

REFERENCE GUIDE

USING THE BISPECTRAL INDEX™ (BIS™) MONITORING SYSTEM FOR CRITICAL CARE



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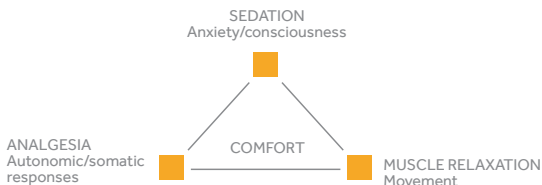
WHAT IS THE BIS™ MONITORING SYSTEM?

The BIS™ brain monitoring system generates a processed EEG parameter that provides a direct measure of the effects of sedatives on the brain. The BIS™ monitoring value is represented as a number from 0 to 100 that is calculated from the raw EEG obtained by a sensor placed on a patient's forehead. The BIS™ value is used in a variety of settings — including anesthesia, critical care, and procedural sedation — to provide objective information about an individual patient's response to sedative drugs.

Definition of key terms:

- **Sedation:** The reduction of anxiety or stress by the administration of a sedative drug; pain and motion may be present.
- **Analgesia:** The absence of a normal sense of pain by the administration of an analgesic drug; anxiety and motion may be present.
- **Neuromuscular paralysis:** Loss of voluntary muscular function by the administration of a drug (neuromuscular blocking agent) that obstructs nerve impulse transmission; pain and anxiety may be present.

ASSESSING COMFORT



ICU sedation: A bipolar challenge

Inadequate sedation may result in oversedation or undersedation. Each is associated with negative consequences.

Oversedation

- Patient unable to participate in care
- Delayed weaning
- Ventilator-associated pneumonia
- Increases in:
 - Unnecessary testing
 - ICU and hospital length of stay
 - Costs

Undersedation

- Anxiety, agitation
- Increases in:
 - Use of neuromuscular blocking agents
 - Risk of recall/awareness of unpleasant events
 - Unintended removal of medical device

BIS™ SYSTEM RANGE GUIDELINES

BIS™ VALUE RANGE	100	Awake <ul style="list-style-type: none">▪ Responds to normal voice
	80	Light/moderate sedation <ul style="list-style-type: none">▪ May respond to loud commands or mild prodding/shaking
	60	General anesthesia <ul style="list-style-type: none">▪ Low probability of explicit recall▪ Unresponsive to verbal stimulus
	40	Deep Hypnotic state
	20	<ul style="list-style-type: none">▪ Burst suppression
	0	Flatline EEG



Titration of sedatives to the BIS™ monitoring ranges should depend on the individual goals for sedation that have been established for each patient. These goals and associated BIS™ monitoring ranges may vary over time and in the context of patient status and treatment plan.

CRITICAL CARE

The BIS™ monitor provides a direct measure of the effects of sedatives on the brain.

In the critical care setting, the BIS™ monitor is commonly used to allow objective assessment of sedation during:

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

The BIS™ monitoring system is most useful for patients who are chemically paralyzed and/or moderately to deeply sedated. Muscle activity may interfere with reliable BIS™ monitoring performance.

Important information for using BIS™ monitoring in the ICU

- Reliance on the BIS™ value alone for sedative management is not recommended.
- Always use clinical judgment when interpreting the BIS™ value in conjunction with other available clinical signs.
- Interpret BIS™ monitoring readings over time and in response to stimulation, and in the context of patient status and treatment plan.
- Movement may occur with low BIS™ values.
- Movement (EMG) may indicate inadequate analgesic level.
- Artifacts and poor signal quality may lead to unreliable BIS™ values. Potential artifacts may be caused by poor skin contact, muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement or skin preparation, and unusual or excessive interference.
- Interpret BIS™ values cautiously in patients with known neurological disorders, in those taking psychoactive medications, and in children less than one year old.
- Natural sleep cycles may affect the hypnotic level.

BIS™ MONITORING DISPLAY INFORMATION

BIS™ value

Displays the current BIS™ monitoring value (0 to 100).



BIS™ trend

Displays the BIS™ monitoring value over time.



EEG waveform

Shows real-time raw EEG.



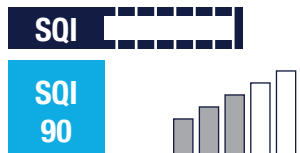
EMG (electromyogram)

Depicts presence of muscle activity or high-frequency artifacts. When present, interpret BIS™ monitoring value with caution; assess source of artifact.



SQI (signal quality index)

Indicates the quality of the signal over the last 63 seconds. May be shown as a bar graph or numerically.



SR (suppression ratio)

Indicates the percentage of the last minute that the EEG signal was suppressed. Burst suppression refers to bursts of EEG activity alternating with isoelectric EEG.

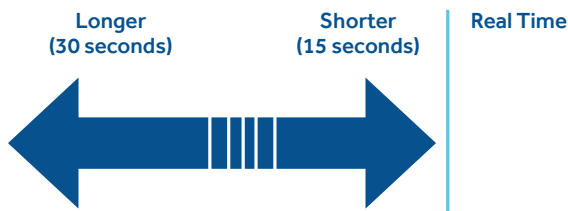


SMOOTHING RATE

Although raw EEG data is acquired and displayed in real time, the BIS™ monitoring value — a processed EEG parameter — is calculated as a rolling average using a moving window of time. This “smoothing” is necessary to prevent excessive fluctuations.

Smoothing rate (or averaging time) is the period (e.g., 15 or 30 seconds) over which artifact-free data is analyzed to calculate the BIS™ value.

Smoothing Rate Effects on BIS™ Monitoring



The smoothing rate effects include:

- Decreased variability
- Decreased delay
- Easier discernment of general case trends
- Increased responsiveness to state
- Decreased sensitivity to artifact
- Changes, bolus administrations

Our BIS™ monitors offer different smoothing rate options. To change your monitor's setting, please refer to your operator's manual.

INTERPRETING BIS™ MONITORING VALUES

BIS™ Value Increases Suddenly or is Higher than Expected

Clinical situations that may indicate the need to increase sedative agents

Is the sedative dose sufficient?

Due to inter-patient variability, some patients may require higher doses than others. If metabolic demands or stimulation have increased, or if patient is becoming tolerant to their therapy, additional sedation may be necessary.

Has the sedation been decreased?

The BIS™ value can be expected to increase as patients are weaned from sedation. If patient is not ready to wean from sedation, additional sedation may be indicated.

Is there an increase in stimulation?

An increase in stimulation may result in patient arousal. Additional sedatives may be indicated.

When was an analgesic last given?

Pain may result in patient arousal. Administration of analgesic and/or additional sedation may be indicated.

Are sedative delivery systems operating properly?

Check patency/integrity of IV lines and pumps that may be used to administer sedation.

EMG and high-frequency activity that may falsely elevate the BIS™ value

Is there any muscle shivering, tightening or patient motion?

The BIS™ value may be higher than the actual hypnotic state due to the presence of EMG. Check EMG bar for presence of EMG.

Did the patient receive any neuromuscular blocking agents that may be wearing off?

Check nerve stimulator for current state of muscle relaxation. Note: Facial muscles will recover sooner than skeletal muscles.

Does the patient have a pacemaker?

Check EEG waveform for presence of pacemaker or EKG spikes.

Note: During these situations, the BIS™ value should be interpreted cautiously and within the context of clinical events.

INTERPRETING BIS™ MONITORING VALUES

EMG and high-frequency activity that may falsely elevate the BIS™ value

Has the use of any mechanical device that could generate high frequency activity (e.g., warming blanket, oscillator ventilator) been initiated, or is any such device (or power cords) in close proximity to the BIS™ sensor (or BIS™ power cord) or monitor?

Artifacts in the higher frequency ranges can artificially increase the BIS™ value. Check EMG bar for presence of high-frequency artifacts. If possible, move offending device away from BIS™ sensor, and plug power cords into separate outlets.

Could the patient be in REM sleep?

In the REM sleep pattern, the low amplitude/high frequency EEG patterns may be similar to those in the awake state, but with coexisting hypotonia and eyeball movement artifacts.

Is the patient seizing?

Seizure-related EEG is typically composed of higher frequency activity that can increase the BIS™ value.

Note: During these situations, the BIS™ value should be interpreted cautiously and within the context of clinical events.

BIS™ Value Decreases Suddenly or is Lower Than Expected

Clinical situations that may indicate the need to decrease sedative agents

Has there been a decrease in stimulation?

A decrease in stimulation may lower dosing requirements for sedation.

Has there been an increase in sedation or has the BIS™ value decreased with no change in sedation dosing?

Excessive sedation or accumulation of sedative drugs over time may decrease the BIS™ values. Patients with kidney and/or liver impairment and/or those receiving longer-acting sedative agents may be at greater risk.

Has the patient recently received neuromuscular blocking agents?

The BIS™ value may drop after a neuromuscular blocking agent is given if excessive EMG was present before.

INTERPRETING BIS™ MONITORING VALUES

Clinical situations that may indicate the need to decrease sedative agents

Has the patient recently received analgesia?

The BIS™ value may drop after (additional) analgesia is given if pain resulted in EMG.

Is the patient significantly hypothermic?

Hypothermia decreases brain activity and hypnotic state may be deepened.

Note: During these situations, the BIS™ value should be interpreted cautiously and within the context of clinical events.

Unique clinical situations in which a decrease in BIS™ value may not necessarily indicate a decrease in sedative needs

Is the BIS™ value decreasing when you think it should be increasing (e.g., sedatives have been discontinued)?

This could be due to an EEG pattern called paradoxical delta (characterized by a pronounced slowing of the EEG), which occurs over a short period (two to three minutes).

Is the temporal electrode of the BIS™ sensor placed properly?

If the sensor is placed over the temporal artery, pulse artifacts can cause the BIS™ value to be inappropriately low. Check the EEG waveform for the presence of pulse artifacts and move the sensor if necessary.

Is the patient blinking or rolling his or her head?

These movements may cause artifacts that mimic slow-frequency EEG patterns.

Is the patient sleeping?

Deep sleep may cause the BIS™ value to decrease to levels equivalent to a very deep sedation state.

Has there been a sudden, significant drop in blood pressure or other signs of ischemic event?

A reduction in cerebral blood flow or cerebral oxygen supply may result in a reduced BIS value. Patients with unilateral brain injuries may manifest asymmetric BIS™ values. Preliminary research suggests that BIS™ values may be lower on the injured side.

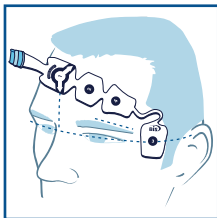
Note: During these situations, the BIS™ value should be interpreted cautiously and within the context of clinical events.

BIS™ EXTEND SENSOR

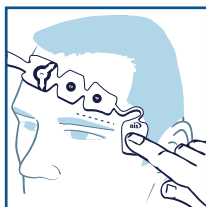
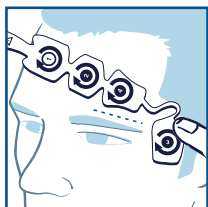
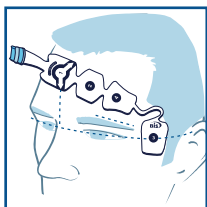
Extended performance in consciousness monitoring

Accurate and precise measure of level of sedation

- Resistant to artifact/EMG



Sensor application



1. Wipe skin with alcohol and dry.
2. Position sensor diagonally on the forehead:
 - 1 At center of forehead, approximately 2 inches (5 cm) above bridge of nose
 - 2 Directly above eyebrow
 - 3 On temple, between corner of eye and hairline
3. Press edges of sensor to ensure adhesion.
4. Press **1**, **2**, **3** and hold firmly for 5 seconds.
5. Insert sensor tab into patient interface cable.

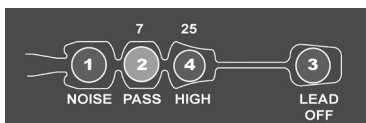
SENSOR TESTING/ TROUBLESHOOTING

Impedance checking

Impedance refers to the electrical resistance of the skin surface to each of the electrodes in the BIS™ sensor. Combined impedance values must be below a certain threshold for the BIS™ monitor to provide a reading.

- Impedances (sensor connection to skin) are tested automatically at start-up.
- Impedances can also be manually tested.

Depending on your monitor, Sensor Check will be on the main screen. If not, press Menu and go to Sensor Check.



In both cases, the screen will provide the status:

PASS — Impedance is good.

HIGH — High impedance. Re-prep (see below).

NOISE — May appear if pressing sensor during check or in the presence of large external stimulus.

LDOFF (lead off) — Element has lifted off. Re-prep. external stimulus

SENSOR TESTING/ TROUBLESHOOTING

BIS™ monitoring will not begin until all impedances are acceptable

Re-prep sensor — For problem element(s), repeat circling and pressing (steps 4 and 5). If unsuccessful, lift sensor and repeat steps 2 to 5.

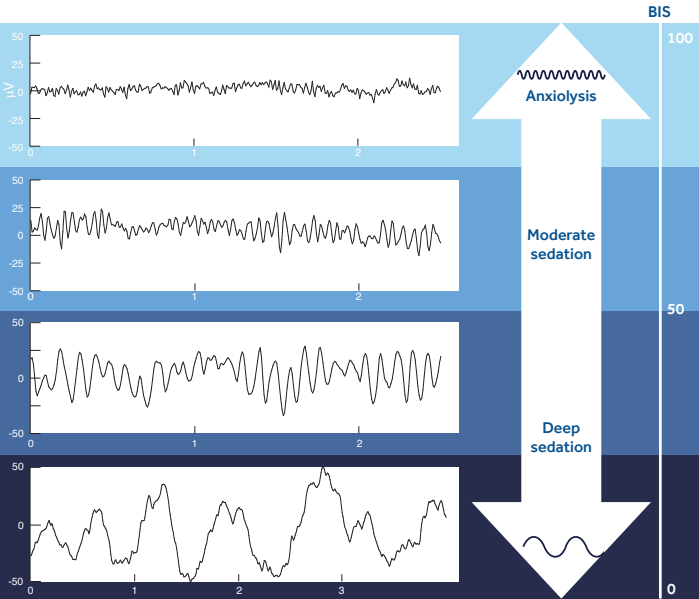
During BIS™ monitoring — If the Re-prep sensor error message appears, a connection problem has been detected. Run the manual impedance check (see above), identify suspect elements, and correct.

BIS™ Extend Software Settings.

When the BIS™ extend sensor is connected to the BIS™ monitoring system, the Extend mode is turned on in the System Configuration menu. The following settings are activated:

- 30-second smoothing rate
- Alarm suspend is on (alarm will only silence for two minutes)
- 60-minute BIS™ log interval

EEG SAMPLE WAVEFORMS



Shown at smaller scale

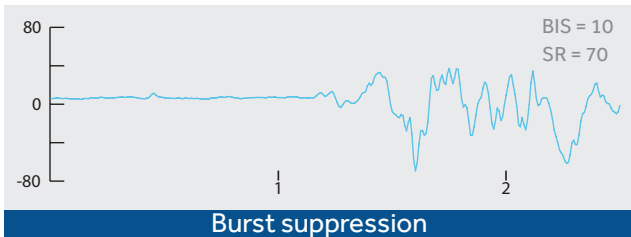
The EEG waves above, while real, represent idealized examples selected for educational purposes. Many commonly seen EEG waves may deviate from these ideals by superimposing the above waves with each other or with artifact.

Real-time assessment using the EEG

While the BIS™ monitoring values require calculation and “smoothing,” raw EEG provides a real-time display of the patient’s brain status.

SENSOR TESTING/ TROUBLESHOOTING

Uncommon EEG States



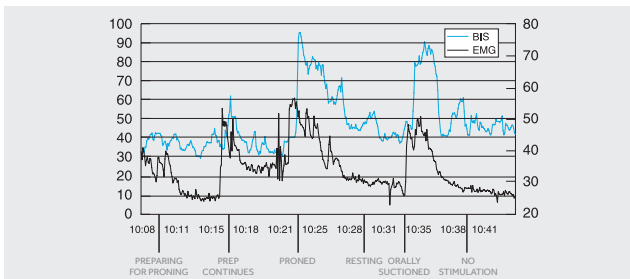
Burst suppression refers to bursts of EEG activity alternating with isoelectric (flat or “suppressed”) EEG, indicating very deep sedation, hypothermia, or ischemia. Level of burst suppression is indicated by suppression ratio (SR on display). In the ICU, barbiturates may be administered in high doses to induce suppression of electrical brain activity.

Suppression ratio (SR) is the percent of time in the last minute the EEG signal is considered suppressed

CASE STUDY

BIS™ Monitoring Response to Stimulation in Sedated Patient

17-year-old, 97 kg female receiving sedation for mechanical ventilation. On continuous infusion of lorazepam 2 mg/hour and morphine 4 mg/hour for past several days. Baseline BIS™ value in 40s.



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