

**OPTIMAL MODALITY OF MARKET ENTRY FOR A  
NEUROMONITORING INNOVATION:  
ASSESSMENT FOR A LEADING MEDICAL DEVICE PROVIDER**

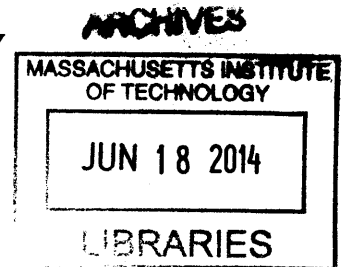
By

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**Sandeep Bothra**

Submitted to MIT Sloan School of Management on May 9, 2014 in  
Partial Fulfillment of the requirements for the Degree of  
Master of Science in Management of Technology

**ABSTRACT**

Technological advances have led to treating complicated surgical indications and early recovery for millions of patients worldwide. Developments that also provide cost benefits and simplify procedures have global appeal.

This report provides an analysis and evaluation of a neuromonitoring technology as applicable to the US medical device market. This technology promises to make surgery safer and reduce the learning curve associated with complicated procedures. The goal is to recommend the optimal mode of market entry for a leading device provider for the US Market.

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I dedicate this thesis to my family, my mom, my dad, my wife, and my beloved children for their constant support and unconditional love.

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# **OPTIMAL MODALITY OF MARKET ENTRY FOR A NEUROMONITORING INNOVATION: ASSESSMENT FOR A LEADING MEDICAL DEVICE PROVIDER**

## **EXECUTIVE SUMMARY**

Technological advances have led to treating complicated surgical indications and early recovery for millions of patients worldwide. Developments that also provide cost benefits and simplify procedures will have global appeal.

This report provides an analysis and evaluation of a neuromonitoring technology as applicable to the US medical device market. This technology promises to make surgery safer and reduce the learning curve associated with complicated procedures. The goal is to recommend the optimal mode of market entry for a leading device provider for the US Market. Three relevant entry modalities are examined:

- 1.Licensing
- 2.Buy Out
- 3.In House Development

Research methodology comprised of secondary (database) and primary research, including interviews of key stakeholders (Surgeons, Industry experts, Hospital Administrators and internal employees of the company). The report examines prospects of the technology in its current shape and discusses key developmental opportunities.

The major area of weakness that requires further investigation is the adaptability of the technology to the current product streams of the company across different geographic locations.

Dimensions analyzed include:

- Current & Future trends of the neuromonitoring industry
- Industry: Technology/Product and Market
- Opportunities & Challenges for the organization
- Key Risks vis-à-vis technology adoption
- Key considerations for the optimal mode of entry

### **Recommendation**

Licensing is determined to be the most appropriate modality for operationalizing this innovative technology at the current time. Therefore licensing is recommended as the mode of entry after careful analysis of the data and current market situation, cost-benefit analysis and risk assessment of the three modes of entry-licensing, buy out and in-house development.

### **Next Steps**

As next steps the research lays out a pilot program between the periods of Jan2015 to June 2015, for the roll out of this technology. Key assumptions and projected sales revenues associated with the pilot roll out with a scenario analysis under optimistic, pessimistic and base conditions are presented.



## 1. INTRODUCTION

Innovation in the Medical Devices industry has made a variety of surgical procedures simpler and complicated procedures are now globally accepted and performed. Millions of<sup>1</sup> patients have benefited from path breaking technological innovations from the medical device companies. In the US alone almost 15% of the population is above 65 years and a study by the Agency for Healthcare Research and Quality (AHRQ) found that there were 38.6 million hospital stays in the U.S. in 2011, an 11 percent increase since 1997. Since the population also grew during this period, the hospitalization rate remained stable at approximately 1,200 stays per 10,000 populations. This creates a huge burden on the society in terms of costs associated with the treatment and loss of man-hours from work.

Surgeons operating on indications requiring correction of spinal cord have to navigate complex arrangement of nerves in order to treat the condition. These surgeries are very challenging and a slight error of judgment (placement of nerves) could lead to fatal or life changing injuries. Technological advances have facilitated development of tools that allow navigation of though these complex structures with the help of specialized instruments.

This study provides an analytical overview of operationalizing an Innovative Technology solution in the neuromonitoring space that helps making complex surgeries simpler, by locating live nerves during surgery. It discusses a variety of considerations including regulatory, IP and operational issues after having analyzed secondary data comprising of varied research reports a primary data from a diverse group of stakeholders. An optimal mode of market entry for the near to mid term is then proposed for a major medical device provider for the U.S. market based on above considerations and scenario analysis.

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<sup>1</sup> [http://en.wikipedia.org/wiki/Health\\_care\\_in\\_the\\_United\\_States](http://en.wikipedia.org/wiki/Health_care_in_the_United_States)

## 1.1 Methodology

The research methodology was divided into different phases, where series of primary and secondary research helped gather data from established journals and experienced industry professionals. This was followed by analysis and drawing of inferences.

**Phase 1** – During the phase 1 (20<sup>th</sup> Dec 2014- 15<sup>th</sup> March 2015) the research looked at gathering information about neuromonitoring and the industry from a variety of journals, industry reports and materials available online (details in appendix). This data gathering exercise was followed by interviews of key stakeholders including Hospital Administration, Customers, Industry Experts and internal company employees.

**Phase 2** – During Phase 2 (March 15<sup>th</sup> 2015 to 15<sup>th</sup> April 2015) the research focused on analysis of data gathered during phase 1 and reviewing frameworks that could help establish a sound strategy for the different modalities as applicable for the roll out of the technology in the US.

**Phase 3** – During the Phase 3 (15<sup>th</sup> April to 7<sup>th</sup> May 2015) the content of the report was drafted in a logical sequence to present a complete assessment of the different entry modalities and develop recommendation for an appropriate mode of entry.

The report is organized as follows:

Chapter 2 reviews the neuromonitoring technology and its operational nuances in the US market. Market overview is described in Chapter 3. Chapter 4 elaborates on the competitive scenario while chapter 5, 6 & 7 describe various considerations for market entry modality, its assessment criteria and recommendation with next steps respectively.

## 2. TECHNOLOGY OVERVIEW

### 2.1 What is Neuromonitoring

Intraoperative neurophysiologic monitoring (IONM) is a valuable technique for assessing the nervous system. It replaces the neurologic examination when the patient is under general anesthesia and cannot cooperate with a face-to-face examination. It allows for assessment of many neural structures including the neuromuscular junction, peripheral nerve, spinal cord, brainstem, and cortex during surgery. (Adapted from Nuwer MR<sup>2</sup>)

The most commonly employed techniques during spinal procedures are: transcranial motor evoked potentials (Tc-MEPs), upper and lower somatosensory evoked potentials (upper and lower SSEP), pedicle screw simulation, and spontaneous electromyography (EMG). A number of other techniques have been used over the years that include direct spinal cord stimulation and reflex monitoring.

In the USA one of the most commonly option for monitoring Spinal Surgeries are SSEPs (Somatosensory Evoked Potentials) and MEPs (Motor Evoked Potentials as compared to EMG (Electromyography). While EMG is largely used for Spinal Deformity Correction, tumors and lumbar instrumentation – SSEPs and MEPs are used for Scoliosis, Cervical and thoracic procedures.

Intra operative neuro physiological monitoring represents the application of electrophysiological techniques to detect the functional changes of nervous system consistent with ischemia/injury.

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<sup>2</sup>Nuwer MR, Dawson EG, Carlson LG, et al. Electroencephalography & Clinical Neurophysiology

The Mechanism of IONM is as follows:

- Electrophysiological techniques assist in localizing the neural structures, identifying the specific cortical functional areas and delineating epileptogenic cortex
- The information obtained also determines the mechanism of injury and prevent damage by detecting the dysfunction prior to reaching an irreversible stage.

## 2.2 Different types of Neuromonitoring Technologies

This section describes different options a neuromonitoring technology offers and their usage across different procedures:

1. **SSEP:** When a sensory impulse reaches the brain, a specific response is created (evoked) in the cortical area appropriate to the modality and site of stimulation. SSEPs distinguish between lesions located in the peripheral nerve or the spinal cord (dorsal column pathway) or both during surgical procedures.
2. **MEP:** MEPs are recorded electrical responses in to the stimulation of the primary motor cortex and evaluate the functional integrity of the motor pathways. Mostly used in procedures, as they are more sensitive to changes.
3. **EMG:** EMG results reflect both the integrity of the functioning connection between a nerve and its innervated muscle and the integrity of the muscle itself and hence used for both diagnostic and surgical purposes.
  - a. Spontaneous EMG: Used for indicating the activity of the muscle that might cause nerve damage i.e. when there is spontaneous activity of EMG it indicates that surgeon is causing nerve damage.
  - b. Simulated EMG: helps in locating the nerve suspected to be there in tumor mass and helps the surgeon in deciding whether to go for dissection or not/ helps in tumor margins

4. **EEG:** During electroencephalography (EEG), the electrical signals of the brain are recorded and used for diagnostic purposes in epilepsy. It helps in understanding the brain activity in anesthetic patients during surgeries and also in assessing the involuntary movements during surgical procedure
5. **Others:** Brainstem evoked potentials (BAEPs/BAERs) indicate the abnormality at a specific anatomic site in the acoustic nerve or brainstem. Electrocorticography (ECoG) is generally used for epileptic cases to monitor muscle contractions.

These options are supplied to the hospitals and get used as per the requirements of the patient indications determined by the surgeons.

### 2.3 Roll out of Neuromonitoring Technology

Once the requirement of technology is ascertained, the hospital administration works with its vendors or an internal department to make it available.

Technicians and availability of the technology in hospitals drive IONM surgical procedures. It can be a) in-house where the hospital's purchase the capital equipment or b) outsource the services to a third party provider.

While the above options of technology availability have their own pros and cons – analysis suggests that it's the number of surgeries posted during a day have a major impact on determining the choice of ownership. Hospitals with consistent and higher volumes usually have their own equipment, while smaller hospitals often opt for outsourcing.

In both these cases – advancement of new technology has enabled surgeons to operate this innovative tool in a way that makes the role of the technician obsolete for certain types of procedures.

While the majority of hospitals utilized the IONM as a service either through owning the technology and using services of a third party contractor – the hospitals that were interviewed suggested a mix bag of options. While healthy mix of hospitals was utilizing services of in-house or outsourced – there were large hospitals that were using both options.

While both the options require hospitals to follow similar process of using the technology including professionals and use of technology, outsourced services ensure hospitals remain focused on their core activities. Each option has its own pros and cons, and can be opted for depending on capital and frequency of surgeries that need this technology.

One key difference in the operations is that under the outsourced model the service provider may use the remote monitoring while hospitals that own the same have a dedicated department in house.

While there are different preferences in opting for different models i.e. in-house vs. outsourcing, primary research suggests the following pros and cons of having adopted by different hospitals:

We interviewed 6-hospital administration and 4 surgeons to understand different operational protocols of having used different modalities for procedures. The following were the key findings of the interview:

- There was a clear majority of IONM services being provided by a 3<sup>rd</sup> Party Service provider
- Scheduling of surgical cases being the main concern of the high acceptance of this service modality

## Different Options for Roll Out

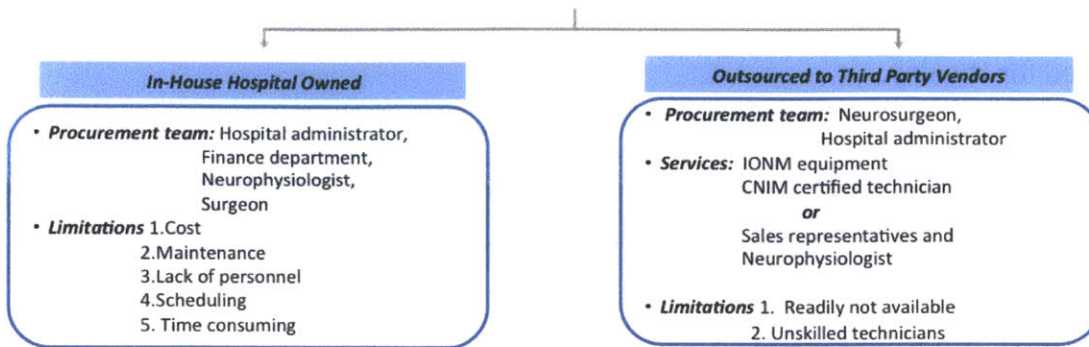


Figure 1 – Source: Voice of customer Hospitals

- Pros of outsourcing to third party vendors
  - Scheduling of surgery is much easier during days that has many surgeries
  - Capital is free and only service needs to be paid for
- Cons of Outsourcing to third party vendors
  - Availability of technology dependent on outsourced partner
  - Standard of service may differ potentially impacting quality
  - Service charges may be prohibitive
- Pros of In-house / Hospital owned
  - Available as required
  - Cost of service contained
  - Check on quality
- Cons of In-house Hospital owned
  - High Capital outlay
  - Dependency on trained professionals as employees
  - Costs of service and maintenance of equipment's

While different hospitals may use one or the other modalities of operations – some may also use a combination of two models depending on their number of surgeries posted for the day.

The hospitals and surgeons that were interviewed had the following concerns while opting for either a Hospital owned or Outsourced to a third party vendor model.

**Hospitals:** While the single largest preference was for outsourced services and majority of hospitals would prefer using outsourced to third party vendor services at different times depending on their planned surgeries for the day – some large volume hospitals also preferred to have an in house department to have the service as per their requirements.

**Surgeons:** surgeons were more concerned about the quality of service and availability and were indifferent to different models of availability i.e. outsourced third party vendor or in-house hospital owned

#### **2.4 Functional options of Neuromonitoring technology**

The primary concern of a surgeon is to ensure the best quality treatment to the patient condition. Technological advancements have allowed surgeons to control many variables simultaneously during the surgical procedure.



Figure 2 establishes the contrast of surgeon driven and technician driven systems

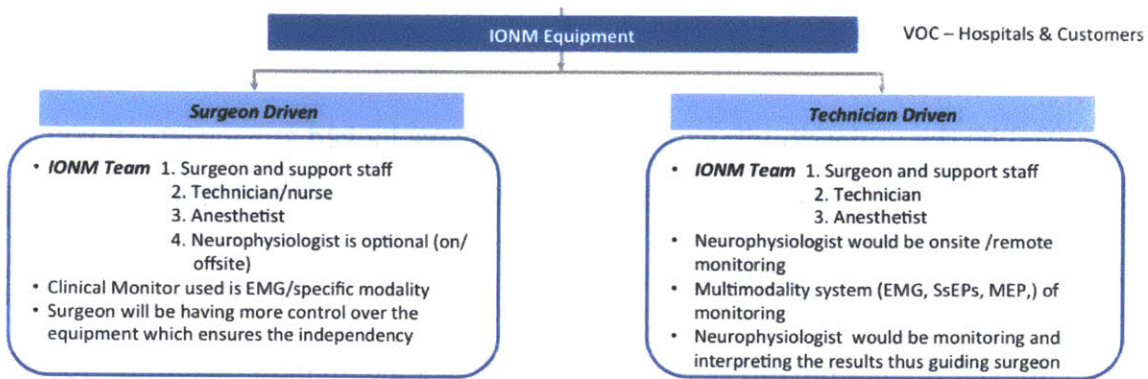


Figure 2 Source: Voice of customer Hospitals & Surgeons

Surgeon driven systems by definition provide more control over the procedure as opposed to the technician driven systems. Surgeon driven systems are newer developments and may be applicable to less complicate procedures only.

Key differences are as follows:

**Surgeon Driven**

1. More customized for specific type of surgeries such as lateral, pedicle screw testing, etc.
2. Primarily involves surgeon, assisting surgeon, technician, anesthetist, nurses
3. More control over system which ensures independence
4. On site/Off site technician/physician may also be provided

**Technician Driven**

1. Provide comprehensive clinical monitors and ensure multimodality monitoring
2. Primarily involves technician, assisting surgeon and anesthetist
3. Neurophysiologist does remote monitoring
4. Dependent on technician for interpreting results during procedures
5. Lot of wiring, electrodes etc. makes it fuzzy

6. Both equipment and initial set up by technician/neurophysiologist is provided on a case by case basis

Supported by the understanding of the technology we looked at a variety of voice of customer interviews to help us gather stakeholder perspective and opinions.

## 2.5 Key Insights from the Interviews

We conducted telephonic interviews of a variety of stakeholders including Hospital Administration Staff and Surgeon Customers.

1. A large majority supported the concept of an outsourced model of service providers as it offered better flexibility.

“The vendor has been there a long time. Technology changes to frequently. We can stay up to date on technology. Capital funds are hard to come by. We would have also had to add staff.” Voice of Customer – Hospital Administration

“It would depend on the technology. It would affect my opinion. The surgeon is busy doing the case. With a tech, you have someone who can draw things to his attention. But anytime you don’t need extra people in the OR, it’s a good thing. Surgeons like having the techs there. He must be seeing an advantage to having the tech there.” Voice of Customer – Hospital Administration

2. Better control as offered by the new technology was also preferred as it reduced cost and enhanced decision making ability of the surgeon

“I think the surgeon would like it. Control is preferable”  
Voice of Customer – Hospital Administration

“Safe, reliable, equivalent to EMG (but not ready to adopt until further studies have been performed)” Voice of Customer – surgeons

“Some differentiation – slightly faster, lower stim currents, able to see waveforms, easy to use” Voice of Customer – surgeons

3. From an operational perspective – hospitals prefer to deal with fewer vendors as it simplifies their operations.

“As per our goal of making our operations efficient – we would prefer to deal with fewer vendors and have a deeper working relationship”

Voice of Customer – Hospital Administration

The analysis of the roll out of the technology combined with the key insights from the voice of customers helped develop the process followed (as detailed in the following section) by surgeons to make the technology available for their procedures.

## **2.6 Process Flow Chart for Request of Neuromonitoring Procedure:**

While different models have different lead times of making the technology available for a procedure – A hospital would typically have a process flow to arrange the technology. This process is critical as there are many stakeholders in the entire chain of making the technology available for use for the procedure. The Patient, Physician, Provider and Payer play an important role in the ordering of the tool for a specific surgery.

Figure 3 below explains the different steps and stakeholders involved in a typical procedure that needs IONM. Once the patient requiring surgical procedures reaches the hospital, depending on the case requirements a neuromonitoring option is scheduled in advance. The use of neuromonitoring however is dependent on the type of procedure. In certain orthopedic procedure (spine tumor) it could be a

mandated standard of care, while (ent) other general procedures could be optional. The surgeon is the primary decision maker for the use of this technology during a procedure.

Once s/he opts for the neuromonitoring to be used for the case – the hospital administration requests the department or the third party provider to make the technology available at the date and time of the surgery.

However in cases of emergency the surgeon may decide to proceed without the technology or wait as he deems fit.

### Process Flow Chart

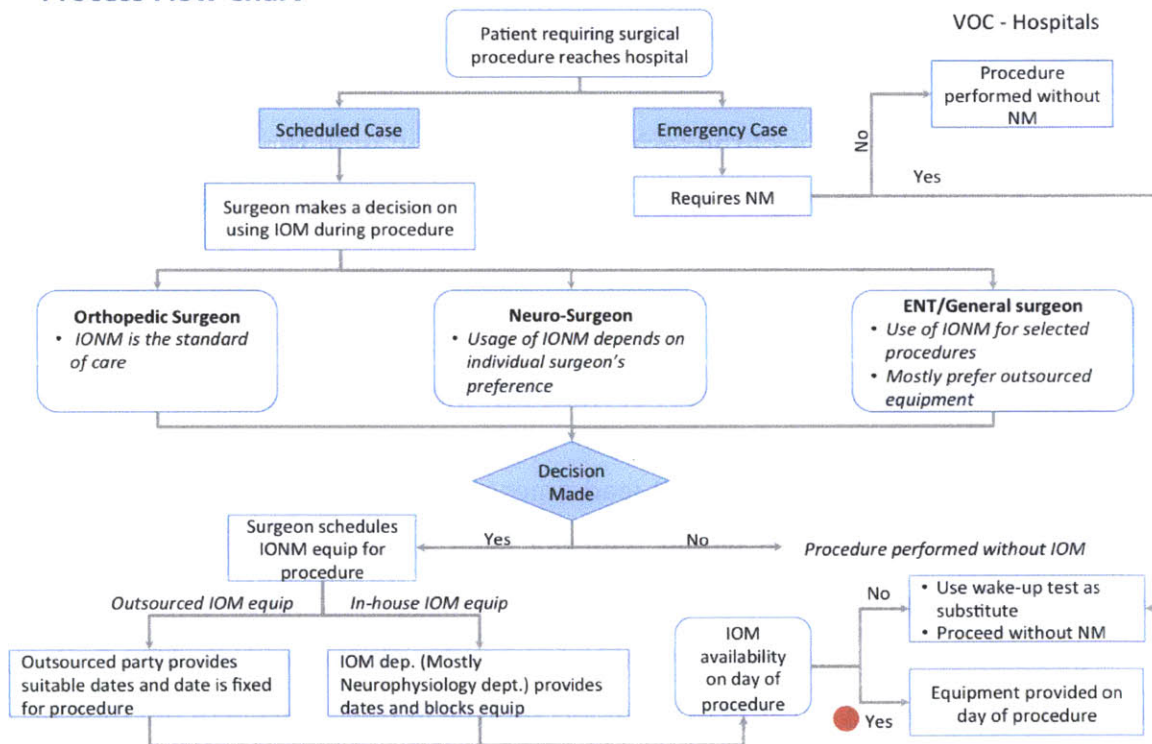


Figure: 3 Source: Voice of customer Hospitals

## 2.7 How is Neuromonitoring used in the Operation Theatre?

Once the IONM equipment is ordered as per the request of the surgeon, the hospital will have the technician provide the equipment at the day of the surgery.

The role of the technician is paramount in using of this technology in the operating theatre. His/her presence is very critical to the successful roll out of the technology. A qualified technician is a person who has at least 2 years of practice and has to clear a professional certification course to be able to deliver this technology in a hospital. H/she is responsible to take consent from the patient for the use of the technology in a way that the surgeon is able to record the feedback on a computer during surgery with the help of a probe.

The technician is a trained and qualified professional who places the disposable leads on the patient before the surgery. H/she is responsible to set up the wires connecting the leads to the computer and making connections to the instruments that is used during the procedure. The technician reads the feedback during the procedure and keeps an eye on the feedback and communicates and informs the surgeon as appropriate.

Post the surgery the technician un-installs the technology and sends the invoice for the services used to the hospital. The following flow chart explains how neuromonitoring is rolled out in hospitals for a procedure in a local hospital.

The figure 4 below explains a typical process by which a neuromonitoring technology is rolled out in a hospital. The technician takes consent from the patient on its use before the surgery. While the patient is being anesthetized, the technician places the leads in the form of patches and needles and measures the base line values through a computer attached with the help of wires.

Once the surgery begins the technician monitors the information captured by the computer and informs the surgeon for any abnormality. The technician un-installs the leads after the procedure.

## How is Neuromonitoring Utilized?

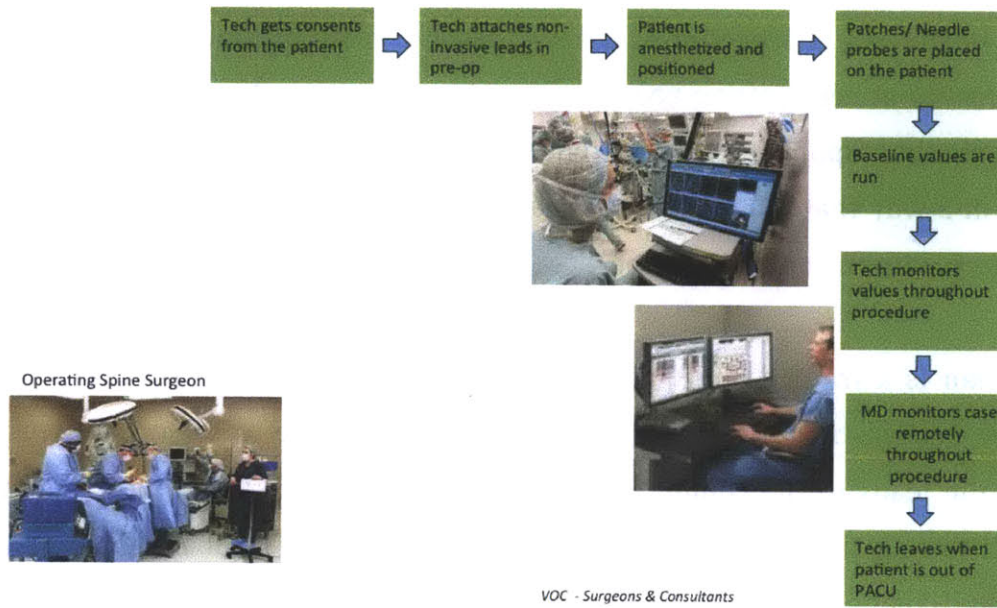


Figure 4 Source: Voice of customers Hospitals & Surgeons

### 3. MARKET OVERVIEW

#### 3.1 Neuromonitoring Market Size

Primary and Secondary market research suggests there is a consistent rise in the adoption of IONM across various spinal procedures. From an adoption of 5% in 2001 the estimated adoption is at 36% as of 2012.<sup>3</sup>

The cost of neuromonitoring would depend on the complexity of the procedure and duration used and the professional fees of the technician – on an average the range could be between 600\$-3500\$. Secondary market research analysis suggests that the outsourced market is growing at a faster pace (15%) as opposed to the in house / insourced hospital owned systems (2%) with the overall market in 2011 being approximately \$800M.

This presents a huge growing market as the rise in number of spine surgeries across the 2001-2008 time frame has been over 137% as per published reports.

What is also driving the outsourced delivery to grow at a faster speed is the rise in number of small hospitals doing different types of procedures. Technology and its availability are fueling the appetite of a wider number of hospitals being able to perform difficult procedures. These small hospitals lack the financial capital for making an in house department in as much as they don't have many surgeries planned – outsourced model helps in maximizing their resources.

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1. <sup>3</sup> “IONM: Intra-Operative Neuro-Physiological Monitoring” Orthopedic Network News Estimates, Nov. 10, 2008.

**US IONM Market : Current market (2011) is estimated to be around \$ 800Mn and is expected to reach \$1.6Bn by 2020**

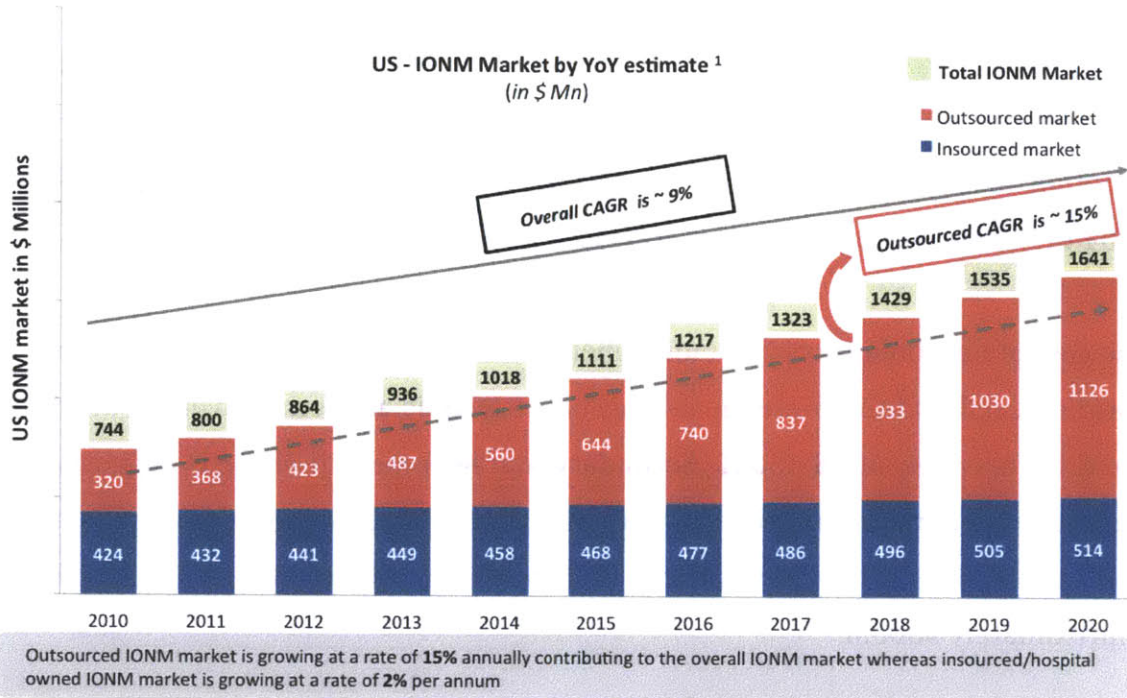


Figure 5 Source: Company Presentation. “Monitoring Procedurally integrating products and services raising the bar for patient care”

### 3.2 Landscape: Segments & Opportunities

While there are different modalities in the IONM service as required by different types of procedures, for the purposes of our analysis we looked at different growth opportunities as presented by different segments. (Figure 6)

While the total Market is around \$800M – this is split 75%/550M\$ for MMG, EMG, SSEP and TcMEP and 25% 250M\$ for EEG, AEP and DBS which is primarily used for brain related neuromonitoring.



## IONM Landscape

Modalities	MMG	EMG	EMG	SSEP	TcMEP	EEG	AEP	DBS
	Surgeon Driven	Tech Driven	Tech Driven	Tech Driven	Tech Driven	Tech Driven	Tech Driven	Tech Driven
Response	Real Time	Real Time	Real Time	Time Lag	Real Time	Time Lag	Time Lag	Real Time
Application	Xlif/Cervical Fusions	Xlif/Cervical Fusions	Xlif/Cervical Fusions	Sensory function of Cord – Xlif / Dformity / T&T	Motor Function of Cord - Cervical TL/ T&T	Cardiopulmonary Bypass	Acoustic Neuroma/ Vestibular Nerve	Parkinson's Disease Etc
Stimulation	Peripheral Nerve	Peripheral Nerve	Peripheral Nerve	Peripheral Nerve	Scalp	Scalp	Auditory System	Scalp
Recording	Muscles	Muscles	Muscles	Scalp / Brainstem / Reference Points	Peripheral Nerves	Scalp	Scalp	Shoulder
Anesthesia	TIVA	TIVA	TIVA	GA	TIVA	GA	GA	GA

18%/95Mn \$
75%/550Mn \$
82% 455Mn \$
25%/250Mn \$

Figure 6 Source: Company websites of leading IONM providers / DS Internal research reports

There are differences in each modality across a variety of attributes. Each difference in operationalizing the technology could be critical for different types of procedures.

The opportunities under each segment is promising and depending on the focused procedure – targeted promotion with training and education of professionals and surgeons can be strategic and a profitable venture.

For the purposes of our research and technology we focus on procedures that can benefit from the EMG and MMG options where the technology is most applicable – currently estimated to be approximately \$95M. Interviews and data research suggests growing unmet need of surgeon control systems; hence our current focus is on the MMG segment.

### 3.3 Factors influencing the growth of neuromonitoring

Almost 30% of all neuromonitoring used in the USA are on spinal procedures which involves complicated indications such as Cervical, Lumbar Fusion, Scoliosis where chances of neurologic damages are high.

While major deformity corrections and tumor procedures routinely use this technology to map nerves – other procedures are now seen it increasingly adopting this technology for a safer procedure.

Some of the reasons for increase in adoption of IONM are:

- **Safety:** With the use of neuromonitoring the risk of surgeries drops by over 90% as per data from the primary and secondary market research. This safety feature has ensured it has been acceptable widely.
- **Medico-Legal obligations:** A very important reason that has been seen as a driver of the adoption of IONM is the medico-legal lawsuits by patients in the country. The fear of lawsuits is also a potential driver of this technology adoption by customers and hospitals.
- **Growth in Surgeries:** there has been a huge growth in number of technically demanding surgeries as such technological advanced tools and their development and use has gained huge importance. The number of trained surgeons is far less and advancement of technology is helping the learning curve of newer surgeons to take up challenging procedures early on in their career.

## 4. COMPETITOR LANDSCAPE

### 4.1 Industry Overview

The industry seems to be fragmented with a number of local service providers spread out in the country. There are more service providers of the technology than there are manufacturers of the different types of technology.

- **Manufacturers:** These are players who are involved in manufacturing the technology solutions. They are located and spread out across different pockets and supply different modalities to hospitals and service providers and maintain the upkeep of instruments.
- **Service Providers:** These are players who are professionals in the delivering the technology to different hospitals. They have special contracts with hospitals and co-ordinate amongst the professionals (technician) and manufactures (technology) to offer a standard package as solution to hospitals.
- **Implant Companies:** Implant companies who sell implants (screws, rods, cages, biomaterials) for different types of procedures related to spine and neuro indications have also operationalized alliances with neuromonitoring companies to offer this as a complementary product. This strategic alliance creates an entry barrier for their competition and blocks possibility of an entry. They have been proactive into making this technology a value added service along with their existing relationship with the providers and customers.

## Overview of Landscape of major players in US in IONM space

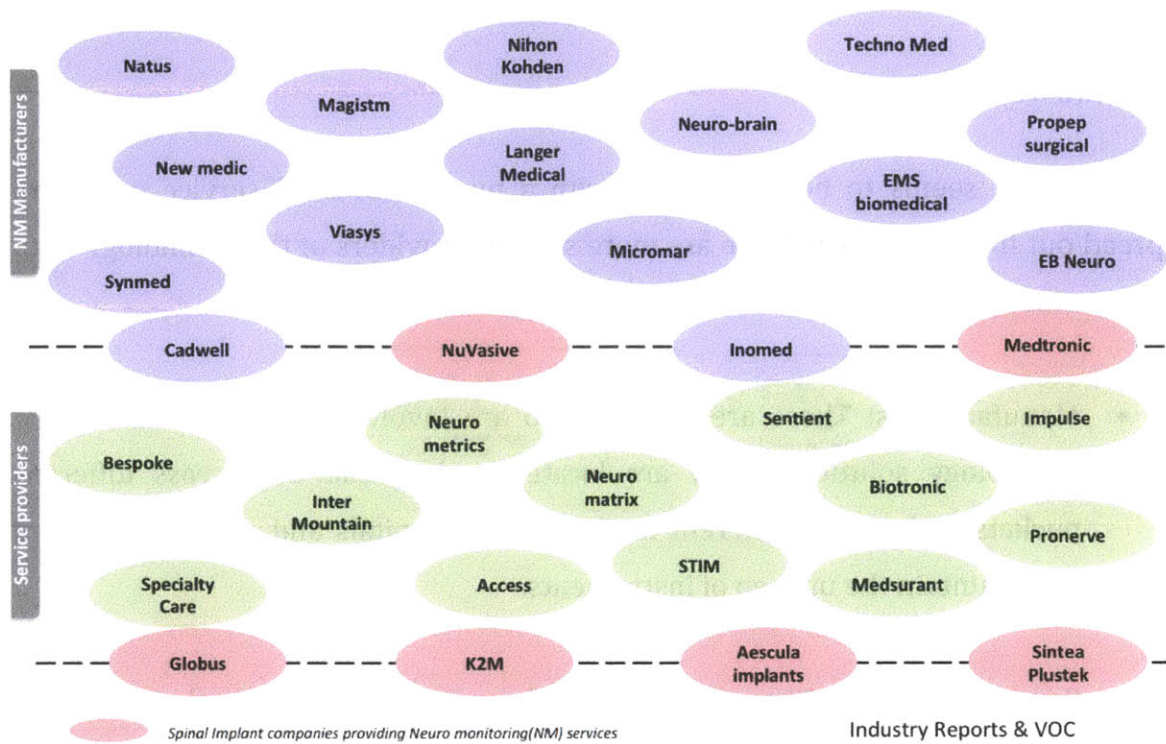


Figure 6 Source: Orbees market research report 2012

Over the last 6 years there has been a move by Implant companies to acquire this technology and provide this as a packaged solution to the hospitals and surgeons. While this feeds into the requirement of the hospital purchase department to have fewer vendors – this also ensures that this technology makes exit or entry barrier for competing companies.

### 4.2 Product Overview

While comparing various technological solutions available in the market today to that of the targeted technology we could appreciate the differences and the similarities. Key players have captured differentiation in a fragmented market scenario.

The targeted solution XX (disguised name of the brand) stands out in that this allows surgeon to be in control of the procedure. The surgeon can handle the

surgery and make better decisions as he controls the technology. This also makes the technician redundant, in a way that surgeon can have a better control and make timely decisions during the procedure.

### Product Comparison Chart

Source Company websites and internal product literature

		Players			
	Criteria	M5	NIM	XX	3 <sup>rd</sup> Party
1	Automated EMG	😊	😞	😊	😞
2	Free Run EMG	😊	😊	😊	😊
3	SSEP/tcMEP	😊	😊	😞	😊
4	Surface / Needle Electrodes	Both	Needle	Surface	Needle
5	Nerve Mapping / Distance	😞	😞	😊	😞
6	Patient Prep	Pre-Anes	Post - Anes	Pre-Anes	Post-Anes
7	Surgeon Controls Handpiece	😊	😞	😊	😞
8	Surgeon Graphical User Interface	😊	😞	😊	😞
9	Surgeon-Readable Waveform	😞	😞	😊	😞
10	Sensitivity to lower response ampl.	😞	😊	😊	😞
11	Open Architecture	😞	😞	😊	😊

Figure 7 Source: Company websites and product literatures

Figure 7 briefly explains key differentiation offered by 4 major players (M5, NIM, XX, 3rd Party) with similar technologies in the market across different criteria. This analysis has been adapted from different company websites with the key attributes considered critical by hospital and customers. The targeted technology XX scores better across most of the criteria except its ability to have different types of monitoring (SSEP/TcMEP) in its current form. While these are developmental opportunities for the future – the company can look at developing extensions if required.

The targeted technology XX fares better across the main aspects such as automated, surgeon directed options and sensitivity to responses, which is critical for better patient response reading.

## 5. POTENTIAL MODALITY OF MARKET ENTRY

As we began analyzing different modalities of market entry, we felt it was important to lay down Risks associated with having this technology as a part of our current work stream or not.

### 5.1 Key Risks

The industry is in a mode of consolidation and larger players are developing service-oriented products to stay connected with customers. The core products have become a commodity and differentiation on product attributes has become a challenging issue coupled by downward erosion of prices by large consumers.

The analysis looked at few risks of having this technology within the current scope of operations:

Having the Technology:

1. Acceptability of the technology by customers: This is a new development in the field of spinal surgery as directed by the surgeon. VOC suggests its applicability needs to be determined across different centers and across a range of procedures to be considered a standard of care.
2. Competitors dropping prices: This introduction may lead to existing customers who own similar technology to drop prices of their products
3. Sales channel challenges: This technology is very different and training is key for sales personnel to be able to effectively sell this to customers. This could be time consuming and cause delay and lead times to market.
4. Professional community acceptance: the neurophys community might not accept this as a standard of care as this makes their presence for certain procedures redundant.
5. Hospital pricing matrix: Established contracts of hospitals with their partners may prohibit entry to larger hospitals

Not having the technology;

1. Competitors: Key Competitors might adopt this technology and intrude into our existing accounts with a complete solution
2. Weaken existing portfolio: without this value added service existing product portfolio will have a tough time competing in the market.
3. Delay: In house development may take longer time and concerns relating to IP

Overall risks vis-à-vis the technology under consideration (MMG)

“MMG may not address many issues with EMG – current shunting, poor techs, patient/tissue variability, anesthesia”

“Large variability of tissues and nerve condition will affect nerve mapping. Genitofemoral nerve can be monitored with EMG, probably not with MMG”

## 5.2 Three Modalities of Market Entry

Primary and secondary research along with analysis of critical operational nuts and bolts assisted in assessing the ideal modality of entry for the medical device provider for the innovative neuromonitoring equipment. The following critical operational groups were analyzed – which are important for efficient and sustainable service to be executed nationally.

These critical considerations hold true and are applicable across different modalities namely:

1. Licensing – this modality looks at an agreement with the technology partner to sell their technology across specific procedures.



2. Buy Out – the buy out modality looks at completely buying out the technology by exchanging a value to its owners.
3. In House development – In house developments looks at the potential of developing the technology from the scratch in house by creating a different business unit.

The three modalities were then mapped across a range of critical consideration that was either common to all the modalities or specific to a modality. The following analysis discusses the common considerations that are applicable across the different modality.

### 5.3 Common Considerations

#### **Reimbursement**

While the IONM as a service is covered by the payor under a specific code – it varies with the type of procedure, usage, professional service rendered and number of disposable used per surgery.

The payouts as approved under private and government insurance is also different in as much as the reimbursement of the technician. The current coverage and payout process is heavily skewed towards complicated procedures, however with the development of technology other simpler procedures will also come in the gamut of reimbursement.

In reviewing the literatures and interviews it came out that while the coverage reimburses the cost of the procedure and neuromonitoring – there are some limitations, to the overall use of this technology as perceived by various authorities.

**Coverage:**

- Maximum of 3 simultaneously monitoring procedures, which are properly documented procedures are only covered
- Supervising physician time spent in the OR includes the time from entering until leaving, except for interpreting baseline values
- For remote monitoring, it includes time from initiation to end of monitoring except for the time spent interpreting the baseline values
- On an average IOM services would cost around \$1000 per case
- CPT 95920 is an add on code and not a stand-alone code, it should be billed as conjunction along with a primary procedure.

**Limitations:**

- IONM billing codes vary for different surgeries even though the modalities monitored might be the same.
- IONM services are reimbursed only when the service provider monitors and bills under their own Medicare number
- Recent changes in CPT codes of SSEPs and MEPs are not listed as primary procedures for CPT 95920
- Lack of sufficient clinical evidence to mandate IONM as a standard during surgeries

Potential of Medico Legal obligations continue to push the adoption of this technology over and above the demands on having executed a safe procedure. However there isn't enough evidence to support specific protocols / guidelines and there isn't a legal requirement yet for the use of these modalities.

The actual payouts vary under different mode of insurance currently applicable in the US. How ever a lot depends on the modality used, including the services and disposables consumed.

	Supervision / Interpretation	Technical	Disposables	Hardware ( Capital Equip)
Medicare	<b>Surgeon Driven</b>			
	<b>Cost</b>	Surgeon Time	Set Up time	100-2000 \$
	<b>Reimbursed</b>	NA	NA	Under DRG
				( No Separate Code)
	<b>Technician Driven</b>			
	<b>Cost</b>	Professional / MD / Neurologist	Set Up time	\$\$
<b>Reimbursed</b>	\$ / Hour	No	Under DRG	
	Avg 150-170 \$ / Hour		( No Separate Code)	
Private Insurance	<b>Surgeon Driven</b>			
	<b>Cost</b>	Surgeon Time	Set Up time	100-2000 \$
	<b>Reimbursed</b>	NA	NA	Under DRG
				( No Separate Code)
	<b>Technician Driven</b>			
	<b>Cost</b>	Professional / MD / Neurologist	Set Up Time	Avg 100-200 \$
<b>Reimbursed</b>	\$\$ / Hour	\$ / Hour	Under DRG	
	Avg 250 \$ / Hour	60-100 \$/Hour	( No Separate Code)	

Figure 8 – Reimbursement Source: Hospital VOC

We analyzed different payment options commonly used by payors for the use of professional services and the technology. Hospital voice of customer interviews suggested that payments made by medicare for the neuromonitoring is less than those by the private insurance counterparts. This is because under the medicare option the technician is not considered for payment and service providers would usually cover their cost through sales of disposables and or equipment.

In both the scenarios the operating surgeons are now allowed to bill the services, only certified trained professionals of neuromonitoring are allowed to execute and invoice for their services.

## **Regulatory Environment**

A brief overview of the competing systems in the market suggests that the targeted technology is approved to identify nerves during surgery including spinal procedures.

## **IP Landscape**

While professional review and details of the patent filing consider the targeted system as second tier, its right to use landscape and initial evaluation is positive.

IP review also suggest a crowded space – where many aspects of the neural monitoring are in the public domain including mechanomyography or MMG.

## 5.4 Considerations that vary across different modalities

This section describes various factors that differ across different modalities:

- **Time to market** – we assessed the time it would take to test and operationalize the technology in the market across different modalities. The licensing option presents an opportunity to roll out this technology in the shortest possible time frame as compared to buy out or in-house development. The benefits of appropriate timing is critical to the overall success of the project given that other players have already rolled out their products gaining inroads into new markets and our customers.
- **Cost** - The total cost associated the commercial use of the technology. Under the licensing option the cost was the lowest as compared to other option, which has complete ownership of title. There are other resource based costing advantages in the licensing option which are being shared by the partner as opposed to buy out and in house development where the organization has to bear the cost in its entirety
- **Training and education** - Training and education is a critical aspect of rolling this technology efficiently in the market. Under the licensing option the technology partner will help train the team and ensure effective roll out. However it would necessitate creating a different team to roll this out in the buy out and in house development options
- **IP** - The IP space is crowded and various filings have ensured that the pathway is difficult to break in. new developments will take a long time. Given the constraints of time and cost associated with the aquisition – it is proposed to license the technology for specific procedures and evaluate the efficacy for future considerations and development

- **Distribution** - The buy out and in-house development would require setting up a completely different distribution channel and hospital contracts. This could prove to be a bottleneck in faster roll out. Under the licensing option we can benefit from existing contracts and hospital network and build on them. Buy out and in-house development options will take longer time.
- **Risk** - As per information gathered from primary sources the efficacy of the technology needs to be assessed across different hospitals and customers. This will help generate confidence and endorsements from a wider customer base necessary for a national roll out. Under the licensing option the risk is spread and insures the company of having a “ test and deploy” strategy as compared to buy out. In case the technology does not show promise from a wider base of users the company can terminate the agreement.

Table 1 Compares and contrasts the key differences between the modalities of market entry

<b>Criteria</b>	<b>L&amp;A</b>	<b>Buy Out</b>	<b>In-House Dev.</b>
<b>Time to Market</b>	Low	Medium	High
<b>Cost</b>	Low	High	Very High
<b>IP</b>	None	Own	Own / Tight
<b>Training</b>	Yes	Yes	Yes
<b>Channel / Dist.</b>	No	Yes	Yes
<b>Risk</b>	Less	High	High

Table 1: Source: Analysis of primary and secondary research

## 5.5 SWOT of the Organization

As a follow up the above mode of market entry analysis it is critical to do an Internal/External SWOT analysis to facilitate deciding on the optimal modality of entry for the medical device provider.

**Strength of the Medical Device Provider:**

- Financial strength to support the technological introduction
- Value added service extension to existing products
- Applicability to other businesses / focus areas
- In house business development capability

**Weakness of the Medical Device Provider:**

- Not the first mover hence can be seen as a follower
- IP and other assets could be costly to acquire
- Scale of existing operations – hence process could be delayed internally
- Existing team and organization structure does not support capital equipment businesses.

**Opportunities of the Medical Device Provider:**

- Growing procedural base leading to more surgeons and hospitals wanting to address gaps in procedural solutions.
- Concern over high cost of existing procedures leading to adoption of technologies that save resources
- Technological solutions helping surgeons to adopt procedures and shorten learning curve
- High growth and acceptance of the service as provided by third party providers – can be an opportunity to create a separate business proposition.

**Threats of the Medical Device Provider:**

- Competitors adopting this or similar technology and bundling this as a procedural solution to existing customers.
- Downward pricing pressure on existing portfolio
- Competitors may drop prices of existing products and services

## 6. ASSESSMENT OF ENTRY MODALITY

After having reviewed the feedback from the customers and analysis from the research followed by assessment of considerations and swot analysis of the organization, we discuss pros and cons of the three modalities of market entry.

### 6.1 Licensing

In the licensing modality we review various pros and cons to assess the applicability of this option given current business context and operational viability of the technology.

#### **Pros:**

1. The time required to have this technology operational and be available to customers is the lowest hence it's better for the company to opt for licensing
2. The cost associated is low as we co-develop and operationalize in different phases, as compared to complete buy out.
3. The risks associated with this new technology and its wider adoption is spread out. Should the technology not perform we can terminate the partnership
4. As per the IP review – current landscape is already crowded. This means in house development will be costlier and might infringe into other IP potentially leading to aggressive response from competitors including lawsuits.
5. Channel and distribution related activities could be outsourced without having to affect existing resourced and network.
6. We can tap into the licensing partner to support into training and operationalizing the technology to select accounts for the initial roll out. This saves valuable resources and also facilitates shorter time to market of this new technology.



**Cons:**

1. The licensing partner can gain market insights of operationalizing this technology and experiment. If successful, may terminate their agreement for a better share of revenues.
2. Competition might respond by a better offer for a complete buy out
3. A wider customer base may not adopt the technology due to the absence of sufficient clinical data.
4. Scalability issues such as qualified and trained manpower and hospital contracts may hamper faster roll out.

**6.2 Buy Out**

Another option we have in consideration is a complete Buy Out of the technology. Careful analysis of this option presented us with the following pros and cons.

**Pros:**

1. The company can completely own the technology and its development immediately and secure from any potential competitors planning a bid
2. Own the IP
3. Get complete access to current and future business opportunities in different potential segments.

**Cons:**

1. The operational formalities of a complete buy out of this technology and merging into the current work streams of a sizable medical device player is complex and time consuming. This process will increase the time to market.
2. Competitive responses may lead to downward pricing pressures of existing technology and hamper adoption.
3. Cost associated is higher

4. Risk of scalability and ability to create an efficient infrastructure of a completely different business unit. (Marketing capital equipment as compared to marketing implants)

### 6.3 In-House development

The option of In-house development considers various aspects of developing this type of technology within the company.

#### **Pros:**

1. Own the entire development and fully resource each activity along with established product development protocols
2. Carefully consider risks associated with the venture
3. Develop internal resources drive this project operationally

#### **Cons:**

1. Technology landscape suggested that this is a crowded IP landscape. As such development of IP could pose a challenge.
2. In house development is very time consuming
3. In House development is costly
4. Operationalizing a capital equipment business is very different as such establishing a network with customers and hospitals could be challenge.
5. Cost of litigation and or competitive downward pricing pressure can make the business proposition unattractive

Given the above analysis the Licensing modality seems to be the best fit to adopting this technology as it has the applicable IP while ensuring faster time to market. Other options are risky and time consuming and may hamper the objective having such a technology early on.

## 7. RECOMMENDATIONS & NEXT STEPS

### 7.1 Recommendation

It is recommended that we proceed with the Licensing option to acquire this technology for a focused procedure and analyze response of customers and competition with a pilot roll out.

### 7.2 Next Steps

#### 7.2.1 Phase 1

##### **Pilot Clinical Evaluation**

As per the VOC from the customers, industry experts this technology needs to be tested across different procedures and patient conditions qualifying its efficacy. Hence a pilot clinical evaluation plan is proposed- which will ensure we have a larger pool of customers trying out this technology across different procedures.

The following is the proposed plan of action:

##### **Timelines**

- Jan 2015 through June 2015

##### **Participants**

- 10 Surgeons, with 10 Surgeries each over the next 6 months
- Target Competition Customers who can give feedback on other systems as well

##### **Assessment Criteria for the Technology**

- Verify if the system works faster
- Verify if the system can be used for other implants
- Verify if current distribution channel and sales team is appropriate

- Gauge competitor response.

### **Operational considerations**

- Use a dedicated team for this roll out
- Use select accounts that can facilitate faster adoption within the 6 months timeframe.

### **Scenario Analysis**

For the pilot program we looked at various scenarios driving the revenues of disposables and implants during the six months that the technology will be used across select hospitals. Depending on customer acceptability and feedback we drew worst case, base case and best case scenarios. These scenarios are dependent on a variety of factors:

- Timely availability
- Trained and efficient staff
- Pricing
- Quality of the technological solution
- Surgeon training and comfort
- Patient consent

Disposables Sales Forecast

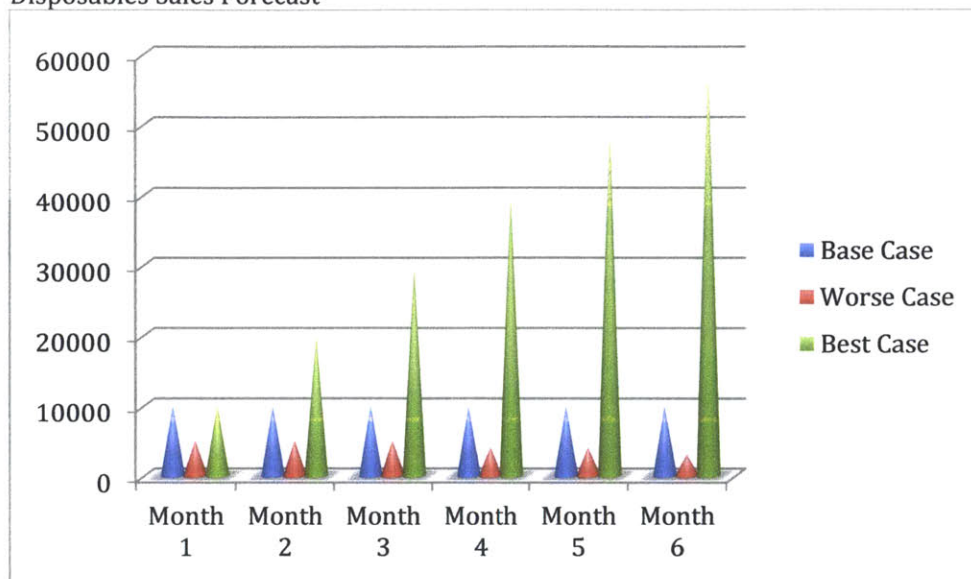


Figure 9 Source: Internal analysis

Implants Sales Forecast

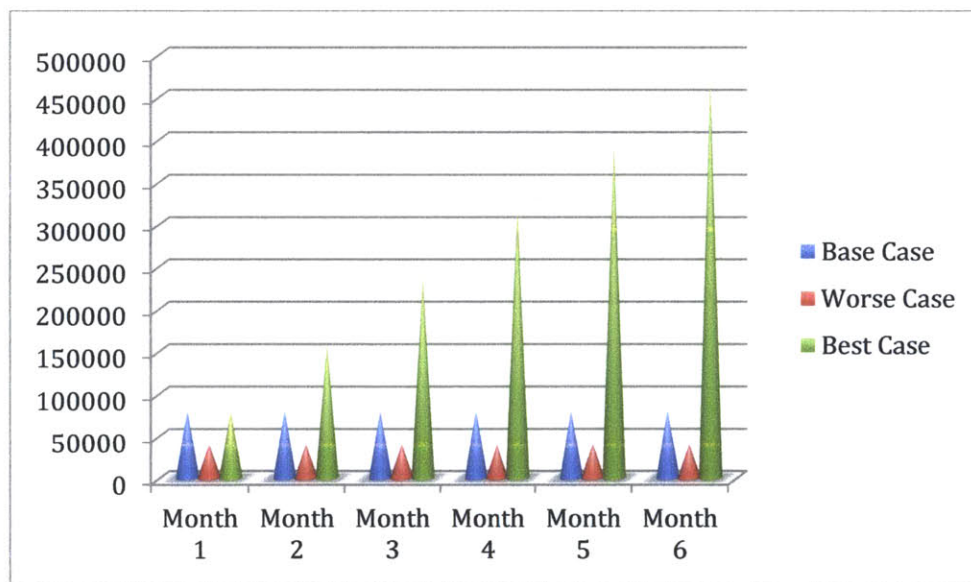


Figure 10 Source: Internal analysis

During the Pilot program of 6 months we are expecting to roll out the technology across different hospitals for specific types of surgeries. These surgeries will utilize the neuromonitoring technology XX and implants from the medical device provider.

**Key assumptions:**

Following are the assumptions for the different case scenario

- As per pilot plan we aim to achieve 100 surgeries in 6 months with 10 surgeons across 6 different hospitals
- Average selling price of disposables used per surgery 1000 \$
- Average Selling price of Implants used per surgery 8000 \$

We look at 3 scenarios of Optimistic, Pessimistic and base case scenario of the response from different customers to help support customers with timely availability of products and services

**7.2.2 Phase 2**

1. It is also proposed to look out for strategic partnership with a full service third party partner who can support the current technology with a complete range of services that can be offered to hospitals as a “One stop shop”

2. This technology may also be applicable for other focus procedures for the medical device provider as such a dedicated team can explore opportunities where its use can benefit the organization.

## IONM – Current & Future Applications

Procedures	Market Size US (Volume / approx)	Penetration 2011	Value Proposition
Spine Fusions	4,00,000	<50%	Nerve Mapping / Integrity
Spine - Decompression	3,50,000	<5%	Adequacy of Decompression
ENT Mastoid	2,50,000	<50%	Nerve Mapping
Reconstruction Revisions	50,000	<5%	Reduced Nerve Injury
Ortho Trauma	5,00,000	<5%	Less Nerve Fatigue than EMG
Maxillofacial	3,00,000	<10%	Reduced Nerve Injury

Source VOC – Industry Experts  
Orthopedic Network News Estimates

Figure 9 Source: voice of customer Industry Experts / Orthopedic News Estimates

Primary and secondary research suggests that the IONM technology has various applications across different surgical procedures. We looked at some growing procedures and its applicability to the technology. While these applications may not be currently related to the organization – however in the future these can be treated as a new business developmental opportunity.

In summary, the market for innovative medical technologies is ripe for disruption as challenges in the healthcare industry pushes innovators to look out for simpler and cost effective solution for treating complex surgical indications.

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