Aspect’s Continuum of Care

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Important Information about BIS Monitoring

Reliance on BIS values alone for anaesthetic and sedation management is not recommended. As with any other monitoring parameter, clinical judgement should always be used when interpreting BIS readings in conjunction with other available clinical signs. BIS readings should be interpreted over time and in response to stimulation, and in the context of patient status and treatment plan.
1. Introduction to BIS

The BIS Solution

Aspect Medical Systems has developed an easy to use, inexpensive, non-invasive device that continuously measures the effects of anaesthetics and sedatives on the brain. This device, known as the BIS monitor, is currently being used by hospitals around the world as a means of improving patient safety, optimising clinical outcomes, improving efficiency, and ultimately decreasing costs for the hospital.

BIS works by obtaining the raw EEG from the patient via a forehead sensor. The BIS system then processes the EEG information and calculates a number between 0 and 100 that provides a direct measure of the patient’s level of consciousness. A BIS value near 100 indicates the patient is fully awake whereas a BIS value of zero indicates the absence of brain activity.

BIS has proven benefits for a wide range of patients across the continuum of care. BIS monitoring is indicated for use and has demonstrated outcome benefits for adults\(^1\)\(^2\)\(^3\) and paediatrics\(^4\) in the critical care setting, as well as paediatric\(^5\), elderly\(^6\) and adult patients\(^7\) in the Operating Room. BIS monitoring correlates with the OAA/S scale and therefore provides an objective measure of sedation during endoscopy\(^8\).

The BIS technology is available in both standalone and modular formats. Please refer to our website for more details of BIS solutions.

Adoption Statistics (as of December 2006)

- 39,922 worldwide installed base
- More than 18.7 million patients monitored
- Available in 160 Countries
- Licensed for integration into the patient monitoring systems of all leading manufacturers to assist in sedation and anaesthetic delivery across your continuum of care
2. Anaesthesia

Current Anaesthetic Practice

Historically, anaesthesia providers have had no direct means of assessing a patient’s level of consciousness during surgery and have relied on recommended drug dosages and indirect indicators of consciousness, including changes in blood pressure and heart rate. Variability in patient response causes two possible adverse outcomes – a patient receives too little or too much anaesthetic. If patients receive too little anaesthetic, they could potentially become awake during surgery. Research has shown that intraoperative awareness is an important clinical problem, occurring in 0.1-0.2% of patients, which has the potential to cause significant psychological injury. This experience can be traumatic for both patients and providers. On the other end of the spectrum, receiving too much anaesthesia can result in unnecessary drug costs, unpredictable wake-ups, more nausea and vomiting, and prolonged recoveries. These factors, in turn, can lead to inefficiencies in OR and PACU scheduling and increased personnel costs.

Patient Safety and Economic Benefits

Improved Patient Safety

Reduced risk of awareness – Studies have confirmed that awareness with recall is a universal problem regardless of geographic location or differences in anaesthesia technique. The incidence of intraoperative awareness with recall has been shown to be approximately 1 to 2 cases per 1,000 patients receiving general anaesthesia, suggesting that it occurs in about 20,000 to 40,000 patients each year. Some patients who experience intraoperative awareness with recall develop significant psychological problems, including post-traumatic stress disorder, severe anxiety, nightmares, flashbacks, and avoidance of medical personnel. Scientific evidence has shown that use of the BIS technology reduces the risk of awareness by approximately 80% in adult patients undergoing general anaesthesia or sedation.

In 2004, as a result of these studies, the FDA cleared the BIS technology for a new indication for use which states that “use of BIS monitoring to help guide anaesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anaesthesia and sedation”.

![Graphs showing reduction in awareness with BIS monitoring](image-url)
Consciousness Monitoring Statements
(See Addendum)

Summary of Consciousness Monitoring Statements

• Not routinely indicated
• Decision to be made on a case by case basis
• HR and BP are not reliable
• Agent monitoring/MAC has not decreased the incidence of awareness
• Agent monitoring is of no value during TIVA cases
• Brain Function Monitoring should be available for High Risk Patients

An overview of various perioperative factors that put patients at increased risk for awareness is what we will refer to as At Risk Patients

<table>
<thead>
<tr>
<th>Patient and Anaesthetic History</th>
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<tr>
<td>Previous episode of awareness</td>
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<td>Substance use or abuse</td>
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<td>Chronic pain patients on high doses of opioids</td>
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<td>History of, or anticipated difficult intubation</td>
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<td>ASA physical status IV-V</td>
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<td>Limited haemodynamic reserve</td>
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<th>Surgical Procedures</th>
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<td>Cardiac surgery</td>
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<td>Cesarean section</td>
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<td>Trauma surgery</td>
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<td>Emergency surgery</td>
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<th>Anaesthetic Management</th>
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<td>Planned use of:</td>
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<td>Muscle relaxants during maintenance phase</td>
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<td>Total intravenous anaesthesia</td>
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<tr>
<td>Nitrous oxide-opioid anaesthesia</td>
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<td>Reduced anaesthetic doses during paralysis</td>
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Source: ASA Practice Advisory White Paper. Available at: http://www.aspectmedical.com
Improved patient satisfaction

Addressing patients’ concerns - Intraoperative awareness is a leading cause of patient dissatisfaction with anesthesia\(^1\). BIS is the only consciousness monitoring technology proven to reduce the incidence of awareness and to improve patient satisfaction\(^2\).

Reduced postoperative nausea and vomiting - Patients undergoing general anaesthesia for outpatient surgery that were monitored with the BIS system reported statistically less postoperative nausea and vomiting during the recovery period\(^3,4\).

Improved recovery - Studies have shown that BIS monitored patients were twice as likely to be rated as “excellent – fully oriented” upon admission to the PACU, and that BIS titrated patients show significantly improved recoveries as determined by blinded PACU nurse assessments\(^5\).

Improved efficiency

Faster wake-ups - Studies have shown BIS monitored patients wake-up 30-40% faster (approximately 3 to 6 minutes faster)\(^6\).

Shorter PACU stay - BIS monitored patients were discharged from the PACU sooner (approximately 28 minutes faster)\(^7\).

Reduced costs

Reduced hypnotic drug use - Prospective, randomised studies have consistently shown reductions in the use of hypnotic anaesthetics (propofol, isoflurane, desflurane and sevoflurane) ranging from 15-39% compared to standard clinical practice\(^8\).
2a. Patients "At Risk"

Today, nearly 30% of patients entering the operating room will present with or be at risk for coronary disease. 10 to 15% of these patients will experience a cardiovascular complication as a result of their procedure. Hence, Anaesthesia providers face a distinct challenge in their practice: How to care for these patients in a manner that reduces their risk of a perioperative complication.

BIS monitoring can supply information to help anaesthesia providers implement effective, tailored patient management plans that provide cardiovascular stability and protection.

One goal during surgery is to minimise the potential harmful effects of a “stress response” on a particular patient – either through prevention or blockade of that response. A variety of cardiac medications (β-blockers, α-2-adrenergic agonists, nitrates, calcium channel blockers, etc) have been tested for this application. These medications not only alter patients’ vital signs, such as heart rate and blood pressure, but also the anaesthetic requirement measured by MAC. This exemplifies one context where BIS monitoring can provide guidance by independently measuring anaesthetic effect. It is sensitive and responsive to anaesthetic levels in situations where blood pressure and heart rate responses may be compromised. Moreover, it enables the clinician to see the synergistic effect of all medications on a particular patient.

During certain types of surgery the incidence of awareness may rise to 1.5% and in trauma patients percentages of up to 43% have been reported. Below is a sample of patient groups known to be at risk during anaesthesia. This is not a comprehensive list:

- Cardiac
- Trauma
- Emergency Caesarean-section
- Elderly
- Obese

**Cardiac**

During cardiac surgery many clinicians limit the concentration of volatile anaesthetics because of concern about myocardial depression, especially around the time of separation from cardio-pulmonary bypass (CPB), when haemodynamic instability is common.

Changes in the level of surgical stimulation, plasma binding of propofol and hypothermia may lead to clinically significant changes in the anaesthetic drug effect in patients undergoing CPB.

The incidence of awareness during general anaesthesia for cardiac surgery has been reported at 1.1% to 1.5%. Reasons for this higher incidence may be explained by high dose opioid techniques (with minimal hypnotic drug administration), impaired cardiovascular function, which can be further compromised by anaesthetic drug administration, and the dilutional effects of cardio-pulmonary bypass.

BIS-titrated use of short acting anaesthetic agents such as remifentanil and propofol may reduce adverse haemodynamic effects, allow for early tracheal extubation, and ensure that risk of awareness is reduced.

**Trauma**

Many trials have investigated the incidence of awareness among individuals undergoing general anaesthesia, with a wide range of results. The rate of awareness amongst trauma patients is between 11% and 43% in major trauma cases. This incidence varies according to the amount of anaesthetic given. The rate of recall during trauma surgery has been reported to be increased depending on the severity of injury and the ability to deliver anaesthetic agents. Lack of past medical history, marked blood loss (hypovolaemia), haemodynamic instability and not always knowing the extent of the injuries, all add to these patients being at increased risk of awareness.

**Emergency Caesarean Section**

In cases where light anaesthesia is deemed necessary such as emergency caesarean section, awareness, pain and unpleasant dreams have a high incidence; approximately 0.4%. In obstetric practice low levels of anaesthesia are given to maintain maternal unconsciousness and haemodynamic stability and avoiding neonatal depression.
Elderly
Numerous studies have documented a decreased inhalational anaesthetic requirement in elderly patients, due to pharmacokinetic differences such as less muscle mass, lower cardiac output, a fact that may complicate agent dosing. However, because BIS monitoring can consistently trend hypnotic effects of inhalational anaesthetics in adults independently of patient age or haemodynamic compromise, it is of particular benefit in these cases. Specifically BIS can confirm desired hypnotic effects at the lower inhalational anaesthetic requirement typical of the elderly population leading to a reduction in and faster emergence from anaesthesia.

It has been observed that BIS values in awake patients affected by Alzheimer’s or vascular dementia show lower BIS baseline values compared with a population of age-matched controls. However, it is not known whether dementia changes individual anaesthetic requirements.

Obesity
Intraoperative anaesthesia management in the obese patient population is challenging. Pharmacokinetic characteristics of the agents may be altered due to changes in distribution and clearance patterns. Pharmacodynamic alterations may produce varied responses such as altered sensitivity to respiratory depression. As a result, dosing of intravenous anaesthetics and opioids may be more challenging. Similarly, the behaviour of inhalational agents will differ from expected norms because of the larger potential uptake into adipose tissues.

Use of BIS monitoring can help to achieve intraoperative haemodynamic stability and predictable early and intermediate recovery.

2b. Total Intravenous Anaesthesia (TIVA)

No technology is able to provide a rapid measurement of drug concentration during intravenous anaesthetic techniques, unlike end-tidal monitoring with volatile anaesthetics. There is also the potential for a 3-5 fold interpatient variability in the response to most intravenous agents. BIS monitoring provides direct feedback on patient response to IV-based anaesthesia and allows for individual dosing adjustments. Struys et al found BIS monitoring allowed better targeting of propofol and resulted in a more consistent level of sedative effect, less movement and less implicit memory.

The American Society of Anesthesiologists (ASA) Practice Advisory mentions TIVA as a potential risk factor for awareness. The UK professional bodies, Royal College of Anaesthetists (RCoA) and Association of Anaesthetists of Great Britain and Ireland (AAGBI), highlight the fact that current measurements such as minimal alveolar concentration (MAC) are of no value when TIVA is used. (See Addendum)

The incidence of awareness in general surgical cases is approximately 0.2% and the incidence is reported to be similar after TIVA. The main challenge and concern here is the difficulty in gauging the level of sedation. There is significant inter-individual variability in the pharmacokinetics of intravenous anaesthetics, and during routine anaesthesia the plasma drug concentration cannot adequately be predicted from the dose administered. Even with a computer controlled infusion pump (TCI system) using population-based pharmacokinetic data for drug delivery, the plasma concentration can deviate significantly from the target, often resulting in too low or too deep a plasma drug concentration.

2c. Paediatrics

In a number of clinical utility and validation studies, BIS monitoring has been found to be reliable in determining the level of consciousness in paediatric patients undergoing general anaesthesia and sedation. Results from paediatric studies to date demonstrate that the BIS monitoring provides useful clinical information in infants and children.

A prospective cohort study found that intraoperative awareness in 864 children aged between 5-12 years, may be 8 times higher (0.8%) than in adults. For more detailed information please refer to Aspect’s Paediatric White Paper: Update 2005: Bispectral Index™ Monitoring in Children. This is available on request from Aspect and www.BISeducation.com.

Until additional data are available BIS in children less than 12 months old should be interpreted with caution.
3. Critical Care

Until now, sedation assessment has been primarily guided by vital signs or subjective sedation assessment any individual critically ill patient will depend on their condition, such as the nature and severity. Sedation goals must be identified and reviewed regularly. Inadequate sedation can adversely affect a patient’s condition. The incidence of awareness with recall in the intensive care has been shown to be higher than that of general anaesthesia ranging from 4 – 36%.

Complications of under sedation can cause the following:
- Fear, anxiety, and agitation
- Unpleasant recall
- Medical device removal
- Additional cost
- Increased nursing time

Complications of over sedation can cause the following:
- Increased time on mechanical ventilation
- Increased length of stay in ICU and/or hospital
- Additional cost of care
- Increased risk of complications
- Need for additional diagnostic testing

It should be noted that as BIS reflects the state of brain metabolic activity it can be affected by natural sleep, neurological disease, encephalopathy, cerebral ischaemia and hypothermia.

Once patients become unresponsive to verbal and physical stimuli subjective sedation scores loose their value and ability to track level of sedation. BIS provides an objective way to assess sedation, the BIS monitor can help determine a patient’s level of sedation and the ability to make informed decisions about the titration of sedative drugs.

The following patient types are most suitable for BIS monitoring in the ICU:
- Deeply sedated and ventilated
- Those receiving neuromuscular blockade
- Those in barbiturate coma
- Those requiring short term sedation for bedside procedures.

3a. Paediatric Critical Care

There are a number of clinical areas, outside of operating rooms where sedation is often required and administered to children for treatment, procedures, or as an adjunct to other therapies. Areas including paediatric intensive care units (PICU), radiology, gastroenterology suites, and emergency departments have previously relied solely on standard-dosing and/or subjective sedation scales to control and document the depth of sedation in children.

A number of BIS related paediatric studies have included evaluation with subjective sedation scales including COMFORT Score, Ramsay Sedation Score (RSS), Observer’s Assessment Awareness/Sedation Scale (OAAS), University of Michigan Sedation Scale (UMSS) and a variety of other scales.

Assessment of sedation and analgesia during neuromuscular blockade and barbiturate coma is difficult and a gold standard is lacking. Physiological parameters are not always reliable to assess sedation and analgesia.

Several case studies have demonstrated the use of the BIS monitor during titration of barbiturate coma, procedural sedation, sedation assessment during mechanical ventilation, and sedation while administering potentially confounding medications.

Until additional data are available BIS in children less than 12 months old should be interpreted with caution.
4. Procedural Sedation

Sedation is routinely given to patients to minimise discomfort, alleviate anxiety and improve satisfaction during a range of procedures\(^4\).

The challenge of procedural sedation is to avoid crossing over into general anaesthesia, preventing over sedation. One paediatric study followed personnel administering sedation who were blinded to the BIS score. In over 35% of procedures BIS score was less than 45 and more than 8% experienced episodes of airway compromise and desaturation associated with deeper levels of sedation\(^4\).

Clinical studies have shown that BIS monitoring correlates with commonly used sedation and provides an objective, reproducible measure of sedation levels in both adults and paediatric patients\(^9,10,50\).

BIS may be an effective tool to assist in managing the sedation needs of patients undergoing procedures such as endoscopy, interventional radiology, oral surgery and painful diagnostic procedures\(^11,12,51\).
5. Addendum

5a. Consciousness Monitoring Statements Released By Professional Bodies and Other Organisations in International Countries

Key points from the following statements have been highlighted. Please refer to the original documents for full details. You can find the website addresses listed below.

Spain - May 2006
Sociedad Madrid Centro de Anestesiologia y Reanimacion

Despertar Intraoperatorio
La primera medida de prevención para minimizar las posibilidades de que se produzca un despertar intraoperatorio debería ser individualizar la técnica anestésica(36) de modo que garantice la inconsciencia, amnesia y analgesia, especialmente en pacientes de riesgo(37)......El BIS es el único monitor, que hasta la actualidad, ha demostrado ser eficaz en la disminución de la incidencia de despertar intraoperatorio.*

www.sarmadrid.org/pdf/despertar_intraoperatorio_maqueta1.pdf

*Translation: The primary means of prevention for minimising the risk of intraoperative awareness is to individualise the anaesthetic technique in a way that guarantees unconsciousness, amnesia and analgesia, especially in patients at risk. ..... BIS is currently the only monitor that has demonstrated its efficacy in reducing the risk of awareness.

Australia – Feb 2006
Australian and New Zealand College of Anaesthetists (ANZCA)

Recommendations on Monitoring During Anaesthesia
When clinically indicated, equipment to monitor the anaesthetic effect on the brain should be available for use on patients at high risk of awareness during general anaesthesia. ["Recommendations" are defined as ‘advisable course of action’].


UK – Jan 2006
Royal College of Anaesthetists (RCoA) and Association of Anaesthetists of Great Britain and Ireland (AAGBI)

Loss of Consciousness Monitoring - A Joint Statement by the RCoA and the AAGBI
This document highlighted the following key points:

www.rcoa.ac.uk/index.asp?PageID=64&NewsID=134

Spain - June 2005
Task Force of Sociedad Espanola de Anestesiologia, Reanimacion y Terapeutica del Dolor (SEDAR)

Anestesia en el consultorio. Documento de consenso

www.sedar.es/revistasedar/sedar200510/indice.htm

Body temperature, neuromuscular blockade and depth of anaesthesia should be monitored when needed

USA – May 2005
American Association of Nurse Anesthetists (AANA)

Position Statement 2.12 Unintended Awareness Under General Anaesthesia
Brain function monitoring, if available, should be considered particularly in situations where the risk of intraoperative awareness is increased.

www.aana.com/Resources.aspx?ucNavMenu_TSMenuTargetID=51&ucNavMenu_TSMenuTargetType=&ucNavMenu_TSMenuID=6&id=1747
Practice Advisory for Intraoperative Awareness and Brain Function Monitoring
Although brain function monitoring is not indicated for all patients, “the decision to use a brain function monitor should be made on a case-by-case basis by the individual practitioner for selected patients”. 
www.asahq.org/publicationsAndServices/AwareAdvisoryFinalOct05.pdf

ASA Member Survey: Brain Monitoring Role

“Brain function monitors are valuable and should be used to reduce the risk of intraoperative awareness for patients with conditions that may place them at risk for intraoperative awareness.”

Source: ASA Practice Advisory White Paper.
Available at: http://www.aspectmedical.com

USA – Oct 2004
Joint Commission on Accreditation of Healthcare Organizations (JCAHO)

Sentinel Event Alert, Issue 32
These devices may have a role in preventing and detecting anaesthesia awareness in patients with the highest risk, thereby ameliorating the impact of anaesthesia awareness.
www.jointcommission.org/SentinelEvents/SentinelEventAlert/sea_32.htm
5b. Family of Sensors and Sensor Application

Aspects family of sensors have been developed to meet the needs of our customers. Aspect released its new sensor design in early 2005. The new features include:

- **New Shape:** designed to improve fit and adhesion
- **New Graphics:** on sensor, sensor pouch and product insert, with clarified sensor placement instructions

The semi reusable sensor (SRS) was designed to meet the needs of those customers looking for the same quality sensor and ease of use but with a lower cost of ownership and environmentally friendly. Each kit consists of one reusable cable and 100 disposable electrodes.

The Quatro, Paediatric and SRS sensors are compatible with the BIS XP system which has features which include:

- Resistance to electrocautery
- Detection and filtration of EMG
- Enhanced performance during cardiac and other deep anaesthesia techniques

(N.B. whilst no age range recommendation is given for the use of the paediatric sensor anecdotal reports show that most children over the age of 10 years will fit an adult sensor.)
Correct placement of the sensor is of utmost importance to the signal obtained. Hence, Aspect developed a single montage sensor to assist with quick, easy and correct placement.

The skin is the major contributor to impedance. The outer layer of (dead) skin cells causes the electrode/skin impedance to be very high. Aspect sensors are able to achieve low impedance levels without the need for harsh abrasive skin prepping, as the flexible tines contained within the electrode, part the outer layer of dead skin cells and allow the hydrogel, contained within, to reach the next layer of epidermis, which is more conductive. The larger surface area of these electrodes, compared to needle electrodes, is another contributing factor to bringing down the impedance levels. There are also some impedance-related artefacts that can arise from electrode drift on the skin, bunching and folding of skin, and puckering of the epidermis. The adhesive surrounding Aspect sensors prevents this from occurring.

Sensor placement can be on either the left or right side of the head as seen below;

The forehead should be clean and dry before applying the sensor. This can be achieved by wiping the forehead with alcohol and drying (never use benzine or ether). Position sensor diagonally on the forehead with electrode No.1 at the centre of the forehead, approximately 2 inches (5cm) above the bridge of the nose. Electrode No.4 directly above eyebrow and electrode No.3 on the temple, between the corner of the eye and hairline.

Press the edges of the sensor to ensure adhesion and seal in the gel. Then press electrode Nos. 1-4 firmly for 5 seconds each. The sensor is then ready to be connected to the patient interface cable.

All electrodes are single patient use and for those patients being monitored on Critical Care sensors must be changed every 24hrs. Often these patients may be pyrexial and skin may be slightly sweaty. Anecdotal reports have shown that recommended skin preparation and the use of an anti persperant spray across the forehead may help with sensor adhesion.
6. References


47. Sedation and Monitoring of Patients Undergoing Gastrointestinal Endoscopic Procedures, American Society of Gastrointestinal Endoscopy, ASGE Publication No. 1022, 2195.


