

DEVICE INTEROPERABILITY WITHIN THE

Neuromonitoring Market

A CASE STUDY BY NEUROVISION MEDICAL PRODUCTS

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The Current IOM Market

Interoperability/ Device Interchangeability is becoming more prevalent than ever in the medical industry. In 2017, the US FDA released final guidance for smart, safe, and secure interoperability, with both among medical devices and with IT systems. There are many examples of medical-surgical accessories that offer high levels of interoperability, including blood pressure gauge components, monopolar and bipolar cautery devices, as well as laser probe and illumination components. Additionally, almost all manufacturers are moving toward greater interoperability across brands and platforms, even where it has traditionally been lacking. These include big industry names, such as GE. But there are companies that have been committed to interoperability long before the FDA guidance was released, and practical application of these products in a real-world setting can demonstrate the benefits of adopting devices and accessories that offer full interoperability with many existing intraoperative neuromonitoring (IOM) systems.

The current IOM market provides many device options, leaving clinicians with a variety of choices. Further complicating the decision-making process are the different features that are available with various IOM platforms and accessories, particularly with the emergence of specialty electrodes and probes. While this is desirable from a competitive perspective, it poses many challenges in evaluating and selecting the most optimal solution for any given clinical environment. The market is also clouded by lingering perceptions that some systems are incompatible with their competitors' systems, despite the fact that there is widespread demonstrated system compatibility. This misconception leaves many clinicians and institutions believing that once they have selected a specific vendor, they are bound to continue purchasing and utilizing the accessories to meet their IOM needs. This is often considered by consumers of any product as a "purchasing trap."

SURGICAL EXPERIENCE UTILIZING EMG

Approx. 2,000 surgical procedures utilizing EMG

Approx. 1,200 total head and neck procedures

Approx. 1,000 facial nerve IOM procedures

Approx. 1,000 RLN IOM procedures

Advanced Technology, Interoperability and Ease of Use

Neurovision Medical Products (NMP) Tools

As a developer of intraoperative nerve monitoring devices and surgical tools, Neurovision Medical Products, Inc. (Ventura, CA) has been serving the medical community for over 35 years. Their surgical solutions are designed with interoperability in mind and their products have been shown to enhance medical outcomes. This is accomplished while also establishing that health care facilities are not bound to a single vendor – a mindset that frequently hampers the adoption of innovation and limits access to superior clinical care. Moreover, it also removes any opportunity to realize the potential cost savings, which is an activity that is becoming increasingly essential in an era of cost containment.

Perhaps the greatest indication that speaks to the reliability and superiority of the product lies in the evidence-based testimonials of clinicians (including physicians and neurophysiologists) who work with the products every day. Mike Demarco, an IOM clinician, has over 30 years of experience working in Intraoperative Monitoring and Neurodiagnostics. Having monitored over 6,000 procedures, Mr. Demarco has practiced at some of the most distinguished medical centers in the country, including Cedars Sinai. As a highly experienced neurophysiologist, he has found NMP IOM products to be comparable to competitors in terms of functionality and compatibility, and superior to other IOM products

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that Mr. Demarco has used.

Full Interoperability in Action

Mr. Demarco has extensive experience with many different IOM platforms, including over ten years with the Cadwell Cascade (Kennewick, WA) nine years with the Medtronic Nerve Integrity Monitor (NIM) 2.0 (Jacksonville, FL) and intermittent use of Medtronic NIM Spine (Jacksonville, FL) over the span of thirteen years. He also has experience with the Medtronic NIM 3.0 (Jacksonville, FL). In addition to his vast knowledge of many different platforms, Demarco has extensive experience over the thirteen year period in a variety of different procedures, including:

- Approx. 2,000 surgical procedures utilizing EMG; of which, approximately 250 were thyroid procedures.
- Approx. 1,200 total head and neck procedures, including 800 skull base procedures.
- Approx. 1,000 facial nerve IOM procedures; the majority of which were acoustic neuromas, (others were mastoid and parotid, for instance).
- Approx. 1,000 RLN IOM procedures that include thyroid, parathyroid, ACDF, and skull base.

As previously mentioned, Mr. Demarco has performed over 6,000 procedures over a thirteen year period. During this time, he was able to utilize NMP devices and accessories. Throughout his thirteen years of experience, he has repeatedly validated ongoing interoperability with NMP IOM accessories with other platforms. His clinical IOM routine remained the same while utilizing the company's devices and accessories. Mr. Demarco has noted that the NMP devices provided functional compatibility. Furthermore, no changes were needed regarding the protocols and settings on the existing platforms in order to use the NMP devices. As Mr. Demarco has experienced and reported in his very long career, the full interoperability provided by NMP offers a reliable alternative that leads to a better standard for patient care.

Ease of Use

While using NMP products, Mr. Demarco reported that several features lead to a greater ease of use, including:

- Intubation was reportedly easier due to the flexibility of the Cobra ET.
- The sizing matched standard endotracheal tube sizing configurations.
- The electrode geometry provided for robust and reliable monitoring of nerve integrity via the vocal cords during relevant procedures.
- The atraumatic electrodes were safe and effective on any platform and provided optimal ET tube placement for reliable RLN nerve monitoring.
- The connectors were universal and color coded using a standardized scheme to prevent confusion.
- Built-in safety features of the devices worked effectively with various IOM platforms to alert the clinician when warning signs were present.

When working together, these features all contribute to the delivery of better patient care and with the full interoperability of NMP products, there is no loss of any functionality across the different platforms.

Reliability

Mr. Demarco's experiences with NMP products also serve as a testament to their reliability. In over ten years of working with them, Mr. Demarco reports only two failures. This level of reliability is impressive, even within the context of an industry known for precision and dependability. His experiences demonstrate first-hand the quality and compatibility of the products that customers can expect with NMP. When interoperability is achieved with a high degree of



Cobra EMG ET tube features atraumatic electrodes on a standard endotracheal tube

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performance, the result can be optimal for medical institutions and clinicians – as there may be administrative, logistical or financial advantages in being able to procure accessories from additional sources. Medical device platform and accessory interoperability is widespread in many other clinical modalities. For instance, in electrosurgery it is common to use many different monopolar and bipolar devices that may not be manufactured by the electrosurgical platform vendor itself. Similarly, with laser probes and light pipes, companies such as Bausch and Lomb (Synergetics) and Alcon (Infinitec) have been used with HGM and Coherent lasers for almost 25-30 years, demonstrating a very lengthy history of successful interoperability. This is consistent with Mr. Demarco's, and other clinicians', experiences when using NMP devices and accessories across different IOM systems.

EASE OF USE

Cobra EMG ET tube flexibility allows for easier intubation

Standard ET tube size configurations

Electrodes provided robust and reliable monitoring of nerve integrity via vocal cords

Atraumatic electrodes were safe and effective on any platform

DIN connectors are universal and follow standard color coding

Built-in safety features worked effectively with various IOM platforms to alert when warning signs were present

Customer Support

Testament from Mike Demarco

“In my experience with the company, it's clear that Neurovision Medical Products prides itself on its superior customer service and support. The company makes it easy for customers to interface directly with support services. Their team has always been highly responsive when I've had questions or wanted to provide feedback on one of their products. Given their ease of use, interchangeability, and the reliability of the devices, it's clear that Neurovision Medical Products are designed by physicians themselves based upon feedback from other clinical users.”

About Mike Demarco

Mr. Demarco has been a clinician practicing IOM for over thirty one years. His early medical education was at an X-Ray Tech School, followed by a two year experience in the Air Force as a paramedic providing direct patient care. After military discharge, he began working with Clinical Neurodiagnostics and IOM. His experience and interest led to him practicing at a variety of different distinguished medical facilities, including Cedars Sinai. At this point in his career, Demarco has performed over 6,000 IOM procedures. As a user of NMP for the last thirteen years, he has found a high level of satisfaction with NMP devices and accessories.

Neurovision's Continued Commitment to Interoperability

Founded in 1973 on the principles of surgery and electrical engineering, The company has demonstrated its commitment to interoperability across the spectrum of their products. With the recent adoption of interoperability standards by the FDA, many medical device companies find themselves in a position where they must evolve by adopting a different business model as well as potentially having to make functional changes to their product line. In this regard, NMP stands head and shoulders above the competition, simply because the company has the expertise and a proven track record of successful interoperability. This commitment to interoperability has been a key force in shaping the company throughout its history, and this will undoubtedly continue throughout the ongoing evolution of IOM.