Advancing the Art and Science of Anesthesia Control

SNAP II™ Monitor at a Higher Level
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1. INTRODUCTION

The SNAP II™ monitor represents innovation, precision, and the most advanced technology. Stryker introduced the SNAP II™ monitor to supplement clinical judgment in hemodynamic and anesthetic monitoring. It’s used in addition to standard methods of anesthesia control to measure a patient’s brain activity level during surgery and helps facilitate an optimal patient surgical experience.

The SNAP II™ monitor analyzes the electrical activity of the brain and offers increased sensitivity in measuring patients’ level of consciousness while under anesthesia. It responds to changes in level of consciousness rapidly, providing clinicians with an important advanced technology to optimize their practice. This monograph provides a review of the technological foundation for SNAP II™, how the device works, and its role in the surgical suite.

1.1. Art and Science of Anesthesia Management

Anesthesia (also spelled anaesthesia, from Greek an- ["without"] and aisthesis ["sensation"] is the term used to describe the blockade of pain and other sensations. Anesthesia allows patients to undergo surgery and other medical procedures without the distress or discomfort they would otherwise experience. An anesthesia cocktail also causes patients to remain motionless, allowing surgery to proceed uninterrupted.

The type of anesthesia a patient receives is dependent on the type of surgery being performed, as well as specific patient needs. The anesthesiology professional will select a specific type of anesthesia in consultation with the patient and surgical team. Local anesthesia is usually used to numb a specific region of the body, while regional anesthesia, such as epidural delivery of an anesthetic compound, targets multiple nerve clusters (American Society of Anesthesiologists, 1994). General anesthesia is usually used to induce a lack of consciousness and awareness and loss of sensation during large and extensive procedures. Typically, general anesthesia includes the use of paralytic agents to prevent voluntary and involuntary movements in response to surgical manipulation. With this type of anesthesia, it is very important for an anesthesiology professional to monitor a patient’s level of consciousness in order to control and stabilize the patient’s bodily functions (American Society of Anesthesiologists, 2005).
Society of Anesthesiologists, 1994). Subsequent doses of anesthetic are typically adjusted based on changes in vital signs. However, vital signs are unreliable guides to a patient’s LOC, as anesthetic agents medicate the patient’s brain, not the heart rate and blood pressure. In certain cases, the anesthesia provider may overmedicate or supply a controlled overdose to ensure patients are actually asleep.

Different types of surgery require different depths of anesthesia. For instance, with Caesarian sections (“C-sections”), rapid return to consciousness is required to allow the mother to interact with the newborn. With most types of anesthesia, upon completion of the surgery, the patient is usually sent to the recovery room, where he or she will be evaluated while emerging from the anesthesia. One of the most important priorities during this period is for the patient to fully regain consciousness, a goal that depends greatly upon the depth of anesthesia achieved during surgery (American Society of Anesthesiologists, 1994).

According to the American Society of Anesthesiologists (ASA), depth of anesthesia is a continuum of central nervous system (CNS) depression and decreased responsiveness to stimuli. Consequently, there are several different stages of anesthesia (Figure 1). The period of induction, when the anesthesiologist administers the initial dose of anesthetic, is Stage I of anesthesia. Upon entering Stage II, the patient progressively loses consciousness and vital signs may become irregular. Stage III of anesthesia, also known as “surgical anesthesia,” consists of deep, regular breathing and stable vital signs of anesthetic (in kilograms). The anesthetic can be administered intravenously (IV) (e.g., propofol and sodium thiopental), via inhalation (e.g., enflurane and halothane), or a combination of both (American Society of Anesthesiologists, 1994). Neuromuscular blockers (paralytics) are also commonly used to prevent the patient from moving during a surgical procedure and to facilitate intubation. Muscle relaxants are another option; these agents include succinylcholine (Anectine, Suxcstrin), atracurium (Tacrium) and pancuronium (Pavulon) (Webster’s Medical Dictionary, 2006).

During surgery, the anesthesiology professional continuously assesses the health and well-being of the patient by monitoring vital signs (e.g., body temperature, blood pressure, heart rate, respiration, etc.) as well as the patient’s level of consciousness (LOC) (American Society of Anesthesiologists, 1994). Subsequent doses of anesthetic are typically adjusted based on changes in vital signs. However, vital signs are unreliable guides to a patient’s LOC, as anesthetic agents medicate the patient’s brain, not the heart rate and blood pressure. In certain cases, the anesthesia provider may overmedicate or supply a controlled overdose to ensure patients are actually asleep.

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![Figure 1 - Stages of Anesthesia](image.png)
signs. The last stage of anesthesia, Stage IV, represents a serious depression of the CNS; this can occur if an excess of medication has been administered. Patients may require cardiovascular and respiratory support to return to Stage III from Stage IV (Calmes, 2002).

For patients contemplating surgery, apprehension regarding anesthesia, coupled with fear of the unknown, can exacerbate preoperative stress (Osinaike et al., 2007). Patients often have many questions about the surgical procedure and the anesthesia process. Communication is, therefore, an important aspect of the clinician-patient relationship. It is important for patients to have a meaningful dialogue with an anesthesiology professional prior to surgery to ensure that the patient is aware of the benefits and risks of anesthesia, and to ensure that the patient is prepared both physically and emotionally. In fact, according to the ASA, “studies have shown that well-informed patients heal faster and report a better overall surgical experience” (American Society of Anesthesiologists, 2007).

1.2. Anesthesia and Intraoperative Awareness

Anesthesia awareness (AA) is an uncommon but serious event that occurs when a patient under general anesthesia stays conscious or becomes conscious during surgery due to delivery of an inadequate amount of anesthetic. Such an experience may be extremely traumatic for the patient, who may feel pressure or pain from the surgery, may hear conversations, or may feel unable to breathe. The condition is exacerbated when the patient is unable to communicate, particularly when movement is inhibited by delivery of a paralytic or muscle relaxant. The most traumatic case of anesthesia awareness is full consciousness during surgery, whereby the patient experiences pain and explicit recall of intraoperative events; some patients experiencing extreme cases compare it to torture. About half of those who endure anesthesia awareness complain about mental distress following surgery, a problem that sometimes manifests itself as post-traumatic stress disorder (PTSD) (Sebel et al., 2004; JCAHO, 2004). The trauma may be so profound it can dissuade sufferers from ever undergoing surgery again. In severe cases, patients have described having flashbacks and panic attacks triggered by the smell of rubbing alcohol, the sound of metal on metal (reminding them of surgical instruments), or media images of people wearing surgical scrubs.

The incidence of AA in the United States is believed to be 20,000 to 40,000 cases per year, which represents 0.1% to 0.2% of all patients undergoing general anesthesia (JCAHO, 2004). Awareness claims formed 2% of all malpractice claims from 1990 to 2001 (Figure 2), including 56 claims for recall under general anesthesia and nine claims for awake paralysis. While extremely unlikely, based on the large number of surgeries, AA is nonetheless reported between 100-200 times daily in this country — and may be under-reported. Research suggests that women wake up significantly faster than men from general anesthesia (Gan et al., 1999), and AA is more common in women under the age of 60, a population that comprises more than 70% of AA claims (Brown, 2007). Certain types of surgery for which “light” anesthesia is desired (e.g., C-section, cardiac bypass surgery) are also associated with higher rates of AA. Of all AA cases, 2.5% to 4% are associated with complications from C-sections, while 23% occur during cardiac surgery (Brown, 2007). In addition, AA seems to occur between four to six times more often in pediatric surgeries, where incidences have been reported to be as high as 0.3% to 1.7% (Davidson et al., 2005). Overall, surgeries involving major trauma or shock have been associated with 11% to 43% of AA cases.
The "average" anesthetic dose can vary greatly, depending on the type of drug(s) used, the patient's metabolism, and the patient's genetic makeup. Consequently, response to anesthesia can also vary greatly from patient to patient. Although a few AA cases may be caused by a lack of attention to clinical signs, the risk of AA is largely related to the surgery itself and to the anesthesiology professional's desire not to over-sedate the patient. For certain operations, or in patients who are hypovolemic or hemodynamically unstable, the anesthesia provider may aim to provide light anesthesia in order to keep the patient safe and stable (Harvard Health Publications, 2005). However, judgments of depth of anesthesia may not be precise or consistent between anesthesia professionals. As a result, consciousness may occur. Other factors contributing to the risk of AA include the increasing use of IV delivery of anesthesia, as opposed to inhalation, and the premature lightening of anesthesia at the end of procedures to facilitate operating room turnover.

"The most traumatic case of anesthesia awareness is full consciousness during surgery, whereby the patient experiences pain and explicit recall."

1.3. Public Perceptions of Anesthesia Awareness

In recent years AA has emerged as a source of public controversy and concern, largely due to campaigns waged by patients who have suffered from intraoperative recall, news media coverage of such cases, portrayals of recall in TV medical dramas, and the increasingly public profile of level of consciousness (LOC) monitors for assessment of depth of anesthesia in clinical practice. Over 68% of Americans who have had major surgery or plan to have it in the near future have heard of AA; among 18-34-year-olds, 31% cite AA as the greatest concern related to general anesthesia (Kelton Research, 2007a). The rising awareness of AA has created an environment in which patients routinely voice anxiety about this rare but devastating occurrence during pre-anesthetic assessments (Kelton Research, 2007a). In fact, 91% of Americans who have had or are planning to have major surgery wish to be given the option of LOC monitoring. Reciprocally, one-third of anesthesiologists would use LOC monitoring on request, as revealed by a survey of 153 anesthesiologists conducted at the 2007 annual meeting of the American Society of Anesthesiologists. Unfortunately, 42% of those polled said they never or rarely use an LOC monitor, largely due to the unavailability of the device in their surgical setting, or to a lack of training. Additionally, nearly half of the survey respondents (48%) would elect to have the anesthesiologist use an LOC monitoring device if they or a
loved one were on the operating table, yet only 11% indicated that they always use an LOC device as a standard of care in their own practices (Kelton Research, 2007b).

It is important to note that minimizing the risk of AA is largely a matter of understanding the latest technologies in LOC monitoring. Current anesthesiology practice standards acknowledge AA as a problem and encourage physicians and patients to discuss the risks of AA and the means to prevent its occurrence. Given the inadequacy of vital signs in detecting fluctuations in consciousness (Sebel et al., 2004), efficient LOC monitoring can lessen the risk of AA and allay patient concerns. Various methods of LOC are currently available; one of which, EEG monitoring, is believed to be a more reliable guide than vital signs in measuring the brain’s response to anesthetic agents.

2. LEVEL OF CONSCIOUSNESS MONITORING

2.1. Level of Consciousness Monitoring

Each day in the U.S., many thousands of patients undergo surgical procedures that require general anesthesia. The sheer number of procedures, coupled with the increasing sophistication of surgical techniques, makes the use of advanced anesthesia technology especially important in optimizing patient safety and surgical outcomes. In addition to keeping anesthesia professionals advised of the patient’s vital signs, the LOC monitor provides important information about the adequacy of anesthetic depth in the form of electrical activity in the brain. Yet although the LOC monitor is widely regarded as an effective tool in anesthesiology, this innovative device is not used to its full potential in the surgical suite.

The routine use of a reliable LOC monitor adds a new dimension to the practice of anesthesia, reducing the risk of predictable and unpredictable occurrences of AA, and facilitating anesthesia dosing and titration. Access to this innovative technology places anesthesiologists and other healthcare professionals in a better position to devise and implement an anesthesia monitoring plan that is specific to the needs of each patient, thereby improving patient outcomes and safety.

An ideal LOC monitor would provide accurate, quantitative measurement of LOC under anesthesia with great sensitivity and a fast response time. The response rate is critical to providing the anesthesia professional with an early action window in case a change in consciousness occurs unexpectedly during anesthesia. Due to the variability in patients’ metabolic rates and susceptibility to the anesthetic drugs, as well as the varying effects of these drugs on the electrical activity of the brain, an LOC monitor must be compatible with a range of anesthetic agents and should derive information that accounts for these confounders. In addition, a
monitor must be sensitive both to the depth of anesthesia and to the waking status of the patient.

The SNAP II™ LOC monitor was designed to meet these surgical needs and provide anesthesia professionals with an efficient and reliable tool to enhance the clinical judgment of a patient’s LOC and return to consciousness. The monitor is intended to supplement the multiple modalities traditionally used to assess LOC, including the observation of clinical signs, anesthetic agent analysis, and conventional monitoring of hemodynamic and respiratory systems (Kaul, H.L. & Bharti, N., 2002).

There are no risks to a patient from noninvasive LOC monitoring; nor are there significant costs. Incorporating an LOC monitor is, therefore, an important strategy for reducing the risk of AA and ensuring patient safety and comfort – both before and during surgery. Recent technological advances in electroencephalograph (EEG) monitoring, incorporated into the SNAP II™ monitor, have brought the science of anesthesia to the next level.

### 2.2. Physiology of Consciousness

Using EEG signals to measure LOC provides an accurate depiction of a patient’s response to anesthesia. This is because cells in the brain communicate with each other by producing electrical signals; electroencephalography is the measurement of the electrical activity of the brain. An added advantage of analyzing EEG signals to monitor LOC is that it can facilitate the titration of anesthetic and sedative drugs, thereby helping to minimize the potential risk of under-medicating — or the more common occurrence of over-medicating — a patient (Crippen, 1997).

Electric potentials, or voltages, in the brain fluctuate back and forth rhythmically, causing electricity to flow to areas of low voltage in a manner similar to how water flows until it seeks level ground. Like water, electricity produced by the brain travels in waves and the flow can vary in frequency (i.e., the number of waves per second). Each frequency correlates with specific mental states of consciousness. Four major types of rhythmic EEG brain waves are recognized: alpha, beta, delta and theta (Figure 3). The continuum from wakefulness to sleep involves a progressive decrease in activity in the beta and alpha bands and an increase in the other bands, as depicted in Table 1 (Crippen, 1997).

The interpretation of EEG signals can be affected by many factors such as carbon dioxide and oxygen levels, body temperature, sensory stimulation, and blood flow to the brain (Crippen, 1997). Therefore, it is important to monitor these factors to interpret EEG signals correctly.

Table 1 - Brainwave frequencies and corresponding mental states

<table>
<thead>
<tr>
<th>WAVE</th>
<th>FREQUENCY</th>
<th>ASSOCIATED MENTAL STATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beta ($\beta$)</td>
<td>$\geq 13$ Hz</td>
<td>Wide awake, active, busy or anxious thinking and active concentration. Most people are in this mental state during the day.</td>
</tr>
<tr>
<td>Alpha ($\alpha$)</td>
<td>8 Hz – 12 Hz</td>
<td>Relaxed, alert state of consciousness. Best seen with closed eyes. Attenuates with drowsiness and open eyes. Variants of this wave may attenuate when there is an intention to move.</td>
</tr>
<tr>
<td>Theta ($\theta$)</td>
<td>4 Hz – 8 Hz</td>
<td>Light sleep or extreme relaxation, daydreaming, trances, or hypnosis. Associated with drowsiness.</td>
</tr>
<tr>
<td>Delta ($\delta$)</td>
<td>$&lt; 4$ Hz</td>
<td>Deep, dreamless sleep. Delta is the slowest band of brainwaves. Completely unconscious.</td>
</tr>
</tbody>
</table>
monitors on the market function this way, monitoring low-frequency EEG signals (up to 80 Hz) to measure LOC and the effects of anesthesia and sedation. Yet, research has suggested that this range is predominated by the electrical activity of muscles, which is measured by electromyograph (EMG) signals, and not the electrical activity of the brain (Wong et al., 2005). In addition to noise from other signals, gamma \( (\gamma) \)-frequency waves, a subset of upper beta waves (40 – 80 Hz), can also be undesirably altered by anesthetics (Faulkner et al., 1998; Faulkner et al., 1999, as reviewed in Wong et al., 2005).

In contrast to other monitors, the SNAP II™ algorithm ignores contaminated frequencies from 40 to 80 Hz. The SNAP II™ algorithm, instead, incorporates ultra-fast, high-frequency (80 – 420 Hz) EEG signals, a range thought to provide useful information regarding the state of consciousness and cognitive function (Wong et al., 2006; Sing et al., 2005).

Given the influence of anesthesia on this frequency range, analysis of high-frequency EEG signals may be particularly useful in evaluating transition phases between the awake and anesthetized states (Draguhn et al., 1998, as reviewed by Wong et al., 2005). Monitoring both high- and low-frequency EEG signals is a novel technique that improves anesthesia control and produces positive results for patients as well as physicians.

### 2.3. Benefits for Patients and Physicians

Innovations in LOC monitoring equipment and technology can confer important benefits to patients and physicians, among them the ability to develop a more trusting patient/clinician relationship through greater control over the patient’s LOC. Enhanced control over anesthetic dosing allows patients to wake up 30-40% faster (Gan et al., 1997; Song et al., 1997; Wong et al., 2002b) and significantly reduces postoperative nausea and vomiting during the recovery period (Luginbuhl et al., 2003; Nelskyla et al., 2001). The presence of a high-tech device specially designed to guide the anesthesiology professional in patient monitoring can ultimately help to allay any concerns patients may have about AA and anesthesia in general. Early large-scale prospective studies show that the use of a standard monitor to assess and titrate sedation in patients receiving continuous infusions of paralytics reduces the incidence of AA with recall by up to 80% (Ekman et al., 2004; Myles et al., 2004). In addition to assisting the clinician through the anesthesia process, LOC monitoring optimizes post-surgical outcomes and enhances patient satisfaction (Bower et al., 2000). Studies have also shown that monitored patients are eligible for discharge from the post-anesthesia care unit (PACU) 16% sooner, and that 87% of patients are more likely to be fully awake and oriented upon arrival to the PACU (Gan et al., 1997; Song et al., 1997).

LOC monitoring technology has recently evolved to provide an unequaled level of reliability, demonstrating clear benefits in clinical outcomes and risk management by advancing the ability of the anesthesia provider to carefully optimize anesthesia. The anesthesiology community believes that universal monitoring is poised to become a formal standard of care for patients undergoing general anesthesia due to its potential to decrease the incidence of AA to very low levels. (Brown, 2007).
2.4. Benefits to Healthcare Delivery Systems

A hospital’s mission is to offer its patients the best and safest clinical practice possible. The best hospitals are known to have adopted measures that dramatically reduce preventable medical accidents. While various risk factors may predispose an individual to anesthesia awareness while under general anesthesia, studies have shown that adopting the use of LOC monitors can prevent up to 80% of AA cases (Ekman et al., 2004; Myles et al., 2004).

As mentioned previously, while not its intended purpose, LOC monitoring can enhance drug titration and result in an improved clinical outcome and rational cost-containment. Prospective, randomized studies have consistently associated LOC monitoring with 15-58% reductions in the use of hypnotic anesthetics and sedative drugs, as well as average per-patient savings ranging from $150 - $185 (Bannister et al., 2001; Gan et al., 1997; Kaplan, L.J. & Bailey, H., 2000; Olson, D.M. et al., 2003). In addition, systematic LOC monitoring during surgical procedures that require general anesthesia can drastically reduce hospital liability; if patients perceive a change in the standard of care for preventing AA, that perception may be reflected in an uptick in the frequency of claims, which may increase the hospital’s liability burden (Domino, K.B., 2007; Kent & Domino, 2007), as already observed in the past (Table 2).

2.5. Guidelines and Recommendations of the Healthcare Community

In order to standardize and optimize patient care in the surgical setting, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) issued a Sentinel Event Alert (JCAHO, 2004) calling for an effort to manage and help reduce the risk of anesthesia awareness. The Alert, which is designed to provide practical advice to healthcare organization leaders and healthcare professionals, proposes developing and implementing an AA policy that addresses the education of clinical staff, the identification of patients at proportionately higher risk, and the application of available anesthesia monitoring techniques on a hospital-by-hospital basis.

The JCAHO Sentinel Alert was issued at a time of growing public concern over the risk and incidence of anesthesia awareness, and it was soon followed by AA advisories from the American Association of Nurse Anesthetists (AANA) and the American Society of Anesthesiologists (ASA) (Tunajek, S., 2005; Practice Advisory for Intraoperative Awareness and Brain Function Monitoring, 2006). These reports signaled a heightened concern regarding awareness during general anesthesia and established an important role for LOC monitors within the anesthesia practice. More than two-thirds of ASA members (69%) that were surveyed as part of that organization’s advisory agreed on the value of LOC monitors. The ASA’s overall recommendation suggests that anesthesia providers consider the option of utilizing an LOC monitor, particularly in clinical situations that place a patient at increased risk for AA.

Table 2 - Inflation-Adjusted Payments for Anesthesia Awareness. Source: Kent, 2006.

<table>
<thead>
<tr>
<th>Year</th>
<th>Claims for Awareness</th>
<th>Payment made*</th>
<th>Payment made in 1999 dollars</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1970s n=669</td>
<td>1980s n=2,959</td>
<td>1990s n=3,183</td>
</tr>
<tr>
<td>Claims</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>awareness</td>
<td>7 (1%)</td>
<td>57 (2%)</td>
<td>65 (2%)</td>
</tr>
<tr>
<td>Payment</td>
<td>4 (67%)</td>
<td>32 (62%)</td>
<td>31 (52%)</td>
</tr>
<tr>
<td>made*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Payment</td>
<td>$32,060</td>
<td>$21,455</td>
<td>$33,599</td>
</tr>
<tr>
<td>made in</td>
<td>$5,217</td>
<td>$2,325</td>
<td>$1,220</td>
</tr>
<tr>
<td>1999 dollars</td>
<td>$46,000</td>
<td>$846,000</td>
<td>$840,000</td>
</tr>
</tbody>
</table>

*Claims with missing data excluded

“LOC monitoring can prevent up to 80% of anesthesia awareness cases.”
3. SNAP II™ MONITOR

The SNAP II™ LOC monitor is superior in form and function to other LOC monitors, surpassing the expectations set forth by the competition. The advanced SNAP II™ technology incorporates an innovative and proprietary algorithm and database system that collects high- and low-frequency EEG signals and compares them to the signals of other patients that have undergone surgery. The device uses the information provided by the algorithm and historical database to determine a probability projection of a given patient's LOC. The technology allows SNAP II™ to produce faster, more consistent results than its competitors.

3.1. Product Overview

The SNAP II™ algorithm collects and distills ultra-fast, high-frequency EEG signals as well as the most useful bands of low-frequency EEG. As discussed previously, incorporating high-frequency EEG signals makes the SNAP II™ a better predictor of a patient's return to consciousness, not just an indicator of sleep status. The algorithm also reduces signal contamination by eliminating EEG bands (beta waves as low as 20 Hz and up to 80 Hz) that are prone to electrical interference.

In addition to the algorithm, the SNAP II™ boasts a proprietary database that compares brain wave readings to patient signals stored in the historical database. The database is rich in high- and low-frequency EEG data from multiple paralysis studies involving large groups of patients and controls. The patients in these studies represent a range of patient groups: from surgical patients under general anesthesia (with or without paralytics) to wide-awake control subjects given a paralytic to model the state of AA and to boost the specificity of the database. As such, this highly developed database is able to provide useful information on a patient's waking status, enhancing the sophistication and accuracy of the device itself.

“Incorporating high-frequency EEG signals makes the SNAP II™ a better predictor of a patient’s return to consciousness.”

The SNAP Index, reflected in the large readout in the upper left-hand corner of the device (Figure 4), is derived from the database and uses a scale from 0 – 99. The index is not a definite determination of a patient's state of consciousness, but a probability projection. For example, at a SNAP Index of 71, it can be inferred (with a 95% level of confidence) that a patient is probably unconscious. If the index trend is decreasing, it means the patient is becoming more unconscious. If the trend is increasing, then the patient is returning to consciousness. The trend responds to changes in brain activity in real time, which means that it corresponds directly to clinical events — an important advantage when inducing anesthesia or when patients are emerging from anesthesia in the recovery phase.

The unique design of the SNAP II™ monitor allows it to be mobile, and its convenient size facilitates placement in hospital surgery rooms, intensive care units, ambulatory surgery centers, and office-based practices, whether mounted on a tabletop or on an IV pole. The screen projects a sharp, crystal-clear image displaying the EEG signal.

**Technology Features:**
- Minimizes bands most heavily contaminated by EMG
- Captures most useful information in low-frequency EEG
- Utilizes high-frequency EEG in return to consciousness
- Processes both high- and low-frequency EEG to create the SNAP Index
- Utilizes comprehensive historical database involving 8 clinical trials
- Fast speed of recovery
the SNAP Index, and the index trend. The device is easily navigated, and setting it up is an intuitive process. With other monitors, EEG signals are measured by applying multiple electrical leads to a patient’s head. The SNAP sensor combines all of the cumbersome leads into one easy-to-apply, sterile, and disposable sensor. The flexibility of the sensor’s three lobes make it a one-size-fits-all component. Each lobe is placed on a specific area of the forehead: Lobe 1 (or 3) is placed in the center of the forehead, Lobe 2 is placed over the arch of the eyebrow, and Lobe 3 (or 1) is placed at the end of the eyebrow line near the temple. The top of the sensor connects to the patient interface cable, which easily plugs into the left side of the monitor. These features reflect Stryker’s dedication to meeting clinicians’ needs in the surgical suite, and to designing and developing innovative products for use by anesthesiology professionals.

**Device Features:**

**Self-Contained or Pole-Mounted Portability**
- Minimal space requirements
- Easily transported with the patient or physician
- Weight: 24 oz.

**Color Touchscreen**
- Crystal-clear, high-resolution color touchscreen
- Visual and audible alerts with user-definable limits
- Real-time EEG graph and SNAP Index

**Battery Operation**
- Four hours of full operation on rechargeable battery
- Comes complete with AC power supply and power cord

**Performance**
- Activates patient database
3.2. Product Comparisons

The sensitivity of the SNAP II™ monitor in indicating return to consciousness has been demonstrated in more than 20 clinical studies. Five of these studies highlight the importance of high-frequency EEG monitoring and the superiority of SNAP II™ over its competitors (Appendix A).

Direct competitors to the SNAP II™ include the Bispectral Index (BIS) monitor by Aspect™, the SEDLine monitor by Hospira, the Entropy monitor by GE, and the Cerebral State Monitor (CSM) by Danmeter. Whereas the BIS is the most commonly used monitor on the market (90% share), it represents an aging technology with key limitations, including a significant lag time between response of the device and clinical events (Wong et al., 2005; Wong et al., 2006). According to a survey of healthcare professionals who use BIS, many feel limited by the BIS device, and would warmly welcome a newer technology (Brown, 2007).

In comparison to the BIS monitor, SNAP II™ is superior in detecting “unintentional awareness” (Wong et al., 2006; Wong et al., 2002a). The BIS also falls short in comparison to SNAP II™ in several categories (Table 3). For example, the SNAP II™ is the only device on the market that incorporates low- and high-frequency EEG monitoring (Figure 5). Additionally, the proprietary SNAP II™ algorithm eliminates the frequency range that is most heavily contaminated with EMG signals. Those features make SNAP II™ faster, more consistent, more stable, and more sensitive to brain activity, resulting in greater specificity, enhanced utility, and a quicker response to changes in a patient’s anesthesia status.

Anesthesiology professionals who have used the BIS monitor recognize its significant delay during surgical maintenance (approximately 25 – 40 seconds). The SNAP II™ only takes 10 seconds to analyze EEG signals and provide an initial LOC Index, which is then updated every second, correlating with clinical events. SNAP II™ boasts an advanced technology that makes it a more sensitive indicator of return to consciousness, making it useful in both the induction and recovery phases of anesthesia management.
## Table 3 - SNAP II™ vs. Competitors

<table>
<thead>
<tr>
<th>Technology</th>
<th>SNAP II™ Stryker</th>
<th>BIS Aspect™</th>
<th>SEDLine Hospira</th>
<th>Entropy GE</th>
<th>CSM Danmeter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology</td>
<td>High- and low-frequency EEG</td>
<td>Low-frequency EEG</td>
<td>Low-frequency EEG</td>
<td>Low-frequency EEG and FEMG</td>
<td>Low-frequency EEG</td>
</tr>
<tr>
<td>Sensor</td>
<td>Single lead</td>
<td>Single lead</td>
<td>N/A</td>
<td>Uses Aspect disposables</td>
<td>N/A</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>Derived EEG measure indicates brain activity level</td>
<td>• Monitor state of brain-EEG • May be used as an aid in monitoring effects of certain anesthetic agents • May be associated with reduction of incidence of awareness</td>
<td>• Monitor state of brain-EEG • Computed EEG variable, related to effect of anesthetic agents</td>
<td>• Monitor state of CNS-EEG and FEMG in the anesthesia environment • May be used as an aid in monitoring effects of certain anesthetic agents</td>
<td>Monitoring state of brain-EEG</td>
</tr>
<tr>
<td>Device Features</td>
<td>• Color touchscreen • IV pole mount • Weight: 24 oz. • 4 hours full operation • Internal database</td>
<td>• IV pole mount • Weight: 3 lbs. • 20 minutes continuous battery operation with a 10-hour recharge time • Vista-Color touchscreen</td>
<td>• No IV pole mount • Weight: 20 lbs. • 20 minutes with a 10-hour recharge time</td>
<td>• Module-based</td>
<td>• Handheld • Weight: 130 g. • Alkaline: 32 hours • Rechargeable: 12 hours</td>
</tr>
</tbody>
</table>
4. FINAL WORD

While anesthesia awareness (AA) is a rare phenomenon, it has nonetheless generated widespread public concern. The impact of AA on patients who experience it can be lasting and damaging. Stryker, therefore, encourages patients and physicians to engage in active dialogue on how to optimize the anesthesia experience through the use of advanced monitoring technology. Ultimately, millions of patients will undergo major surgery in the next year. For those patients, access to the latest anesthesia technology — as well as to useful information about that technology — can allay their concerns about AA while reducing their risk of this rare but frightening occurrence.

5. REFERENCES


## 6. APPENDICES

### 6.1 Appendix A - Studies Relevant to SNAP II™

<table>
<thead>
<tr>
<th>STUDY</th>
<th>N</th>
<th>SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SNAP II™ &amp; BIS Efficacy Studies</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wong et al., 2006</td>
<td>42</td>
<td>Compares SNAP II™ and BIS XP during sevoflurane and sevoflurane/nitrous oxide anesthesia. Found that the indices of the two monitors are not interchangeable. In addition, the SNAP Index returns to baseline before awakening, whereas the BIS index remains below baseline at awakening, suggesting that the SNAP Index may be more sensitive to unintentional awareness.</td>
</tr>
<tr>
<td>Ruiz-Gimeno et al., 2005</td>
<td>70</td>
<td>Investigates behavior patterns and capability of SNAP II™ to monitor the hypnotic effect induced by sevoflurane-nitrous oxide in comparison with the BIS index. Authors suggest that the SNAP Index correlates with variations in the hypnotic effect induced by sevoflurane-nitrous oxide anesthesia when compared with the BIS index. In this context, a SNAP Index ranging from 58 to 70 would be equivalent to the BIS index range 40 to 60 and, therefore, is accurate for surgical performance.</td>
</tr>
<tr>
<td>Schmidt et al., 2005</td>
<td>19</td>
<td>Compares accuracy of SNAP Index, BIS, spectral edge frequency, mean arterial blood pressure and heart rate in distinguishing different states of propofol/remifentanil anesthesia in female patients who were undergoing minor gynecological surgery. Authors suggest SNAP Index and BIS were superior to mean arterial blood pressure and heart rate and spectral edge frequency in distinguishing between different steps of anesthesia with propofol and remifentanil and provided useful additional information.</td>
</tr>
<tr>
<td>Wong et al., 2005</td>
<td>220</td>
<td>Determines the relationship of the SNAP Index with loss of consciousness in subjects receiving propofol. Found that the SNAP Index correlated with propofol-induced loss of consciousness and appears to be a useful indicator of loss of consciousness.</td>
</tr>
<tr>
<td>Wong et al., 2002a</td>
<td>39</td>
<td>Evaluates the relationship between the SNAP and BIS indices. Found that SNAP-derived indices were more consistently in the 50-65 range during anesthesia and &gt; 65 upon awakening than BIS values.</td>
</tr>
</tbody>
</table>

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**Advising the Art and Science of Anesthesia Control**

SNAP II™

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Table 5 - Summaries of Studies Relevant to SNAP II™ Technology

<table>
<thead>
<tr>
<th>STUDY</th>
<th>SUMMARY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depth of Anesthesia Monitoring Studies</td>
<td></td>
</tr>
<tr>
<td>Voss &amp; Sleigh, 2007</td>
<td>Investigates literature on inhibitory effects of anesthetic agents reflected in EEG. Literature reveals many instances where EEG pattern is dissociated from conscious state (e.g., an awake-looking EEG, but an unresponsive patient; or a slow-wave EEG in an awake patient).</td>
</tr>
<tr>
<td>Sing et al., 2005</td>
<td>Investigates high-frequency EEG (HFE) as a potential predictor of alertness/drowsiness. Found that HFE may provide a quantitative measure of cognitive function capacity and may be applied for EEG monitoring of cognitive performance.</td>
</tr>
<tr>
<td>Rungreungvanich et al., 2005</td>
<td>Analyzes anesthesia awareness using database of Thai Anesthesia Incidents Study (THAI Study) with regard to frequency, contributing factors, and preventive and corrective strategies. In this study, incidence of recall of awareness was 0.08%. Corrective strategies included guideline practice, additional training, quality assurance activity, and improved supervision.</td>
</tr>
<tr>
<td>Dressler et al., 2004</td>
<td>Evaluates the performance of each frequency in the power spectrum regarding detection of awareness. Found that the best performance for the detection of awareness was achieved by EEG power spectral frequencies from &gt;35 Hz up to 127 Hz, although some frequencies in this range are dominated by muscle activity.</td>
</tr>
<tr>
<td>Kaul &amp; Bharti, 2002</td>
<td>Reviews anesthetic agents used in general anesthesia as well as techniques employed to monitor depth of anesthesia. Suggests that it is unlikely that any single method reliably measures the depth of anesthesia for all anesthetic agents. In addition, the authors suggest the only reliable way of determining depth of anesthesia requires a measure of cerebral activity and a localization of the activity to specific cortical regions and areas in the brain stem, in real time.</td>
</tr>
<tr>
<td>Daunderer &amp; Schwender, 2001</td>
<td>Reviews several different procedures developed to monitor and avoid intraoperative situations of wakefulness during general anesthesia. Methods reviewed include the PRST-score, the isolated forearm technique, spontaneous EEG and its derived parameters, and mid-latency auditory evoked potentials.</td>
</tr>
<tr>
<td>Draguhn et al., 1998</td>
<td>Reports that high-frequency network oscillations (150-200 Hz) are present in rat brain slices in vitro. Authors suggest high-frequency oscillations synchronize the activity of electrically coupled subsets of principal neurons within the well-documented synaptic network of the hippocampus.</td>
</tr>
<tr>
<td>Rampil, 1998</td>
<td>Reviews the technical bases of developing a comprehensive &quot;anesthetic depth&quot; monitor and provides a synopsis of the relevant physiology involved in the generation and modulation of the EEG.</td>
</tr>
<tr>
<td>Crippen, 1997</td>
<td>Reviews factors that limit the use of EEG for real-time evaluation of brain wave function in modern intensive care units (ICUs). Author suggests that portable, computer processed, bedside EEGs provide real time brain wave appraisal for some brain functions and are an objective method for assessing and controlling sedation.</td>
</tr>
</tbody>
</table>
6.2 Appendix B - Glossary

**AANA** Founded in 1931, the American Association of Nurse Anesthetists is the professional association for more than 35,000 Certified Registered Nurse Anesthetists (CRNAs) and student nurse anesthetists. CRNAs are advanced practice nurses who are the hands-on providers of approximately 65% of all anesthesia given in the United States each year.

**Accuracy** The degree of conformity of a measured or calculated quantity to its actual (true) value.

**Anesthesia** The condition of having the feeling of pain and other sensations blocked. General anesthesia in its most general form can include: analgesia (blocking the conscious sensation of pain), hypnosis (producing unconsciousness), amnesia (preventing memory formation), relaxation (preventing unwanted movement or muscle tone), and obtundation of reflexes (preventing exaggerated autonomic reflexes).

**Anesthesia awareness (also called “unintended intraoperative awareness”)** Occurs during general anesthesia, when a patient has not had enough of a general anesthetic or analgesic to prevent consciousness and the recall of events.

**ASA** The American Society of Anesthesiologists is an educational, research and scientific association of physicians organized to raise and maintain the standards of the medical practice of anesthesiaology and to improve the care of the patient. Since its founding in 1905, the Society’s achievements have made it an important voice in American medicine and the foremost advocate for all patients who require anesthesia or relief from pain.

**C-section (also called “Caesarean section”)** A form of childbirth in which a surgical incision is made through a mother’s abdomen and uterus to deliver one or more babies. It is usually performed when a vaginal delivery would put the baby’s or mother’s life or health at risk.

**CNS** The central nervous system (CNS) represents the largest part of the nervous system, including the brain and the spinal cord.

**Hemodynamics** The study of the properties and flow of blood.

**Induction** The first stage of anesthesia.

**Infusion** The intravenous process of administering anesthesia.

**Intubation (tracheal)** The placement of a flexible plastic tube into the trachea to protect the patient’s airway and provide a means of mechanical ventilation.

**JCAHO** An independent, not-for-profit organization, The Joint Commission on Accreditation of Healthcare Organizations accredits and certifies nearly 15,000 healthcare organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization’s commitment to meeting certain performance standards.

**Sedation** The depression of a patient’s awareness to the environment and reduction of his or her responsiveness to external stimulation.

**Sensitivity** The minimum magnitude of input signal required to produce a specified output signal having a specified signal-to-noise ratio.

**Titration** The guided search of the optimal anesthetic dose to be administered to a patient.