Bispectral Index™ technology (BIS™) monitors the direct effects of anesthetics and sedatives on the brain to help clinicians optimize anesthesia delivery. Though there are several brain monitors to choose from, no two perform exactly alike. It's critical to know:

- How the technology works
- Whether the monitor is clinically validated
- What differentiates the monitor from other similar technologies

**HOW DOES BIS™ TECHNOLOGY WORK?**

In short, BIS™ monitors help anesthesia care providers customize anesthetic dosing for each patient by linking brainwave data to the individual’s clinical state:

- A BIS™ sensor collects low-frequency electroencephalograph (EEG) data
- The raw data is interpreted and translated into the BIS index
- Using the BIS index to guide titration may improve clinical outcomes

To truly demystify this powerful technology, however, a deeper dive is necessary.

**HOW IS THE LOW-VOLTAGE EEG SIGNAL ACQUIRED?**

Traditionally, EEG data is collected through sensors placed all over the patient’s shaved scalp. The preparation process is arduous, and the resulting signal must be interpreted by specially trained staff.

BIS™ technology enables simple EEG data collection via a non-invasive sensor applied to the patient’s forehead. Only proprietary BIS™ sensors offer:

- Zipprep™ technology, which enhances conductivity and cuts down prep time by clearing away the first layer of skin
- A wide selection of sensors to meet the unique needs of individual patients in diverse clinical settings

**BIS™ SENSORS FOR VIRTUALLY EVERY SCENARIO**

- 4-Electrode Adult Sensor
  - For general use in the OR and PACU
  - Product ID: 186-0106

- Extended Sensor
  - For use in the ICU
  - Product ID: 186-0160

- Bilateral Sensor*
  - For added symmetry monitoring
  - Product ID: 186-0212

- Pediatric Sensor
  - For children ages 4 and up
  - Product ID: 186-0200

*Not compatible with BIS™ 2-channel systems. BIS™ LOC 4-channel cables required.
HOW DOES BISPECTRAL ANALYSIS INTERPRET THE RAW EEG DATA?

Like the sine wave below, every waveform is made up of certain characteristics:

- **Amplitude** denotes half the peak-to-peak height (Amplitude$^2 = \text{Power}$)
- **Frequency** means repetitions per second, measured in hertz (Hz)
- **Phase** refers to the relative shift of the waveform from its origin

Sample Waveform Analysis

An EEG is made up of multiple sinusoids at different frequencies all combined into a single signal. The power and frequency of those underlying components can change based on level of consciousness.

But analyzing only a single characteristic (such as power) doesn’t offer a complete picture of how the component sinusoids influence the main signal. That’s why bispectral analysis reflects changes in the power, frequency and phase of the waveforms that comprise the EEG signal.

WHAT IS THE BIS INDEX?

The clinically validated BIS index is a number between 0 and 100 that continuously indicates a patient’s response to anesthetic agents. It is the result of in-depth signal processing via the proven BIS algorithm, which isolates and analyzes the EEG features that correlate best with clinical endpoints.

CREATING THE BIS ALGORITHM

1. More than 5,000 adult EEG segments with clinically assessed associated hypnotic states or sedation levels were analyzed. Segments containing artifact were rejected.
2. In the remaining EEG segments, analysis revealed that the features that correlated best to anesthetic-induced changes were:
   - **Power spectrum** (reflects the amplitude of each frequency in the signal)
   - **Bispectrum** (indicates the level of synchronization in the EEG and helps classify amplitude and frequency)
   - **Nearly and fully suppressed EEG periods** (the length of time of near EEG suppression and full EEG suppression or “flat line”)
3. The validated BIS algorithm enables the optimum combination of these features using multivariate statistical modeling techniques.
4. The result is a reliable, clinically validated, processed EEG parameter that continuously indicates anesthetic and sedative effects.

<table>
<thead>
<tr>
<th>BIS INDEX</th>
<th>CLINICAL STATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>100</td>
<td>Awake</td>
</tr>
<tr>
<td>80</td>
<td>Light/Moderate Sedation</td>
</tr>
<tr>
<td>60</td>
<td>General Anesthesia</td>
</tr>
<tr>
<td>40</td>
<td>Deep Hypnotic State</td>
</tr>
<tr>
<td>20</td>
<td>Burst Suppression</td>
</tr>
<tr>
<td>0</td>
<td>Flat Line EEG</td>
</tr>
</tbody>
</table>

BIS$^\text{™}$ technology quantifies the relationships between changing signal components to reflect synchronization in the EEG.

BIS Index Range and Clinical State
CLINICALLY PROVEN TO ENHANCE OUTCOMES

Unlike other consciousness-monitoring technologies, thousands of peer-reviewed, published articles have confirmed that BIS-guided anesthesia can result in improved patient outcomes:

- Up to 50% reduction in propofol use in the ICU
- Up to 50% decrease in anesthetic drug use in the OR
- Up to 40% faster wake-up times
- Faster recovery and extubation times
- 87% increase in “Excellent/Fully Oriented” status on PACU admission
- 32% faster eligibility for PACU discharge
- Up to 80% lower incidence of intraoperative awareness with recall in adults
- Improved patient satisfaction

AWARENESS-PREVENTION GUARANTEE: ASSURANCE YOU WON’T GET ANYWHERE ELSE

If one of your patients experiences a case of anesthesia awareness while using either standalone or integrated OEM platform Bispectral Index™ technology, and the electronic record shows that the BIS index value was below 60 at the time of anesthesia awareness, indemnification will be provided in accordance with the terms agreed upon between Covidien and the hospital or purchaser.

HEAD-TO-HEAD COMPARISONS: BIS™ TECHNOLOGY ADVANTAGES

<table>
<thead>
<tr>
<th>BIS™ TECHNOLOGY COMPETITIVE DIFFERENTIATORS</th>
<th>BIS™ (Covidien)</th>
<th>ENTROPY™ (GE Healthcare)</th>
<th>SEDLine® (Masimo®)</th>
<th>SNAP II® (Stryker®)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both standalone and modular hardware options available</td>
<td>✓</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>Unilateral, bilateral, ICU and pediatric sensors available</td>
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<td>X</td>
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<tr>
<td>Indicated for reduced awareness with recall in adults</td>
<td>✓</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Indicated for reduced anesthetic use and emergence time</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Published meta-analysis of randomized clinical outcomes trials for ambulatory anesthesia</td>
<td>✓</td>
<td>✓</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>
ONLY BIS™ TECHNOLOGY OFFERS ALL OF THE FOLLOWING:

- More supporting clinical evidence than any competing product with over 4,000 published materials
- Cochrane meta-analysis focused on anesthetic delivery and recovery
- FDA 510(k) clearance (#K072286) for reductions in primary anesthetic consumption, emergence and recovery times and intraoperative awareness
- An awareness-prevention guarantee†

†See inside for full details.

Find out how BIS™ technology can help you improve clinical outcomes and enhance your approach to patient-targeted anesthesia at www.covidien.com.

BIS™ Complete
4-Channel Monitor

Product ID: 186-1014

BIS™ Brain Monitoring Solutions
The Bispectral Index Difference

 technologies to monitor anesthetic delivery and recovery.

BIS™ TECHNOLOGY COMPETITIVE DIFFERENTIATORS

<table>
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<tr>
<th>Technology (Maker)</th>
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<th>SEDLine®*</th>
<th>SNAP II®*</th>
</tr>
</thead>
</table>
| Time-saving and cost-saving 
Rehabilitation and postoperative care | X | X | X | X |
| Enhanced patient safety and outcomes | X | X | X | X |
| Improved communication and coordination | X | X | X | X |
| Optimal patient care and outcomes | X | X | X | X |
| 50% reduction and cost-savings | X | X | X | X |

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