BIS™ Module, E-BIS™ Module

For monitoring the state of the brain in the OR, ICU and procedural sedation locations with the BISx™ platform.



The E-BIS™ Module with the BISx™ digital signal processing unit from Medtronic provides a Bispectral Index™ value (BIS™), a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. The BISx™ unit receives, filters, and processes patient EEG signals using bispectral analysis and the BIS™ algorithm to derive BIS™ Index values. The system complies with IEC 60601-1 3rd edition.

Benefits of BIS™ monitoring

Use of the Bispectral Index™ technology (BIS™) in adults and pediatrics may enable clinicians to:

- Assess the level of consiousness and sedation
- Titrate anesthetic drugs to individual patient requirements, and reduce the use of hypnotic anesthetics
- Aid in faster and more predictable wake-up and extubation

Features

- Improved performance in electromyogram (EMG) conditions
- Enhanced resistance to electrocautery
- Improved performance in both light and deep states of anesthesia and sedation
- Family of sensors available: BIS™ quatro 4-electrode sensor, BIS™ pediatric sensor, and BIS™ extend sensor

Display options

- BIS™ information integrated into CARESCAPE™ monitor screens
- In addition to the BIS[™] value, the GE monitors display one channel of raw EEG waveform, Suppression Ratio (SR), Signal Quality Index (SQI) and Electromyography (EMG)
- Trending of BIS™ values, EMG and SR for up to 24 hours in anesthesia and 72 hours in critical care

Technical specifications

Direct function keys

BIS™ Opens BIS™ menu

Check Sensor Starts impedance measurement of

electrodes

BIS™ EEG values

EEG scales $25 \text{ to } 500 \,\mu\text{V}$

EEG sweep speeds 12.5/25/50 mm/sec

BIS™ 0 to 100 SQI 0 to 100 %

EMG 25 to 100 dB (70 to 110 Hz)

Suppression ratio (SR) 0 to 100%

Filters ON (2 to 70 Hz with notch),

OFF (0.25 to 100 Hz)

Mode Sensor automatically selects mode

BIS™ rates

Update rate 1 second for BIS index

Smoothing rate User selectable in BIS menu,

15 or 30 seconds

BISx™ (Digital Signal Processing Unit)

Analog to digital converter Noise-shaped sigma-delta

Sampling rate 16,384 samples/second

Resolution 16 bits at 256 samples/second

Input impedance > 50 Mohms typical

Noise $< 0.3 \mu V RMS (2.0 \mu V peak-to-peak)$

0.25 to 50 Hz

Common mode rejection 110 dB at 50/60 Hz to earth ground

(Isolation mode)

Bandwidth 0.25 to 100 Hz (-3dB)

Sensor compatibility

 $\mathsf{BIS^{\textsc{tm}}}$ quatro 4-electrode sensor, $\mathsf{BIS^{\textsc{tm}}}$ pediatric sensor, and

BIS™ extend sensor

Monitor compatibility

CARESCAPE modular monitors

Environmental specifications

Operating conditions

Temperature 10 to 40°C (50 to 104°F)

Relative humidity 10 to 95% non-condensing

Storage conditions

Temperature -25 to 70°C (-13 to 158°F)

Relative humidity 10 to 95% non-condensing

Physical specifications

E-BIS™ Module

Dimensions (H x W x D) 11.2 x 3.7 x 18.9 cm (4.4 x 1.5 x 7.4 in)

Weight 0.3 kg (0.66 lb)

BISx™ Digital Signal Processing Unit

Dimensions

(diameter, thickness) 9.5 cm, 6.3 cm (3.75 in, 2.5 in)

Weight 0.284 kg (0.6 lb)

Integral BISx™ Cable

Length 2.7 m (9 ft)

Patient Interface Cable (PIC Plus)

Length 1.3 m (4 ft)

A NOTE ABOUT the BIS™ system: The CARESCAPE monitors use a component BISx™ device purchased from Medtronic in deriving the Bispectral Index™ (BIS™) values. It is important to recognize that this index is derived using solely that company's proprietary technology. It is recommended that clinicians review applicable information on its utility and/or risks in Medtronic's "Monitoring Consciousness - Using the Bispectral Index During Anesthesia, A Pocket Guide for Clinicians" (Second Edition), Scott D. Kelley, MD, or contact Medtronic if they have clinical-based BIS™-monitoring questions relating to this module portion of the monitor.

BIS™ technology is a complex monitoring modality intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting the BIS™ values in conjunction with other available clinical signs. Reliance on the 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.



Imagination at work

Product may not be available in all countries and regions. Full product technical specification is available upon request. Contact a GE Healthcare Representative for more information. Please visit www.gehealthcare.com/promotional-locations.

Data subject to change.

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