An Improved Recurrent Laryngeal Nerve-Monitoring Device: Technical Note for NIM Vital™

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ABSTRACT

A new device for monitoring the laryngeal nerves during thyroid surgery has been developed. NIM Vital™ (Medtronic Xomed, Inc., Jacksonville, FL, USA) incorporates (a) a new wireless design, (b) NIM NerveTrendTM (Medtronic Xomed) EMG reporting, (c) intelligent noise-reduction technology that suppresses artifacts, (d) smart troubleshooting pop-up alerts, and (e) NIM Nervassure ™ (Medtronic Xomed) for continuous monitoring. This device offers enhanced stability and flexibility for both intermittent and continuous laryngeal nerve monitoring. The new NIM NerveTrend ™ EMG reporting makes it possible to track the recurrent laryngeal nerve condition throughout a procedure, even when using intermittent nerve monitoring. During both continuous and intermittent monitoring, green, yellow and red status bars provide visual information and associated tones provide audible cues, making it easy to monitor nerve function and interpret EMG trends. This new tool for laryngeal nerve monitoring has the potential to augment nerve dissection during surgery. Measurements of long-term outcome are needed to establish their efficacy.

INTRODUCTION

Injury of the inferior laryngeal nerve represents one of the most serious complications of thyroid surgery.[1] The mean incidence of recurrent laryngeal nerve (RLN) paralysis, both permanent and temporary, after thyroidectomy is between 2.3% and 9.8%.[1,2] Therefore intraoperative neuromonitoring (IONM) is expressly recommended for thyroid surgery by most General, Endocrine and Head and Neck Surgery Associations.[2,3] Documenting the monitoring process and performing it in the fastest and most intuitive way are crucial in surgery of the thyroid gland.[4]

Specifically, the combination of IONM technology and clinical and experimental practice is a valuable tool for studying the anatomy and pathophysiology of RLN injury, improving surgical technique, validating other technologies, and research (Fig. 1).[5,6] The benefits of IONM are even greater in endoscopic and robotic practice (Fig. 2).[7-10]

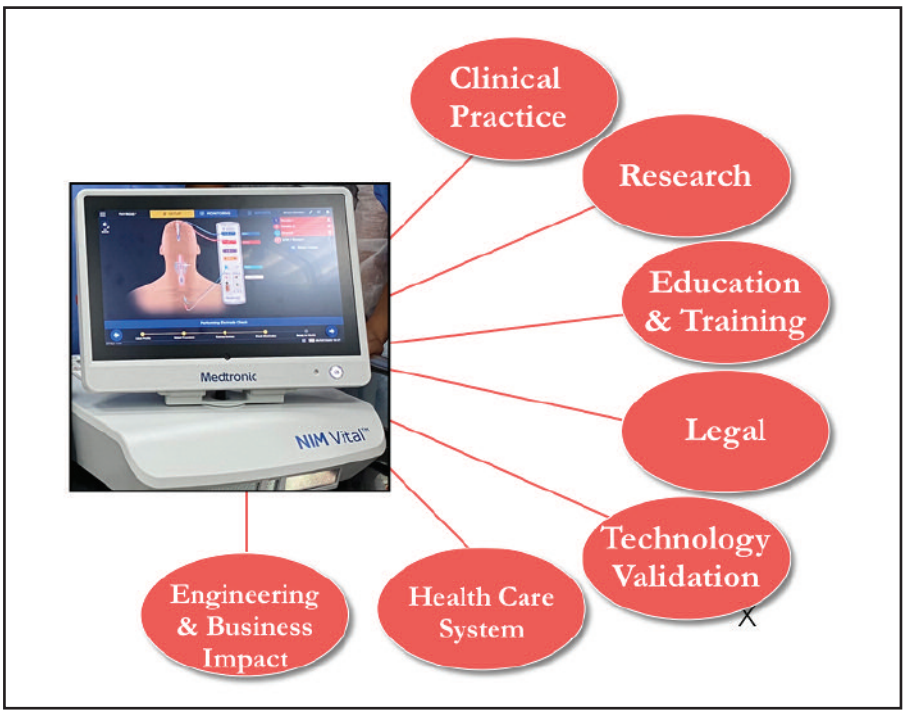

Figure 1. Consequences of IONM use.

Progress is defined as the process of gradually getting nearer to achieving something or completing something; an advance or movement toward an objective or a goal.[11] IONM is a form of surgical progress because it (i) improves RLN control during dissection, and (ii) increases our knowledge of RLN neurophysiology and pathology (Fig. 3).[12-16]

Herein, we present technical notes for the new NIM Vital™ system (Medtronic Xomed, Inc., Jacksonville, FL, USA) in IONM during thyroid surgery. We describe a standardized step-by-step IONM procedure using NIM Vital™ as an example.

DEVICE

The NIM Vital™ system consists of a new audio+graphics IONM monitor. Currently, audio+graphics IONM monitors are preferable to audio-only IONM systems. Table I details the advantages of an audio+graphics IONM monitor over an audio-only system. For predicting post-operative vocal cord (VC) function, one study revealed that an audio+graphics IONM monitor had a NPV of 99.7%, an accuracy of 99.4%, and a PPV of 90.9%, while an audio-only system had a lower NPV (99.4%), accuracy (97.0%), and PPV (66.7%).[17] Furthermore, an audio+graphics IONM monitor is a prerequisite for (i) loss of signal (LOS) ascertainment, (ii) external branch of superior laryngeal nerve (EBSLN) moni-

toring and (iii) continuous IONM (C-IONM) compatibility. The NIM Vital™ system has an adjustable graduated touchscreen with a voltage threshold display. The monitor can be controlled remotely by an incrementing stimulus probe.

PRE- & POSTOPERATIVE MANAGEMENT

Laryngeal examination

Table II summarizes the standardization process for IONM according to the International Neural Monitoring Study Group.[2,3] If IONM is used, pre- (L1) and postoperative (L2) laryngeal examinations are still mandatory (a) because L1 is a reference for V1 and R1 stimulation, (b) because L2 is a reference for R2 and V2, (c) to achieve proper VC clinical assessment (IONM is not a substitute for L1 or L2), (d) to improve the prognostic correlation between neural stimulation and pre- and post-operative VC function, and (e) because the NIM Vital™ IONM system is in the early development phase (Table II).

Informed consent

Surgeons should not overstate the potential benefits of IONM to patients; RLN still occurs with the use of IONM.

Informed consent should include the consequences of thyroidectomy, the possible risks of thyroidectomy and the possible consequences of IONM, i.e., the possibility of staging surgery and IONM failure.[18]

Documentation

The IONM documentation archiving process is critical. Dralle et al. described the role of IONM practice standardization in medical malpractice litigation. If IONM is not applied in a standardized manner and/or without EMG documen-

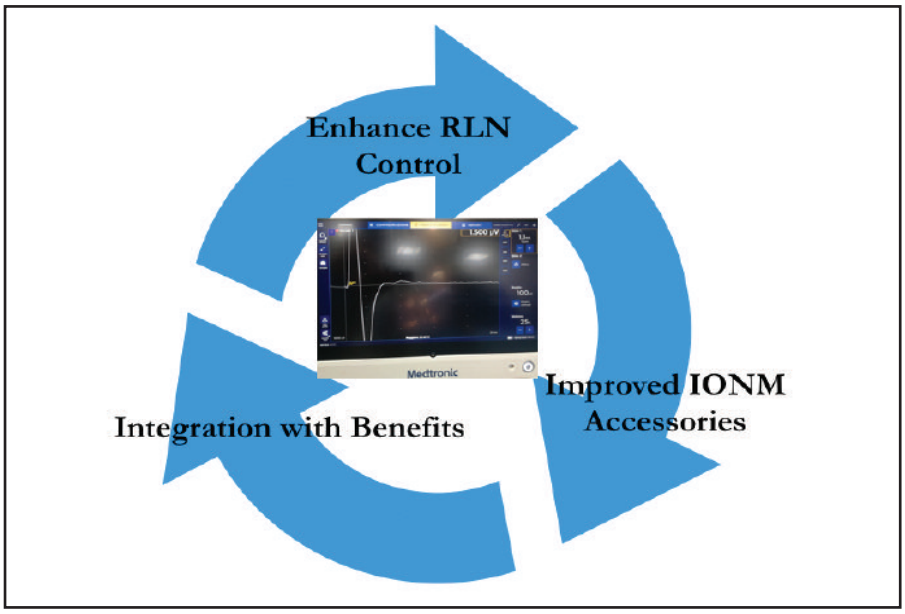

Figure 2. Consequences of IONM use in Endoscopy and Robotics.

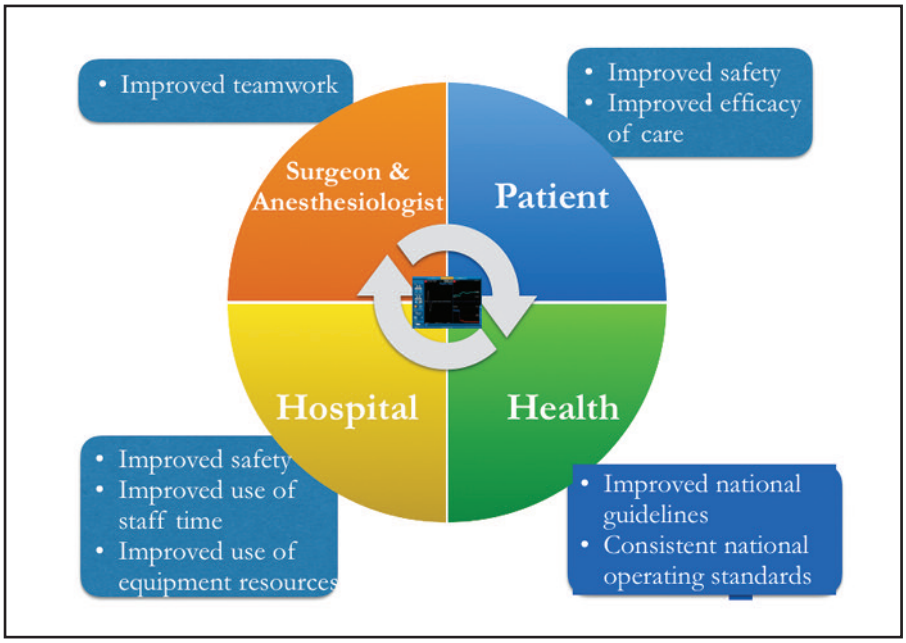

Figure 3. Benefits of IONM use: Surgeons, Anethesiologists, Residents, Patients, Hospital, Health Care system.

Table I
IONM Audio and Graphic Monitor Upgrade

- ↑↑Surgeon-IONM interaction
- Comprehensive documentation
- EMG quantification & time-frame
- EMG recording & storage
- Removal of EMG artifacts
- Optimize RLN dissection
- Support surgical deliberations
- Forensic use
- Research/statistics

Table II
Standardization of IONM

L1	Pre-operative laryngoscopy
V1	Test VN before identification of RLN
R1	Test RLN when it is identified
S1	EBSLN stimulation at identification
S2	EBSLN stimulation after STA ligation
R2	Test RLN after completely dissected
V2	Test VN after complete hemostasis
L2	Post-operative laryngoscopy

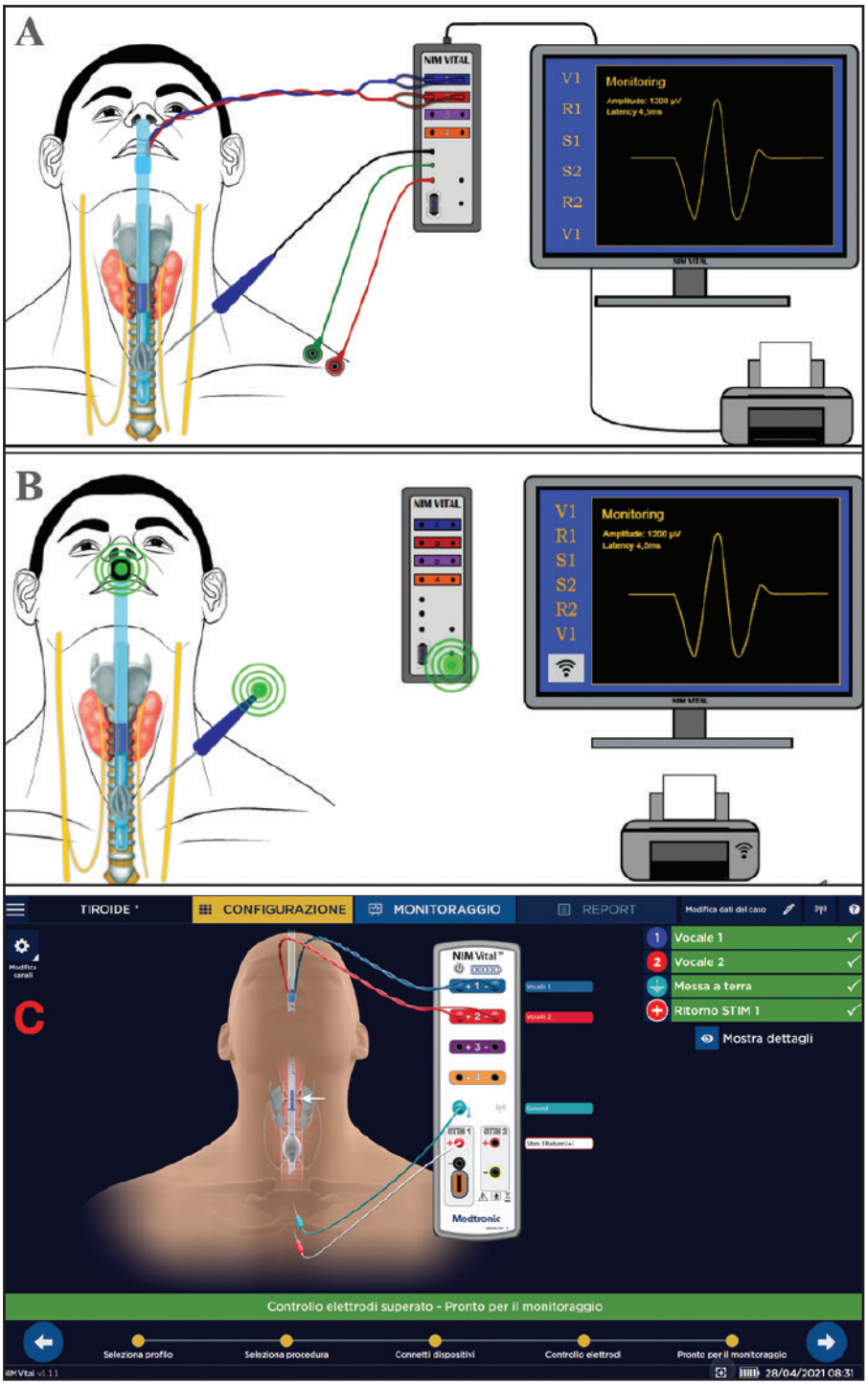

Figure 4. (a) Details of NIM Vital™ (Medtronic Xomed) set-up. (b) NIM Vital™ uses wireless technology, which allows the untethered use of different IONM accessories and imaging displays. Wireless equipment can be moved freely from one side of the patient to the other, without having to disconnect and reconnect cables. Advanced ORs are often challenged with video signal complexities and incompatible inputs and outputs, which can lead to delays. As an example of an integrated solution, a surgical monitor may receive video from the NIM Vita™ system in an operating room setting in which connection time is critical. (c) The NIM Vital™ main and introductory screens present set-up details.

tation, IONM cannot be used as a discussion item in forensic practice. The authors stated that IONM documentation can be (a) Optimal, i.e., V1, R1, S1, S2, R2, V2 EMG signals per side, or (b) necessary/minimum, i.e., V2 first-side resection (to justify bilateral procedure); (c) the surgeon should always indicate the time-frame and side.[19] The documentation process for the new NIM Vital™system is supported by an integrated database, in which it is possible to store all the records and patient data. Access to data is available at any time. All stimulation responses are automatically stored in long-term memory. Curves can be selected for reporting during or after monitoring via the report function. After surgery, a report can be easily created to be archived in the patient record. Reports can be generated with or without a trend chart. The NIM Vital™ system can be connected to a wireless printer or a compact flash USB storage device.

NIM VITAL SET-UP

Figure 4a,b shows the details of NIM Vital™ set up. NIM Vital™ also features wireless technology (Fig. 4b). The surgeon and anesthesiologist play primary roles in all of the stages of IONM (Fig. 5). The anaesthesiologist is responsible for correct positioning of the endotracheal tube and for the correct induction and maintenance of anesthesia without curare. Figure 6 summarizes the advantages of pre-packaged EMG tubes. It is preferable to choose an EMG tube with a ½ size-greater ID and avoid gel lubrication to achieve perfect contact of VC with the surface electrodes.[20-24] According to the manufacturer, the NIM TriVantage™ EMG Tube is a standard size, non-reinforced, DEHP-free PVC tube with an inflatable high-volume, low-pressure cuff. Each tube is imprinted with two pairs of bipolar conductive silver ink electrodes. Its innovative low-profile, smooth-surface design allows for enhanced RLN EMG recordings, helps optimize contact with the vocal cords, even under tube rotation and movement, and enables precise recording of the EBSLN.[21,22] Induction and maintenance anesthesia use depolarizing and non-depolarizing drugs. Depolarizing drugs should have ultrashort-term effects (<5 min); e.g., Succinylcholine (Anectine®, Relaxin®).[21] However, succinylcholine is associated with various adverse effects (including muscle pain, cardiac dysrhythmia, malignant hyperthermia, hyperkalemia, rhabdomyosis, and anaphylaxis).[21] Thus, non-depolarizing drugs are preferable; for example (i) short-term (< 15 min), such as Mivacurium (Mivacron®), or (ii) intermediate-term (≈ 30 min), which are considered to be safer, such as Vecuronium (Norcuron®), Atracurium (Genso®, Tracrium®), Rocuronium (Esmeron®), and cis-atracurium (Nim-

bex®).[21] During an operation, repeated use is prohibited. In the case of misuse, surgeons are encouraged to wait for spontaneous recovery (30~60 mins) or give reversal agents (i.e., neostigmine, sugammadex).[21] Finally, another useful tool to promote IONM safety and quality is the surgical setting (Fig. 7). The NIM Vital™ system has some features to consider when setting up the operating room. The NIM Vital™ system should be located approximately three meters from the surgical field and as far away from the electrosurgical unit as possible, consistent with the surgeon's personal preferences regarding location and visibility (Fig. 7). NIM Vital™ uses radiofrequency energy only for its internal function. Therefore, the RF emissions are very low and are unlikely to cause interference in nearby electronic equipment.

NIM VITAL™ POWER-ON

When the NIM Vital™ system is turned on, an internal check of the integrity of the console and connected accessories is performed. When this integrity check is complete, the "Select Profile "screen is displayed. The Setup screen has the following functions: (a) global setting (in Settings), (b) set-up configuration, (c) profile options, and (d) progress bar. On this screen, the surgeon can choose an existing user profile or create a new one. The surgeon can also select the surgical procedure category to be carried out (neuro/otology, head/neck, peripheral). Next, the surgeon can further select the head/neck procedure for (i) parotid 2channel (CH), (ii) parotid 2CH with nervassure, (iii) parotid 4CH, (iv) parotid 4CH with Nervassure™, (v) thyroid, (vi) thyroid with Nervassure™, and finally neck dissection (Fig. 8). After the procedure is selected, the patient interface is removed from the console base and the wireless connection symbol on the patient interface lights up to confirm correct association. When the patient interface is connected wirelessly, the "wireless" symbol appears in the upper-right corner of the monitor. If the wireless connection is not available, the patient interface can be connected to the NIM Vital™ console with the connection cable. When the patient interface is connected with the cable, the "socket" symbol appears in the upper-right corner of the monitor.[8]

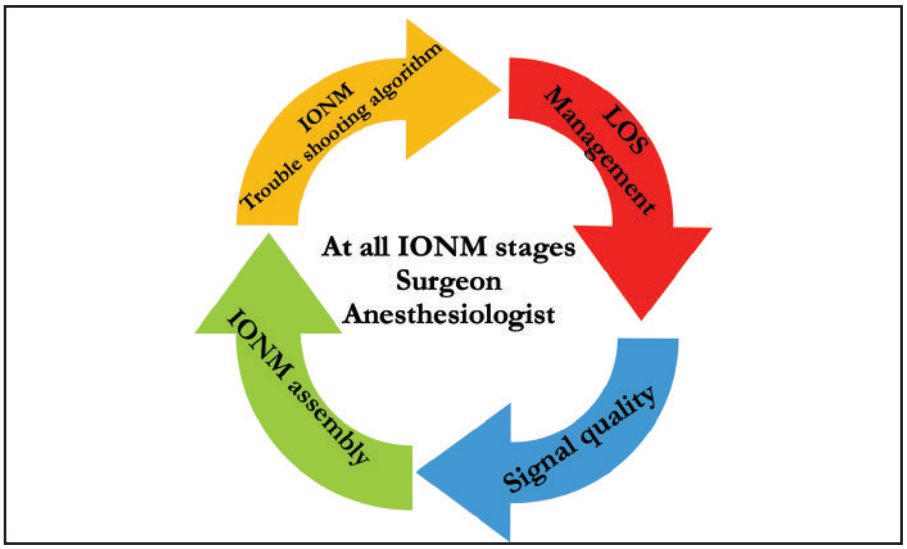

Figure 5. Anesthesiologist and surgical IONM components interact in a synergistic manner.

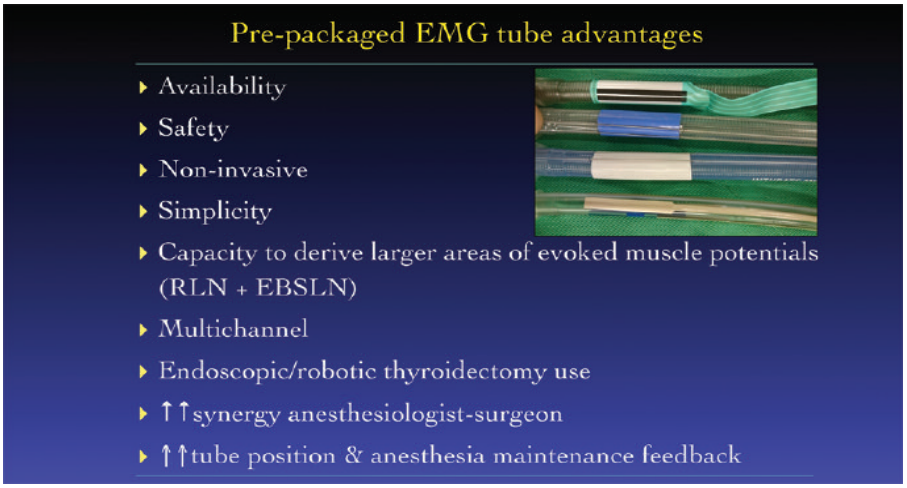

Figure 6. Advantages of pre-packaged EMG tubes.

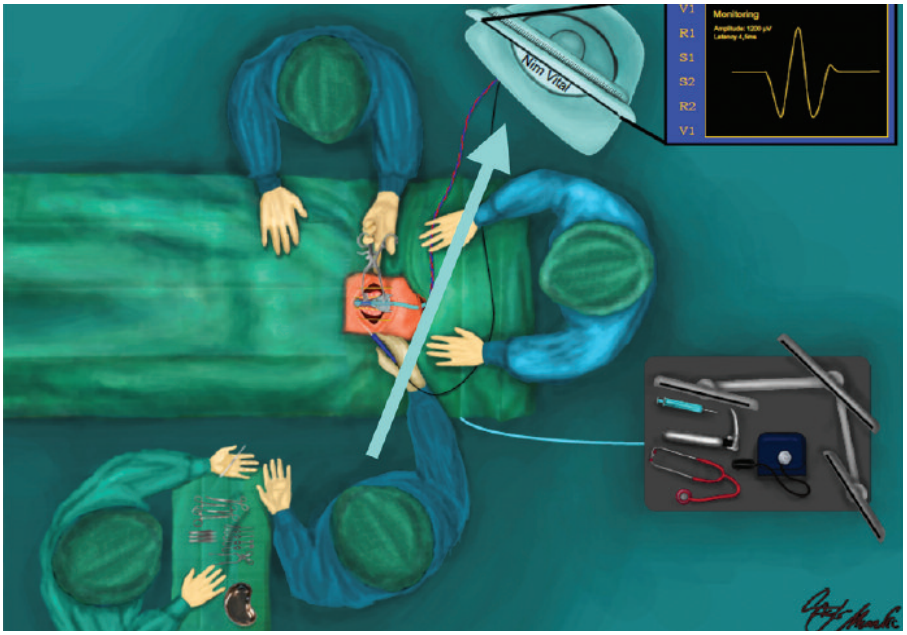

Figure 7. IONM surgical setting. The IONM screen must be placed in front of the first surgeon to better appreciate the EMG signal during surgery.

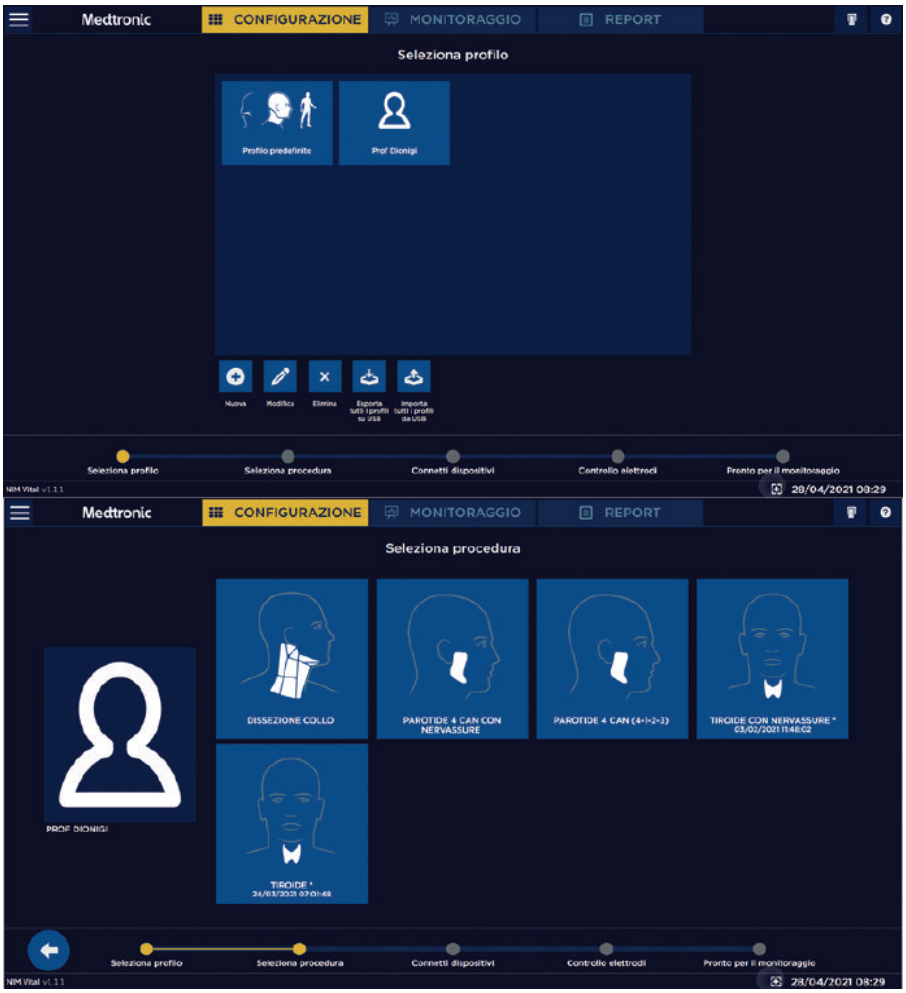

Figure 8. Several procedures can be selected with the Vital NIM™ system.

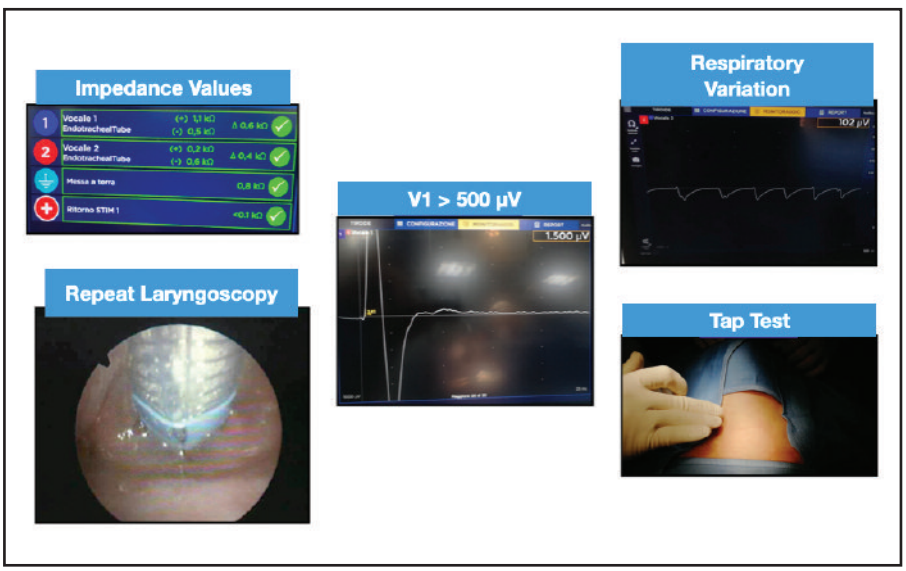

Figure 9. EMG tube position verification tests.

Once the interface is connected (patient interface highlighted with a green border on the monitor), the Check Electrodes screen, which shows the electrode check status, is presented. The surgeon positions the sensing electrodes corresponding to the muscles innervated by the nerve to be monitored, the ground and the return of the stimulus, as indicated in the image dedicated to the selected procedure.[11] The electrode connectors are connected to the patient interface following the color code. According to the manufacturer's guidelines, the EMG tube verification test includes (a) impedance values, (b) repeat laryngoscopy, (c) V1 signal >500µV, (d) respiratory variation, and (e) the tap test (Fig. 9).

STIMULATION

Nerve-monitoring probes

A complete line of instruments and accessories for intraoperative nerve monitoring, such as monopolar and bipolar probes, disposable or reusable, are currently available (Fig. 10). Most stimulating probes feature a sterile, slim, flexible insulated tip with a 360-degree contact area that allows proper access to neural structures.[4,7] The distance between the cathode and anode at the probe tip is 0.5 mm for minimal shunting.[11] The Incrementing Probe from Medtronic allows surgeons to easily adjust the stimulus level from within the surgical field, adjust the volume of the monitor, take pictures and print or save the screen display. Stimulators can also be used as a surgical dissection tool (Fig. 11).[12]

Threshold

The threshold is the current that is initially applied to a nerve to trigger minimal EMG activity. Interestingly, the nerve fibers of the VN, RLN and EBSLN begin to be recruited and stimulated with currents of about 0.5-0.8 mA. With 1.0 mA, 100% of the fibers are recruited/stimulated.[18-20] Therefore, in clinical practice, we conventionally use 1.0 mA for nerve confirmation. We use higher intensities for nerve identification (mapping), and lower intensities (0.5 mA) to identify nerve branches, i.e., intraoperative characterization of RLN ramifications (Figs. 12, 13).

Nerve mapping: modeling trans-tissue RLN stimulation

Shiban et al. examined how to determine the distance from a nerve structure under stimulation.[23,24] According to Shiban et al., each 1 mA of stimulation intensity needed to elicit an EMG response corresponds to 1 mm distance from a nerve. Thus, there is a linear correlation between stimulation intensity and distance (0.3 ms pulse width).[21,22]

RLN SIGNAL

Why stimulate the VN?

In the event of problems related to the position of the EMG tube at the beginning of surgery, there is an intraoperative option for verifying the correct positioning of the tube: stimulation of the pre-dissection vagus nerve (V1).[23] With this simple technique required for all patients at the beginning of the operation, in all cases, if EMG with vagal stimulation is satisfactory, correct positioning of the endotracheal tube will be demonstrated (Table II). This check also guarantees the absence of paralyzing agents and the integrity of the stimulator function.[3,24,25] Also, before definitively establishing that the tissue is negative (it is not the RLN) and confirming the overall function of the system, the surgeon visually identifies the vagus nerve and obtains a true positive result.[7,26-28] Only then can they be sure that the IONM system works perfectly and that, in the event of a negative answer during the RLN search, the result is really negative. An important aspect to underline is that vagal stimulation is the first (V1) and last phase of any intervention (post-dissection vagus nerve stimulation after hemostasis control: V2). VN stimulation is the reference for RLN stimulation. VN stimulation can detect any injury to the RLN circuit (Fig. 14).

How to stimulate the VN

Figure 15 illustrates how to stimulate the VN. In I-IONM, VN stimulation is achieved without dissecting or partially dissecting the carotid sheath sheet.[10,29-32] On the other hand, due to the C-IONM probe geometry and design, VN stimulation for C-IONM requires 360° VN dissection.[4,5,8,29,33]

VN and RLN EMG signals

The standard definitions and terminology used for EMG can be applied to IONM for laryngeal nerves. The basic waveform evoked for the RLN or the VN is generally biphasic (Fig. 16). This generally biphasic waveform represents the overall potentials of the motor action unit of the ipsilateral muscle of the vocal cords.[16] Amplitude measurements are generally believed to be related to the number of muscle fibers that participate in polarization during stimulation. Vocal cord depolarization amplitudes range from 100 to 800 µV during normal voluntary speech.[33-39] Referring to the existing standards in EMG monitoring physiology, we define the oscillation amplitude between the initial height-apex of the positive wave and the lowest point in the subsequent phase of opposite polarity of the wave itself.[34]

Amplitudes during IONM can vary significantly in the same patient and

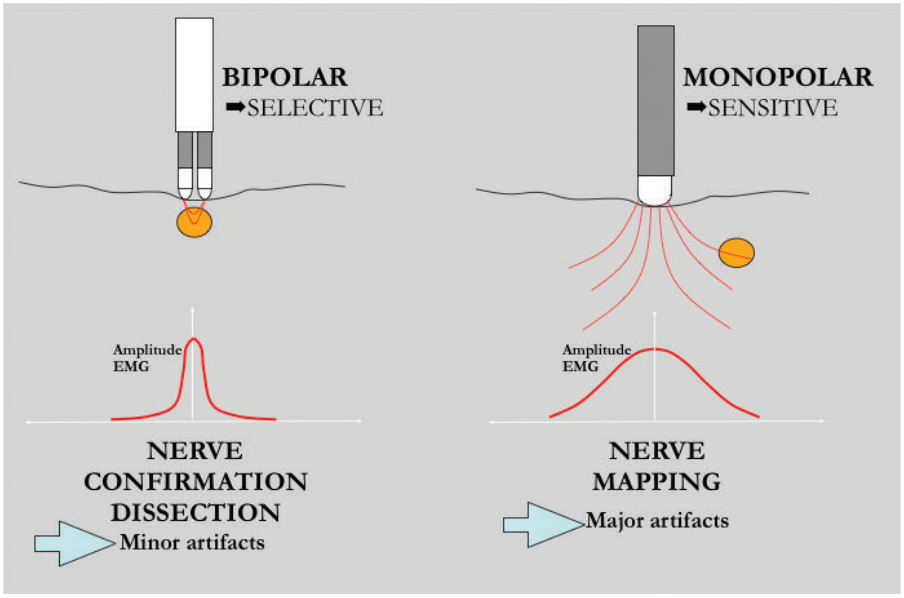

Figure 10. Nerve-monitoring probes: monopolar versus bipolar.

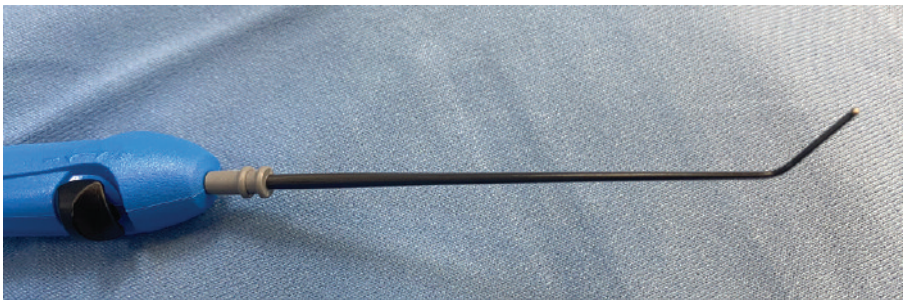

Figure 11. The incrementing probe (Medtronic).

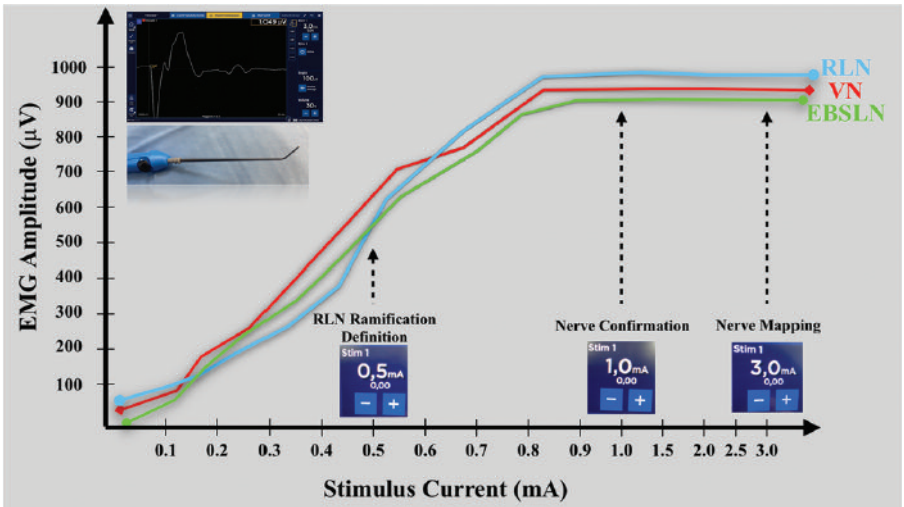

Figure 12. Definition of threshold; i.e., the current applied to a nerve to trigger minimal EMG activity. The nerve fibers of the VN, recurrent laryngeal nerve (RLN), and external branch of the superior laryngeal nerve (EBSLN) begin to be recruited and stimulated with currents of about 0.5-0.8 mA. With 1.0 mA, 100% of the fibers are recruited/stimulated. Therefore, in clinical practice, we conventionally use 1.0 mA for nerve confirmation. We use higher intensities for nerve identification (mapping), and lower intensities (0.5 mA) for the definition of nerve branches.

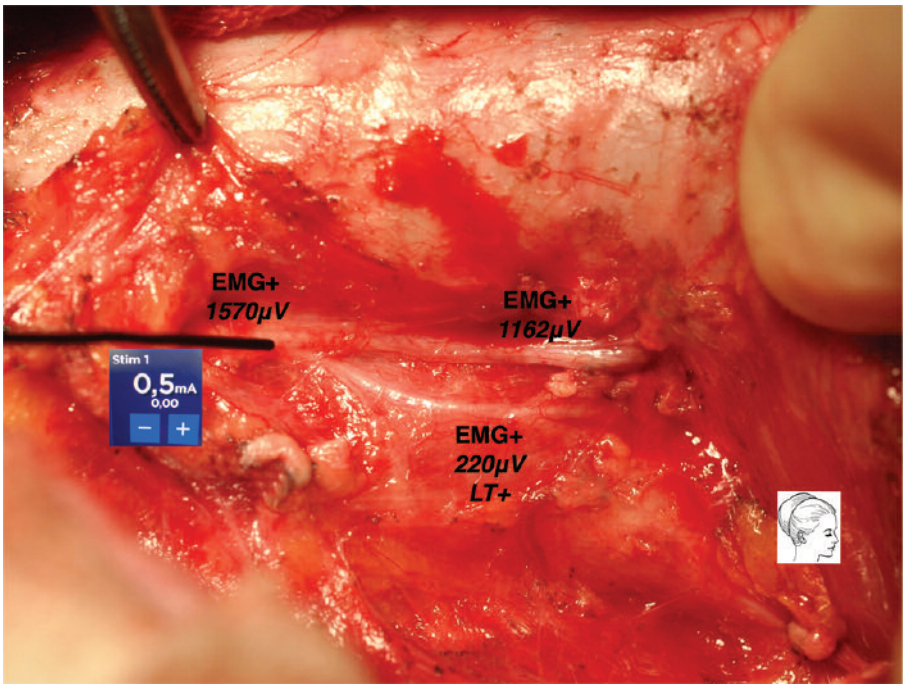

Figure 13. Intraoperative characterization of RLN ramifications. (LT+=laryngeal twitch).

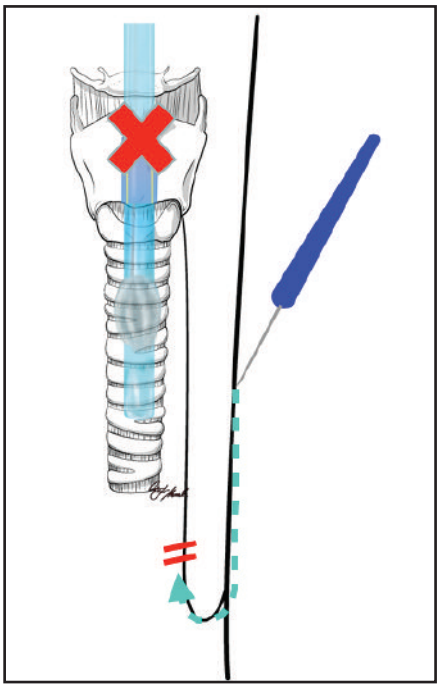

Figure 14. Only with the most proximal stimulation of the RLN, therefore indirect stimulation by the vagus nerve, can we be sure of the integrity of the entire RLN circuit.

between different patients.[29-34] During IONM of the nerve, the amplitude can change due to variations in several factors:

- ◆presence of liquid or blood (the operating field should be kept dry)
- ◆correct and timely probe-nerve contact during stimulation;
- ◆nerve stimulated anchor covered by fabric/headband;
- ◆variation of the ambient temperature or of the irrigation liquid used;
- ◆variation of the endotracheal tube on the superface of the recording electrode.

While amplitude is considered to be an index of the number of fibers participating in the depolarization event, latency is usually believed to be associated with the speed or ease of depolarization induced by stimulation and depends on the distance between the stimulation point and the ipsilateral vocal fold.[34-39]

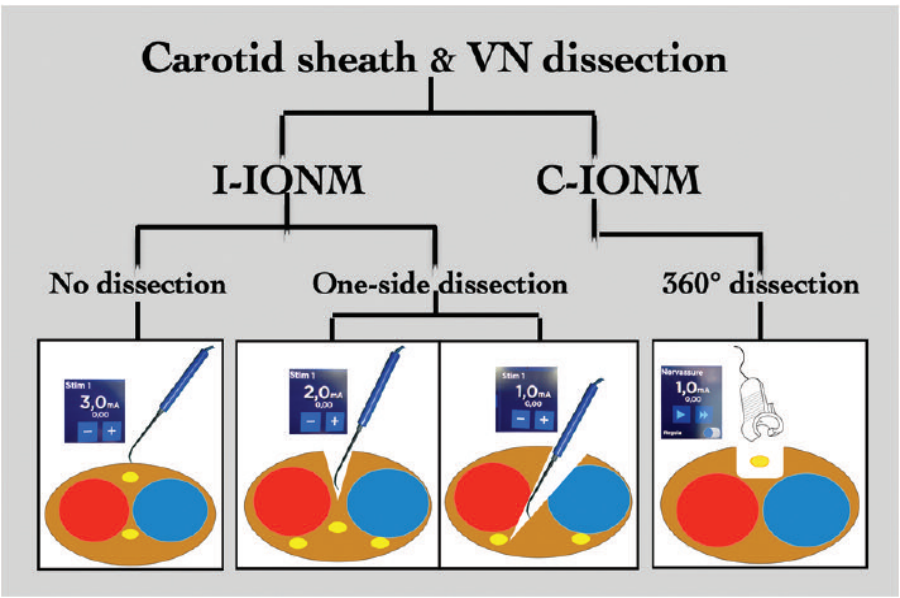

Figure 15. Dissection of the VN is not necessary in I-IONM.

Given the different lengths of the vagus nerve on both sides, the latency is significantly greater on the left side than on the right side. Referring to the existing standards in the physiology of monitoring and in the evoked acoustic response test, we define latency as the time elapsed from stimulation to the first evoked peak of the waveform.[40]

NIM VITAL™ ADVANTAGES

There have been incredible advances in the evolution and contextual maturity of both IONM equipment and the surgeon's knowledge of IONM (Fig. 17). Today, IONM is available in all operating rooms with a high volume of surgical activity.[16] NIM Vital ™ is a four-channel EMG monitoring system for intraoperative use during surgeries where inadvertent manipulation could damage a motor nerve.[5,15,22,33] The NIM Vital™ system records the EMG activity of the muscles innervated by the affected nerve. The monitor assists the surgeon in the initial identification of the nerve and is therefore useful for locating and identifying a specific nerve at risk within the surgical field.[39] The system offers three types of monitoring: intermittent, comparative and continuous.

Intermittent mode (I-IONM)

In the intermittent mode of IONM,

the surgeon wields a stimulation probe to perform tissue mapping, localization and dissection of the nerves. During surgery, the IONM screen provides visual, graphic and audible feedback regarding EMG responses and profiles in a time-frame analysis.[34-42] The displayed curves have different colors and shapes: (i) positive EMG response: white sinusoidal biphasic curve; (ii) recognized artifact: curve with irregular yellow peaks; and (iii) response to nervous stress (thermal, mechanical-chemical): curve with irregular white peaks. Unlike in the previous NIM (3.0), the IONM monitor chooses the channel with the best/greatest amplitude and latency recorded by the multichannel EMG tube (Fig. 18). Therefore, monitoring is easier for the surgeon to read.[25,26] The screen is bright without causing any reflex problems and visual disturbances for the surgeon. The screen highlights the standardization process: the stimulations V1, R1, R2, and V2 are set as a reminder in the screen (Fig. 18). The surgeon can subsequently associate precise nerve stimulations corresponding to V1, R1, R2, andV2.

Comparative mode (NerveTrend™)

NerveTrend™ (Medtronic) is another significant improvement of the NIM Vital™ system. It is very useful for surgeons, especially those who still prefer to use intermittent monitoring. In the comparative mode (NerveTrend ™), nerve stimulations can be compared in a chart that shows the trend to evaluate the EMG response's temporal evolution.[16] The NerveTrend™ function allows the operator to compare the trend over time of the monitored nerve responses on a graph. Figure 19 shows how to enable the NerveTrend™ feature. The surgeon needs to press the "Baseline" key and perform a series of stimulations (minimum 20) on the nerve using the stimulation probe to start the calculation of the initial reference values of EMG Amplitude and Latency.[7] Finally, the surgeon chooses the channel and operating side to start the NerveTrend™ chart. The NerveTrend™ function allows the surgeon to report the trend of the EMG responses selected as trend points in a dedicated graph (Fig. 20). The reference values determined by the Baseline are also used to calculate two alarm thresholds: at 10% above the baseline value for latency, and at 50% below the baseline value for amplitude, according to INMSG Guidelines.[8] The points recorded as trend

Figure 16. EMG signals: (a) VN stimulation (b) RLN stimulation. The difference in latency (longer for VN) defines the two nerves. The NIM Vital™ screen highlights laterality (left), signal amplitudes, latency (VN 5.03 ms, RLN 2.47 ms), the biphasic curve, and stimulation intensity (3 mA). The difference in signal amplitudes (VN 828 µV, RLN 1.049 µV) is due to the fact that the VN is stimulated at a distance by placing the stimulator on the carotid, not directly on the VN (i.e., without opening the carotid sheet), while the RLN is stimulated with perfect application of the stimulating probe on the nerve.

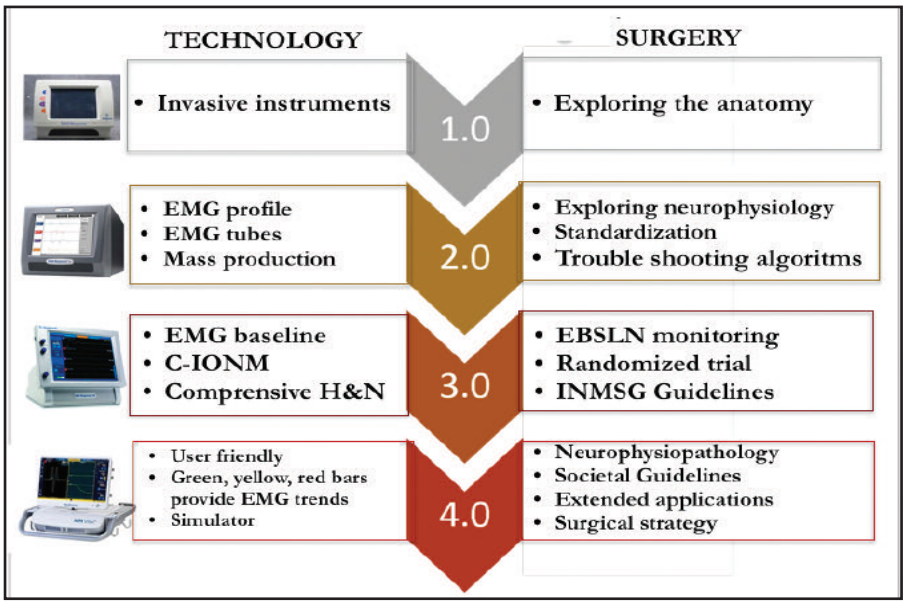

Figure 17. The maturity of IONM.

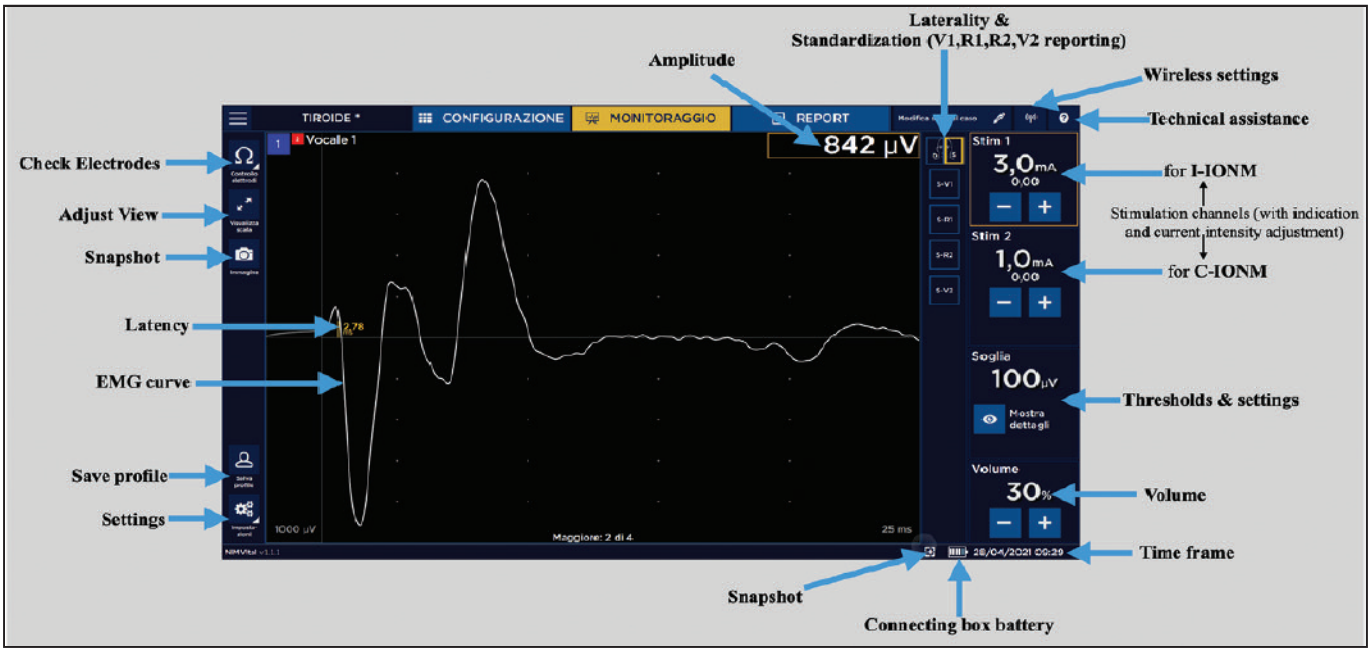

Figure 18. Unlike the previous NIM3.0, the IONM monitor chooses the channel with the best/greatest amplitude and latency. Furthermore, the screen presents in a simple, intuitive and immediate way all the information on the neurophysiology and neurophysiopathology of the laryngeal nerves. Most of the screen functions can be controlled remotely by a button on the incrementing probe (volume, intensity of stimulation and photographs).

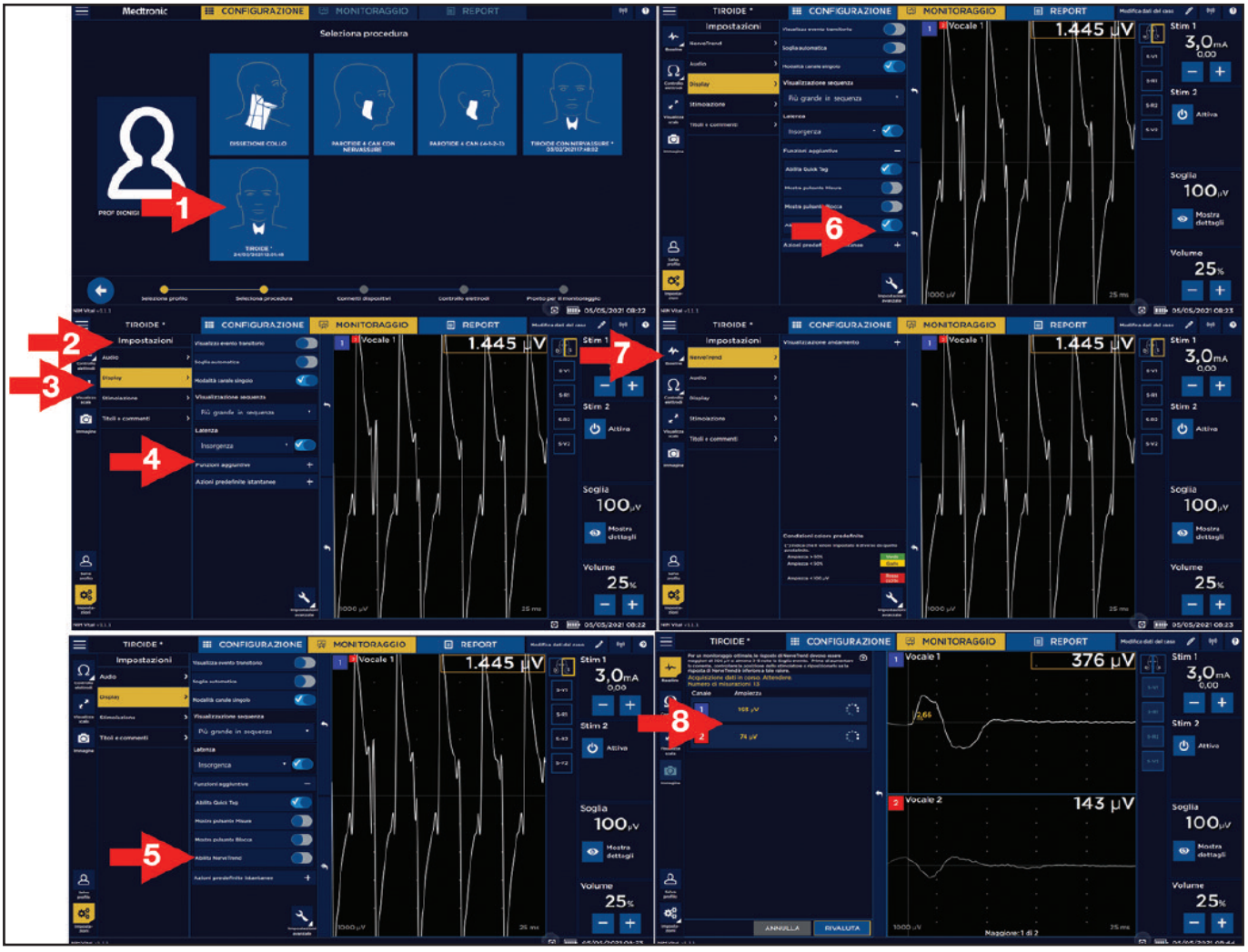

Figure 19. How to enable the NerveTrend™ feature.

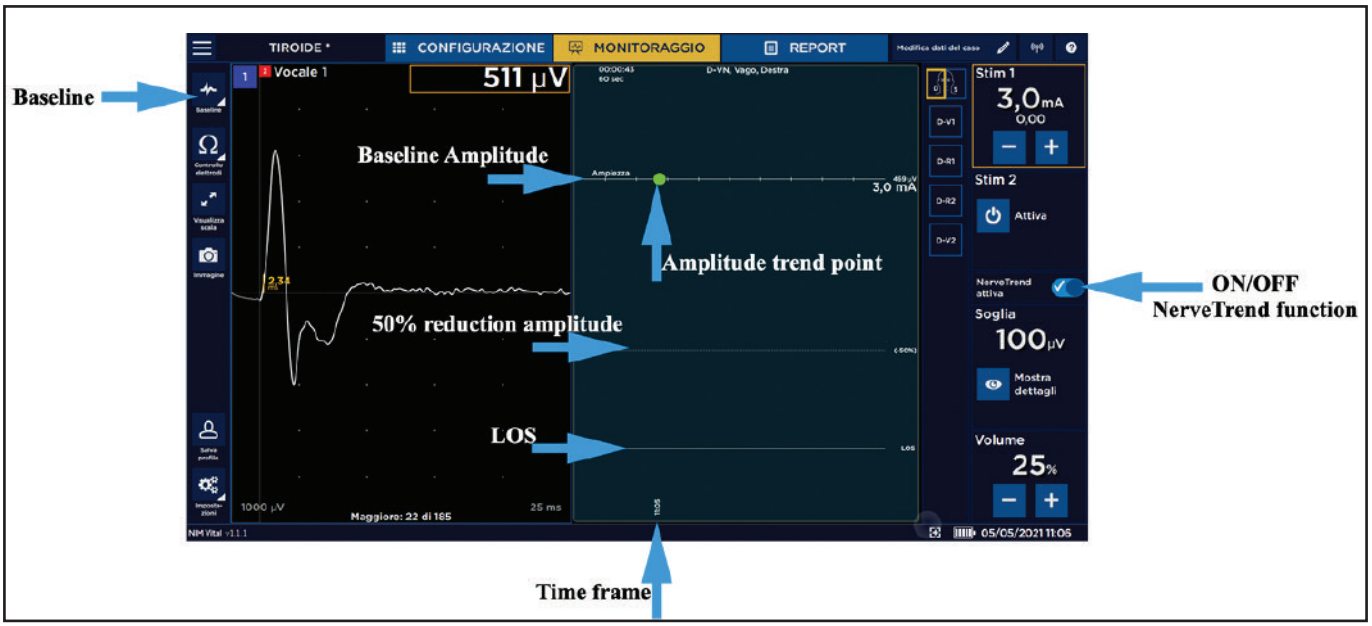

Figure 20. NerveTrend™ feature.

Figure 21. How to enable Nervassure ™ with an APS™ electrode.

points, corresponding to the stimulations of interest, have different colors depending on their position with respect to the alarm thresholds: (i) Green: Amplitude and latency values are within the alarm threshold; (ii) Yellow: Either the amplitude or latency value is beyond the alarm threshold (with audible alarm); (iii) Red: Amplitude and latency values are beyond the alarm threshold (with audible alarm).[1-3,7,17,27,32,39]

Continuous mode (Nervassure™ with an APS™ electrode)

In continuous mode (Nervassure ™ with an APS ™ electrode), the operator uses, in addition to the stimulation probe, an electrode capable of constantly stimulating the vagal nerve to provide real-time feedback on the quality of the EMG response during surgical dissection.[8] The system continuously monitors the EMG activity of the muscles innervated by the nerve at risk to minimize trauma, alerting the surgeon if a particular nerve is stressed. Figure 21 shows how to enable Nervassure ™ with an APS

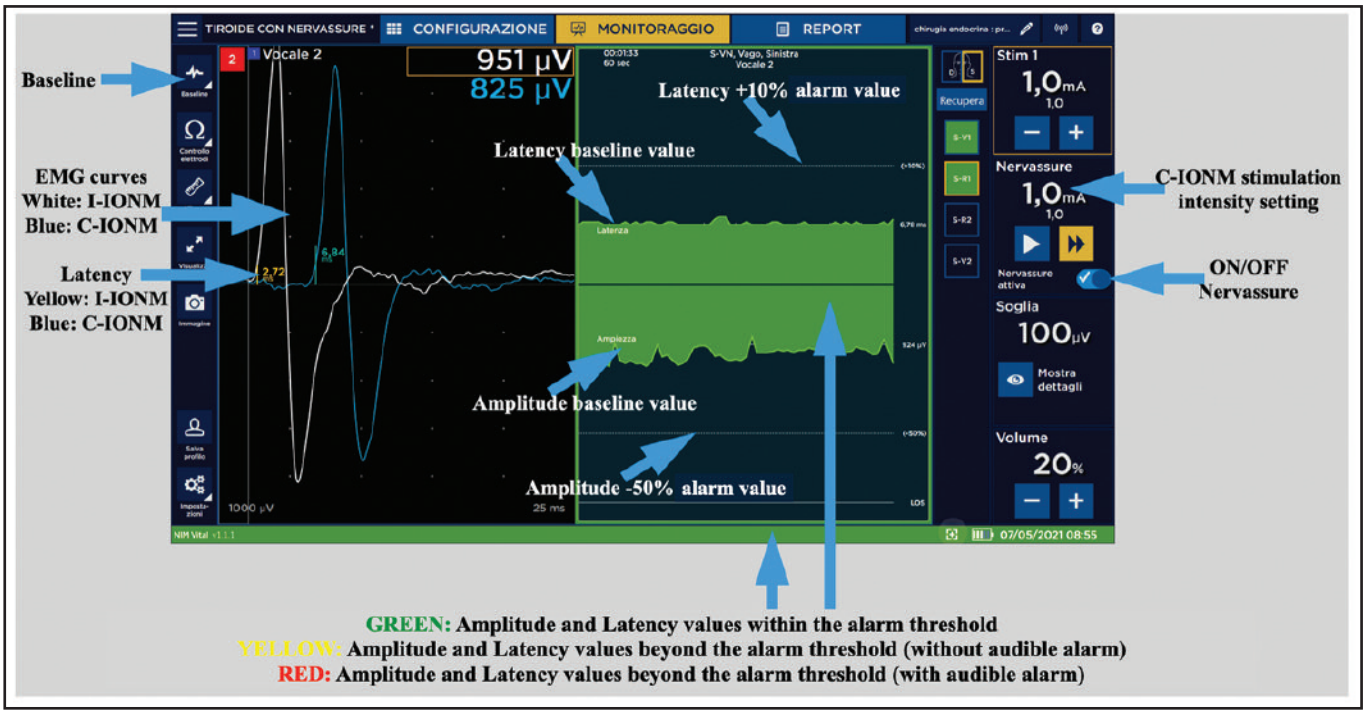

Figure 22. Nervassure™ with an APS™ electrode.

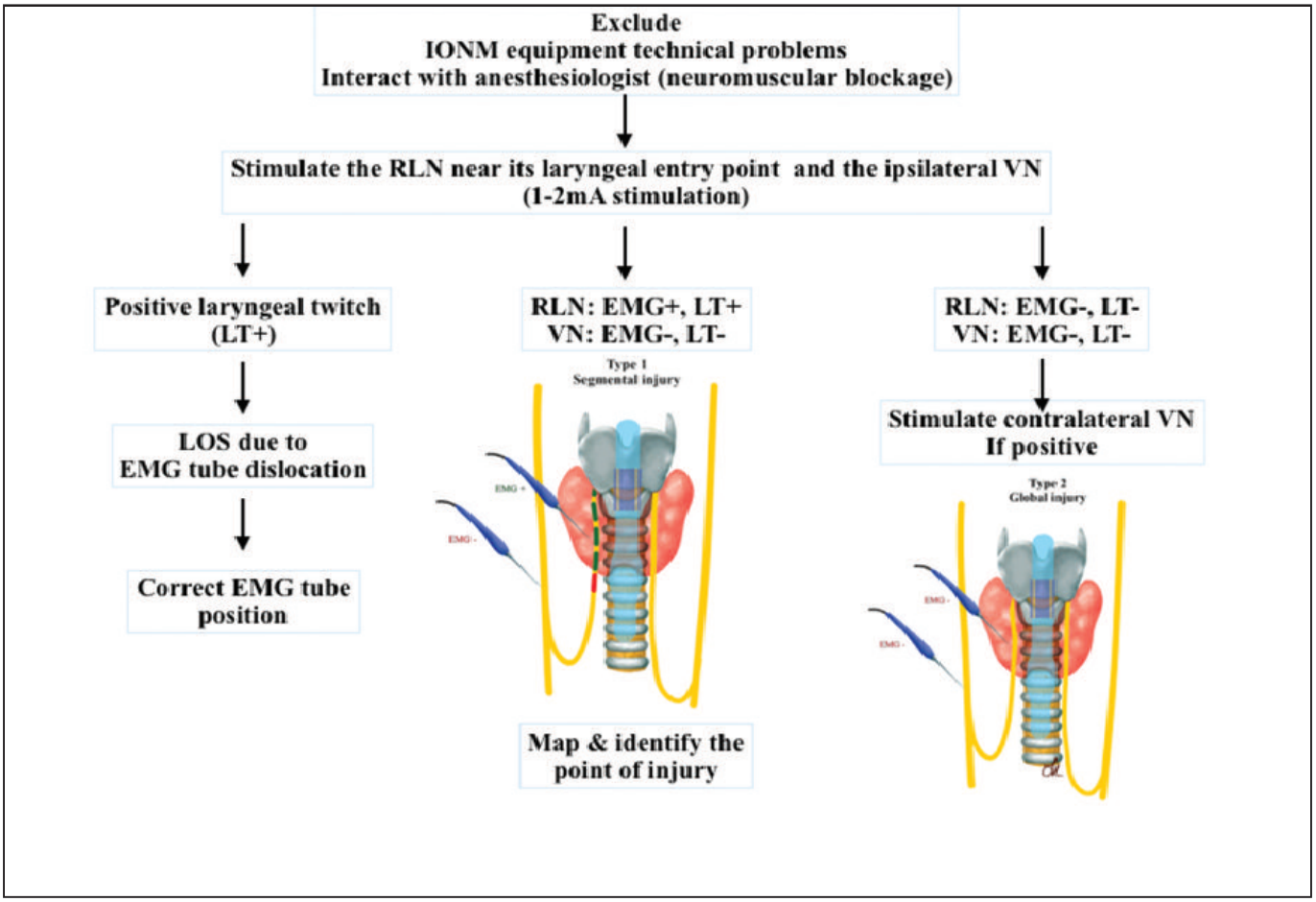

Figure 23. The technical knowledge of surgeons and trainees varies widely in the area of IONM-related troubleshooting. This systematic, practical algorithm may help to guide all surgeons to adopt a uniform approach, thereby improving patient safety and higher IONM quality outcomes.

™ electrode. The Nervassure™ function provides for periodic automatic stimulation of the nerve to be monitored. The Nervassure™ function is available for the "Thyroid" and "Parotid" procedures, using the APS stimulation electrode (Medtronic). The resulting EMG response is monitored continuously and in real time, graphically recording the trends of (a) EMG amplitude (peak-to-peak, response to stimulation) and (b) latency (the time from stimulation to the onset or peak of the EMG response). The screen is divided into two panels: the left panel shows the EMG response curves (direct stimulation curve and APSTM stimulation curve), and the right panel shows the time course of the amplitude and latency parameters at each APSTM stimulation (Fig. 22). The surgeon presses the "Baseline" button to start the calculation of the initial amplitude and latency reference values, obtained by averaging over a minimum of 20 APSTM stimulations, and then selects the operative side. The reference values are also used to calculate two alarm thresholds, set at 10% above the baseline value for latency, and at 50% below the baseline value for amplitude. The points corresponding to the amplitude and latency values associated with the APS stimulations have different colors depending on their position with respect to the alarm threshold values: (a) Green: Amplitude and latency values are within the alarm threshold; (b) Yellow: Either the amplitude or latency value is beyond the alarm threshold (with audible alarm); (c) Red: Amplitude and latency values are both beyond the alarm threshold (with audible alarm). For a more immediate reading of the information on the stress state of the monitored nerve, the APS stimulation box and the status bar also follow the same color code as described above. If both values are over the alarm threshold (red) and the amplitude has a value lower than 100µV, the message "LOS" will appear on the APSTM stimulation box to indicate a loss of signal (Fig. 22).

TROUBLE SHOOTING ALGORITHM

The NIM Vital™ software assists the surgeon and anaesthesiologist by making various tools available: (a) positioning images of the nerve electrodes to be monitored and by type of procedure; (b) audio samples; (c) integrated user manual; (d) algorithm for solving problems in case of signal loss; and (e) contacts for technical assistance (Fig. 23).

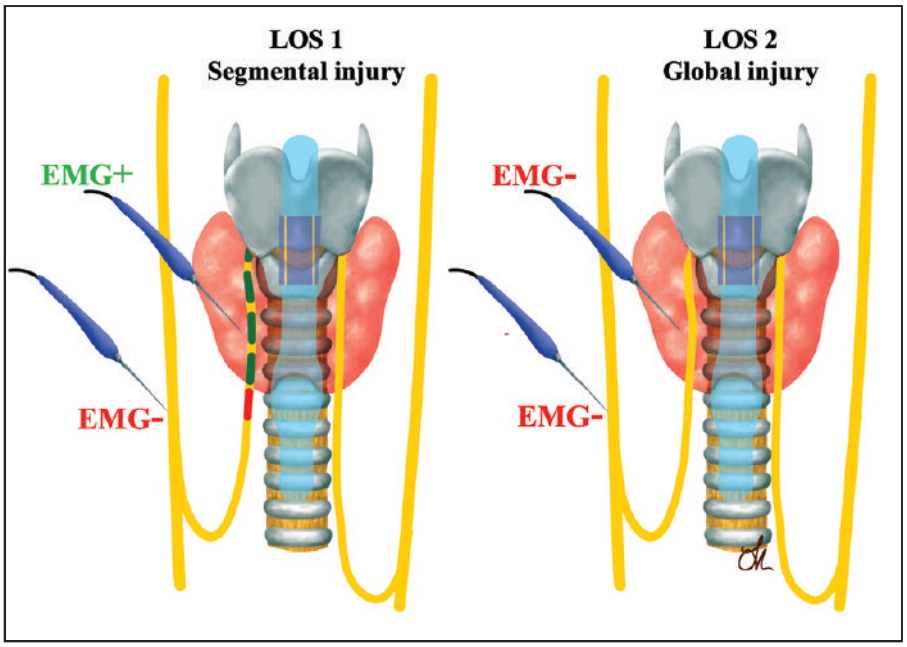

Figure 24. Segmental (LOS1) versus global (LOS2) RLN injury.

Table III
True LOS

- Prudence & experience
- Identification of site of lesion
- Stratification LOS 1 vs LOS 2 (prognosis)
- Elucidate mechanism of injury
- Corrective action (remove clip, ligature - RLN-RLN anastomosis)
- Predict the outcome (traction/thermal/section injury)
- Modify surgical maneuver
- Wait & see (intraoperative recovery of LOS)
- Steroid (iv/topical)
- Consideration of optimal contralateral surgery timing
- Inform anesthesiologist & patient (plan therapy)

LOS CODING

LOS coding includes (a) L1 with normal VC movement, (b) initial EMG satisfactory (V1>500µV), (c) no EMG response (1-2mA - dry field), (d) low response <100µV (1-2mA - dry field), (e) no laryngeal twitch (LT-), and (f) troubleshooting algorithm applied systematically. Figure 24 depicts the categorization of LOS1 and LOS2. Table III summarizes the consequences of LOS and how to use this information.[6]

NIM VITAL™ REPORT AND DOCUMENTATIONS

The NIM Vital™ report screen allows surgeons to quickly compose, print and/or save reports using a report builder. Even when the report screen is open, monitoring remains active, emitting background audio signals. The report screen has the following functions: (i) Categories and data acquired for export; (ii) Preview of the report; (iii) Case in progress; (iv) Edit Report Panel, and (v) Type of export (Save to USB storage device or Print). The surgeon can make a final review of the report before exporting, using the Preview window. The system creates file

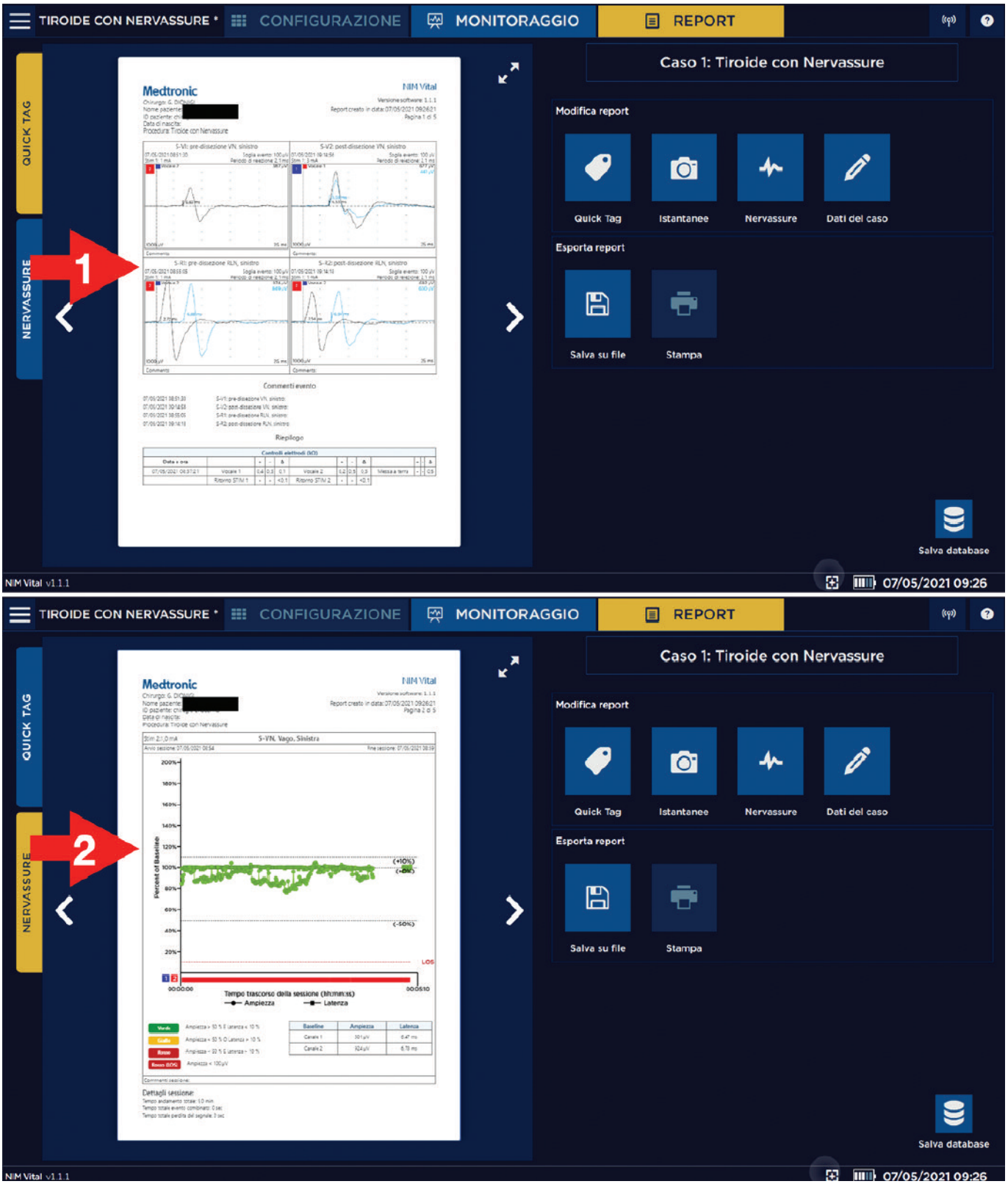

Figure 25. NIM Vital™ reporting.

names using the format report type, year, month, day and time; for example, Report_20200505_193005.pdf (Fig. 25). The reports are placed in a case folder that is labeled by the date, the serial number of the case and the type of procedure. Finally, all case data (snapshots, log files, Nervassure™ and Report data) are lost when the unit is turned off.

CONCLUSION

IONM represents a highly complex organizational/procedural framework that must respond to specific standard-

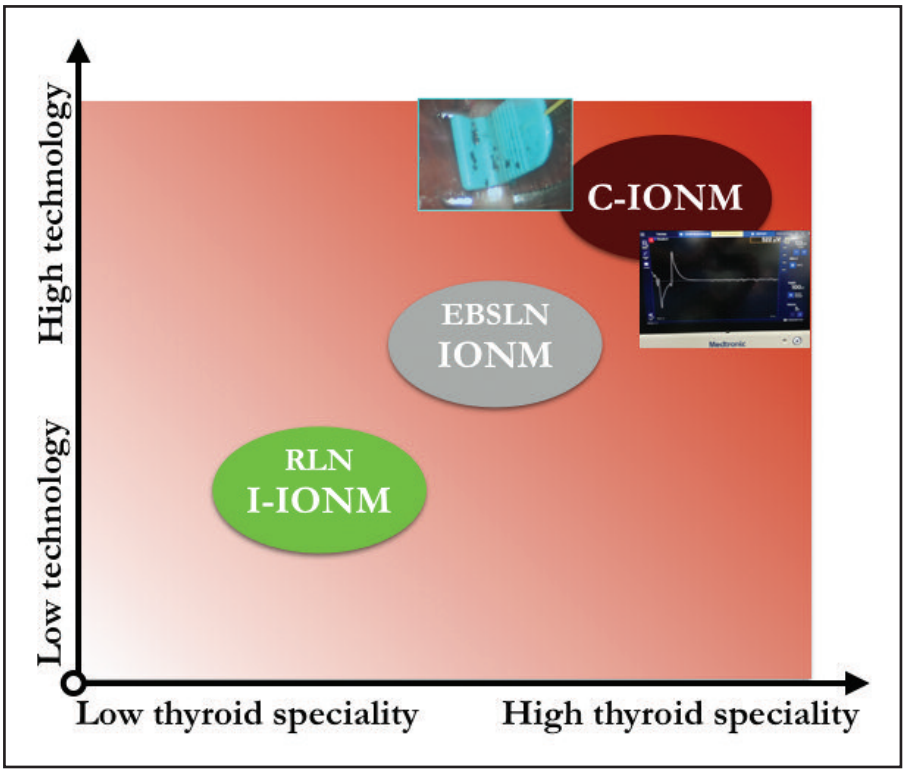

Figure 26. Centralization of C-IONM.

ized criteria (Fig. 26). The main purpose of standardization is the continuous improvement of IONM quality.[43] Another purpose of standardization is to reduce variability in IONM use.[42] The quality and benefits of IONM are strictly dependent on standardization. IONM standardization is a continuous process with incessant improvement and consolidation.[41] This technical report promotes the dissemination of a new tool for IONM and aims at improving IONM outcomes in clinical practice, thus increasing the appropriateness and effectiveness of IONM use.[5,8,9,39] This technical report, produced through a rigorous methodological process, sought to simultaneously improve the quality of IONM results and support professional autonomy for surgeons using the new NIM Vital™ system (Medtronic Xomed).[39-43] We hope to improve the safety of IONM by defining and promoting recommendations and standards that can be adapted, thus strengthening pre-, intra- and post-operative NIM Vital™ processes. The potential impact of such standards in terms of public health is enormous if we consider the immense number of endocrine surgical procedures performed worldwide. It is essential that an appropriate training strategy be developed for the new NIM Vital™ system aimed at all operators involved in endocrine surgery activities, with the goal of increasing both technical and cognitive-behavioral IONM skills.[2,5,8,9,22,39] STI

AUTHORS' DISCLOSURES

The authors declare that there are no conflicts of interest.

REFERENCES

1. Zhang D, Pino A, Caruso E, Dionigi G, Sun H. Neural monitoring in thyroid surgery is here to stay. Gland Surg 2020 Jan;9(Suppl 1):S43-S46.
2. Schneider R, Randolph GW, Dionigi G, et al. International neural monitoring study group guideline 2018 part I: Staging bilateral thyroid surgery with monitoring loss of signal. Laryngoscope 2018 Oct;128 Suppl 3:S1-S17.
3. Wu CW, Dionigi G, Barczynski M, et al. International neuromonitoring study group guidelines 2018: Part II: Optimal recurrent laryngeal nerve management for invasive thyroid cancer—incorporation of surgical, laryngeal, and neural electrophysiologic data. Laryngoscope 2018 Oct;128 Suppl 3:S18-S27.
4. Iwata AJ, Liddy W, Barczyński M, et al. Superior Laryngeal Nerve Signal Attenuation Influences Voice Outcomes in Thyroid Surgery. Laryngoscope 2021 Jan 31. doi: 10.1002/lary.29413.
5. Huang TY, Lin YC, Tseng HY, et al. Full percutaneous intraoperative neuromonitoring technique in remote thyroid surgery: Porcine model feasibility study. Head Neck 2021 Feb;43(2):505-13.
6. You JY, Kim HY, Park DW, et al. Transoral robotic thyroidectomy versus conventional open thyroidectomy: comparative analysis of surgical outcomes using propensity score matching. Surg Endosc 2021 Jan; 35(1):124-9.
7. Wang T, Dionigi G, Zhao Y, et al. Tensile strength analysis of automatic periodic stimulation for continuous intraoperative neural monitoring in a piglet model. Sci Rep 2021 Mar 15;11(1):5898. doi: 10.1038/s41598-021-84988-y. PMID: 33723308.
8. Zhang D, Fu Y, Zhou L, et al. Prevention of non-recurrent laryngeal nerve injury in robotic thyroidectomy: imaging and technique. Surg Endosc 2021 Mar 15. doi: 10.1007/s00464-021-08421-1. Epub ahead of print. PMID: 33721091.
9. Erol V, Dionigi G, Barczyński M, Zhang D, Makay Ö. Intraoperative neuromonitoring of the RLNs during TOETVA procedures. Gland Surg 2020;9:S129-S135.
10. Zhang D, Li S, Dionigi G, et al. Stimulating and dissecting instrument for transoral endoscopic thyroidectomy: proof of concept investigation. Surg Endosc 2020;34(2):996-1005.
11. Sinclair J. Collins Cobuild English Dictionary. London: Harper Collins, 1995.
12. Sun H, Wu CW, Zhang D, et al. New Paradigms for Neural Monitoring in Thyroid Surgery. Surg Technol Int 2019;18;34.
13. Zhao Y, Li C, Liu X, et al. Investigation on EMG Profiles of the Superior Laryngeal Nerve in a In Vivo Porcine Model. J Invest Surg 2019;15:1-9.
14. Kim HK, Chai YJ, Lee HY, Kim HY, Dionigi G. Translational Study on Recurrent Laryngeal Nerve Temperature Susceptibility. J Surg Res 2019;234:7-12.
15. Zhou L, Dionigi G, Pontin A, et al. How does neural monitoring help during thyroid surgery for Graves' disease? J Clin Transl Endocrinol 2018;15:6-11.
16. Zhao Y, Li C, Zhang D, et al. Experimental study of needle recording electrodes placed on the thyroid cartilage for neuromonitoring during thyroid surgery. Br J Surg 2019;106(3):245-54.
17. Barczyński M, Konturek A, Pragacz K, Papier A, Stopa M, Nowak W. Intraoperative nerve monitoring can reduce prevalence of recurrent laryngeal nerve injury in thyroid reoperations: results of a retrospective cohort study. World J Surg 2014 Mar;38(3):599-606. doi: 10.1007/s00268-013-2260-x. PMID: 24081538; PMCID: PMC3923121.
18. Dionigi G, Lombardi D, Lombardi CP, et al. Intraoperative neuromonitoring in thyroid surgery: a point prevalence survey on utilization, management, and documentation in Italy. Updates Surg 2014 Dec;66(4):269-76. doi: 10.1007/s13304-014-0275-y. Epub 2014 Dec 3. PMID: 25465057.
19. Dralle H, Lorenz K, Machens A. Verdicts on malpractice claims after thyroid surgery: emerging trends and future directions. Head Neck 2012 Nov;34(11): 1591-6. doi: 10.1002/hed.21970. Epub 2012 Mar 20. PMID: 22431167.
20. Lu IC, Wu SH, Chang PY, et al. Precision Neuromuscular Block Management for Neural Monitoring During Thyroid Surgery. J Invest Surg 2020 Aug 14:1-8. doi: 10.1080/08941939.2020.1805055. Epub ahead of print. Erratum in: J Invest Surg 2020 Sep 7;:1-2. PMID: 32791867.
21. Kim HY, Tufano RP, Randolph G, et al. Impact of positional changes in neural monitoring endotracheal tube on amplitude and latency of electromyographic response in monitored thyroid surgery: Results from the Porcine Experiment. Head Neck 2016 Apr;38 Suppl 1:E1004-8. doi: 10.1002/hed.24145. Epub 2015 Jul 18. PMID: 26040955.
22. Darr EA, Tufano RP, Ozdemir S, Kamani D, Hurwitz S, Randolph G. Superior laryngeal nerve quantitative intraoperative monitoring is possible in all thyroid surgeries. Laryngoscope 2014 Apr;124(4):1035-41. doi: 10.1002/lary.24446. Epub 2014 Jan 23. PMID: 24115215.
23. Shiban E, Zerr M, Huber T, et al. Poor diagnostic accuracy of transcranial motor and somatosensory evoked potential monitoring during brainstem cavernoma resection. Acta Neurochir (Wien) 2015 Nov;157(11):1963-9; discussion 1969. doi: 10.1007/s00701-015-2573-7. Epub 2015 Sep 7. PMID: 26347046.
24. Shiban E, Krieg SM, Haller B, et al. Intraoperative subcortical motor evoked potential stimulation: how close is the corticospinal tract? J Neurosurg 2015 Sep;123(3):711-20. doi: 10.3171/2014.10.JNS141289. Epub 2015 Jun 5. PMID: 26047412.
25. Zhang D, Li S, Dionigi G, et al. Animal Study to Evaluate the Effect of Carbon Dioxide Insufflation on Recurrent Laryngeal Nerve Function in Transoral Endoscopic Thyroidectomy. Sci Rep 2019 27;9(1):9365.
26. Zhang D, Zhang J, Dionigi G, et al. Recurrent

Laryngeal Nerve Morbidity: Lessons from Endoscopic via Bilateral Areola and Open Thyroidectomy Technique. World J Surg 2019 Nov;43(11):2829-41. doi: 10.1007/s00268-019-05092-x.
27. Miccoli P, Dionigi G. Tailored approach for recurrent laryngeal nerve dissection according to different endoscopic endocrine surgery. Head Neck 2019 Nov;41(11):4060-1. doi: 10.1002/hed.25901.
28. Sun H, Kim HY, Carcoforo P, Dionigi G. Cost and training are diffusion patterns limits for neural monitoring in thyroid surgery. Gland Surg 2019;8(4):334-5.
29. Wang T, Dionigi G, Zhang D, et al. Diagnosis, anatomy, and electromyography profiles of 73 nonrecurrent laryngeal nerves. Head Neck 2018;40(12): 2657-63.
30. Sun H, Zanghì GN, Freni F, Dionigi G. Continuous and intermitted nerve monitoring in thyroid surgery: two complementary devices. Gland Surg 2018;7(Suppl 1):S80-S81.
31. Cavicchi O, Burgio L, Cioccoloni E, et al. Intraoperative intermittent neuromonitoring of inferior laryngeal nerve and staged thyroidectomy: our experience. Endocrine 2018;62(3):560-5.
32. Kim HK, Chai YJ, Lee HY, Kim HY, Dionigi G. Comparing the safety of harmonic ACE and ACE+ around the recurrent laryngeal nerve in swine models. Ann Surg Treat Res 2018;94(6):285-90.
33. Zhang D, Li S, Dionigi G, et al. Feasibility of Continuous Intraoperative Neural Monitoring During Transoral Endoscopic Thyroidectomy Vestibular Approach in a Porcine Model. J Laparoendosc Adv Surg Tech A 2019 Dec;29(12):1592-7. doi: 10.1089/lap. 2018.0054.
34. Zhao Y, Li C, Wang T, et al. Translational Study to Standardize the Safe Use of Bipolar Forceps, LigaSure, Sonicision and PlasmaBlade Around the Recurrent Laryngeal Nerve in Thyroid Surgery. Surg Technol Int 2018; 23;31.
35. Liu X, Zhang D, Zhang G, et al. Laryngeal nerve morbidity in 1,273 central node dissections for thyroid cancer. Surg Oncol 2018;27(2):A21-A25.
36. Sun H, Dionigi G. Additions of neural monitoring for thyroid surgery. Endocrine 2018;;61(3):547.
37. Dionigi G, Wu CW, Tufano RP, et al. Monitored transoral endoscopic thyroidectomy via long monopolar stimulation probe. J Vis Surg 2018 Jan 26;4:24.
38. Sun H, Wu CW, Kim HY, Dionigi G. Neural monitoring represent central safety asset for new technologies in thyroid surgery in translational protocols. Am J Surg 2018;216(6):1235-6.
39. Christoforides C, Papandrikos I, Polyzois G, Roukounakis N, Dionigi G, Vamvakidis K. Two-stage thyroidectomy in the era of intraoperative neuromonitoring. Gland Surg 2017;6(5):453-463.
40. Wang T, Kim HY, Wu CW, et al. Analyzing cost-effectiveness of neural-monitoring in recurrent laryngeal nerve recovery course in thyroid surgery. Int J Surg 2017;48:180-8.
41. Mangano A, Kim HY, Wu CW, et al. Continuous intraoperative neuromonitoring in thyroid surgery: Safety analysis of 400 consecutive electrode probe placements with standardized procedures. Head Neck 2016;38 Suppl 1:E1568-74.
42. Lee HY, Lee JY, Dionigi G. The Efficacy of Intraoperative Neuromonitoring During Robotic Thyroidectomy: A Prospective, Randomized Case-Control Evaluation. J Laparoendosc Adv Surg Tech A 2015; 25(11):908-14.
43. Mangano A, Wu CW, Lianos GD, et al. Evidence-based Analysis on The Clinical Impact of Intraoperative Neuromonitoring in Thyroid Surgery: State of the Art and Future Perspectives. Surg Technol Int 2014;25:91-6.

Surg Technol Int. 2021, June 3;38. pii: sti38/PMID: 34081771