12.8in (w) x 9.8in (l) x 4.1in (h)] Docking station: 35.1 cm (w) x 27cm (l) x 10cm (h) [13.8in (w) x 10.6in (l) x 3.9in (h)]
Packaged Weight	Monitor: 2.3kg (5.1lb) Docking station: 1.1kg (2.4lb)
Operating Temperature	0 ºC to +35 ºC (32°F to 95°F) 0°C to +40°C (32°F to 104°F) for BISx
Operating Pressure and Altitude	107kPa (430m [1410ft] below sea level) to 54kPa (5000m [16400ft] above sea level) for monitor, docking station and adapter cable

Item	Value
	800 mm Hg (-457 [1500ft] below sea level) to 360mm Hg (6100 [20,000ft] above sea level) for BISx module
Operating Humidity	10% to 95%, non-condensing for monitor, docking station, adapter cable, power supply and removable battery
Storage and Transport Temperature	-20 ºC to +60 ºC (-4 ºF to 140 ºF) for monitor, docking station and adapter cable -10 ºC to +60 ºC (14 ºF to 14 ºF) for BISx module
Storage and Transport Pressure and Altitude	107kPa (430m [1410ft] below sea level) to 54kPa (5000m [16400ft] above sea level) for monitor, docking station and adapter cable
Storage and Transport Humidity	10% to 95%, non-condensing, for monitor, docking station, adapter cable, power supply and removable battery 15% to 95% for BISx module
Start-up Time	Up to 2 minutes
Ingress Protection marking	Ingress Protection marking of the tablet, docking station, adapter cable, and power supply is IPX2; this is applicable only if the door on the right edge of the tablet is closed. IPX2 protection of the docking station is applicable only if the tablet is connected to the docking station. For BISx and BISx4 modules, IP rating is IPX4

Item	Value
Protection Type	Internally powered when operating on internal battery Class II with isolated functional earth when operating on AC power
Degree of Protection	Type BF (defibrillator-proof)
Mode of Operation	Continuous
Isolation	The system includes 2MOPP isolation in its power supply (PMB4000PWS), as well as 1MOPP isolation in the BISx module.
Electromagnetic Compatibility	IEC 60601-1-2 (3rd and 4th Edition)

7.6.2. Operating Environments

The user should determine what mounting and use configuration best fits his needs, and order the relevant mounting accessories based on this decision. A list of the available mounting accessories appears in *Table 34. BIS™ Advance Accessories* on page 252.

Table 28. OR Configurations

Configuration	Tablet Mounted in Docking Station	BISx/BISx4 Unit	Required Accessory
1 - OR Pole	Mounted to a pole using clamp mount	Clamped to the IV pole / Clamped to the bed frame	GCX clamp mount (PMB4000PMT)

2 - OR Anesthesia Machine	Mounted to the post using a clamp mount	Clamped to the IV pole / Clamped to a handle on the anesthesia machine / Attached to the bed frame	One of the below, depending on requirements: GCX clamp mount (PMB4000PMT) Channel mount (standard mount to be purchased separately) Pivot arm (standard mount to be purchased separately) Post (standard mount to be purchased separately)
3 – OR Desk Top Mounting	Mounted to the tablet desktop mount	Clamped to the IV pole / Attached to the bed frame	Desktop mount (PMAC71STAND)
4 - Transit IV Pole	Mounted to a pole using clamp mount	Placed on the patient's bed or clamped to the IV pole	GCX clamp mount (PMB4000PMT)
5 - Transit on Patient's Bed	NA	Clamped to the patient's bed or placed on the patient's bed. Monitor and BISx unit should not touch the patient directly.	GCX clamp mount (PMB4000PMT) or no mount

7.6.3. Power Supply

Item	Value
Input	100-240 VAC, ±10% 50-60 Hz, 1.5A
Output Voltage and Power	19V DC, 3.15A ~ 4.73A
Maximum System Power consumption	Up to 25W
Power supplied to system	60W

7.6.4. Battery Specifications

Item	Value
Battery Type	2S1P -Lithium-ion Polymer
Battery pack nominal voltage and energy	Nominal Voltage -7.4V Nominal energy -38.036Wh
Battery Operational Temperature	During battery charging (when connected to AC power): 0° to 45° C When battery is not charging (when not connected to AC power): -20° to 60° C
Battery Charging Time	To provide battery power sufficient to power the monitor for at least 1 hour, charging time is up to 4 hours when the monitor is powered off and up to 8 hours when the monitor is functioning.
Battery Storage	Batteries may be stored for up to three months at -20° C to + 45° C.

	For time periods over three months, batteries should be stored at 25±3° C If the monitor is to be stored for three months or more, store the battery outside the monitor.

7.6.5. Controls and Connectors

Item	Value
Monitor Front Panel	Function button Home button ON/OFF button
Connectors	Power, microphone/earphones, USB, mini USB, reset button, HDMI, docking station connector
Docking station	RS-232, VGA, Network, USB, Power, dock for tablet
RS-232	Serial port Baud rate: 9600 for ASCII protocol 57,600 for binary protocol

7.6.6. Alarms

Item	Audible Alarm	Visual Alarm
High Priority Alarm	Beep pattern repeated every 5 ± 1 seconds.	Flashing red square under alarming parameter
Medium Priority Alarm	Beep pattern repeated every 7 ± 1 seconds	Flashing yellow square under alarming parameter

Low Priority Alarm	Single beep repeated every 17 ± 1 seconds	Yellow square under alarming parameter
Messages	Single beep	None

7.6.7. Display

Item	**Value**
Display size	10.1 Inch IPS Display with LED Backlight Active Display Area: 216.81 (horizontal) 135.50 (vertical) mm
Display characteristics	Multi-touch projected capacitive display Contrast Ratio 800:1 Brightness 600 nits TYP.
Screen resolution	1920 (horizontal) x 1200 (vertical) pixels
PPI (pixels per inch)	224.17 pixels per inch
Pixel Pitch	0.11292 x 0.11292 mm
Viewing angle	Viewing angle (side) 140° Viewing angle (above/below) 120°
Operator position for visibility	BIS value: visible at up to 4 meters from the monitor EMG data: visible at up to 1 meter Graphs and status data: visible at up to 45 cm

7.6.8. Sound Pressure Data

Sound pressure values when measured at a microphone positioned in a distance of 1 m, behind the monitor, are as follows (higher value is when used with a docking station):

Item	Minimum Volume Setting	Maximum Volume Setting
High priority alarms	60-63 dB(A)	81-84 dB(A)
Medium priority alarms	53-56 dB(A)	75-78 dB(A)
Low priority alarms	47-50 dB(A)	68-71 dB(A)
Info messages	47-50 dB(A)	68-71 dB(A)

7.6.9. BIS Specifications

Parameter	Range	Units
Bispectral Index (BIS™)	0-100	Integer, absolute number
SQI Number	0-100, where each bar is 20%	%
ASYM	0-100%	%
EMG	decibels (dB)	30-80 dB as a trend 30-55 dB as a bar
SR	0-100%	Percent
ST	Hours, minutes, seconds	00:00 to full case; case is up to 24 hours
MF	1 Hz-30 Hz	Frequency - [Hz] units

SEF	1 Hz-30 Hz	Frequency - [Hz] units
DSA	NA (graphic representation)	NA (graphic representation)
EEG	µV/mm	Display gain 2, 5, or 10 [µV/mm]
Burst Count	Bursts/Minute	0 - 30

7.6.10. EEG Specifications

Item	**Value**
Epoch Duration	2 seconds
Artifact Rejection	Automatic
Input Amplifier Range	±1 mV
EEG Amplitude	Default for all layouts which include an EEG graph: ±50 µV (full scale) In full screen layouts, option to view graph with ±100 µV amplitude
EEG Scale	In two-channel mode, 2 or 5 µV/mm: 2 µV/mm is default for full screen or ½ screen EEG graph, and 5 µV/mm is default for 1/3 screen EEG graph) In four-channel mode, 2, 5, or 10 µV/mm: 2 µV/mm for full screen EEG graph 5 µV/mm for ½ screen EEG graph 10 µV/mm for 1/3 screen EEG graph
EEG Sweep Speed	6.25, 12.5, 25, or 50 mm/sec

	Default 6.25 mm/sec
Computed Parameters	Bispectral Index, Suppression Ratio, Suppression Time, EMG, Signal Quality Indicator, and Burst Count
User-defined Displays	Trend and real-time EEG waveforms
Update Rate	1 second for BIS™ number, 10 seconds for Trend
Alarms	Auditory and visual, user adjustable limits
Filters	ON (2-70 Hz with notch) or OFF (0.25-100 Hz)
Mode	Sensor Automatically selects mode two-channel or 4-channel)

7.6.11. BISx Module Specifications

Item	Value
Weight	10.0 oz (0.284 kg) including integral cable
Dimensions	3.75 in. (9.5 cm) diameter x 2.5 in. (6.3 cm) thick
Cable Length	9 ft (2.7 m) Integral BISx Cable 4 ½ ft (1.4 m) from BISx to sensor connector
Analog to Digital Converter	Noise-shaped sigma-delta
Sampling Rate	16,384 samples/second
Resolution	16 Bits at 256 samples/second
Input Impedance	50 M ohms typical (DC) 5 M ohms typical (at 10 Hz)
Noise	< 0.3 µV RMS (2.0 µV peak-to-peak);

	0.25 Hz to 50 Hz
Common Mode Rejection	110 dB at 50/60 Hz to earth ground
(Isolation mode)	0.16–100 Hz

7.6.12. Software/GUI Specifications

Item	Value
Screen refresh rate	60 Hz
GUI languages	Bulgarian, Chinese, Croatian, Danish, Dutch, English, French, German, Greek, Hungarian, Italian, Japanese, Macedonian, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovak, Slovenian, Spanish, Swedish
Case storage	Case limited to 24 hours (a new case will open if monitoring time exceeds 24 hours) Monitor can store up to 50 cases

7.7. Electromagnetic Compatibility Specifications

The BIS™ Advance monitor complies with the requirements of IEC 60601-1-2 (3rd and 4th Editions) when used with the accessories listed in this manual (reference *Table 34. BIS™ Advance Accessories* on page 252). In addition, the BIS™ Advance monitor must be used only with the power cord provided.

When using a removable drive to load new versions of software into the BIS™ Advance monitor, no cables or other accessories should be connected to the device. The BIS™ Advance monitor should be connected to AC power through the appropriate power cord, and the removable drive should be plugged into the USB-A connector on the monitor or the docking station. For location of those ports, reference *Figure 4. BIS Monitor Connectors* on page 46 and *Figure 11. BIS™ Advance*

Docking Station Connectors on page 54. These ports are for use with a USB flash drive only.

WARNING: Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS™ Advance monitor system.

WARNING: The BIS™ Advance monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS™ Advance monitor should be observed to verify normal operation in the configuration in which it will be used.

WARNING: 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 60601-1-1 harmonized national standard.

The monitor complies with the applicable requirements of IEC 60601-1-2.

This section provides the appropriate specification tables for the BIS™ Advance monitor as per IEC 60601-1-2 (3rd and 4th Editions), IEC 60601-2-26 (2nd and 3rd Edition), and 80601-2-26:2019.

The monitor is suitable for use in the specified electromagnetic environment. The user of the monitor should assure that it is used in an electromagnetic environment as described below. Working in an environment other than the environment described below can result in a considerable reduction in device performance and is not recommended.

Note: Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Table 29. Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic Environment – Guidance**
RF Emissions CISPR 11	Group 1	The BIS™ Advance monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The BIS™ Advance monitor is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

The recommended electro-magnetic environment for operation of the monitor is described in *7.7 Electromagnetic Compatibility Specifications* on page 237.

For all immunity tests, the system is set up to recover within 30-50 seconds with no operator intervention and no data loss.

Table 30. Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines. ± 1 kV for input/output lines.	± 2 kV for power supply lines. ±1 kV for input/output lines.	Mains power quality should be that of a typical hospital environment.
Surge IEC 61000-4-5	0.5 kV, 1.0 kV, and 2.2 kV, line to earth. 0.5 kV and 1.1 kV, line to line. (0, 90, 180, and 270 degrees)	0.5 kV, 1.0 kV, and 2.2 kV, line to earth. 0.5 kV and 1.1 kV, line to line. (0, 90, 180, and 270 degrees)	Mains power quality should be that of a typical hospital environment.
Voltage dips IEC 61000-4-11	U_T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 350 degrees)	U_T = 0%, 0.5 cycle (0, 45, 90, 135, 180, 225, 270, and 350 degrees)	Mains power quality should be that of a typical hospital environment. If the user of the BIS™ Advance monitor requires continued operation

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
	U_T = 0%, 1 cycle U_T = 70%, 25/30 cycles (0 degrees)	U_T = 0%, 1 cycle U_T = 70%, 25/30 cycles (0 degrees)	during power mains interruptions longer than 45 minutes, it is recommended that the BIS™ Advance monitor be powered by an uninterruptible power supply.
Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_T = 0%, 250/300 cycles	U_T = 0%, 250/300 cycles	Mains power quality should be that of a typical hospital environment. If the user of the BIS™ Advance monitor requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the BIS™ Advance monitor be powered by an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	30 A/m, 60 Hz	30 A/m, 60 Hz	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Note: U_T is the AC mains voltage prior to the application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms, 150 kHz to 80 MHz 6 Vrms (ISM Bands)	3 Vrms, 150 kHz to 80 MHz 6 Vrms (ISM Bands)	Portable and mobile RF communications equipment should be used no closer to any part of the BIS™ Advance monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$, 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$, 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m).
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m 80 MHz to 2.7 GHz	

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Field strengths from fixed RF transmitters, as determined by electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

Note:

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIS™ Advance monitor is used exceeds the applicable RF compliance level above, the BIS™ Advance monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the BIS™ Advance monitor.

The BIS™ Advance monitor is intended for use in the electromagnetic environment specified below. The customer or user of the BIS™ Advance monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
[b] Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m. ……			

The BIS™ Advance monitor is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.

Table 31. Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BIS™ Advance Monitor

Rated maximum output power of equipment **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3

Rated maximum output power of equipment **W**	**Separation distance according to frequency of transmitter** **m**		
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 32. Proximity Field Immunity Compliance

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2, 4th Edition)							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max. Power (W)**	**Distance (m)**	**Immunity Compliance Level (V/m)**	**Immunity Test Level (V/m)**
385	380 to 390	TETRA 400	Pulse Modulation 18 Hz	1.8	0.3	27	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5kHz deviation 1 kHz sine	2	0.3	28	28
710	704 to 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
745	704 to 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
780	704 to 787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.2	0.3	9	9
810	800 to 960	GSM 800/900, TETRA 800,	Pulse Modulation 18 Hz	2	0.3	28	28

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2, 4th Edition)							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max. Power (W)**	**Distance (m)**	**Immunity Compliance Level (V/m)**	**Immunity Test Level (V/m)**
		iDEN 820, CDMA 850, LTE Band 5					
870	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	2	0.3	28	28
1720	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2, 4th Edition)							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max. Power (W)**	**Distance (m)**	**Immunity Compliance Level (V/m)**	**Immunity Test Level (V/m)**
1845	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
1970	1700 to 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	2	0.3	28	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	2	0.3	28	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9

Guidance and Manufacturer's Declaration—Electromagnetic Immunity (IEC/EN 60601-1-2, 4th Edition)							
Test Frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Max. Power (W)**	**Distance (m)**	**Immunity Compliance Level (V/m)**	**Immunity Test Level (V/m)**
5500	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
5785	5100 to 5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.2	0.3	9	9
Note: The distance values represent the recommended separation distance between interfering equipment and the monitor.							

7.8. Product Compliance

Standard
RoHS 3 Directive 2015/863
WEEE 2012/19/EU
PSE Act. Compliance (Batteries)

PSE Marking for power supply
FCC ID, FCC CFR 47 Part 15
Directive 2006/66/EC
UL 2054, 2nd edition (batteries)
IEC 62133-2 2017-02. (batteries)
UN 38.3
EU 2017/999 (REACH)
IEC 60601-1:1988 +A1/A2 & EN 60601-1:1990 +A11/A12/A13 Medical Electrical Equipment Part 1: General Requirements for Safety (China)
IEC 60601-1:2005 + A1:2012 (medical devices in general) 2012.08 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1:2006 + A12:2014
CAN/CSA-C22.2 No. 60601-1:14 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (Adopted IEC 60601-1:2005, 2005-12), includes Corrigendum 1:2011.
EN/IEC 60601-1-2: 2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests, and the following requirements defined in the EEG particular standard: 1. For Electrostatic Discharge (ESD) tests, ME Equipment may show temporary degradation during discharges. Within 30 [seconds] the system shall resume normal operation in the previous operating mode, without loss of any operator settings or saved case data, and shall continue to perform its intended function. 2. For Radiated electromagnetic fields immunity - the test level shall be 3 V/m. 3. During Electrical Fast Transients (EFT) test, the system shall continue to display the EEG waveform.

EN/IEC 60601-1-6: 2010 +A1: 2015 - Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability.
EN/IEC 62366-1:2015 Medical Devices – Application of usability engineering to medical devices
IEC 60601-1-8: 2006 + A1: 2012 - Medical electrical equipment: General requirements for basic safety and essential performance, Collateral Standard, General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
EN 60601-2-26: 2012- Medical Electrical Equipment – Part 2-26: Particular Requirements for the Safety of Electroencephalographs.
EN 80601-2-26: 2019 - Medical Electrical Equipment – Part 2-26: Particular Requirements for the Safety of Electroencephalographs.
EN 60601-2-26: 2003- Medical Electrical Equipment – Part 2-26: Particular Requirements for the Safety of Electroencephalographs (China).
ANSI / AAMI ES 60601-1:2005+A1:2012 Medical electrical equipment— Part 1: General requirements for basic safety and essential performance
IEC 60601-1:2012 Section 11.6.6, Cleaning and disinfection of ME equipment

7.9. BIS™ Advance Components, Accessories, and Documentation

A list of the components of the BIS™ Advance system appears below.

Table 33. BIS™ Advance Monitor Components and Sensors

Product Name	Description or Application	Part Number
BIS™ Advance Monitor	BIS monitor that can be used with either a BISx or BISx4 module	PMB4000 (an additional suffix may denote region)
BIS™ Advance docking station	Docking station to permit easy mounting of monitor	PMB4000DOC
BIS™ Advance Adaptor cable	Adapter cable used to connect monitor to BISx module	PMB4000ACBL
BISx module	Processes 2 channels of EEG information (one brain hemisphere) to work with BIS™ Advance Monitor	186-1095-xxx
BISx4 module	Processes 4 channels of EEG information (both side of the brain) to work with BIS™ Advance Monitor	186-0224-xxx

A list of BIS™ Advance accessories appears below. Some of these are components which are also available for purchase separately.

Table 34. BIS™ Advance Accessories

Product Name	Description or Application	Part Number
BIS™ Advance docking station	Docking station to permit easy mounting of monitor	PMB4000DOC
BIS™ Advance Adaptor cable	Adapter cable used to connect monitor to BISx module	PMB4000ACBL
GCX clamp mount	Clamp mount for docking station with monitor. For purchase directly from GCX.	PMB4000PMT

Product Name	Description or Application	Part Number
GCX desktop mount	Desktop mount for docking station with monitor. For purchase directly from GCX.	PMAC71STAND
GCX mount for anesthesia machine	Mounting accessories for mounting monitor with docking station to anesthesia machine. The clamp mount can be purchased from Medtronic. The other parts are for purchase directly from GCX.	Requires one or more of the following parts: Channel mount (GCX PN OH-0010-80) Pivot Arm (GCX PN PQ-0008-03) Post (GCX PN PQ-0008-11 12" [inch]) GCX clamp mount (PMB4000PMT)
Power supply	Used to connect the docking station to AC power; may also be used directly with the monitor	PMB4000PWS
Removable battery	Used to supply battery power to the monitor	PMB4000BAT
North America power cord	Power cord used with monitor for connection to AC power in North America	PT00059589
Japan power cord	Power cord used with monitor for connection to AC power in Japan	PT00059590
South Korea power cord	Power cord used with monitor for connection to AC power in South Korea	PT00059576
Continental Europe power cord	Power cord used with monitor for connection to	PT00059577

Product Name	Description or Application	Part Number
	AC power in continental Europe	
UK power cord	Power cord used with monitor for connection to AC power in the United Kingdom	PT00059578
Israel power cord	Power cord used with monitor for connection to AC power in Israel	PT00059579
Australia power cord	Power cord used with monitor for connection to AC power in Australia	PT00059581
China power cord	Power cord used with monitor for connection to AC power in China	PT00059582
Argentina power cord	Power cord used with monitor for connection to AC power in Argentina	PT00059583
Switzerland power cord	Power cord used with monitor for connection to AC power in Switzerland	PT00059584
Denmark power cord	Power cord used with monitor for connection to AC power in Denmark	PT00059585
Italy power cord	Power cord used with monitor for connection to AC power in Italy	PT00059586
Brazil power cord	Power cord used with monitor for connection to AC power in Brazil	PT00059587

Product Name	Description or Application	Part Number
South Africa power cord	Power cord used with monitor for connection to AC power in South Africa	PT00059588
BISx (previously known as LoC 2 Channel)	Processes 2 channels of EEG information (one brain hemisphere) to work with BIS™ Advance Monitor.	185-1014-xxx
BISx4 (previously known as LoC 4 Channel)	Processes 4 channels of EEG information (both side of the brain) to work with BIS™ Advance Monitor.	185-1016-xxx
Sensor Simulator	Simulated sensor, to test system functioning	186-0137
Quatro	Quatro Sensor for adult patients undergoing general anesthesia or sedation.	186-0106
Extend	Extend Sensor for adult patients undergoing general anesthesia or sedation in environments such as the ICU.	186-0160
Pediatric	Pediatric Sensor for pediatric patients ages four and up.	186-0200
Bilateral	Bilateral Sensor that detects hemispheric differences in the brain (for advanced monitoring applications). Requires use of the LoC 4 Channel device.	186-0212

The system may be operated on a desktop, mounted to the patient's bed, a pole, or other mount in the patient's environment or mounted on an anesthesia machine. The user should consider the use case environment. Reference *Table 28. OR*

Configurations on page 229 and determine which solution is best for the specific environment.

To purchase accessories, please contact BISTechnicalsupport@medtronic.com.

The BIS™ Advance monitor is packaged with a manual and clinical quick guide cards in English and other languages in soft copy on a flash drive.

A list of documentation available in multiple languages in hard copy is listed below. These items may be ordered from your local Medtronic representative.

Item	Language	Part Number
Operator's Manual	Brazilian Portuguese	PT00136161
Operator's Manual	Bulgarian	PT00136162
Operator's Manual	Chinese (simplified)	PT00136165
Operator's Manual	Croatian	PT00136166
Operator's Manual	Czech	PT00136167
Operator's Manual	Danish	PT00136168
Operator's Manual	Dutch	PT00136169
Operator's Manual	English	PT00117625
Operator's Manual	Estonian	PT00136170
Operator's Manual	Finnish	PT00136171
Operator's Manual	French	PT00136172
Operator's Manual	German	PT00136173
Operator's Manual	Greek	PT00136175
Operator's Manual	Italian	PT00136174

Item	Language	Part Number
Operator's Manual	Hungarian	PT00136176
Operator's Manual	Japanese	PT00136177
Operator's Manual	Kazak	PT00136178
Operator's Manual	Korean	PT00136180
Operator's Manual	Latvian	PT00136181
Operator's Manual	Lithuanian	PT00136182
Operator's Manual	Macedonian	PT00136183
Operator's Manual	Norwegian	PT00136184
Operator's Manual	Polish	PT00136185
Operator's Manual	Portuguese	PT00136186
Operator's Manual	Romanian	PT00136187
Operator's Manual	Russian	PT00136179
Operator's Manual	Serbian	PT00136188
Operator's Manual	Slovak	PT00136189
Operator's Manual	Slovene	PT00136190
Operator's Manual	Spanish	PT00136191
Operator's Manual	Swedish	PT00136192
Operator's Manual	Turkish	PT00136193
Operator's Manual	Ukrainian	PT00136194

Item	Language	Part Number
Clinical quick guide cards	Brazilian Portuguese	PT00134375
Clinical quick guide cards	Bulgarian	PT00134376
Clinical quick guide cards	Chinese (simplified)	PT00134377
Clinical quick guide cards	Croatian	PT00134378
Clinical quick guide cards	Czech	PT00134379
Clinical quick guide cards	Danish	PT00134404
Clinical quick guide cards	Dutch	PT00134406
Clinical quick guide cards	English	PT00134374
Clinical quick guide cards	Estonian	PT00134408
Clinical quick guide cards	Finnish	PT00134409
Clinical quick guide cards	French	PT00134410
Clinical quick guide cards	German	PT00134411
Clinical quick guide cards	Greek	PT00134412

Item	Language	Part Number
Clinical quick guide cards	Italian	PT00145105
Clinical quick guide cards	Hungarian	PT00145106
Clinical quick guide cards	Japanese	PT00145107
Clinical quick guide cards	Kazak	PT00145108
Clinical quick guide cards	Korean	PT00145110
Clinical quick guide cards	Latvian	PT00145111
Clinical quick guide cards	Lithuanian	PT00145112
Clinical quick guide cards	Macedonian	PT00145113
Clinical quick guide cards	Norwegian	PT00145114
Clinical quick guide cards	Polish	PT00145115
Clinical quick guide cards	Portuguese	PT00145116
Clinical quick guide cards	Romanian	PT00145118
Clinical quick guide cards	Russian	PT00145109

Item	Language	Part Number
Clinical quick guide cards	Serbian	PT00145119
Clinical quick guide cards	Slovak	PT00145120
Clinical quick guide cards	Slovene	PT00145121
Clinical quick guide cards	Spanish	PT00145122
Clinical quick guide cards	Swedish	PT00145123
Clinical quick guide cards	Turkish	PT00145124
Clinical quick guide cards	Ukrainian	PT00145125

7.10. Warranty

Covidien warrants to the initial Purchaser that the BIS™ Complete monitor and the BISx ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of three years ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Covidien's obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Covidien reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

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