OVERVIEW
The BISx system utilizes the latest BIS™ XP platform from Covidien to provide depth of consciousness and sedation monitoring for use in the OR, ICU and other clinical settings.

PARTNERING TO IMPROVE PATIENT OUTCOMES
BIS™ monitoring is most widely used in the OR to:

- Reduce emergence and recovery time\(^1\)
- Reduce anesthetic drug use\(^1\)
- Reduce the risk of awareness during surgery\(^2,3\)

In the ICU, BIS monitoring has been shown to reduce recall of unpleasant experiences\(^2,3\) and provide objective sedation assessment during:

- Mechanical ventilation
- Neuromuscular blockade
- Barbiturate coma
- Bedside procedures

HOW BIS WORKS
BIS brain function monitoring is a direct measure of the effects of anesthetic and sedative agents on the brain. Using a sensor placed on the patient’s forehead, BIS monitoring translates brain electrical activity into a single number between 100 (wide awake) and zero (absence of brain electrical activity) that represents the patient’s level of consciousness. This enables clinicians to customize the precise type and amount of anesthetic or sedative medication based on each patient’s needs.
**BISx™ MONITORING TECHNICAL SPECIFICATIONS**

### Output Parameters/BIS Specifications

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bispectral index (Bis)</td>
<td>0 to 100</td>
</tr>
<tr>
<td>Electromyographic Strength (EMG)</td>
<td>30 to 80 dB (where 1 µV^2 = 40 dB)</td>
</tr>
<tr>
<td>Signal Quality Index (SQI)</td>
<td>0 to 100%</td>
</tr>
<tr>
<td>Suppression Ratio (SR)</td>
<td>0 to 100%</td>
</tr>
<tr>
<td>Spectral Edge Frequency (SEF)</td>
<td>0.5 to 30.0 Hz</td>
</tr>
<tr>
<td>Total Power</td>
<td>40 to 100 dB (where 1 µV^2 = 40 dB)</td>
</tr>
<tr>
<td>Burst Count</td>
<td>0 to 30 (with an Extend Sensor only)</td>
</tr>
<tr>
<td>EEG (Continuous, two channel, real-time EEG waveform)</td>
<td>&lt; 0.3 µV RMS (2.0 µV peak-to-peak): 0.25 Hz to 50 Hz</td>
</tr>
<tr>
<td>BIS Numeric Update Frequency</td>
<td>Once per second</td>
</tr>
<tr>
<td>EGG Bandwidth</td>
<td>0.25 Hz to 100 Hz (-3 dB) +/- 10%</td>
</tr>
</tbody>
</table>

Electrode to skin impedances are continuously measured.

### Filters

Users can select from a range of low-pass and high-pass filters that are available for artifact rejection. The low-pass filters allow the rejection of muscle artifacts. The high-pass filters allow the rejection of ECG signal interference. In addition, a notch filter suppresses line frequency interference. The BIS XP technology built into the BISx system suppresses interference from electrosurgery, EMG, and other high frequency noise sources.

### Physical Specifications

**BISx System**

- Size: 98 mm (3.85") diameter x 63.5 mm (2.5") height (including clamp)
- Weight: 211 g (7.44 oz) without cables. 434 g (0.96 lb) with cables
- Integrated clamp: Can accommodate pole up to 32 mm (1.25 in.) in diameter

**BISx Integral Cables**

- Host Monitor Cable: 2.7 m (9 ft) with Hypertronics Hypergrip connector
- Patient Interface Cable (PIC+): 1.4 m (4.5 ft)

### Safety Specifications

The BISx system complies with the essential requirements of the Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC, as well as IEC 60601-1-2:2002 and UL60601-1-2003. It is a Type BF applied part. It has internal optical interface specifications and is resilient to artifact from electrosurgery.

### Data Exchange Summary

The BISx system communicates with the host monitor through asynchronous serial communication (RS-232 or USB). The protocol is packet oriented with binary data and ACK/NACK handshaking. The host monitor can:

- Choose the communication protocol by an input select line in the host cable
- Request BISx hardware & software revision information
- Send commands to the BISx system to change smoothing rate (making the BIS parameter more or less sensitive to sudden changes in patient measurements), change filter settings, and initiate a sensor check.

The information specified in the “Output Parameters” section of this data sheet is transmitted from the BISx system to the host once per second. Each of these processed variables packets is 198 bytes long. Additionally, the BISx system will transmit EEG waveform data to the host eight times per second. Each of these raw EEG packets is 154 bytes long.

### Interface Specifications

<table>
<thead>
<tr>
<th>Interface Specification</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>BISx Host Connector</strong></td>
<td>12 pin barrel-style connector, P/N HG2P14GY1204MRH, yellow color, visual &amp; mating keys</td>
</tr>
</tbody>
</table>

### Input Power Requirements

The BISx system adheres to the power requirements of the USB 1.1 Spec.

- Voltage Input: +5VDC +/- 5%
- Max Current Draw: 500 mA
- Supply Voltage Ripple: <100 mV at all frequencies

### Communication Requirements

- Protocol: RS-232 or USB (selectable via line select)
- Rate: 5.76 Kbps
- Data: 8 bit
- Stop: 1 bit
- Parity: None
- Flow Control: None

### USB Communication

Conforms to the USB 1.1 spec for a full-speed device.

- Rate: Up to 12 Mbps

### Environmental Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Temperature Range</strong></td>
<td></td>
</tr>
<tr>
<td>Operating</td>
<td>0 to 40° C (32 to 104° F)</td>
</tr>
<tr>
<td>Storage</td>
<td>-40 to 70°C (-40 to 158°F)</td>
</tr>
<tr>
<td><strong>Humidity</strong></td>
<td></td>
</tr>
<tr>
<td>Operating</td>
<td>10 to 95% RH at 40°C (104° F), non-condensing</td>
</tr>
<tr>
<td>Storage</td>
<td>10 to 95% RH at 60°C (140° F), non-condensing</td>
</tr>
<tr>
<td><strong>Altitude Range</strong></td>
<td></td>
</tr>
<tr>
<td>Operating</td>
<td>Up to 6,130 m (20,000 ft)</td>
</tr>
<tr>
<td>Storage</td>
<td>Up to 15,300 m (50,000 ft)</td>
</tr>
</tbody>
</table>

### Product Information

**BISx System**

- 185-0145-SF: BISx (Standard Format)

### Ordering Information

**BISx SYSTEM**

- 186-0195-SF: BISx (Standard Format)

### Replacement and Exchange Parts

- 186-0107: Patient Interface Cable (PIC+)
- 186-0201-SF: Replacement Host Cable
- 186-0202: Replacement Bulkhead Connector

For more information or details on compatibility and module components, contact your Covidien sales representative.