



Summary

The Bispectral Index (BISx™) module acquires real-time electroencephalogram (EEG) data for adult and pediatric patients and processes it into a Bispectral Index® (BIS®) number between 0 and 100. BIS analysis is a mathematical calculation derived from the frequency, power, and phase throughout the entire frequency range of the EEG.

The BISx Module may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.



Features

Product Configurations

Display Formats	Single zone: The BIS trend and numeric are displayed. Three-zone (bedside monitor only): The BIS and EMG trends are displayed, as well as one EEG waveform (waveform is user selectable).
Data Storage	Predefined EEG trends for easy setup; BIS, Spectral Edge Frequency (SEF), Median Power Frequency (MF), Electromyographic Strength (EMG), Signal Quality Index (SQI), and Suppression Ratio (SR) data; Burst Count (BC) data is available when using the BIS Extend Sensor.
Electrode Impedance Testing	Manual or Auto modes; the combined BIS sensor impedance measurements are checked continuously; the impedance of the ground element is checked every 10 minutes.
Module Configuration Manager	Provides the ability to define the module's user-configurable settings. Once a module has been configured, these settings control its operation whenever the module is powered ON.
Patient Compatibility	Adult and pediatric. <i>Note:</i> <i>Module use is restricted to one patient at a time.</i>

Product Specifications

Number of Channels	Two
Sweep Speeds	15, 30, 50 mm/second
EEG Input Signal	1 mV to $\pm 1000 \mu V$
EEG Bandwidth	0.25 to 100 Hz



EEG High Pass Display Filters	30, 50, 70 Hz, and NONE
EEG Low Pass Display Filters	0.25, 1, and 2 Hz
EMG Bandwidth	70 to 110 Hz
DC Offset	±300 mV maximum
Input Impedance	>50 MΩ
Common Mode Rejection	>110 dB (50/60 Hz notch filter)
Input Noise	<.3 μV RMS (2 V peak-to-peak, 0.25 to 50 Hz)
Alarm Display Options	Audible alarms for HI and LO alarm limits, and caution alarm

Classification

MDD	Class IIb
EN 60601-1	Externally powered; rate for continuous operation
BISx Pod	Type BF; defibrillator-proof Body Floating applied part

Electrical Specifications

Patient Leakage Current	<100mA
Operating Voltage	+5 VDC, ±12 VDC
Power Consumption	4.5 watts maximum
Isolation	4000 VAC

Environmental Requirements

Storage

Temperature	-25° to 60° C (-13° to 140° F)
Humidity	95% (non-condensing)
Altitude	0 to 12,192 meters (0 to 40,000 feet)

Operating

Temperature	0° to 40° C (32° to 104° F)
Humidity	95% (non-condensing)
Altitude	0 to 3,000 meters



Dimensions

Height	11.4 cm (4.5 inches)
Width	5.6 cm (2.2 inches)
Depth	17.8 cm (7 inches)
Weight	0.45 kg (1.01 lbs)

Accessories

Refer to the Spacelabs Healthcare Supplies and Accessories Catalog for availability of BISx sensors and accessories.

BISx kit; includes BISx pod, patient interface cable (PIC), host monitor cable	P/N 719-0006-xx
BISx Patient interface cable (PIC)	P/N 719-0004-xx
BIS Pediatric sensor	P/N 719-0001-00 or 719-0001-10
BIS Quatro sensor	P/N 719-0002-00 or 719-0002-10
BIS Extend sensor	P/N 719-0003-00 or 719-0003-10

Documentation

CD-ROM Part Numbers	Bedside, Central, and Telemetry Systems CD-ROM (P/N 084-1101-xx) Spacelabs Healthcare Service Documents CD-ROM (P/N 084-0700-xx)
Supplies and Accessories	Spacelabs Healthcare Supplies and Accessories Catalog (sa.spacelabshealthcare.com)

Regulatory Approvals



The BISx device has been tested and certified by Underwriter's Laboratories to meet IEC/UL 60601-1 for product safety and IEC 60601-2-26, Second Edition, for EEG performance.



CSA certified. Meets IEC 60601-1, CAN/CSA C22.2 No. 60601-1, and ANSI/AAMI ES60601-1 for electrical safety, and IEC 60601-2-26: EEG.



CE marked in accordance with the Medical Device Directive 93/42/EEC.



Does not contain hazardous substances - Europe



Does not contain hazardous substances - China

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