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Horizon scanning prioritising summary

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Bispectral index monitoring (BIS): For measuring the depth of anaesthesia and to facilitate anaesthetic titration

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PRIORITISING SUMMARY

REGISTER ID: **000105**

NAME OF TECHNOLOGY: **BISPECTRAL INDEX MONITORING (BIS)**

PURPOSE AND TARGET GROUP: **TO MEASURE THE DEPTH OF ANAESTHESIA AND FACILITATE ANAESTHETIC TITRATION**

STAGE OF DEVELOPMENT (IN AUSTRALIA):

☐	Yet to emerge	☐	Established
☐	Experimental	☐	Established *but* changed indication or modification of technique
☐	Investigational	☐	Should be taken out of use
☒	Nearly established		

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

☒	Yes	ARTG number	90447
☐	No	☐	Not applicable

The Aspect Medical Systems BIS™ is available as a stand-alone monitor (A-2000 Monitor) or as BIS modules. The A-2000 Monitor is currently listed on the Australian Register of Therapeutic Goods (ARTG) and is distributed by Datex-Ohmeda Pty Ltd. Philips Medical Systems, Datex-Ohmeda and GE Medical Australia all have BIS modules currently registered on the ARTG. The United States Food and Drug Administration gave a 510 (K) approval for the Aspect Medical Systems Paediatric EEG BIS sensor in the year 2000.International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
Australia	✓		
United States	✓		
Taiwan	✓		
Japan	✓		

IMPACT SUMMARY:

Aspect Medical Systems Inc manufacture Bispectral Index™ (BIS™) with the purpose of providing information in respect to the effectiveness of anaesthesia, thereby reducing the risk of patient awareness during surgical procedures. The technology is available through public and private hospitals for surgical procedures for which there is a high risk of awareness.

BACKGROUND

Patients undergoing surgery require an adequate level of hypnosis, that is, an impairment of consciousness and memory, or oblivion to external stimuli. The post-operative recollection of events during general anaesthesia, or awareness, may be distressing to the patient. Patients affected by awareness report perceptions of paralysis, conversations and surgical manipulations, giving rise to feelings of fear, pain and helplessness. Post-traumatic stress disorders may develop in some patients who have experienced awareness (Myles et al 2004).

Patients undergoing general anaesthesia may be monitored by the observation of physical signs (heart rate) and responsiveness to voice or touch, which may not be satisfactory for all patients. Continuous monitoring of brain activity using electroencephalogram (EEG) allows the measurement of the hypnotic state and the effect of anaesthesia without disturbing the patient. EEG changes from a low amplitude, high frequency signal (Figure 1A) while in the wake state to a large amplitude, low frequency signal (Figure 1B) when anaesthetised. The BIS™ monitor uses a single use sensor strip, placed on the patient's forehead to measure the electrical activity in the brain (Aspect Medical 2001). Using an algorithm, the monitor translates this activity into a score, which may range between zero (absence of brain electrical activity) to 100 (wide awake). BIS™ values between 40-60 are considered suitable for anaesthesia (Myles et al 2004). The EEG waveform is displayed on the monitor along with the bispectral index number (Figure 2).

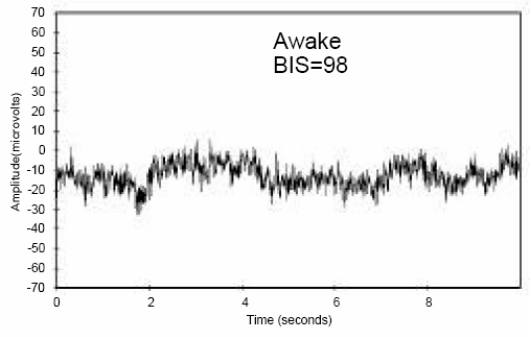

Figure 1A EEG in awake state

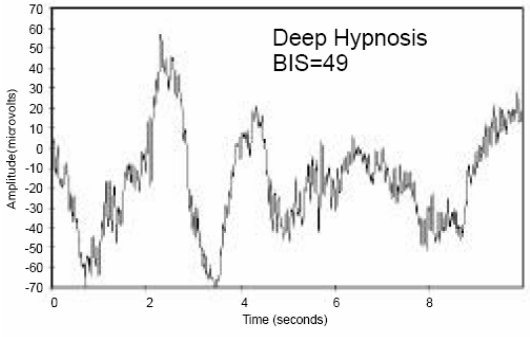

Figure 1B EEG during anaesthesia

The BIS™ monitor has been suggested for use in patients undergoing high-risk surgery or for those patients considered to be at risk of awareness during anaesthesia. These patients include those undergoing caesarean section, high-risk cardiac surgery (ejection fraction <30%, severe aortic stenosis, pulmonary hypertension), off-pump coronary artery bypass surgery or bronchoscopy. Patients to be considered at risk include those with a past history of awareness, a history of heavy alcohol intake, chronic users of benzodiazepine or opioids, or patients with severe end-stage lung disease (Myles et al 2004). In addition to monitoring awareness in patients undergoing surgical procedures, the BIS™ monitor has been suggested for use in monitoring consciousness in critically ill patients in intensive care units who are sustained by mechanical ventilation (Ely et al 2004).

Figure 2 BIS™ monitor and sensor strips (Aspect Medical Systems 2004)

CLINICAL NEED AND BURDEN OF DISEASE

The Australian and New Zealand College of Anaesthetists (ANZCA) acknowledge that it is difficult to estimate the number of anaesthetics administered annually in Australia. ANZCA have relied on indirect statistical evidence based on the number of surgical and other procedures performed where anaesthesia is likely to have been required, using the number of separations from both private and public hospitals. ANZCA estimate the number of

procedures that required an anaesthetic to be 3.4 million for the period 1997-98. This figure does not include private hospital separations from Tasmania, the Australian Capital Territory or the Northern Territory. This figure represents an increase from the estimated 2.8 million procedures for the period 1995-96 (Mackay 2002). The incidence of awareness is approximately 0.1-0.2% in the general surgical population, but is increased during cardiac surgery, caesarean section and trauma surgery (Myles et al 2004). During 1998-99, the number of public, acute and psychiatric hospitals in Australia was 755, and the number of private hospitals was 312 (AIHW 2001).

DIFFUSION

There are approximately 400 BIS monitoring devices distributed amongst 20-30 per cent of all major hospitals in Australia. Use of the device may be limited to those patients considered to be at high-risk, either from past surgical history or due to the type of procedure being conducted eg cardiac surgery. Consumption of the single use sensors may indicate the growing level of use. Aspect Medical Systems currently supply 5,000 sensors per month to Australia, versus 800 per month in 2003, representing approximately 1.7 per cent of all anaesthetic procedures (personal communication, Aspect Medical Systems Australia).

COMPARATORS

Standard practice for the intraoperative maintenance of anaesthesia requires all patients to be assessed for signs of inadequate anaesthesia. The criteria for inadequate anaesthesia are:

- Hypertension: blood pressure >20% increase from baseline
- Relative tachycardia: heart rate >90 beats per minute
- Somatic: movement, grimacing, eye opening, coughing.

Patients are also assessed for significant hypotension or bradycardia:

- Blood pressure >20% decrease from baseline
- Heart rate: >20 beats per minute decrease from baseline.

Inadequate anaesthesia is managed with increased doses of anaesthetic agent or the administration of an antihypertensive. Hypotension and bradycardia are managed with appropriate dose reductions of anaesthetic agent, adjustment of fluid status, or other pharmacologic agents as required (Gan et al 1997).

EFFECTIVENESS AND SAFETY ISSUES

In the double-blind RCT conducted in Australia by Myles et al (2004), high-risk patients were assigned randomly to the group receiving BIS™ monitoring (n= 1,248) and standard care (n= 1,263). Baseline characteristics of patients and the type of surgery conducted were similar in both groups. A BIS™ sensor was applied to all patients foreheads and anaesthesia was adjusted to maintain the BIS™ readings to between 55-70. In patients allocated to standard care the BIS™ monitor was not switched on and anaesthesia was adjusted according to heart rate and blood pressure readings. Follow-up was a structured, unvalidated interview conducted by a blinded assessor. The primary endpoint was the incidence of confirmed awareness. Secondary unblinded endpoints included recovery times, amount of anaesthetic administered and incidence of hypotension. There were two reports of awareness in the BIS™ guided group compared to 11 reports in the standard care group ($p = 0.022$). Although Myles et al (2004) report that BIS™-guided anaesthesia significantly reduced the risk of awareness by 82%, the wide confidence interval (95%CI [17, 98]) illustrates the rarity of the event in both groups.

An RCT conducted by Meissieha et al (2004) in the United States, randomly assigned children undergoing anaesthesia for dental day surgery to either a BIS™ monitored group (n=10) or standard care (n=10). The BIS™ group had anaesthesia adjusted to maintain the BIS™ readings to between 60-70 and the standard care group were maintained according to heart rate and blood pressure. Duration of surgery between the two groups did not differ

significantly, 139 ± 43 minutes versus 162 ± 35 minutes for the BIS™ and standard care groups respectively (p= 0.2). The patients in the BIS™ group were however, discharged significantly earlier (60 ± 13 minutes) than the standard care group (90 ± 11 minutes), (p = <0.001).

COST IMPACT

The current listed price for the A-2000 BIS monitor is $11-15,000, and the single use BIS Quatro Sensors cost between $15-40.

The randomised controlled trial (RCT) by Myles et al (2004) reported the cost of routine BIS™ monitoring to be $22 per use in Australia. With a number needed to treat of 138, the cost of preventing one case of awareness in high-risk patients was approximately $2,200.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

Despite the risk of awareness being minimal, patients should not be subjected to the possibility of undergoing surgery whilst awake.

CONCLUSION:

There is already widespread diffusion of the BIS™ monitor in Australian hospitals. Level II evidence suggests that BIS™ monitoring may reduce the incidence of awareness during anaesthesia and time spent in post-anaesthesia care. In addition a Cochrane review is being conducted on this technology.

HEALTHPACT ACTION:

Therefore it is recommended that this technology be archived.

SOURCES OF FURTHER INFORMATION:

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SEARCH CRITERIA TO BE USED:

*Anesthesia, General/adverse effects/methods/Recovery Period
*Awareness
*Monitoring, Intraoperative
Postoperative Complications
Electroencephalography/*drug effects/*instrumentation
Evoked Potentials, Auditory/*drug effects