

Medtronic

Nerve Integrity Monitor

NIM Vital™



Instructions for use

RxOnly

FCC use only, not for Medical use

The information contained in this document is accurate at time of publication. Medtronic reserves the right to make changes to the product described in this manual. Refer to **manuals.medtronic.com** for the current version.

The following are trademarks or registered trademarks of Medtronic in the United States and other countries: NIM Vital™, APS™, Nervassure™, and NerveTrend™. All other trademarks, service marks, registered trademarks, or registered service marks are the property of their respective owners in the United States and other countries.

Table of Contents

Intended use	2
Indications for use	2
Device description	2
Contraindications	2
Warnings and precautions	2
Warnings.....	2
Precautions.....	3
NIM quick monitoring set-up	4
The basics of what you will see and hear during monitoring.....	5
Unboxing and installing the system	5
Setting up the NIM Vital console.....	6
Installing the NIM Vital battery.....	6
Setting up the NIM Vital cart.....	6
Connecting NIM Vital accessories.....	6
First time user interface setup.....	6
Set the time zone, date, time, and date/time format.....	6
Create a surgeon profile.....	7
Saving to a surgeon profile.....	7
Save custom profiles to a USB drive.....	7
Import custom profiles from a USB drive.....	7
Components	8
Power Cords.....	11
Software overview	11
Turning the system on.....	11
SETUP tab.....	11
Select user profiles or default categories.....	13
Select a default procedure.....	13
Select a user profile.....	13
Connect Devices screen.....	14
Check Electrode screen.....	14
MONITORING tab.....	15
EMG Display.....	15
EMG display area.....	16
Recognizing stimulus artifacts.....	16
Understanding and recognizing other artifacts.....	17
MONITORING tab right panel.....	17
MONITORING tab Left panel.....	18
NerveTrend (only available in select procedures).....	20
NIM Vital bottom panel.....	21
NIM Vital top panel.....	22
Settings overview.....	26
Global settings.....	26
Accessing settings.....	26
Nervassure settings panel.....	26
NerveTrend panel.....	27
Audio panel.....	27
Display Settings panel.....	28
Stimulation panel.....	30
Identify STIM 1 and STIM 2 types.....	31
Important note on stimulator adjustments.....	32
Titles and comments.....	32
Optional features in monitoring.....	33
Quick tags.....	33
Probe-based functions.....	33
The REPORTS mode.....	35
Include quick tags on a report.....	35
Delete quick tags from the report.....	35
Edit the snapshot title and comments.....	35
Include snapshots on a report.....	36
Edit sessions.....	36
Include trending graphs in a report - Nervassure and NerveTrend.....	36
Edit case information on a report.....	36
Generate the report.....	37
Nervassure overview.....	37
Nervassure case set up.....	37
Nervassure Monitoring Screen details.....	37
Monitoring a Nervassure case.....	38
Thyroid with Nervassure specific features.....	40
Muting a Nervassure alarm.....	40
Default Nervassure alarm criteria.....	41
Default Nervassure trend settings.....	41
Audio – understanding what you hear.....	43
Alarms.....	43
Voices.....	44
Tones.....	44
Other sounds.....	45
Powering down the NIM Vital system.....	45
Visual error and informational messages	45

System set-up	46
Operating room set-up.....	46
Anesthesia requirements.....	46
Patient Interface setup.....	46
Stimulators.....	47
Patient Interface box and stimulator combinations.....	49
For installing the stimulating electrode.....	50
Surgery Notes.....	51
After surgery.....	51
When the case is complete.....	51
When monitoring is complete.....	51
Managing patient interface boxes	51
Power backup	51
General operation.....	51
Charging the patient interface box.....	52
Loss of power during surgery.....	52
Console battery charging.....	52
Using the console with no battery installed.....	52
Troubleshooting	52
Patient interface troubleshooting.....	54
Reprocessing and maintenance	54
Cleaning.....	54
Disinfection.....	55
Storage.....	55
Maintenance.....	55
System self-tests.....	55
System quick check.....	55
Annual planned maintenance.....	55
Annual system quick check.....	55
Accessories	56
System description.....	56
Simulator set-up.....	56
Use the patient simulator.....	57
Confirming electrodes.....	57
Electrode lead off.....	58
Stimulation.....	59
External display support.....	61
Wireless display module.....	61
NIM Vital Mute adapter (optional).....	61
NIM Muting detector (optional).....	61
Muting Detector setup.....	62
Additional mute probe adapter information.....	64
Muting.....	64
STIM Bur Guard.....	64
Accessories / parts list.....	64
System components & accessories.....	64
Installing the optional power isolator.....	65
NIM Probes and electrodes.....	66
Fuses.....	68
Patient Interface fuse replacement.....	69
Technical specifications	70
NIM Vital Compatible Accessories.....	72
The NIM Vital equipment cart	73
NIM Vital lockdown.....	73
NIM Vital cart repair.....	73
Display default settings	75
STIM 1 & 2 default settings	75
Legal information	76
Contact information.....	76
Open source software disclosure.....	76
Guidance and manufacturer's declaration – electromagnetic emission and immunity.....	76
Limited warranty.....	78
Transmissible Spongiform Encephalopathies (TSE).....	78
Glossary.....	79
Buttons and indicators.....	80
Symbols.....	84

Intended use

The NIM Vital is intended for locating and monitoring, including stimulation, of cranial, spinal, peripheral motor and mixed motor-sensory nerves and registering EMG responses during surgery.

Indications for use

The NIM Vital system may be used for EMG monitoring in support of surgical procedures including: intracranial, extracranial, intratemporal, extratemporal and surgeries associated with the neck, spine, thorax, and upper and lower extremities.

Device description

The NIM Vital system is an intraoperative EMG monitor that enables users to locate and confirm the integrity of nerves during surgical procedures.

The system stimulates nerves (propagates an action potential) through a variety of stimulation probes that causes the muscle associated with the nerve to contract. The system then picks up these electric signals from the muscles through a variety of electrodes and converts this information into meaningful graphs and sounds that the system displays on the monitor.

The system also continuously monitors EMG activity from the muscles innervated by the nerve at risk.

Contraindications

The NIM Vital system is contraindicated for use with paralyzing anesthetic agents that will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation.

Warnings and precautions

It is important that the NIM Vital system intended operators be familiar with this manual: its warnings, precautions, procedures and safety issues. Disregarding the information on safety is considered abnormal use.

Warnings

- W1 The NIM Vital system does not prevent the surgical severing of nerves. If monitoring is compromised, the surgical practitioner must rely on alternate methods, or surgical skills, experience, and anatomical knowledge to prevent damage to nerves.
- W2 If paralyzing anesthetic agents have been used, patient must regain muscle activity prior to use of the NIM Vital EMG Monitor.
 - a. To limit the paralytic effect of anesthetic agents, the anesthesiologist should monitor Train-of-Four (TOF) to prevent diminished EMG activity. Consult anesthesiologist if EMG changes are observed.
- W3 Surgical Identification of exposed nerves is key to their preservation. Failure to use Medtronic's Nerve Stimulation Probe may contribute to unintended surgical nerve damage or resection.
 - a. The user is responsible for ensuring the electrodes are placed, or inserted into the target muscles. The electrode check, or tap test only indicates that the electrodes are making contact with the patient's tissue and does not indicate that the needle is inserted into the correct muscle.
- W4 To avoid the risk of fire or explosion, do not use the Medtronic NIM Vital system in the presence of flammable anesthetics and/or oxygen rich environment.
- W5 After each procedure, properly clean and disinfect all reusable system components.
- W6 To avoid alternate site patient burns or lesions when patient interface is connected to the NIM Vital console through the patient interface cord:
 - a. Do not activate the electrosurgical instruments (ESU) while stimulator is in contact with tissue.
 - b. Do not leave dissection instruments, stimulating electrodes, or probes in surgical field.
 - c. Do not store dissection instruments, stimulating electrodes, or probes in electrosurgical instrument holder.
 - d. Do not allow a second surgeon (for example, fat harvesting) to use electrosurgical instruments while stimulator is in use.
 - e. Do not activate electrosurgical instrument for prolonged periods while ESU is not in contact with tissue.
 - f. Do not activate electrosurgical instrument near the recording or stimulating electrodes.
 - g. Do not allow patient interfaces or recording / stimulating electrodes sites to be flooded with saline.
 - h. Do not allow excessive stray AC or DC leakage currents from patient connected equipment; Avoid creating an unintended grounding path through applied electrodes.
Practitioner is responsible for proper use, periodic safety certification of patient connected equipment, and AC power grounding in accordance to the appropriate IEC 60601-1 and/or IEC 60601-1-1 medical safety standard.
- W7 Disconnect power to the console before cleaning the unit to avoid electrical macro shock.
- W8 Achieve electrical grounding reliability with proper connections. Connect the console to hospital grade receptacles only.
- W9 Do not use any parts:
 - a. other than Medtronic components as damage or substandard performance could result.
 - b. that are damaged components or accessories.

- W10 This medical device complies with IEC/EN60601-1-2 safety standard for electromagnetic compatibility, requirements and test. However, if this equipment is operated in the presence of high levels of electromagnetic interference (EMI) or highly sensitive equipment, interference may be encountered and the user should take whatever steps are necessary to eliminate or reduce the source of the interference. Diminished performance may lengthen operating time for anesthetized patient.
- W11 It is important that the NIM Vital operator be familiar with this manual, its precautions, procedures and safety issues.
- W12 To avoid electrical shock, do not attach unapproved components or accessories to the Medtronic NIM Vital system.
- W13 All service must be performed by Medtronic qualified personnel only, unless otherwise noted.
- W14 Do not directly contact active, implanted devices with the stimulator as it may disrupt the implanted device's operation. Consult medical specialist before use.
- W15 Electrocardiogram monitoring artifacts may be caused by Medtronic NIM stimulus current delivery or EMG electrode impedance monitoring.
- W16 Use of unapproved stimulators, stimulus probes, stimulus dissection instruments or electrodes may result in compromised Medtronic NIM operation, such as, but not limited to decreased accuracy.
- W17 Repair and/or modification to the Medtronic NIM or any accessory by anyone other than qualified service personnel may significantly compromise the unit's ability to monitor nerve activity and/or void the equipment warranty.
- W18 To avoid the risk of infection, the user must maintain good sterility practices.
- W19 False negative responses, failure to identify nerve, a condition where probe is on nerve but you do not get an EMG tone may result from:
- Shorted EMG electrode or cabling (conductive parts of applied needle electrodes or cables contacting each other).
 - Patient Interface fuse blown and not detected (32 mA, 250 V. Xomed Part No.: 8253075).
 - Patient Interface defective.
 - Inadequate stimulus current.
 - Inadequate current for stimulation of nerve through hardware, such as stimulus dissection instruments, may vary based on the physical size, shape characteristics, and design of the hardware and proximity to the nerve.
 - Simultaneous stimulation of the nerve and the surrounding tissue, resulting in current shunting (inadequate delivery of stimulus current to target nerve tissue).
 - Flatline on the EMG channel caused by shorted internal amplifier (characterized by baseline activity of $< 3 \mu\text{V}$ peak-to-peak).
 - EMG electrodes not positioned properly in the target muscles.
- W20 Stimulator current may cause involuntary patient movement resulting in patient injury.
- W21 If the incrementing probe handle malfunctions, it could result in increased current delivery to the patient. Immediately disconnect the Control Plug from the Patient Interface box and use the console to adjust stimulus current.
- W22 Be careful not to damage vascular or neural structures when preparing the nerve for the installation of the continuous monitoring electrodes.
- W23 Electrode integrity should be checked after electrode insertion and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If the system indicates improper electrode impedance, consult the "Troubleshooting" topic for impedance value troubleshooting.
- W24 Remove continuous monitoring electrode from patient prior to using external defibrillator to prevent thermal injury to patient at continuous monitoring electrode site.
- W25 Operation in close proximity to high frequency (shortwave or microwave) equipment may produce instability in the electrical stimulator output.
- W26 Safe stimulus levels are dependent on various conditions including but not limited to: type of excitable tissue, Charge Per Pulse, and Charge Per Unit Area. Waveform morphology, repetition rate, and stimulator effective surface area must be considered. Special operator (Neurophysiologist) attention is required for stimulus levels which exceed default settings or conditions. Levels higher than 2 mA RMS/cm² (3 mA) for Slim Prass Probe and Prass Bipolar Probe may result in tissue damage.
- W27 Do not perform Magnetic Resonance Imaging (MRI) on a patient with electrodes, probes, and EMG tubes in the field. The effect of MRI is unknown on these devices.
- W28 Loud extraneous monitoring noise may be caused by activation of electrosurgical unit. Muting Detector, if necessary, must be properly attached to the active electrosurgical lead.
- W29 User is responsible for at minimum annual functional and safety checks.
- W30 Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.
- W31 Do not use if sterile package has been opened or is damaged.

Precautions

- P1 Medical Electrical Equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this Guide.
- P2 Portable and mobile RF including cell phones and communications equipment can affect Medical Electrical Equipment.
- P3 Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
- P4 The NIM Vital system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NIM Vital should be observed to verify normal operation in the configuration in which it will be used.

Nerve Integrity Monitor

- P5 Avoid accidental contact between 'PATIENT APPLIED PARTS' and other conductive parts including those connected to protective earth.
- P6 The NIM Vital is only compatible with the metal Muting Probe (Ref - 8220325). Earlier model Muting Probes are not compatible.
- P7 The muting detector is susceptible to damage from dropping. Visually inspect inner jaw surfaces for cracking, chipping or damage prior to use. Insufficient muting may result.
- P8 The patient interface is susceptible to damage from dropping. Visually inspect for damage prior to use. Inability to monitor may result.
- P9 The Ethernet connection of the NIM Vital Console, if activated, is intended to be connected to the hospital network. Do not connect it to other equipment.
- P10 At the end of their life cycle, all NIM Vital System electronic components must be sent to a WEEE recycling center or disposed of according to local regulations.
- P11 The NIM Vital console contains a Li-Ion battery pack that the user installs/replaces. Failure to follow the instructions for proper installation/replacement of the Li-Ion battery pack may could result in a hazard.
- P12 The Patient Interface contains a Li-Ion battery pack that must be replaced by trained service personnel only. The replacement of Li-Ion batteries by inadequately trained personnel could result in a hazard.
- P13 The multiple socket outlet (MSO) inside the locked drawer of the NIM Vital Cart is only intended to power the NIM Vital Console and NIM Vital Power Isolator for Printer. Connecting both NIM Vital Console and NIM Vital Power Isolator for Printer into the MSO effectively leads to create a Medical Electrical system. The system has been tested and met the applicable portions of the IEC 60601-1 standard.
 - a. Do not plug any device into the MSO other than the NIM Vital Console and NIM Vital Power Isolator for Printer.
 - b. Do not overload the MSO by using it for multiple systems. The MSO shall be only used for supplying power to one NIM Vital Console and one NIM Vital Power Isolator for Printer.
 - c. Printer shall be always powered through the NIM Vital Power Isolator for Printer.
 - d. Do not plug the power cord of the NIM Vital Cart into an extension cord or an additional MSO.
- P14 The battery inside the NIM Vital Console can only power the system for a short period of time. NIM Vital system shall be always connected to mains power for extended use and loss of power source would result in risk of loss of monitoring.
- P15 To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- P16 A baseline EMG response should be obtained with a stimulating probe once the nerve(s) of interest are identified. Nerve integrity should be checked with a stimulating probe then compared to the baseline throughout the procedure.

NIM quick monitoring set-up

The following procedure for OR staff users is not meant to replace a complete understanding of this user's guide but may serve as a quick reminder of basic NIM setup, monitoring screens, and monitoring sounds. Refer to the "MONITORING tab" topic for more information.

1. Place the NIM Vital system within the surgeon's view and plug the NIM power cord into the dedicated outlet.
2. Press  on the bottom right of the console screen.
3. The system automatically runs the self-test until you hear the bleedle tone.
4. On the NIM Vital Setup screen, select the default profile followed by a surgical specialty and specific procedure to be monitored.
5. After selecting a procedure, the Connect Devices screen appears on the NIM Vital Setup screen. Undock the patient interface from the console base. Wait for the solid blue paired wireless symbol to appear on the patient interface box which indicates a wireless connection.

Note: If the wireless is not available, plug in the PI cord between the console and the PI. The console connector is located on the back-left side and is marked by a PI box symbol (refer to the "Buttons and indicators" and "Symbols" topics for more information).

Anesthesia Note: Do not use long-term paralyzing anesthetics to ensure proper EMG monitoring.

6. After the patient interface connects to the NIM Vital system, press  to progress to the Check Electrode screen. The Electrode placement guide appears indicating how to connect the system.
7. Ensure the date and time are synchronized with the OR clock. **Optional:** Enter case information using the Edit Case information button located on the top right of the screen.
8. Following the illustration on the screen, connect all color-coded cables (subdermal electrodes or EMG tube, ground, and STIM 1 return [red with white wire]) to the corresponding patient interface.

Note: The automatic electrode check shows one of the following for each connection: green bars with white checkmarks confirm the integrity of the connections. Red bars with white Xs indicate a bad connection. White, spinning icons indicate the system is checking the connection.

9. Press  or the MONITORING tab to begin monitoring on the Monitoring screen. The NIM Vital system is ready to monitor with its default settings.
10. After the patient is draped, connect a sterile NIM monopolar stimulator probe to the STIM 1 jack (color-coded black plug and black socket).

The basics of what you will see and hear during monitoring

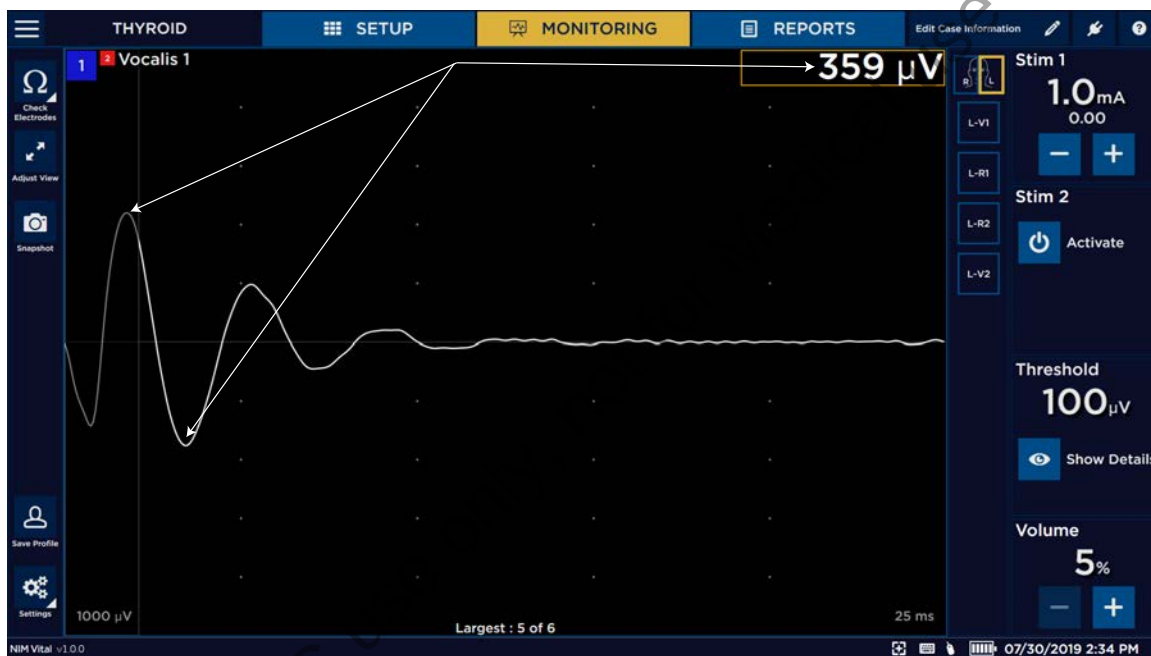
The following procedure is meant to be completed by surgeons and OR staff users. Refer to the “MONITORING tab” topic for more information.

1. The surgeon uses the stimulator probe as the primary means to confirm the location and integrity of the nerves. Refer to warning W3.

One of two events may occur:

- The NIM system sounds a “Current Delivery” tone (a short tweedle sound) when contacting tissue, but not evoking a response. The tone indicates the set current is being delivered.
- Upon stimulation of the nerve, EMG is evoked, and the default audible tone is heard at ~4X/sec and raw EMG (thump, thump, thump). The EMG event is also shown on the monitoring screen as a waveform (figure 1).

Figure 1. Biphasic EMG waveform showing peak-to-peak measurement or amplitude



Note: the latency is measured from the stimulus from the left-hand side of the screen to the start of the EMG waveform.

2. Between probe uses the NIM is passively monitoring muscles and you may hear changes in the EMG, or mechanically evoked nerve responses that look and sound similar to stimulator evoked nerve responses. **Note:** The NIM may not alert the surgeon to all types of surgical manipulation of the nerve including sharp, surgical resection.
3. The surgeon confirms the integrity of the nerve using the probe throughout the entire procedure and at the end of the procedure. Refer to the table of contents “Audio - understanding what you hear” topic for more information.

Unboxing and installing the system

Check off the contents of the box against the packing slip. If incomplete or damaged, notify customer service at +1 800 874 5797. If the container is damaged or cushioning material shows stress, notify the carrier and customer service. Keep the shipping materials for carrier inspection.

After unpacking, save the cartons and packing material. If the NIM Vital system is to be shipped, the shipping package will provide proper protection.

Setting up the NIM Vital console

1. Remove the NIM Vital console from its shipping box.
2. Place the console on a stable counter or on the NIM Vital cart (if purchased). Refer to the “Setting up the NIM Vital cart” topic for more information.
3. Install the NIM Vital battery that shipped separately from the NIM Vital system. Refer to the “Installing the NIM Vital battery” topic for more information.
4. While facing the NIM Vital console’s front, gently pull the monitor up and toward you until it reaches the desired placement.
5. Rotate the monitor until the monitor screen is facing you.
6. If you are not using the cart, plug the power cord into the socket on the rear of the console.

Installing the NIM Vital battery

1. Remove the two screws on the information plate located on the back of the console base between the patient interface cradles using a phillips head screwdriver.
2. Insert the battery into the battery compartment with the pull tab on the battery facing up until you feel the battery engage.
3. Replace the information plate by placing the lip on the bottom of the plate into the bottom edge of the battery compartment.
4. Align the two screw holes and replace the phillips head screws using a screwdriver.

Setting up the NIM Vital cart

1. Remove the cart from its shipping crate. Refer to the uncrating instructions that ship with the shipping crate.
2. At the top of the cart, remove the tape securing the power cord and move it out of the way.
3. Place the NIM Vital console onto the top of the cart making sure to align the two pins on the cart with the holes in the bottom of the console.
4. Reach underneath the console tray and hand-tighten the securing knob.
5. Plug it into the console.
6. Plug the 20 ft Mains power cord into the multi-socket outlet (MSO) located in the lower drawer of the cart.
7. Secure the cord using the cable clamp in the lower drawer using a phillips head screwdriver.

If you plan to add a printer to the bottom shelf of the cart, refer to the “Installing the power isolator” topic.

Connecting NIM Vital accessories

Place the patient interface boxes into the cradles to begin charging them.

First time user interface setup

Refer to the “SETUP tab” topic for more information while performing a basic setup.

1. Connect unit to AC power.
2. Turn power switch On.
3. After the system completes the self-test, press .
4. Select Language (English is default).
5. Press  or  to close Global settings.

Set the time zone, date, time, and date/time format

1. During setup, press time/date in the lower right corner of the screen.
The System Date Time Settings dialog box appears.
2. Select the time zone from the Time Zone drop-down menu.
3. Select the date/time format using the Date Time Format drop-down list.
4. Press  and select the correct date from the calendar.
5. Select the time using the Hours/Minutes/Seconds drop-down lists.
6. Do one of the following:
 - Press **[Confirm]** and the system saves the information.
 - Press **[Cancel]** to exit without saving the information.

Create a surgeon profile

You can create a Surgeon profile from the Select Profile screen.

1. Click **[NEW]** on the initial setup screen.
The New Surgeon Profile dialog box appears.
2. Press the Enter Profile Name text box.
The electronic keyboard appears.
3. Type the name of the Surgeon profile.
4. Click **[CONFIRM]**.
The Edit Profile screen appears.
5. Select a procedure(s) from the Available Procedures lists using the tabs to navigate between specialties.
6. Click  to move the procedures to the Selected Procedures box.
7. Click **[Confirm]** to save the surgeon profile.
8. Do one of the following:
 - Select the profile and press  to continue with the new profile.
 - Press **[Edit]**, then select the new profile to return to the Edit Profile screen and modify the profile.
 - Select **[Delete]**, then select a profile and press **[CONFIRM]** or **[CANCEL]** to either confirm the removal of the profile or cancel the removal.

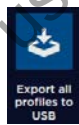
Saving to a surgeon profile

Once the user creates a surgeon profile and selects a procedure, the user can save the settings changes made during monitoring into the profile's procedure as preferences. Refer to the "Create a surgeon profile" and "Select a user profile" topics for additional information.

1. On the Monitoring screen, press .
2. After making changes, press  to save all current changes.
The system removes the save profile button once the system saves the settings until the next time the user changes settings. The next time the user selects the procedure from the surgeon profile, an asterisks appears next to its name to indicate it has been customized and loads with all of the saved surgeon preferences. **Note:** This procedure does not save patient case information.

Save custom profiles to a USB drive

1. Navigate to the Profile Selection screen.
2. Insert a USB drive.



The system detects the USB drive and  appears.

3. Click the button.
The system saves all custom profiles.

Import custom profiles from a USB drive

1. Navigate to the Profile Selection screen.
2. Insert USB drive containing saved custom profiles.



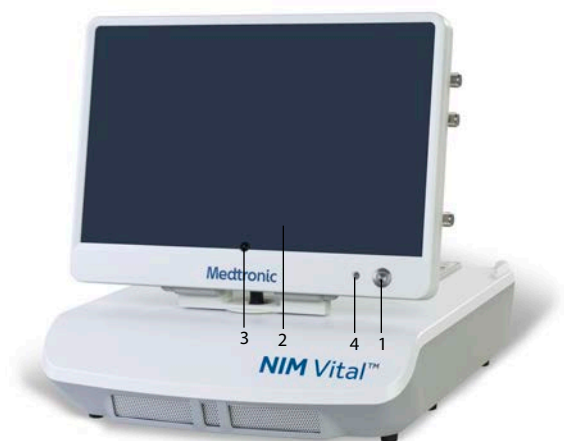
The system detects the USB drive and  appears.

3. Click the button.
The system saves all the custom profiles on the console. Refer to the "Select a user profile" topic for additional information.

Components

Console front

- 1 Power button.
- 2 Screen.
- 3 Camera.
- 4 Microphone.



Console left side

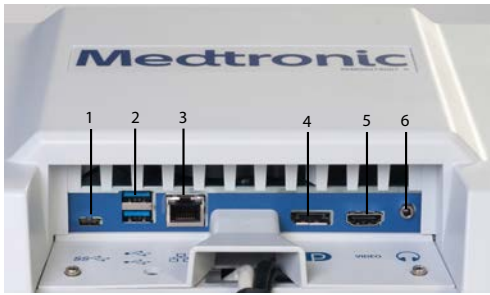
- 1 USB-A (3.0) port.
- 2 USB-C (3.0) port.



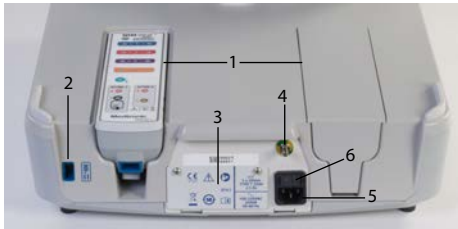
Console right side

- 1 STIM 1 adjustment knob.
- 2 STIM 2 adjustment knob.
- 3 Volume knob.
- 4 Mute detector adaptor connection.



Console screen bottom

- 1 USB-C.
- 2 Dual USB-A.
- 3 Ethernet.
- 4 Display port.
- 5 HDMI. Not specifically for use with a microscope.
- 6 Audio (headphones).

Console base back

- 1 Patient interface docking cradles.
- 2 Wired patient interface box port.
- 3 Battery door.
- 4 Earth ground (P.O.A.G.).
- 5 Power inlet.
- 6 Console fuses.

FCC use only, not for Medical use



Patient Interface

- 1 Electrode ground. Signal return for patient electrodes.
- 2 Stimulating Instrument Jack or Stimulator Probes (Monopolar or Bipolar).
- 3 Incrementing Probe Control Jack. Connects Incrementing Probe controls to the NIM Vital.
- 4 Stimulus (out) Jack, negative (-).
- 5 Stimulus Return, positive (+).
- 6 Patient Interface to console connector.
- 7 The Patient Interface fuses are for Stimulator Output and specifically tested for ECU protection.
- 8 Positive Electrode Jacks. Positive electrodes have matching color-coded wires and plugs.
- 9 Negative Electrode Jacks. Negative electrodes have black wires and color-coded plugs.
- 10 Patient Interface Clips.
- 11 Docking connector.
- 12 Battery indicator LED.
- 13 Fuse indicator LED.
- 14 Power button.
- 15 Spare fuses.

Incrementing Probe Adapter

- 1 Connect to Incrementing probe.
- 2 Connect to PI box.

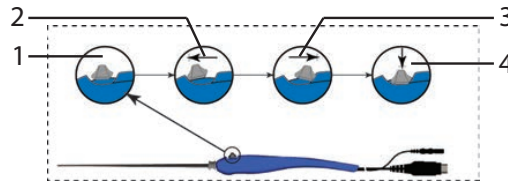
Note: For use with prass incrementing probe (CFN 8225825 and CFN 8225490)

Incrementing probe

The (single use) incrementing probe provides the surgeon with the means to adjust the stimulation current at the surgical site. Refer

to the “Probe-based functions” for additional information on specific button functions.

1. Toggle button normal or at rest.
2. Increase.
3. Decrease.
4. The user can perform the following functions with the toggle button:
 - Momentary press saves the current screen to memory (for reports) and to a selected peripheral device (printer and/or USB flash drive) if the user selected that option in the settings area.
 - Press and hold opens a menu on the user interface with more options.



Power Cords

1895825	Power Cord, 6 Meter, EU
1897821	Power Cord, 6 Meter Standard, U.S.
1895824	Power Cord, 6 Meter, U.K.
1895823	Power Cord, Japan, 100 V

Software overview

Turning the system on

1. Press .

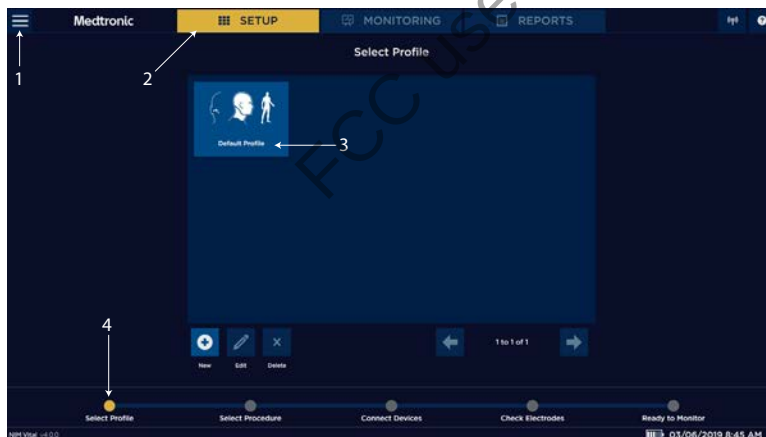
The splash screen appears and automatically performs an internal integrity check. Once the system completes its integrity check, the Select Profile screen appears.

The system automatically performs an internal integrity check on the system and batteries for the console and patient interface, if docked, each time you turn the NIM Vital system ON. If the system encounters any errors during the self-test, the user will not be able to use the NIM Vital system. Refer to the “Maintenance schedule” and “Troubleshooting” topics for more information.

SETUP tab

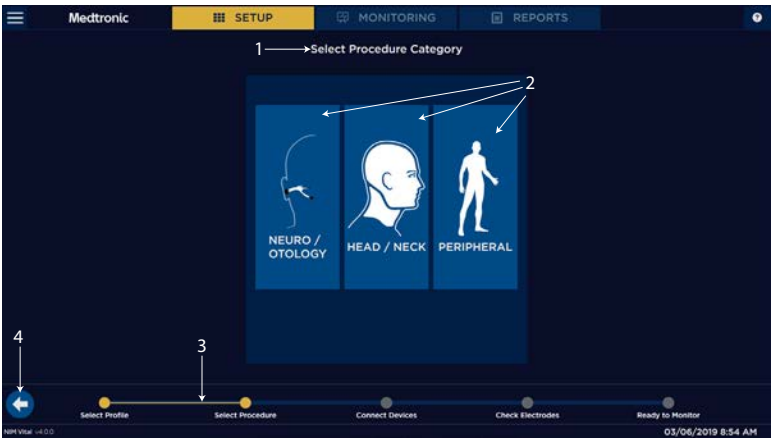
The setup tab consists of the following screens:

Screen 1. Select Profile



- 1 Global settings.
- 2 SETUP tab.
- 3 Profile options.
- 4 Progress tracking bar.

Screen 2. Select Category



- 1 Select Procedure Category (if the user selected the default profile on the previous screen).
- 2 Specialties.
- 3 Progress tracking bar.
- 4 Return to previous screen.

Screen 3. Select Procedure



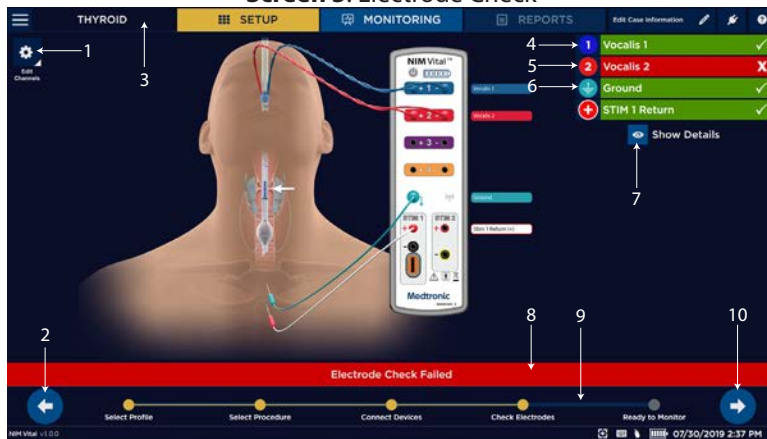
- 1 Go back.
- 2 Selected category.
- 3 Select procedure.
- 4 Progress tracking bar.

Screen 4. Connect Devices



- 1 Go back to previous setup screen.
- 2 Selected procedure.
- 3 Go to next setup screen.
- 4 Status of the patient interface box (connected).
- 5 Progress tracking bar.

Screen 5. Electrode Check



- 1 Edit Channels.
- 2 Go back to previous setup screen.
- 3 Selected procedure.
- 4 Channel 1 electrode check passed.
- 5 Channel 2 electrode check failed.
- 6 Ground check passed.
- 7 Electrode check show/hide details.
- 8 Electrode check status bar.
- 9 Progress Tracking bar.
- 10 Proceed to monitoring.

Select user profiles or default categories

The SETUP screen appears after the system has completed an internal integrity check via the splash screen.

Select a default procedure

During the setup, you can keep track of the progress of setting up the default procedure using the yellow indicator bar at the bottom of the screen.

1. Press **[Default Profile]** on the touchscreen.

The system progresses to the next screen showing the default categories.

2. Select a default category.

3. Press one of the pre-defined procedures on the touchscreen.

The "Connect Devices" screen appears.

4. Undock the patient interface box. If no patient interface box is docked, dock one to register it with the NIM Vital system, then undock it.

The system automatically begins connecting the patient interface box. The Status: Connected message appears with a green border around the Patient Interface selection box and the paired blue wireless symbol illuminates on the patient interface box.

Note: If a wireless connection is not available, plug in the patient interface cable between the NIM Vital console and the PI box. The console connector is located on the back, left side and is marked by a PI box symbol (refer to the "Buttons and indicators" and "Symbols" topics for more information).

5. Press  on the bottom right side of the screen. **Note:** if you press  without connecting to a patient interface box (wired or wirelessly), the Notification dialog box appears with the message, "Monitoring is unavailable until the patient interface is connected. Continue?" The user must select **[CONFIRM]** or **[CANCEL]** before proceeding to the next screen.

The Check Electrode screen appears and shows the status of the electrode check.

6. Place the electrodes on the patient according to the diagram. Refer to the "Help" topic for additional information.

7. Press  on the right of the screen, or the MONITORING tab, to progress to the MONITORING screen.

Note: If you progress to the MONITORING screen without passing the electrode check, the warning message, "Impedance check has failed: Continue?" appears. The user must select **[CONFIRM]** or **[CANCEL]** before proceeding to the MONITORING screen.

Select a user profile

During the initial setup, you can keep track of the progress of setting up the default procedure using the yellow indicator bar at the bottom of the screen.

1. Select a pre-defined user profile. Refer to the "Create a surgeon profile" topic for additional information.

2. Press one of the pre-defined procedures on the touchscreen.

The Connect Devices screen appears. Refer to the "Connect Devices" topic for more information.

3. Undock the patient interface box.

The system automatically begins connecting the patient interface box. The Status: Connected message appears with a green border surrounding the Patient Interface selection box and the paired blue wireless symbol illuminates on the patient interface box.

Note: If a wireless connection is not available, plug in the patient interface cable between the NIM Vital console and the patient interface. The console connector is located on the back, left side and is marked by a patient interface symbol (refer to the “Buttons and indicators” and “Symbols” topics for more information).

4. Press  on the bottom right of the screen.

The Check Electrode screen appears and shows the status of the electrode check. Refer to the “Check Electrode screen” topic for additional information.

5. Place the electrodes according to the diagram. Refer to the “Electrode placement” topic for additional information.

6. Press  on the bottom right of the screen, or the MONITORING tab, to progress to the MONITORING screen.

Note: If you progress to the MONITORING screen without passing the electrode check, the warning message, “Impedance check has failed: Continue?” appears. The user must select **[CONFIRM]** or **[CANCEL]** before proceeding to the MONITORING screen.

The Monitoring screen appears.

Connect Devices screen

The following information is located on the Connect Devices screen.

The  symbol appears in the top right-hand corner of the screen when the patient interface box is cradled.

Wireless connection

Undocking the patient interface box initiates an automatic wireless connection to the console. The Status: Connected message appears with a green border around the Connect device box and the paired light will illuminate on the patient interface box.

The  symbol appears in the top right-hand corner of the screen when the patient interface box is connected wirelessly.

Note: Only undock the patient interface box you plan to use. Once undocked, the system automatically connects to the patient interface box that is undocked first. If you need to switch connection to the other patient interface box, replace the first patient interface box into its dock and undock the other patient interface box.

Wired connection

If a wireless connection is not available, plug in the patient interface box cable between the NIM Vital console and the patient interface box. The console connector is located on the back-left side and is marked by a patient interface box symbol (refer to the “Buttons and indicators” and “Symbols” topics for more information).

The  symbol appears in the top right-hand corner of the screen when the patient interface box is connected with a cable.

Check Electrode screen

The Check Electrode screen assists you with electrode placement.

The surgeon should insert the electrodes into the appropriate target muscle location innervated by the monitored nerve. The surgeon should then insert the ground electrode (green) and the stim return (white) as shown in the electrode placement diagram. Once the surgeon places the electrodes on the patient, the surgeon needs to insert the other end of the electrodes into the patient interface box to complete the electrode setup. NIM Vital systems include nerve and electrode placement guides that are color-coded to help reduce confusion.

The electrode placement guide contains some, but not all, possible electrode placements. Press  on the SETUP screen for an additional list of electrode placement guides (Refer to the help section for electrode placement diagrams).

When the system runs an electrode check, this screen shows the electrodes the system is testing.

- Green bar with white check marks indicate the electrode is connected to the corresponding channel.
- Red bar with white Xs indicate the connection is incomplete.
- A spinning icon indicates the system is calculating.

If you connected all the electrodes properly, all channels will have green check marks indicating the electrode check has passed.

Press  to proceed to monitoring.

STIM 1, STIM 2, Ground - If a spinning icon appears after the system has completed the test, no channel electrode or ground was connected, so the system reads that as a no value (impedance). You must connect at least one channel electrode and ground for the system to read STIM 1, STIM 2, and ground impedance.

If the user needs detailed values, press  to show the more detailed impedance menu. If showing details, use the drop-down menus on the Electrode Type panel (the only screen where you can adjust the electrode type in use) to select the type of electrode you want to use. Refer to the “Troubleshooting” topic for information on electrode troubleshooting.

Note:

- You can bypass the next place electrodes screen by selecting the MONITORING tab or .
- If you bypass the Check Electrode screen, no pre-surgery impedance values of the electrodes, ground, or STIM returns are available for printed/saved reports.
- If the patient interface, electrodes, ground, or STIM returns were disconnected when you exit the Check Electrode screen, any printed reports will show a failure of the impedance values of the disconnected item(s).
- There is no STIM status (blank) if you select Bipolar on the Probe Type (located in the Settings/Stimulation Panel).
- STIM 2 appears after you turn it on using the Activate button located on the main screen, or by selecting the STIM 2 from the drop-down list on the Stimulation Panel.

Edit channel names

From the Electrode Check page, the user can open the Edit Channels panel. This panel enables adding, editing, and removing channels from the selected procedure. Once changes have been made, select **[Apply Changes]** to use the settings in the current procedure only, or select **[Save to Profile]** to save the channels for current and future use. The user can also reset changes to the latest save point (or to default in a default procedure) by selecting **[Reset to Saved]**.

**MONITORING tab**

Access the MONITORING screen by pressing MONITORING on the top tool bar, or .

The main monitoring screen helps provide EMG information to the surgeons. The EMG information can be free running and stimulation evoked.

EMG Display**Free-running EMG**

If the user has Event Capture disabled on the Threshold panel, the NIM Vital system continuously displays free running EMG picked up by the electrodes. If the user enables Event Capture, the system only displays values above the threshold values.

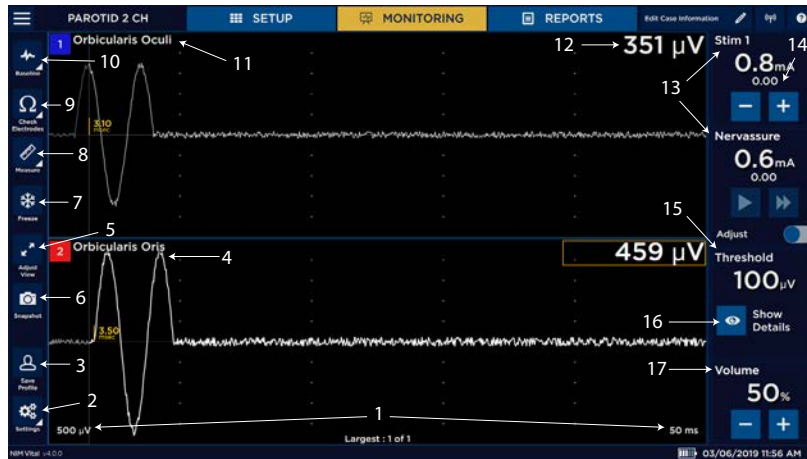
Evoked EMG

The surgeon can use the stimulator probe to confirm the location and integrity of the nerves. When the surgeon touches the surgical site with the STIM probes, one of the two following events happen:

You can expect one of two events:

- **Stimulation with an EMG response** - This event occurs when the stimulation device touches healthy nerve tissue that is capable of propagating an action potential that reaches its innervated muscle tissue. The surgeon will notice the following on the console:
 - Audio (thump, thump, thump, thump)
 - Biphasic wave form
 - An amplitude value
 - A STIM measured value
- **Stimulation of tissue, but no EMG response** - This event occurs when the stimulation device touches non-nerve tissue, or if the current delivered is not sufficient to propagate an action potential. The surgeon will notice the following on the console:
 - Hear the current delivery tone
 - See a STIM measured value

A detailed list and explanations of all the monitoring screen buttons are displayed below.



- 1 Scale. Displays screen scale settings.
- 2 Settings button.
- 3 Save Profile button (only when settings have been changed, but not saved into a profile).
- 4 Trace. Display stimulus nerve activity/inactivity.
- 5 Adjust view.
- 6 Snapshot button.
- 7 Freeze button (when activated).
- 8 Measure button (when activated).
- 9 Check Electrodes button.
- 10 Baseline button (only active if the user activates it on the settings panel).
- 11 Channel label. Displays the channel number and nerve being monitored.
- 12 Amplitude.
- 13 Stim panels.
- 14 Stim return value.
- 15 Threshold panel.
- 16 Show details button. Provides access to event capture and adjust threshold.
- 17 Volume panel. Adjust the system volume.

EMG display area

The amplitude displays activity level in microvolts on each channel:

- A box encloses the activity level of the highest channel.
- If there are multiple channel events, the box encloses the largest.
- If the system detects a signal (response) outside the range of the system's ability to measure (100,000 μV or higher), the system displays the "Out of Measurement Range" message.

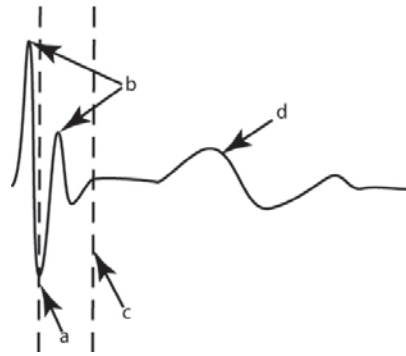
Recognizing stimulus artifacts

Stimulus artifact is a monitoring term for an artifact created by stimulus voltage delivered to the patient, which is picked up as feedback either internally or externally to the monitoring equipment. It is normally small and does not impact monitoring but can, under certain conditions, be displayed and sounded on the monitor. It is important to understand the NIM system's visual and audio feedback so as not to confuse the stimulus artifact with real EMG, or recognize if both the stimulus artifact and real EMG are present at the same time.

The on-screen stimulus artifact, when it appears on the monitoring panel display, is seen as an event (above or below threshold) which starts directly after the stimulus on the left side of the screen and proceeds for a duration into the EMG waveform detection area. The level of the artifact is directly proportional to the stimulus delivery and cannot be EMG because nerve signals need time propagate.

The stimulus artifact sound is the audio representation of stimulus artifact. It is a high frequency sound similar to cymbals and sounds like "ti - - tchi." It is unlike an EMG sound which is similar to a drum sound.

The stimulus rejection period enables you to filter the stimulus artifact (electric noise caused by stimulation) and all other signals in this period.



- a. Original Rejection Period setting.
- b. Stimulus Artifact.
- c. Move Rejection Period line to here to avoid artifact.
- d. EMG Response.

Understanding and recognizing other artifacts

The NIM Vital system features sophisticated artifact rejection technology designed to provide highly sensitive and accurate monitoring. However, there may be electrically generated signals in the range of true response that the NIM Vital system cannot differentiate. Refer to the “Troubleshooting” topic for more information.

Examples:

- A transcutaneous stimulator used by the anesthesiologist might generate an audible signal.
- Any external nerve locator/stimulator may not provide automatic synchronized muting with the NIM Vital system.
- Electrical leakage from faulty thermal cautery units. You can identify the spurious signals by their lack of surgical context (there was nothing the surgeon was doing at that moment that could have caused a true EMG response).
- If the recording electrodes and the stimulator (+) or (-) cables become tangled the resulting stimulus artifact might be spuriously detected as an EMG event. Be careful to route the recording electrodes away from stimulator cables.
- If/when wires must cross, they should cross at right angles. Never run other operating room cords/cables parallel to any of the NIM Vital system wires.
- The pace pulse generated by pacemakers may be detected and displayed by the NIM Vital system as a rhythmic artifact signal. This is caused by the electrode ground or stimulus return electrodes being in close proximity to the pacemaker or its lead wire(s). The artifact caused by the pacemaker may be reduced by repositioning the Electrode Ground and Stimulus Return electrodes to the top of the patient’s shoulder (the Acromion) (use shoulder opposite operated side). The Electrode Ground (green plug green wire) and Stimulus Return (red plug white wire) electrodes should be positioned about 5 cm apart, green Proximal, red Distal. Once the electrodes are repositioned, verify that the Stimulus Return and Ground Impedances are within tolerance (review Setup Mode/Electrode Check).
- There may also be interference-generated signals in the range of true response that the NIM Vital system cannot differentiate. An example of this type of artifact signal could occur when the surgeon strikes two metal instruments together within the surgical field, such as a metal suction tube with a dissecting tool. Such signals are typically monophasic with fast onset and offset. That is, the signals appear on the screen as sharply peaked responses in one direction only.
- While these artifacts are significantly different in waveform appearance from true EMG events (which have a biphasic waveform), the magnitudes of these signals can reach several hundred microvolts causing the event tone to sound. However, the surgeon is usually aware when two instruments have been struck together and can, therefore, relate such “false positive” responses to the surgical context.

MONITORING tab right panel

STIM 1

The STIM 1 panel displays the following settings:

- Stimulation setting (large numbers in mA units)
- Measured value (small numbers)
- Adjustment buttons for the STIM 1 current settings.
- You can adjust the current of the stimulator plugged into the STIM 1 port using **+** or **-**, or the knobs located on the side of the monitor. Refer to the “Stimulation panel” topic for more information.

STIM 2

If the STIM 2 panel is inactive, it displays the Activate button. If active as a second stimulator, its display is the same as STIM 1.

You can adjust the current of the stimulator plugged into the STIM 2 port using **+** or **-**, or the knobs located on the side of the monitor. Refer to the “Stimulation panel” topic for additional information.

Threshold

Use threshold to define where EMG activity becomes significant. EMG activity exceeding the threshold is defined as an event and results in event tones. Any activity below this threshold does not trigger an audible event.

Show details/event capture

The Threshold panel displays the threshold settings and enables you to adjust the setting level (in 5, 10, or 100 μV increments depending on the Threshold value). Press  to access the threshold settings and then press  or  to increase or decrease the value as desired. The system displays the setting in micro-Volts. Press  to access the Event Capture toggle button. When event capture is enabled, the system captures any waveform above the event threshold. The event capture stays on the screen until the next waveform above the threshold appears.

Volume

The Volume panel displays an adjustable volume setting.

You can adjust sound levels using  or  in 5% increments. The default setting is 50.

MONITORING tab Left panel

The NIM Vital left panel contains the following items you can use to adjust the monitoring screen.

Baseline

You can create a baseline and then manually trend future stimulations against the baseline using the trend function. For Nervassure continuous monitoring, select a Nervassure procedure on the Select Procedure screen during initial setup. For non-Nervassure procedures, you can use the NerveTrend function (currently available in thyroid procedures) which works similarly to the trend function.

Electrode Check button

The Electrode Check panel checks the integrity of the patient to the patient interface connections.



- 1 Electrode check button. Opens/closes Electrode Check panel.
- 2 STIM 1, STIM 2, and Ground status fields.
- 3 Electrode Show Details status field:
 - Green check marks. Green check marks appear when the electrodes are connected correctly.
 - Spinning icons. Spinning icons appear while the system runs the electrode test.
 - Red X. A red X es are connected incorrectly/fail.
- 4 The system disables monitoring when the Electrode Check panel is open.
- 5 Show/hide details button.

Note:

- There is no STIM status (blank) if you select Bipolar on the Type Panel (located in the Advanced Settings/Stimulation Panel).
- There is no STIM 2 status (blank) if a single stimulator is connected.
- STIM 1, STIM 2, Ground - If a spinning icon a question mark appears after the system has completed the test, no channel electrode or ground was connected, so the system reads that as a no value (impedance). You must connect at least one channel electrode and ground for the system to read STIM 1, STIM 2, and ground impedance.

Electrode check

You can perform an electrode check on the MONITORING screen using .

Electrode Check panel pass/fail

The system measures impedance values of the electrodes to the patient to confirm the integrity of the connection. The electrode check only indicates that the electrodes are making contact with the patient's tissue. The system does not confirm that the needle is inserted into the correct muscle. The user is responsible for ensuring the electrodes are placed, or inserted into the target muscles.



The above graphic illustrates that all channels have passed the electrode check. A red bar with a white X will replace the green bar with a white checkmark if a channel(s) fails.

Electrode Check Show Details button

Press the Show Details button to see the actual impedance values. Refer to the "Troubleshooting" topic for more information.



Note: When you select , the system displays the normal electrode impedance limits if the number of channels is less than six.

Measure

When activated, press  to enable and adjust the measurement cursor.

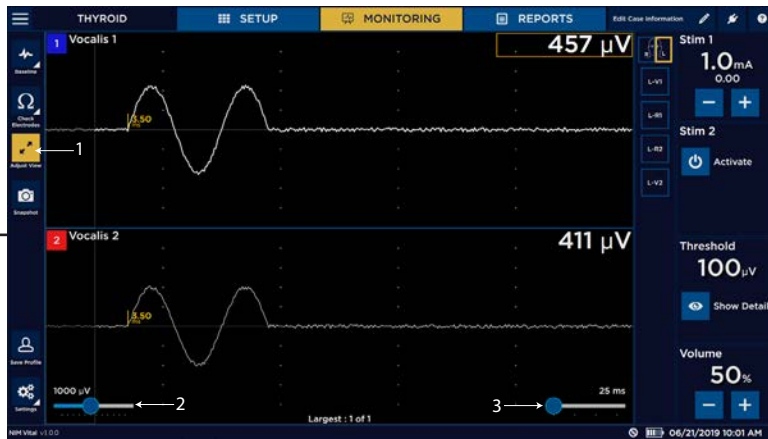
1. Enable the Measurement cursor on the main screen.
2. Select the cursor type. This determines where the cursor is initially displayed.
3. Adjust the cursor position.

Freeze

When activated, press  to freeze the current waveform on the screen. The main screen shows "Display is Frozen" during this time. Press  again to end the freeze. Monitoring continues in the background when enabled and monitoring sounds still play.

Adjust view

Press  to adjust the scale (Y-axis μV [amplitude] and x-axis mS [milli-seconds]).



- 1 Adjust View button.
 - 2 The vertical portion of the EMG display represents peak-to-peak amplitude. You can adjust the scale. The vertical screen is divided into equal sections per channel with 1/2 of each channel positive and 1/2 negative. Each channel is separated by a solid blue line.
 - 3 Time scale is represented by the horizontal portion of the EMG display and is adjustable. The screen is divided into equal sections. This differs from the "Amplitude scale" in that the "Time scale" selection is the entire horizontal portion of the screen.
- Note:** Changing either scale only affects how the data appears on the screen. It does not modify the sensitivity of the unit.

Snapshot

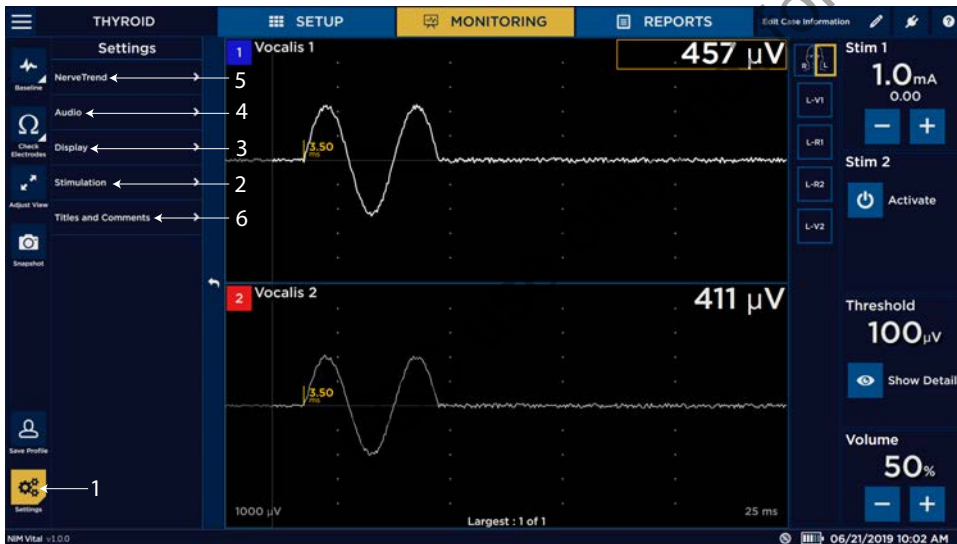
Use the Snapshot Button to save the current screen to memory (for reports). Based on options selected in Settings/Display, taking a snapshot can also ask for additional comments, print, and/or save to file on a connected USB.

Save Profile

Press **[Save Profile]** to save any current settings changes to a user profile. If the user is in a default profile pressing **[Save Profile]** asks the user to enter a new profile name and automatically adds the procedure to the profile. If the user is in a custom profile pressing **[Save Profile]** updates existing stored procedure settings.

Settings

Use the Settings panel to access additional settings/advanced settings and monitoring features.



- 1 Settings button.
- 2 Stimulation settings.
- 3 Display settings.
- 4 Audio settings.
- 5 NerveTrend or Nervassure settings (only available in select procedures).
- 6 Titles and Comments.

NerveTrend (only available in select procedures)

NerveTrend enables users to manually track the status of a nerve over time. The system records EMG responses that the user captures and plots over time using a graph.

Creating a NerveTrend baseline

1. Press .
2. Select Display.
3. Expand Additional Features.
4. Toggle Enable NerveTrend to On.

5. Press .

The NIM Vital system performs a number of measurements (minimum of 20) and shows the results for channels one and/or two with the amplitude and latency (if enabled).

6. Do one of the following:

- Press **[Cancel]** to return to MONITORING without creating a baseline measurement.
- Press **[Re-evaluate]** to direct the system to restart the baseline measurement.
- Press **[Continue]** to use the system's measurements.

If you pressed (insert continue button), the Operating Side panel appears.

7. Select an operating side which auto-generates as session title.

8. Change the session title or add session comments, if desired.

9. Press **[Accept]**.

Using the NerveTrend feature

1. Identify a proximal location on the nerve at risk.
2. Stimulate the nerve at the proximal location using the supramaximal stimulus value.
3. Initiate a NerveTrend baseline. Refer to the "Probe-based functions" and "NerveTrend" topics for additional information.
4. After a successful baseline acquisition, stimulate the same anatomical location at the same stimulus intensity and document the EMG response on the graph using the incrementing probe buttons or the Trend button on the NIM Vital system.

Note: the user can repeat this step multiple times throughout the procedure to visualize a change in the nerve function.

NIM Vital bottom panel

The bottom panel of the NIM Vital displays the following informational symbols.



- 1 Data recording (on).
- 2 System is running on console battery (or No Mains power connected).
- 3 Take a screenshot.
- 4 Patient interface battery status.
- 5 Date/time (settings if in Setup).

Battery status

When The user is connected via wireless, he/she can view the battery status using . The battery indicator enables the user to see the remaining battery in the Patient Interface. A lightning bolt icon appears on the bottom right of the display when the battery is charging.

Recording icon

If the user has enabled data recording, the recording icon appears on the bottom panel until the user turns off the setting.

Console battery icon

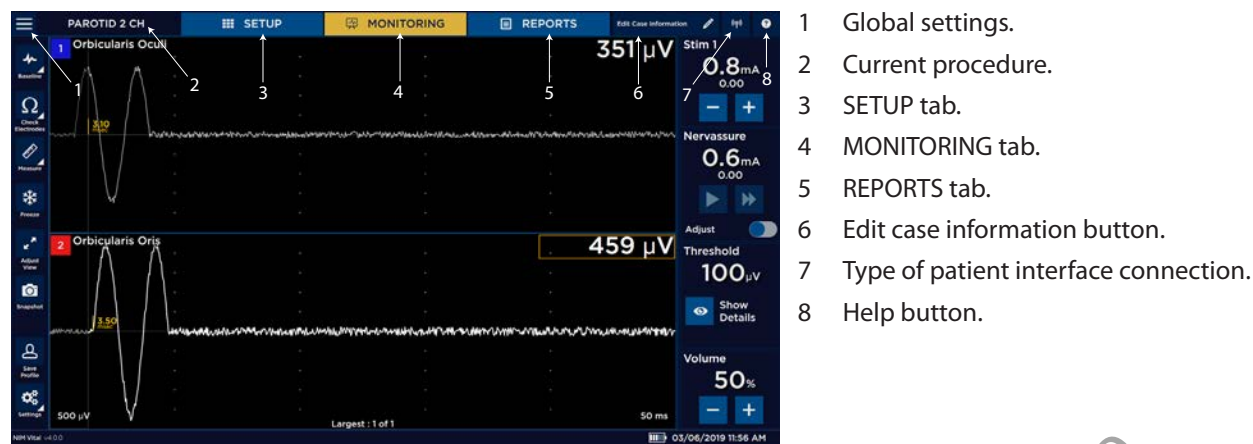
The console battery icon slowly pulses when the console detects that it has lost main A/C power. It remains until the console detects it has regained A/C power.

Screenshot icon

The screenshot icon appears when the console detects a mounted, approved USB. Taking a screenshot captures the entire screen (not just a waveform) and saves it directly to the USB.

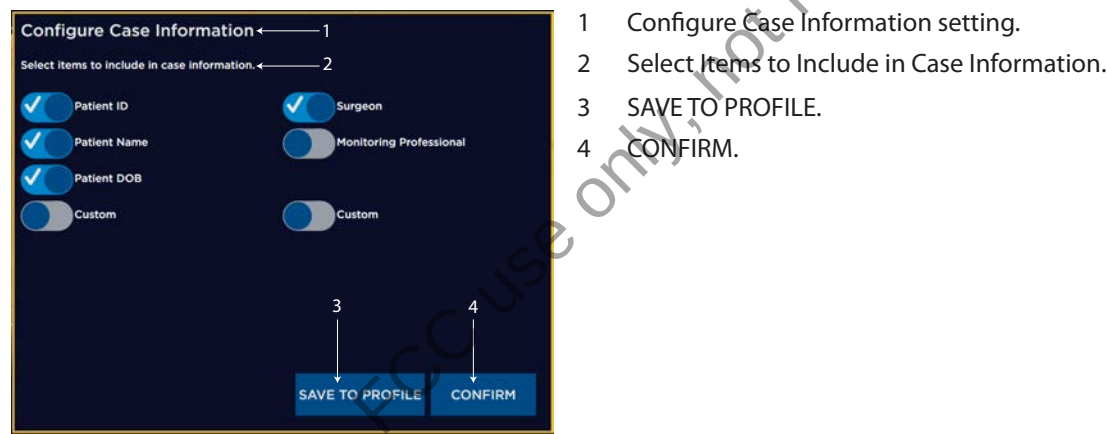
NIM Vital top panel

You can view, add, and update patient information using the Edit case information button located on the top panel of the NIM Vital. You can also access the NIM Vital Help screen and view the connected devices.



Edit/configure case information button

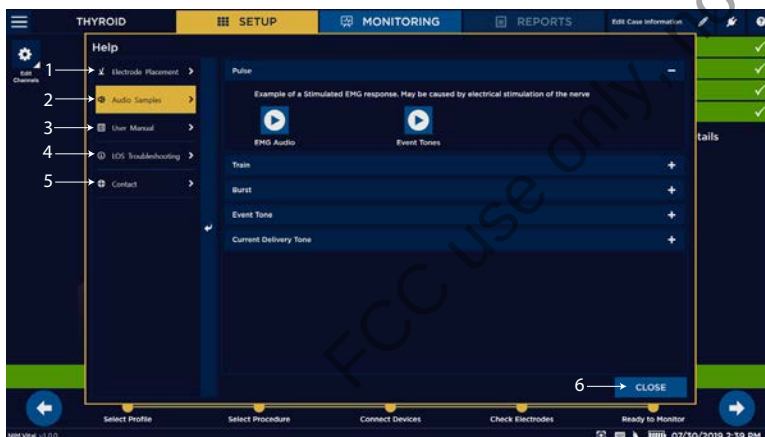
The Configure case information setting enables the user to choose which fields appear on the Edit case information panel. The Edit case information panel opens when you press the Edit Case Information button. Use this screen to enter data into preselected data fields. The user can modify the Data fields displayed by selecting the icon on the top left of the Edit case information panel. In the Configure Case Information window, the user can turn on/off each data field for display in the Edit case information panel. Select **[Save to Profile]** to keep the changes in a surgeon profile, or **[Confirm]** to save the changes for the current case.



- 1 Edit Case Information. Press any of the information fields to open the keyboard for data entry. Changes are saved automatically.
- 2 Patient ID.
- 3 First Name.
- 4 Last Name.
- 5 Date of Birth.
- 6 Profile Name.
- 7 Close the Edit Case Information screen.

1. From the MONITORING screen, press the Edit Case Information button.
The Case Information screen appears.
2. Press the Surgeon box and type the surgeon information using the on screen or attached keyboard.
3. Repeat step 2 and 3 for the following information depending on configuration:
 - Patient ID
 - Patient Name
 - Patient DOB
 - Notes
4. Press the reverse arrow button on the right side panel.
The system returns you to the previous screen.

Help



- 1 Electrode Placement.
- 2 Audio Samples.
- 3 User Manual.
- 4 LOS Troubleshooting.
- 5 Contact.
- 6 Close Button.

The Help screen displays help graphics for locating electrodes, sample audio sounds, an electronic version of the IFU, LOS troubleshooting, and contact information.

You can use the Help screen to view electrode placement graphics which aids in the electrode placement and sample audio sounds.

View Electrode placement using the Help screen

You can use the Electrode Placement tab on the Help screen to view electrode placement graphics.

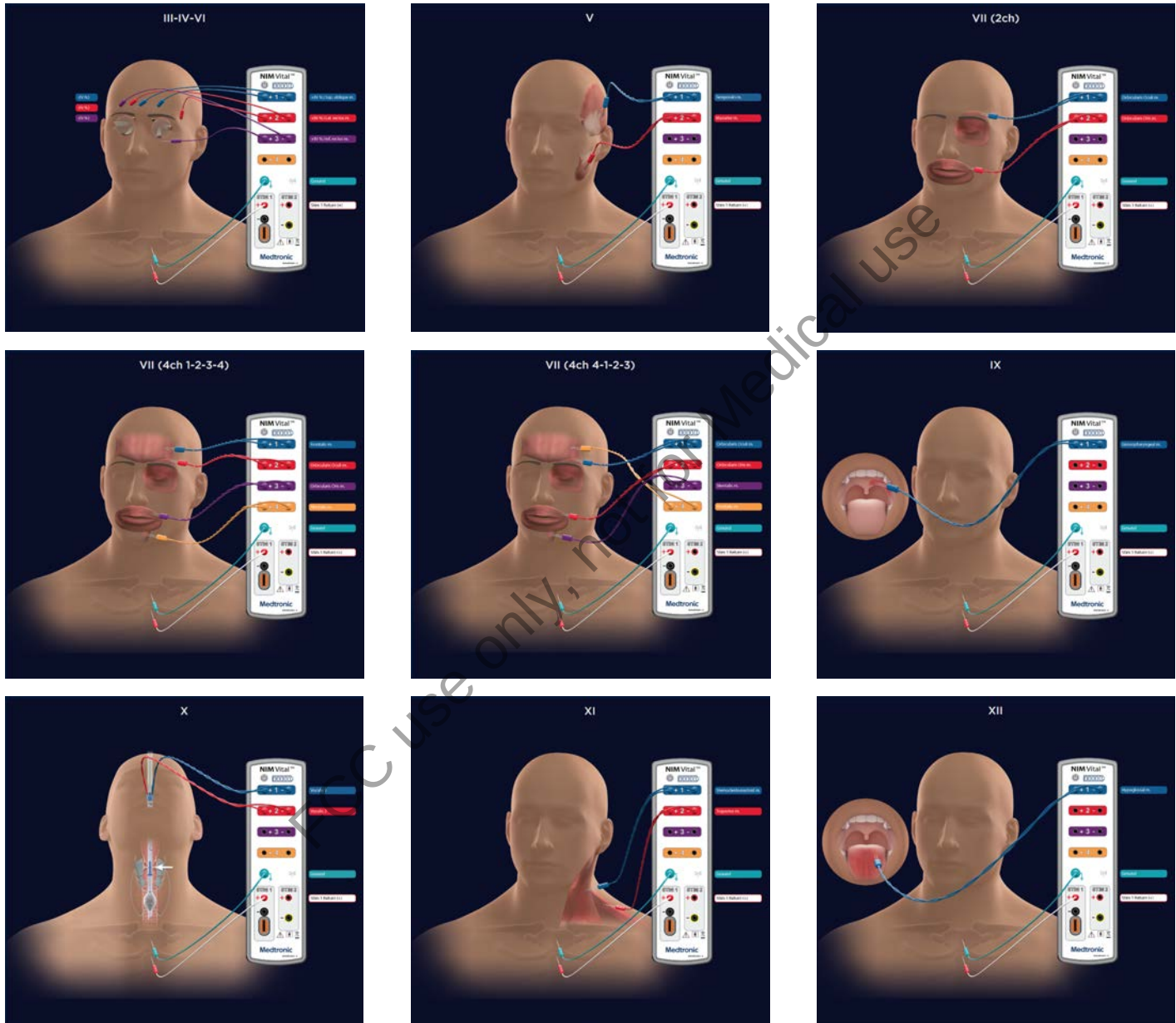
1. In the top right-hand corner of the screen, press .
The Help screen appears.
2. Press **[Electrode Placement]**
3. Place electrodes according to the appropriate help graphic.
4. Press **[Close]** to return to the current screen.

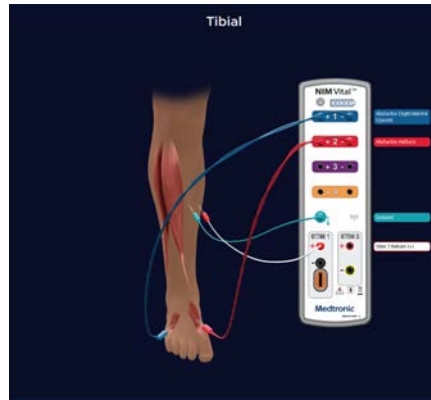
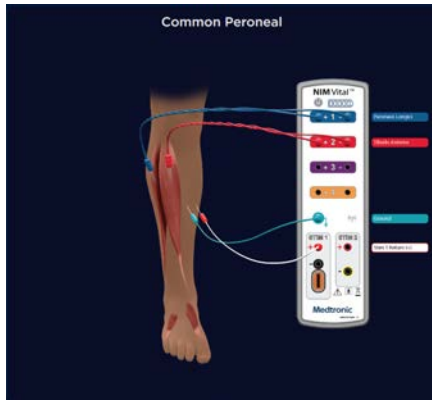
Note: When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

Electrode placement

The surgeon should insert the electrodes into the appropriate muscle location innervated by the monitored nerve. The surgeon should then insert the ground electrode (green) and the stim return (white) as shown in the electrode placement diagram. Once the surgeon places the electrodes on the patient, the surgeon needs to insert the other end of the electrodes into the patient interface box to complete the electrode setup. NIM Vital systems include nerve and electrode placement guides that are color-coded to help reduce confusion.

The electrode placement guide contains some, but not all, possible electrode placements. Press  on the top right-hand corner of the screen for an additional list of electrode placement guides.





Listen to audio samples

You can use the Audio Samples tab on the Help screen to hear multiple types of audio.

1. On the SETUP screen, press  .
The Help screen appears.
2. Select the Audio Samples tab.
3. Select any of the following audio samples:
 - Pulse
 - Train
 - Burst
 - Event tone
 - Current Delivery tone

4. Press **[Close]** to return to the SETUP screen.

Note: When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

View the Instructions for Use

1. On the SETUP screen, press  .
The Help screen appears.
2. Select **[User Manual]**.
The Instructions for Use appears in the right pane.
3. Use the scroll bar on the right to scroll through the Instructions for Use.
4. Select **[DOWNLOAD]** (appears when the system detects a mounted, approved USB).
The system downloads the .pdf file to the USB drive.
5. Press **[Close]** to return to the current screen.

Note: When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

View the LOS troubleshooting information

1. In the top right-hand corner of the screen, press  .
The Help screen appears.
2. Press **[LOS Troubleshooting]**.
3. View the intraoperative LOS troubleshooting algorithm.
4. Press **[Close]** to return to the current screen.

Note: When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

View contact information

1. In the top right-hand corner of the screen, press  .
The Help screen appears.
2. Press **[Contact]**.
3. View Medtronic's contact information/Remote assistance.
4. Press **[Close]** to return to the current screen.

Note: When the user accesses the Help screen from the MONITORING screen, the system disables monitoring.

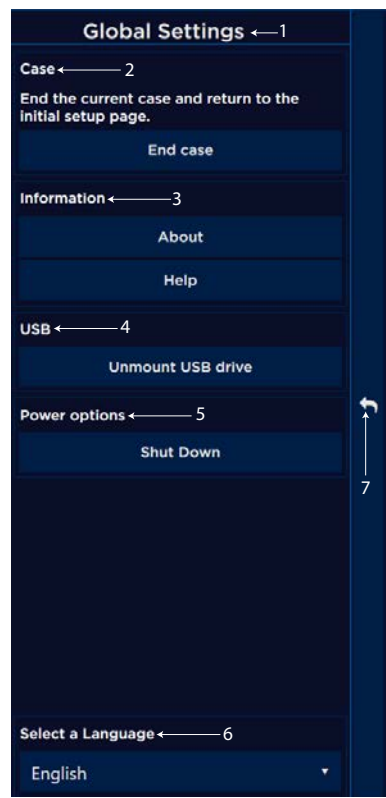
The user views the status of connected devices using . The Connected Devices panel provides detailed information on any connected patient interface whether it is docked, wirelessly connected, or wired.

Settings overview

Settings/Advanced settings adjustments made in the MONITORING mode lasts for the duration of the session unless the user presses **[Save Profile]** which saves the changes in a profile.

Global settings

Press  to access the Global Settings menu on any screens.



- 1 Global Settings screen.
- 2 Case panel. Press **[End case]** to end the current case and return to the Select Profiles screen.
- 3 Information panel. Access the following screens:
 - About
 - Help
- 4 USB panel (appears when the system detects an approved, mounted USB drive). Press **[Unmount USB drive]** to safely remove the USB drive.
- 5 Power options panel. Press **[Shut down]** to shut down the NIM Vital system.
- 6 Select a Language drop-down menu.
- 7 Close the Global settings panel.

Accessing settings

The user can only access/modify these settings from the MONITORING tab.

1. Press .
The Settings slider panel buttons appear (for example: ).
2. Select one of the following settings you want to adjust:
 - Nervassure (available only in Nervassure procedures)
 - NerveTrend (available when enabled in select procedures).
 - Audio.
 - Display.
 - Stimulation.
 - Titles and Comments

The panel slides out enabling you to make the adjustments.

Note: to open any Advanced Settings panel, the user must accept a dialog box that warns her/him about modifying advanced settings.

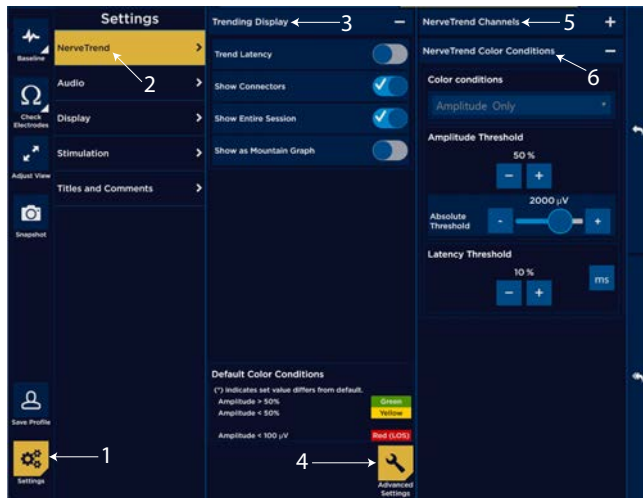
Nervassure settings panel

Refer to the “Nervassure settings” topic for additional information on Nervassure settings.

NerveTrend panel

The user must enable the NerveTrend panel using the Display panel. Go to Display/Additional Features/Enable NerveTrend toggle button. Once the user selects Enable NerveTrend “on”, the system shows the NerveTrend panel and the user can now access the NerveTrend settings/advanced settings.

Note: If you adjust the advanced settings, you will change the default characteristics of your NIM Vital. Only someone with knowledge of the advanced settings and how they impact your NIM Vital should make changes. If the user selects , the system displays a warning. The user must select **[Cancel]** or **[Confirm]** to return to settings or move forward to the advanced settings panel.



- 1 Settings button.
- 2 NerveTrend settings.
- 3 Trending Display expand/collapse menu:
 - Trend Latency.
 - Show connectors.
 - Show Entire Session.
 - Show as Mountain Graph.
- 4 NerveTrend settings advanced settings.
- 5 NerveTrend Channels.
- 6 NerveTrend Color Conditions expand/collapse menu:
 - Color Display Criteria.
 - Amplitude Threshold.
 - Absolute Threshold.
 - Latency Threshold.

On the NerveTrend settings panel you can select the following diverse types of trends to track:

- **Trending Display settings** - you can toggle on/off the following settings from the Trending Display settings panel:
 - Trend latency - Turn on latency for the trending area.
 - Show Connectors - Display connecting lines between trend points.
 - Show Entire Session – When enabled, the system displays the entire session in the trend window. When disabled, the trend is on a rolling timeframe that only shows the most recent portion of the trend session.
 - Show as Mountain Graph - Change the visual layout of the trend.
- **Color Conditions** - View the alarm color conditions. The Color conditions depend on the Alert Type setting (amplitude/latency). The user must enable Trend Latency to use a latency Alert Type.

NerveTrend advanced settings

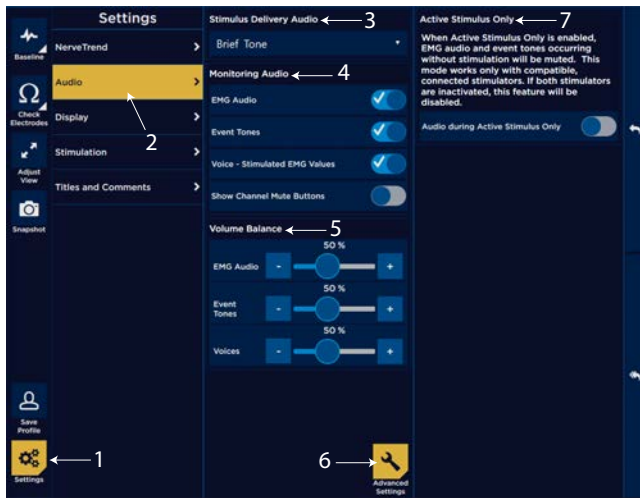
On the NerveTrend advanced settings panel you can adjust the following:

- **NerveTrend Channels** - Toggle on/off the EMG channels in the procedure to trend.
- **NerveTrend Color Conditions** - You can adjust the following color condition information:
 - Alert-Type (amplitude only, latency only, amplitude AND latency, Amplitude OR latency)
 - Amplitude Threshold
 - Latency Threshold

Audio panel

Refer to the “Audio – understanding what you hear” topic for more information on the Audio tab.

Note: If you adjust the advanced settings, you will change the default characteristics of your NIM Vital. Only someone with knowledge of the advanced settings and how they impact your NIM Vital should make changes. If the user selects , the system displays a warning. The user must select **[Cancel]** or **[Confirm]** to return to settings or move forward to the advanced settings panel.



- 1 Settings button.
- 2 Audio panel.
- 3 Stimulus Delivery Audio.
- 4 Monitoring EMG Audio:
 - EMG Audio.
 - Event Tones.
 - Voice - Stimulated EMG Values.
 - Show Channel Mute Button.
- 5 Volume Balance:
 - EMG Audio Volume Balance.
 - Event Tones Volume Balance.
 - Voices Volume Balance.
- 6 Audio Advanced Settings.
- 7 Active Stimulus Only.

Additional options for the Stimulus Delivery Audio panel (3):

- Brief Tone (default). Delivery of stimulus current is accompanied by a brief warbled tone.
- Continuous Tone. Delivery of stimulus current is accompanied by a continuous, warbled, high-low tone (referred to as “Stimulus Warble Tone”).
- Voice - Stimulus. Delivery of current to the surgical field is announced by the word, “STIMULUS”.
- Voice - Setting. Delivery of current to the surgical field is announced by the value of the stimulus setting.

Note: You will not hear the Stimulus Delivery Audio when an event has occurred.

The following options are located on the Monitoring Audio panel. At least one selection must be active, however you may select both options.

- EMG audio is the amplified sound of muscle activity that is heard instantaneously as the nerve is stimulated. All EMG activity, regardless of amplitude, is audible when the EMG audio is ON. The EMG activity may sound like a low-pitched “drumbeat”, a high-pitched “crackle”, or a “growl”. When you monitor multiple channels, it is unlikely that you will be able to differentiate the EMG signals as to their channel of origin strictly by the sounds they produce.
- Event Tones are heard when the EMG amplitude is larger than the Event Threshold setting. The Event Tones are easily heard over O. R. noise and are heard at the same time with the EMG audio, previously mentioned.
- “Voice – Stimulated EMG Values” announces the value of the highest channel in the largest event in a sequence if largest is selected in Display settings (approximately one second after the sequence ends). The system rounds the actual value appropriately for annunciation. For example, the NIM Vital system would announce 623 as “six hundred twenty”.

You can differentiate channels by tone pitch. The tone for channel 1 activity is lower in pitch than channel 2, and so on for channels 3 through 4. When EMG activity exceeding the event threshold occurs at the same time on multiple channels, only the tone of the channel with the highest EMG activity will be produced.

You can mute individual EMG channels by selecting Show Channel Mute Buttons.

Once the user enables a monitoring audio option (EMG Audio, Event Tones, or Voice - Stimulated EMG Values), the system displays a volume balance for the option. All of the balances in this panel default to 50%.

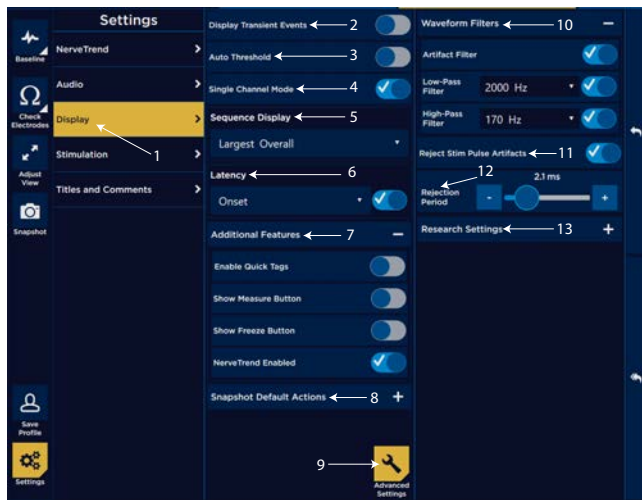
Audio advanced settings

On the Audio advanced settings panel the user can toggle on/off Audio during Active Stimulus Only. When the user enables the Active Stimulus Only, the system mutes the EMG audio and event tones occurring without stimulation. This mode only works with compatible, connected stimulators.

Display Settings panel

Note: If you adjust the advanced settings, you will change the default characteristics of your NIM Vital. Only someone with

knowledge of the advanced settings and how they impact your NIM Vital should make changes. If the user selects , the system displays a warning. The user must select **[Cancel]** or **[Confirm]** to return to settings or move forward to the advanced settings panel.



- 1 Display settings.
- 2 Display Transient Events.
- 3 Auto Threshold.
- 4 Single Channel Mode (in Thyroid procedures only).
- 5 Sequence Display.
- 6 Latency.
- 7 Additional Features:
 - Enable Quick Tags.
 - Show Measure Button.
 - Show Freeze Button.
 - Enable NerveTrend.
- 8 Snapshot Default Actions:
 - Comment.
 - Print.
 - Save To File (only enabled if the system detects a mounted, approved USB drive).
- 9 Display Advanced Settings.
- 10 Waveform Filters
 - Artifact Filter
 - Low-Pass Filter
 - High-Pass Filter
- 11 Reject Stim Pulse Artifacts.
- 12 Rejection Period.
- 13 Research Settings:
 - Display Raw EMG as Transients.
 - Record Waveform Data.

When you activate the Measure button (by enabling it in the display settings), the on screen cursor (green) shows the amplitude (μV) and time (mS) at the cursor location.

- Time is measured from zero (0) not from Stimulus/Rejection Period.
- Amplitude is measured from the channels zero (0) with a minus (-) sign for negative numbers and no minus sign for positive numbers.

If the users selects Display Transient Events, the system enables transient events. With Event Capture disabled, free running EMG signals scroll across the screen at real-time. When an Event occurs, the signal persists as a transient event on the screen for five seconds before fading away.

If you selected Auto Threshold on the Events panel and the event tones are continuous for 10 seconds:

- Auto Threshold automatically calculates a new Event Threshold (to a maximum of $400 \mu\text{V}$).
- You will hear all activity less than the new Event Threshold as raw EMG.
- EMG activity greater than the new Event Threshold or greater than $400 \mu\text{V}$ generates Event Tones.
- The Event Threshold returns to the original value after 10 – 20 seconds of no, or decreased, event activity.
- Single channel mode is only available in Thyroid procedures and is enabled by default. When single channel mode is on, the system presents the channel with the best amplitude. For more on how single channel mode affects trending, see the “Nervassure” topic.
- In the Sequence Display panel, the system selects the Largest Overall option by default. The following happens:
 - If Last and Event Capture are selected, the most recent event appears until replaced with a new or more recent event.
 - If Largest Overall and Event Capture are selected, and multiple events occur over a period of time, then the largest event from the series of events appear as Largest x of x (example 3 of 5).
 - This remains on screen until replaced with the next event or next largest event from a series of events.

On the Latency panel, you can do the following:

- Control whether the system shows latency values in non-Nervassure stimulated waveform sweeps using the Latency selection button.
- Control whether the system measures latency to the onset of the response, or to the highest peak EMG value of the response by selecting Onset or Peak from the drop-down menu.
- If the user has Latency enabled on the Latency panel, then for every stimulation pulse that causes a response greater than 20 μ V, the system displays the Latency value on the waveform. It may be measured to the onset of the response or to the highest peak EMG value of the response depending on the settings you chose.

On the Additional Features panel, the user can do the following:

- Enable Quick Tags. This displays quick tags on the Quick Tags panel on the right hand side of the monitoring screen. See the “Quick Tags” topic for more information.
- Show Measure Button. This displays the measure button in the left panel enabling the user to use the measure feature. See the “Measure” topic for more information.
- Show Freeze Button. This displays the freeze button in the left panel enabling the user to freeze the waveform display. See the “Freeze” topic for more information.
- Enable NerveTrend (available in select procedures). This turns on NerveTrend functionality by presenting NerveTrend settings in the settings panel and enabling NerveTrend baseline to be taken.

On the Snapshot Default Actions panel, you can do the following:

- Choose the default snapshot actions using the Comment, Print, and/or Save To File selection buttons. You can select more than one action.
 - Select the Probe Saves Snapshot to control whether the center position on the incrementing stimulus probe saves a snapshot.
 - If the center button is enabled and the Comment button is selected, then when you press the center probe button:
 - The title/comment box pops out.
 - One of the titles in the list is selected.
 - The up/down buttons on the probe now do not change the stim current, but rather move the highlight bar up and down the title list.
 - Comments. Opens comments box enabling comments and Event Titles (you may enter titles via keyboard or select them from a customized list) to be added to the captured event when you press the Snapshot button. The system displays these comments/ title on the printed and/or saved event. Refer to the “Titles and Comments Panel” topic to customize this list.
- Note:** You can modify Comments and Event Titles in Reports Mode.
- Print. Sends captured event to the printer (with comments enabled) when you press the Snapshot button.
 - Save. Sends captured event to the USB mass storage device (with comments if enabled it) when you press the Snapshot button.

You can use the Waveform Filters panel to toggle the artifact filter on/off. If you select the artifact filter you can control the following waveform filters:

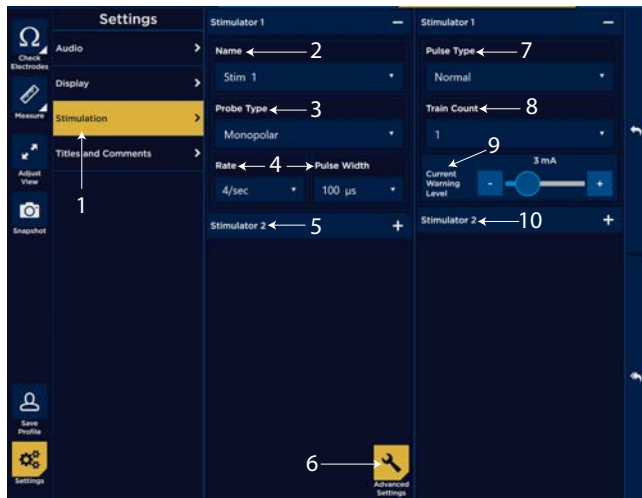
- Artifact Filter: selecting the artifact filter enables the detection of artifact as “Spiked Waveforms”.
- Low-Pass Filter: low frequency response is generally caused by the movement of the electrodes, electrode wires, tissue etc. This can result in a response that is not a true EMG response. Selecting the low-pass filter enables a filter that reduces peak-to-peak amplitude (about 20 %) in a frequency range below 70 Hz reducing unwanted response. The filter is on by default for all procedures.
- High-Pass Filter: reduces frequencies seen below the set value.
- Reject Stim Pulse Artifacts: enables the artifacts rejection filter. Refer to the “Recognizing stimulus artifacts” topic for additional information.
- Rejection Period: the user can set the STIM rejection period time.

Stimulation panel

Use the Stimulation settings panel to make adjustments to stimulators, such as assigning names and probe types.

Note: If you adjust the advanced settings, you will change the default characteristics of your NIM Vital. Only someone with

knowledge of the advanced settings and how they impact your NIM Vital should make changes. If the user selects , the system displays a warning. The user must select **[Cancel]** or **[Confirm]** to return to settings or move forward to the advanced settings panel.



- 1 Stimulation panel button.
- 2 Stimulator 1 Name.
- 3 Stimulator 1 Probe Type.
- 4 Stimulator 1 Rate and Pulse Width.
- 5 Stimulator 2. **Note:** The identical settings for STIM 1 appear for STIM 2 if it is connected and Stim mode is set to normal.
- 6 Advanced Settings button.
- 7 Stimulator 1 Pulse Type.
- 8 Stimulator 1 Train Count.
- 9 Stimulator 1 Current Warning Level.
- 10 Stimulator 2. **Note:** The identical settings for STIM 1 appear for STIM 2 if it is connected and Stim mode is set to normal.

Identify STIM 1 and STIM 2 types

1. Press .

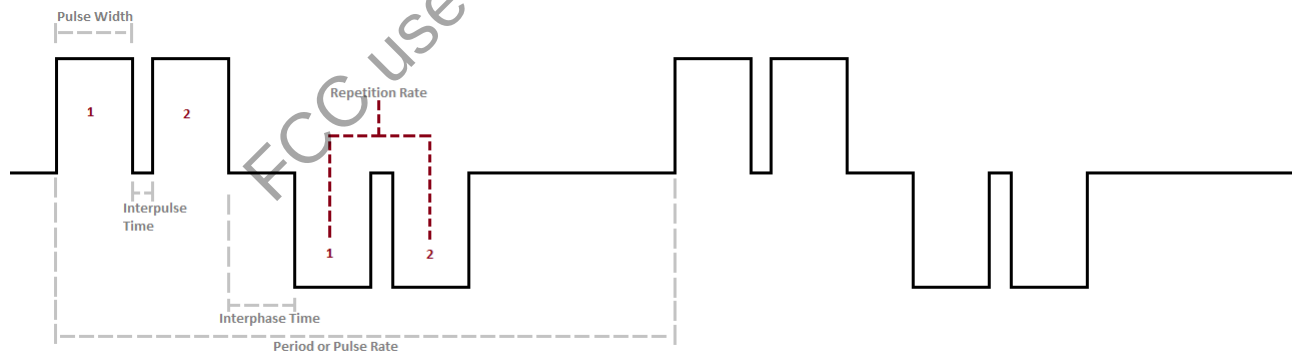
The Settings panel appears.
2. Press the Stimulation button.

The Stimulation panel appears.
3. Do one of the following:
 - Select STIM 1.
 - Select STIM 2.
4. Under the Name field, press the STIM Name drop down arrow.

A list of pre-defined STIM types appears.
5. Select a STIM type from the list.
6. Click  to close the panel.

The system saves the probe name.

The following is an example of a pulse width and rate adjustment performed on the Pulse Width and Rate panels.



Pulse width and Rate diagram (number of pulses per second)

Note: If you selected a Nervassure procedure, then the Stimulator 2 Rate adjustment will be located on the Nervassure Tab.

In the Stimulation advanced settings, the user can change the pulse type which alters the polarity of pulses generated by the stimulator. Selecting any of the biphasic options enables an Interphase Delay option to appear. Interphase Delay changes the time between pulses of different polarities during a single period. The user can also adjust the train count – number of repetitions of a pulse for each polarity that occur within a single period. Selecting any train count (the number of pulses in a series of pulses) higher than one enables an Interpulse Interval. The Interpulse Interval changes the time between pulses that occur in the same polarity. The following is an example of these adjustments.

Important note on stimulator adjustments

By selecting a procedure, the default settings for stimulus intensity normally provide adequate stimulation. The absolute stimulus intensity required to adequately stimulate any motor nerve is determined by a complex combination of several factors including (but not limited to) the following:

- The functional health of the nerve itself.
- The type of stimulation probe used (monopolar or bipolar).
- Proximity to the nerve.
- The pulse width of the stimulus.

You should use the amount of stimulation necessary to elicit a detectable EMG event. Stimulus current levels of 0.3 mA may be high enough for adequate direct monopolar stimulation of the facial nerves, but may elicit little or no response when monitoring nerves during thyroid procedures. The best guideline for setting the stimulus intensity level is to use the lowest amount that produces an EMG event. Under- and over-stimulation are covered under W19, W20, and W26 in the “Warnings” topic.

The surgeon should be aware:

- That STIMULUS is continuously being applied to the STIMULATOR probe and/or the Nervassure stimulator.
- STIMULATING the patient is the result of physical contact between the patient and the STIMULATOR probe.
- The STIMULATOR probe should be kept ISOLATED when NOT STIMULATING the patient (except Nervassure).

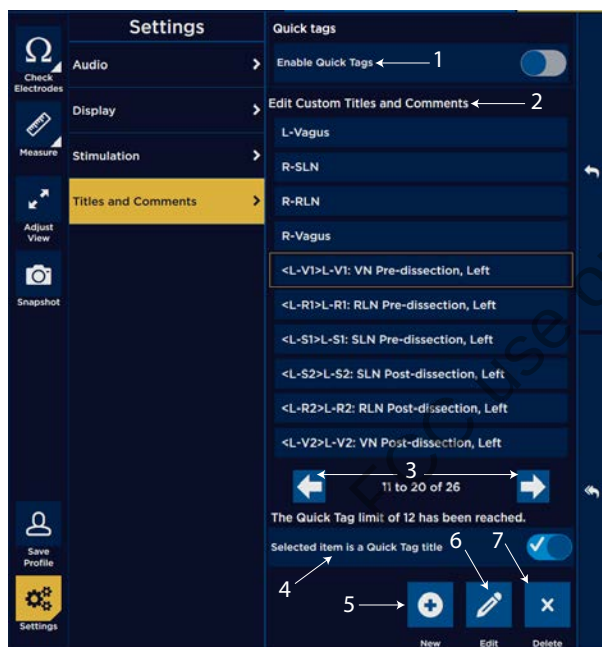
Note: Stimulator adjustment involves the adjustment of the Current, Rate, Pulse Width, and the Stimulus/Rejection Period.

Note: To prevent inadvertent high stimulus levels, the first time the stimulus level exceeds the Current Warning Level (9), a dialog box opens:

- Stimulus in excess of the current warning level (usually 3 mA).
- Press **[CONFIRM]** to enable stimulus.

If using the procedures Lower Extremity, Knee, or Ankle, the stimulus level warning is set at 12.0 mA.

Titles and comments



- 1 Enable quick tags toggle.
- 2 Edit custom titles and comments list.
- 3 Move forward/backward through title/comment list.
- 4 Selected item is a quick tag title toggle.
- 5 Create a new title/comment/quick tag.
- 6 Edit a title/comment/quick tag.
- 7 Delete a title/comment/quick tag.

The edit custom titles and comments feature enables you to create new titles/comments or delete entries that have already been created including the default titles. The Edit and Delete buttons appear when you select an existing item in the list. The titles/comments specific to the procedure type that the user is monitoring.

1. Press .

The Settings panel appears.
2. Press the Titles and Comments button.

A list of titles for the current procedure appears.
3. Do any of the following:

- Select **[New]** to create a custom title/comment. Use the on-screen or attached keyboard to type a title or comment.
- Select a title, press **[Edit]** and then edit the existing title.
- Select a title, press selected item is a Quick Tag title toggle. See the "Quick Tags" topic for more information.
- Select a title, press **[Delete]**. The system deletes the title. This option is not available if the title is a quick tag that has already been used during the procedure.

4. Press  to close the settings panel.

Optional features in monitoring

Quick tags

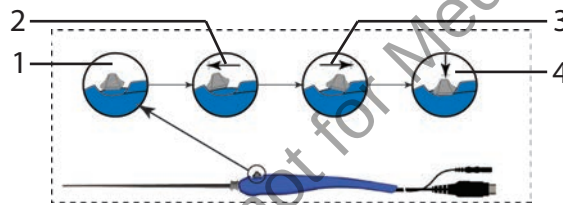
You can use the Enable Quick Tags toggle slider to display the abbreviation of the title that appears on a quick tag button on the tool bar at the right of the screen during the Monitoring phase. You can activate a quick tag by selecting a title and then select "Selected item is a Quick Tag title" toggle. Type an abbreviation for the title of the button using the pop-up that appears.

1. Select the Enable Quick Tags toggle slider.
2. Select the Selected item is a Quick Tag title toggle.
The Edit Title/Comment Abbreviation pop up appears with the title/comment name in the Title/Comment box.
3. Press the Abbreviation box.
The Abbreviation pop up appears with the choice to use an on screen keyboard, or use your attached keyboard.
4. Type the abbreviation you want to use for your quick tag and press **[CONFIRM]**.

Note: the system adds new titles to the end of the quick tag list.

Probe-based functions

The (single use) Incrementing Probe provides the surgeon with the means to adjust the stimulation current at surgical site.



- 1 - Toggle button normal or at rest.
- 2 - Increase current.
- 3 - Decrease current.
- 4 - The user can perform the following functions with the toggle button:
 - Momentary press saves a snapshot of the current screen to memory (for reports) and to a selected peripheral device (printer and/or USB flash drive) if the user selected that option in the settings area.
 - Press and hold opens a menu on the user interface with more options.

Control stimulation and volume using the probe.

By default, the plus/minus buttons control stimulation values and annunciate the newly set stimulation current. There are two methods the user can use to toggle between stimulation and volume controls.

Method 1

1. Press the plus button for two seconds.
The probe's plus/minus positions now control volume and provides audio feedback of the volume level.
2. When in the volume mode, press the plus button for an additional two seconds.
The probe's plus/minus positions now control stimulation. If the probe is in volume mode, after 30 seconds of no use it defaults back to stimulation control.

Method 2

1. Press the toggle button for two seconds.
A menu appears.
2. Use the plus/minus positions to navigate through the menu options and select **[Volume]**.
The probe's plus/minus positions now control volume and provide audio feedback of the volume level.
3. Press the toggle button for two seconds.
A menu appears.

Nerve Integrity Monitor

4. Use the plus/minus positions to navigate through the menu options and select **[Stimulus]**.

The probe's plus/minus positions now control stimulation. If the probe is in volume mode, after 30 seconds of no use it defaults back to stimulation control.

Note: When the user toggles between the stimulation and volume controls an audio cue is heard.

Create a snapshot using the probe

If the user quickly presses the toggle button during monitoring, the system takes a snapshot.

Set a NerveTrend baseline using the probe

If NerveTrend is available for the current procedure and enabled, the user can use the probe to initiate a NerveTrend baseline. Refer to the "NerveTrend" and "Creating a NerveTrend baseline" topics for additional information. You must have NerveTrend enabled to use the following procedure.

1. Press the toggle button for five seconds.

The system begins the NerveTrend baseline process.

2. Use the plus/minus positions to move through the bottom control buttons and select **[Continue]**.

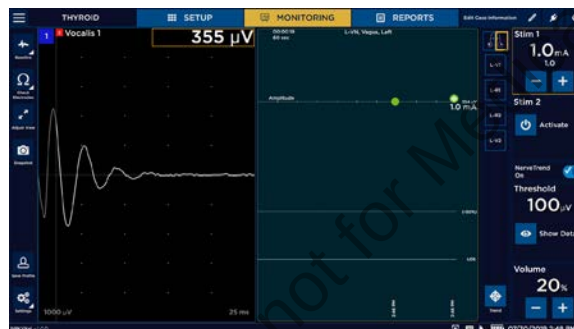
The second baseline screen appears showing the operative side selection panel.

3. Use the plus/minus positions to select the right/left operative side, then press the select button.

Once the user has selected the operated side using the probe, the system focuses on the bottom control buttons.

4. Use the plus/minus positions to move through the bottom control buttons and select **[Accept]**.

Set a NerveTrend trend point



1. Press the toggle button once there is a point ready to trend. Refer to the "Using the NerveTrend feature" topic for additional information.

A menu appears.

2. Use the plus/minus positions to select whether to apply the trend point to the graph (which also takes a snapshot) or only take a snapshot.

3. Press the toggle button to apply your selection.

Select a quick tag using the probe

The user can access quick tags, if they have been enabled (refer to the "Titles and Comments" topic for additional information), using the following procedure.

1. Press the toggle button for two seconds.

A menu appears.

2. Use the plus and minus buttons to navigate through the menu options and select **[Quick Tags]**.

The system expands the quick tag area.

3. Use the plus/minus positions to navigate through the existing quick tag list.

4. Press the toggle button once you have highlighted the specific quick tag you want to use.

The system applies quick tag and closes quick tag area.

Note: If no action is taken for 10 seconds, the quick tag area shrinks.

Nervassure functions using the probe

The following Nervassure functions are available using the incrementing probe.

Set a Nervassure baseline using the probe

1. Press the toggle button for two seconds while in a Nervassure procedure.

A dialog box appears.

2. Use the plus/minus positions to move through the menu options and select **[Baseline]**.

The system begins the baseline process.

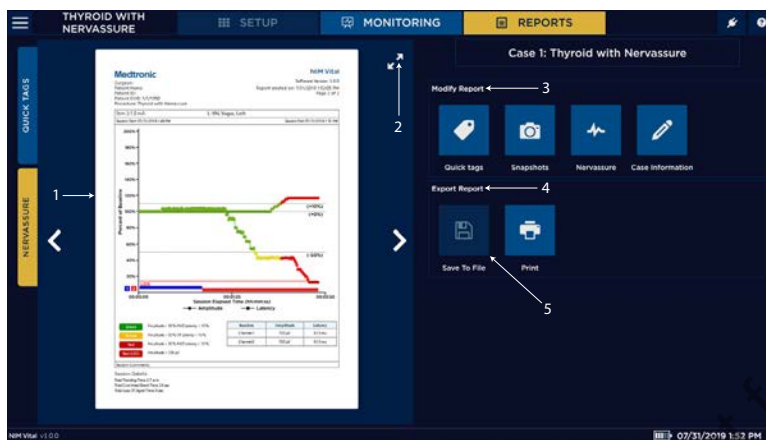
- Use the plus/minus positions to move through the bottom control buttons and select **[Continue]**.
The second baseline screen appears showing the operated side selection panels.
- Use the plus/minus positions to select the right/left operative side, then press the select button.
Once the user has selected the operative side using the probe, the system focuses on the bottom control buttons.
- Use the plus/minus positions to move through the bottom control buttons and select **[Accept]**.

The REPORTS mode

Note: All stored case data (snapshots, log files, Nervassure data, and reports) is lost when unit is powered off.

The REPORTS mode enables you to quickly compose and print/save reports using a report builder. The system provides report templates to simplify report creation.

The REPORTS mode can be active while audio monitoring continues in the background. The system saves all work performed in REPORTS mode if you exit REPORTS and return to MONITORING. For example, you can start a report midway through a monitoring session. When you return to MONITORING to complete the session, all previous work is available when you return to the REPORTS mode. When you turn the system off, you lose all monitoring session data.



- Live Preview window: Displays auto-generated report. Use the tabs to jump to bookmarks within the report.
- Live Preview expand: Expands the report to a two-page at a time view.
- Modify Report Panel: Options to edit Quick Tags, Snapshots, and baseline sessions in the case.
- Export Report Panel: Options to save a .pdf version of the report to a USB (if the system detects a mounted, approved USB) and to print the report with a connected printer.
- Save Database button: Saves a copy of the case database to a USB (if the system detects a mounted, approved USB).

Include quick tags on a report

By default, the system includes all quick tags the user creates during monitoring on the report. Once the user makes all quick tag changes to the snapshots (the user can change multiple quick tags at once), the user can create a report.

- Select **[Edit Quick Tags]**.
The Modify Quick Tags screen appears.
- Select a quick tag from the left side panel.
- Select a snapshot from the center of the screen.
- Press **[Include in Report]**.
The system adds the quick tag to the report.
- Do one of the following:
 - Select **[CONFIRM]** to save your changes.
 - Select **[RESET]** to revert snapshots back to their last saved state prior to the editing session.

Delete quick tags from the report

- Select **[Edit Quick Tags]**.
The Modify Quick Tags screen appears.
- Select a quick tag from the left side panel.
- Press **[Include in Report]** twice to toggle it off.
The system removes the quick tag from the report.

Edit the snapshot title and comments

- Press **[...]** on the snapshot.
The system opens an editing dialog box.

Nerve Integrity Monitor

2. Do one or both of the following:

- Edit the title.
- Add comments

Note: The system displays a larger image of the captured waveforms when the user selects [...].

Include snapshots on a report

By default, snapshots taken during monitoring are not automatically placed in the report.

1. To select a snapshot for inclusion, press the snapshot and the system highlights it.

2. Do one of the following:

- Press **[Select All]** to highlight all of the available snapshots to add to the report.
- Press **[Clear All]** to deselect all of the snapshots on the report.

3. Do one of the following:

- Select **[CONFIRM]** to save your changes.
- Select **[RESET]** to revert snapshots back to their last saved state prior to the editing session.

Note: In a NerveTrend procedure, the user can filter snapshots automatically taken when the user plots a trend point.

Edit sessions

By default, the session includes all sessions started during monitoring on the report.

1. Press [...] on the session.

The system open a dialog box for editing the session title and comments as well as displays the session start and stop times with a composite view of the session trend.

2. Do one of the following:

- Select a single session (the system highlights the selected session).
- Select **[Select All]** to select all sessions.
- Select **[Clear All]** to deselect all session.

3. Do one of the following:

- Select **[CONFIRM]** to save your changes.
- Select **[RESET]** to revert session back to their last saved state prior to the editing session.

Include trending graphs in a report - Nervassure and NerveTrend

After completing either a Nervassure or NerveTrend case with a trend graph, the Reports screen automatically includes all trends in the report. The user can modify the trends shown in the report.

1. From the Modify Report area on the Report Screen, do one of the following:

- Press **[Nervassure]**, or
- Press **[NerveTrend]**

2. Press **[Edit]** to edit the Title or Comment for the trend, then select the trend to modify.

The system opens a dialog box for modifications.

3. Press **[Confirm]** to save changes.

The system includes all trends that have a yellow border in the report.

Remove a trend

1. Click the trend thumbnail to remove the border.

2. Click **[Confirm]**.

The system regenerates the report.

Add a trend

1. Click the trend thumbnail so the yellow border shows.

2. Click **[Confirm]**.

The system regenerates the report.

Edit case information on a report

The system automatically includes Case information on the report. To edit case information prior to saving/printing, use the Edit Case Information tab on the top right of the screen to make any required adjustments.

After completing a case, the user can edit case information on the Reports screen.

1. Press **[Case Information]** from the Modify Report area.

The system opens a panel on the right side of the screen.

- Edit the information for the currently displayed case.
- Press **[Apply Changes]**.

The system regenerates the report with the updated case information.

Generate the report

Once the user is satisfied with the report content, the user can make a final review of the report using the live preview window. The tabs at the top of the window enable the user to jump to bookmarks for each section within the report, or use the expand button to move through the report in its entirety. The user can select from the following options:

- Print button - sends the report to the attached printer.
- Save button - sends the report to the attached USB mass storage device and saves the formatted report as a .pdf format on the USB drive. The system formats the filenames with the report type, year, month, day and time. For example, Report_20190528_112530.pdf.

Reports are located in a case folder titled with date, sequential case, and procedure type.

Nervassure overview

The following topics contain information about how a Nervassure procedure is conducted.

Automatic periodic stimulation (Nervassure) is a process wherein a nerve at risk is continuously stimulated. The resulting EMG is monitored and charted continuously in real time. You can plot and observe trends.

The plotted characteristics are:

- EMG amplitude (peak-to-peak, response to stimulation)
- Latency (time from stimulation to the "Onset" or peak of the EMG response), if enabled.

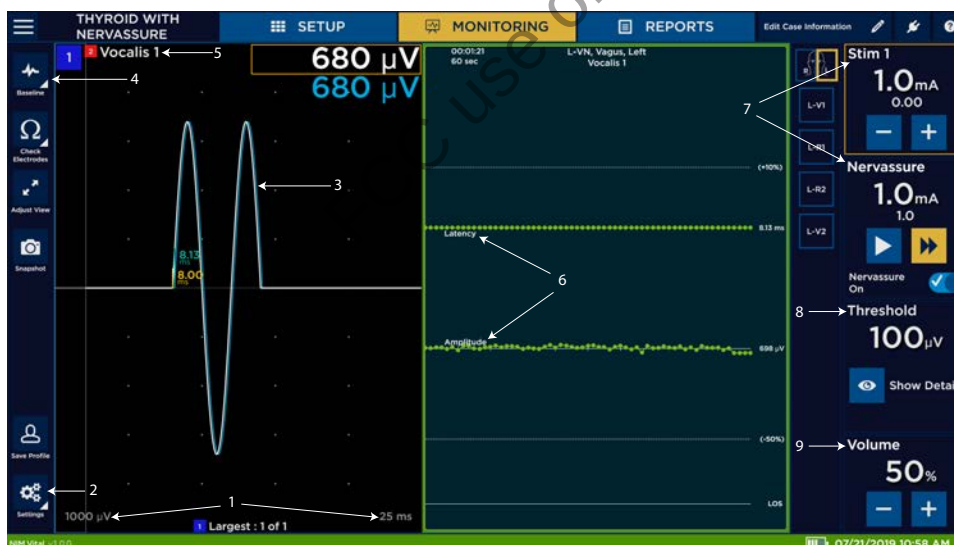
Every point plotted in the bottom half of the trend chart for each channel is a single EMG amplitude response. Each point plotted in the top half of the trend chart for each channel is a latency response.

If a measurement falls outside of the threshold values, the points change color and the console issues an audible alarm to alert you depending on what alarm settings you selected on the Advanced Settings panel.

Nervassure case set up

- Select a user profile that has Nervassure procedures, or a default Nervassure procedure.
- The Check Electrode screen displays two stim return electrodes that need to be connected. A green bar mark will appear in stim return 2, when connected.
- Press  to proceed to monitoring.

Nervassure Monitoring Screen details



- Scale. Displays screen scale settings.
- Settings button.
- Trace. Display stimulus nerve activity/inactivity.
- Baseline button.
- Channel label. Displays the channel number and nerve being monitored.
- Amplitude and latency.
- Stim panels.
- Threshold panel.
- Volume panel. Adjust the system volume.

Right panel for Nervassure procedures

The user can access the following information on the NIM Vital system's right panel when conducting a Nervassure procedure.

Nervassure STIM panel

If the user selected a Nervassure procedure, then the Nervassure STIM appears on the right panel of the monitoring screen. The Nervassure STIM panel contains the following:

- The stimulation setting (shown as the large numbers).
- The measured value in small font below the stimulation setting.
- Slow and fast rate settings which enables users to select between two stimulation rate options. The default rates are specified in the defaults section.
- The adjust mode on/off button (only available prior to taking a baseline). When the user turns the adjust mode on, the NIM Vital console stimulates the nerve at a 1HZ stim rate, and plots the resulting EMG amplitude as a bar graph. These adjustments enable the user to reposition the tube for optimum contact with laryngeal musculature, or to reposition continuous monitoring electrodes for other Nervassure procedures.
- The Nervassure on/off button (only after accepting a baseline). When the user turns Nervassure off, the system removes the trending graphs from the screen and disables the Nervassure stimulator. Turning the setting back on resumes stimulation and trending with the same baseline.

Note: The Slow Rate and Fast Rate buttons are inactive (gray) until after the user establishes a Nervassure baseline.

Left panel for Nervassure procedures

The user can access the following information on the NIM Vital system's left panel when conducting a Nervassure procedure.

Baseline button



The Baseline button enables the user to initiate Nervassure trending by creating a baseline.

Monitoring a Nervassure case

Establishing a baseline

1. Press  located on the left panel of Monitoring screen.

The Baseline panel slides out and the system begins stimulating the nerve at 1Hz using a minimum of twenty stimulations. The system displays the resulting EMG on the electrode channels.

Note: If the baseline was not robust, the system continues to stimulate until the system achieves a stable, consistent signal. It is important to not manipulate the nerve or the surgical field during this time to ensure system records consistent data.

2. Select one or both baselines (both baselines are selected by default).
3. Press **[Continue]**.
4. Select RIGHT or LEFT operating side and type in a session title and session comments (if desired). The user must select at least one of selections to proceed.
5. Press **[Accept]**.

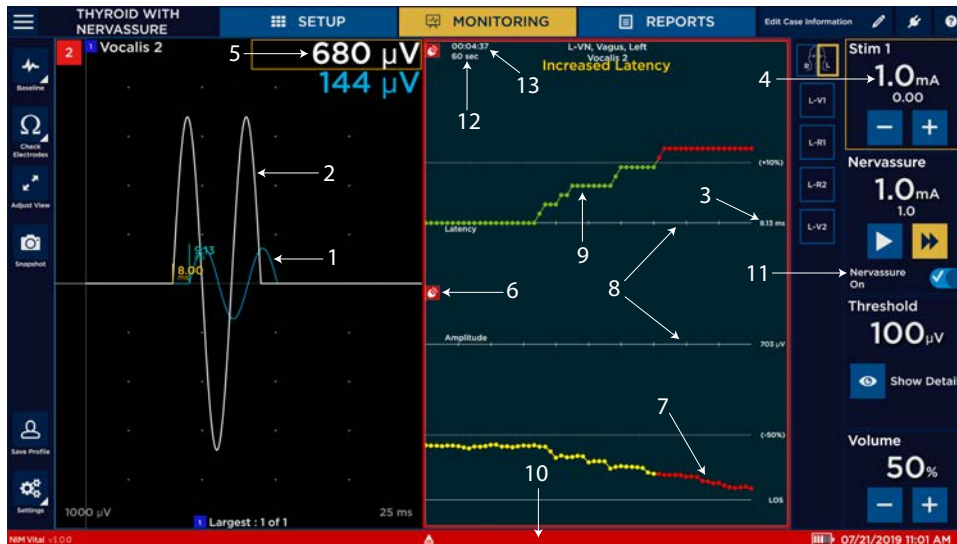
The system closes the Baseline menu and the trend lines appear on the right half of the screen.

If the system does not receive a stable, consistent signal you may see an error message.

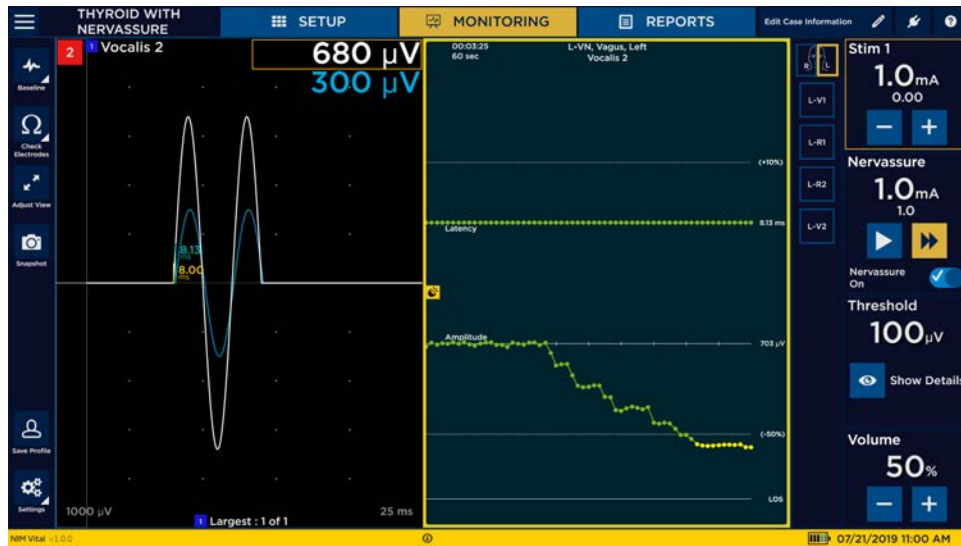
Nervassure trending

The system stimulates the nerve at the default frequency preset for the procedure the user chose. The stimulation is accompanied by a thump sound. Amplitude and latency values from each stimulation are trended over time.

The baseline appears as a solid line with hashmarks, the trend limits for amplitude and latency as dashed lines, and loss of signal as a solid line.

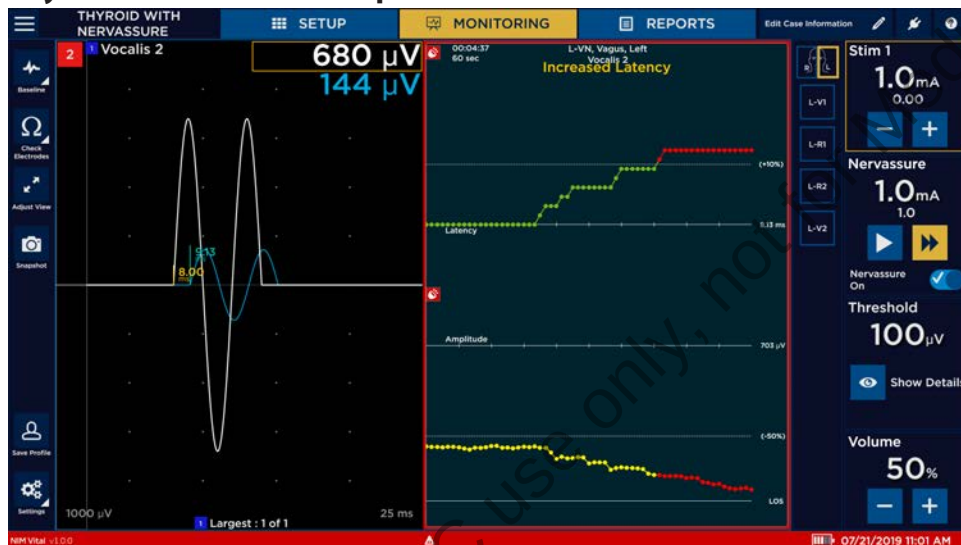


- 1 Nervassure Waveform. Appears as a Blue Trace on all channels if Show Nervassure Waveforms is on (default) in the Settings Nervassure panel.
- 2 EMG Waveform. Appears as a white trace on all channels.
- 3 Nervassure Latency value.
- 4 Nervassure stimulation level.
- 5 Values. The system displays the EMG measured values in white with the largest value boxed in yellow. The system displays the Nervassure values in blue.
- 6 Alarm Mute button. This button shows that an alarm condition is present.
- 7 Limit Lines. The system displays the upper limit for latency and lower limit for amplitude as red dotted lines and the loss of signal (LOS) as a solid line.
- 8 Baselines. The system displays the latency and amplitude baseline as solid lines with hash marks.
- 9 Trend lines. The system displays latency and amplitude as a series of points based on the trend color.
- 10 Alert. The system shows the alarm (if sounded) mute buttons for amplitude and latency separately and colors the bottom bar according to the combined alarm level.
- 11 Nervassure ON selection button. Use this check box to pause/continue Nervassure stimulation once the session has started.
- 12 Time Base.
- 13 Session duration.



If the Nervassure values go above or below the set limits, the stimulation point changes to yellow or red depending on the limits the value crosses. The yellow and red zones have a unique tone associated with their state. Refer to the "Alarms and alarm criteria" topic for additional information.

Thyroid with Nervassure specific features



The thyroid with Nervassure procedure has Best Channel mode turned on by default. Refer to the "Nervassure advanced settings" topic for additional information. Uncheck the Thyroid with Nervassure mode to view.

Muting a Nervassure alarm

When a plotted point falls within the set alarm band, the system displays an alarm button on screen. You can mute this Nervassure alarm on the Monitoring screen using the alarm button. There are three levels of alarm with their availability determined by procedure settings – a red, yellow, and loss of signal. Each level has a separate alarm button with mute functionality that mutes only that level (so muting yellow and the trend moves to the loss of signal limit still sounds the red alarm until that one is muted).

1. Press .

The system mutes the alarm and displays a muted alarm.

2. To unmute the alarm, press the muted alarm button.

Default Nervassure alarm criteria

Default Color Conditions

Amplitude is greater than 50% AND Latency is less than 10%	Green
Amplitude is less than 50% OR Latency is greater than 10%	Yellow
Amplitude is less than 50% AND Latency is greater than 10%	Red (Yellow for INMSG)
Amplitude is less than 100	Red (loss of signal [LOS])

(*) Indicates set value differs from default.

Default Nervassure trend settings

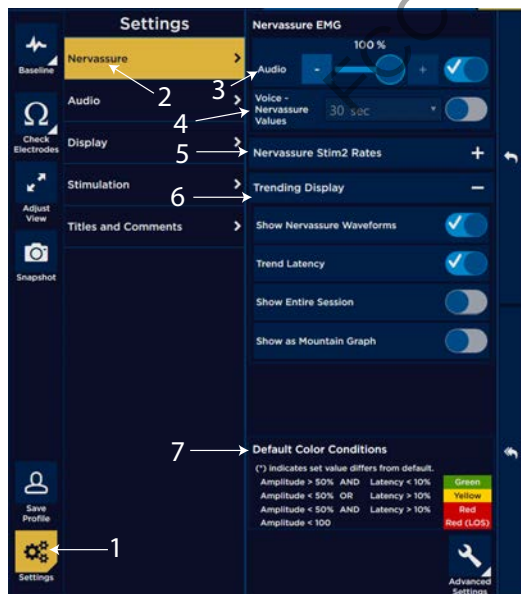
Procedure Name	Thyroid	Parotid	Acoustic Neuroma
Slow Stim Rate	10/min	10/min	10/min
Fast Stim Rate	1/sec	1/sec	1/sec
Baseline Rate	2/sec	2/sec	2/sec
Show as Mountain Graph	No	Yes	Yes
Alert Type	Amplitude OR Latency	Amplitude OR Latency	Amplitude OR Latency
Nervassure Stim Current	1.0 mA	0.6 mA	1.0 mA
Amplitude Threshold	50%	50%	50%
Latency Threshold	10%	10%	10%
Single Channel Mode	Yes	Option not available	Option not available
Alarm on Best Channel	Yes	Option not available	Option not available

Note: When running single channel mode in a Thyroid procedure, the trend graph (right side of the screen) will present the trend with the best plotted amplitude. The waveform graph (left side of the screen) will present the waveform with the best Nervassure amplitude when Stim 1 is not in use. When Stim 1 is used to procedure EMG, the waveform graph will present the waveform with the best EMG amplitude.

On the Nervassure EMG panel, the Show Nervassure Waveforms selection is activated by default. The system shows the waveforms from Nervassure electrode stimulation on the Monitoring Screen as blue with EMG response in white.

You can adjust the following Nervassure settings using the Nervassure panel. The Nervassure settings only appear on the Settings panel when you select a Nervassure procedure.

Nervassure EMG Settings panel



- 1 Settings button. Opens the Settings panel.
- 2 Nervassure settings.
- 3 Nervassure EMG Audio adjustment.
- 4 Voice - Nervassure Values.
- 5 Nervassure Stim 2 rates.
 - Slow rate.
 - Fast rate.
 - Baseline rate.
- 6 Trending Display:
 - Show Nervassure Waveforms.
 - Trend Latency:
 - Show entire session.
 - Show as Mountain Graph.
- 7 Color Conditions panel.

The following settings are available on the Nervassure EMG audio panel:

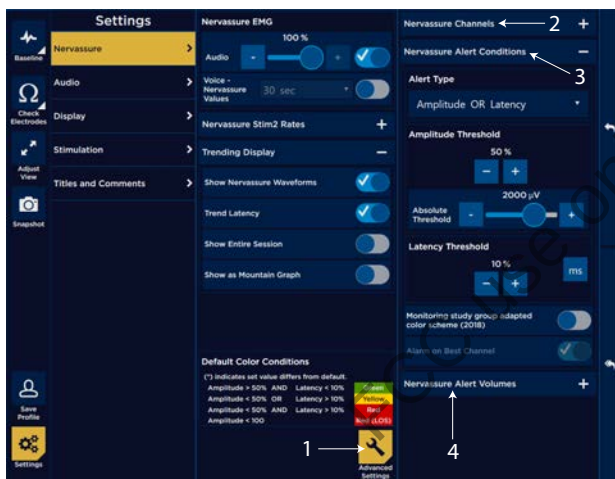
- **Nervassure EMG audio** - Mute the Nervassure EMG Audio using the selection option. If the user turns off the toggle button and selects the Mute check box, then the system mutes the EMG audio for the sweeps initiated by a Nervassure stimulation pulse. If the user turns on the toggle button (on is the default) and deselects the Mute check box, then the volume of the EMG audio for Nervassure sweeps is controlled by the [+] and [-], or the slider bar.
- **Voice - Nervassure values** - if the user selects this toggle button check box, then the NIM periodically announces the last Nervassure EMG value audibly. Use the drop-down menu to select the frequency of annunciation. **Note:** Voice – the user cannot enable Stimulated EMG Values at the same time as Voice – Nervassure values. Therefore, when the user enables Voice – Nervassure, the system automatically disables Voice – Stimulated EMG Values (found in Settings/Audio).
- **Nervassure Stim 2 rates** - you can adjust the following rates and baseline from the Nervassure stimulation panel using values from their dropdown boxes:
 - Slow rate
 - Fast rate
 - Baseline
- **Trending Display** - You can toggle on/off the following settings from the Nervassure display panel using the slide button:
 - Show Nervassure Waveforms
 - Trend Latency
 - Show Entire Session
 - Show as Mountain Graph
- **View Color Conditions** - You can view the Nervassure default alarm color conditions on this panel. The system marks any the modified values with an asterisk.

Nervassure advanced settings

The Nervassure advanced settings enable you to adjust the following settings.

Note: If you adjust the advanced settings, you will change the default characteristics of your NIM Vital. Only someone with

knowledge of the advanced settings and how they impact your NIM Vital should make changes. If the user selects , the system displays a warning. The user must select **[Cancel]** or **[Confirm]** to return to settings or move forward to the advanced settings panel.



- 1 Advanced Settings button. Enables access to the Nervassure advanced settings.
- 2 Nervassure Channels.
- 3 Nervassure Alert Conditions:
 - Alert Type.
 - Amplitude Threshold.
 - Absolute Threshold.
 - Latency Threshold.
 - Monitoring study group adapted color scheme (2018, only in Thyroid).
 - Alarm on Best Channel (only in Thyroid).
- 4 Nervassure Alert Volumes:
 - Yellow.
 - Red.

The following advanced settings are available on the Nervassure advanced settings panel:

- **Nervassure Channels** - Select the EMG channels to trend.
- **Nervassure Alert Conditions**
 - Alert type - Select one of the following alarm types from the dropdown menu:
 - Amplitude only
 - Latency only
 - Amplitude AND latency
 - Amplitude OR latency
 - **Amplitude Threshold** - adjust the amplitude limit using  or .
 - **Absolute Amplitude** - adjust the absolute amplitude using the slider bar or  .
 - **Latency threshold** - adjust the latency limit using  or .
- **Nervassure Alert Volumes** - adjust the red and yellow alert volumes using the slider bar or  .

- **Additional Options** - toggle the following options on/off that are available only in Thyroid procedures:
 - Monitoring study group adapted color scheme (2018) – changes the color conditions for alerts.
 - Alarm on best channel – When the user uses the Alarm on Best Channel, the system assigns the status from the individual trended channel with the highest amplitude as the alarm condition. When the user does not use the Alarm on Best Channel, the system assigns the status from the individual trended channel with the lowest status as the alarm condition. Alarm on Best Channel is on by default and cannot be disabled when Single Channel Mode is in use.

Use the advanced alarm settings selections to customize the following alarm settings (**Note:** These settings may behave differently if Alarm on Best Channel is in use):

- Amplitude Only sets the alarm to sound if the EMG response tolerance limit is reached regardless of the latency (default is 50% less than baseline and lower than 2000 μ V). You can also set an absolute alarm limit in this area.
- Latency Only sets the alarm to sound if the latency tolerance limit is reached regardless of the amplitude (default is latency value plus(+) 10%).
- Absolute alarm limit example: If the baseline amplitude is 3000 μ V, the amplitude percentage limit is 50% (1500 μ V), and Amplitude Absolute limit is 1000 μ V, then a signal of 1400 μ V would not cause an alarm because although the signal has decreased more than 50%, it is still above the absolute limit.
- Absolute Alarm Adjustment. This is an actual EMG voltage response above which the percentage alarm is disabled.
- Amplitude OR Latency sets the alarm to sound if either the EMG amplitude OR the latency limit is reached.
- Amplitude AND Latency only sets the alarm to sound if BOTH the EMG amplitude AND the latency limits are reached.
- The Latency type button is located to the right of the Increase button and toggles between percent (%) and msec.
 - Percentage – this is the percentage increase in latency from the baseline latency at which an alarm condition occurs (for example, if the setting is 10%, then an alarm occurs when the amplitude goes above 110% of baseline - a 10% increase).
 - ms – this is the increase in latency (in milliseconds) from the baseline latency at which an alarm condition occurs (for example, if the setting is 1.5 msec and the baseline latency is 8.0 msec, then an alarm occurs when the latency goes above 9.5 msec).

Audio – understanding what you hear

The NIM Vital system Nerve Monitor produces many different sounds throughout the surgical procedure that alert you to various important information. In addition to EMG sounds, the system uses beeps and voices to provide useful information.

Alarms

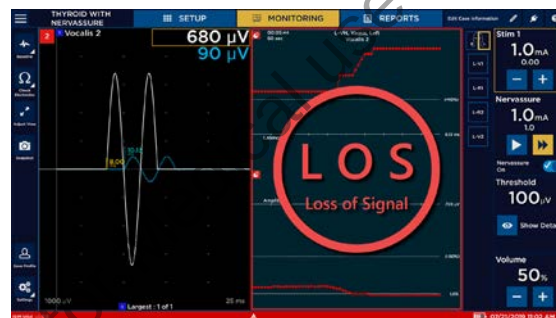
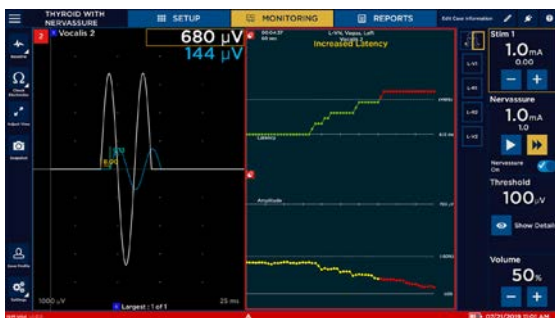
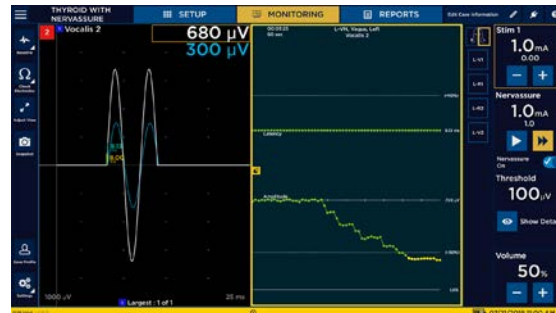
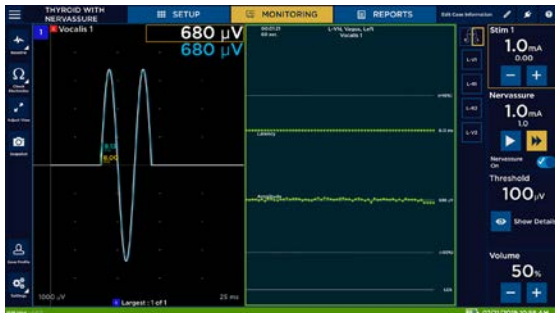
The alarms draw attention to any condition which prevents you from properly monitoring the surgical procedure. You should not ignore any of the audible alarms. You must assume that valid monitoring has stopped and determine immediately why the alarm sounded.

There are four distinct alarms:

- BEEP alarm. This is a high-pitched repetitive beep. You will hear the alarm under the following circumstances:
 - Power on.
 - Power off.
 - System failure. Stop using the NIM Vital system and contact Medtronic.
- Bleedle alarm. This is a three-note alarm (Blee-Dle Deet) that you cannot disable. You will hear the alarm under the following circumstances:
 - Completion of power up.
 - Check electrode. The alarm repeats if there is an electrode issue until you remedy the responsible condition.
 - As soon as contact with an electrode is lost after removal including lost contact with Nervassure electrodes.
 - The channel shows a lead off message.
 - The system mutes the channel until connection is restored.
 - Muting. As soon as the Muting Detector senses current flow, the dialog box “EMG MONITORING IS DISABLED/Muting from external source” appears and the system becomes mute. After 30 seconds, the bleedle alarm sounds followed by the “Muting” voice. The bleedle alarm repeats every 30 seconds until you remedy the condition.
 - Stimulus tone (warbled).

Nerve Integrity Monitor

- Nervassure alarm. The system uses several alarms to notify you when a plotted point is determined to be outside an alarm limit. Refer to the “Muting a Nervassure alarm” topic for more information.
 - Alarm with yellow condition. A single bong alarm sounds every five seconds until the condition is remedied or moves into a different alarm condition.
 - Alarm with red condition. A double honk alarm sounds every five seconds until the condition is remedied or moves into a different alarm condition.
 - Alarm with Loss of Signal (LOS) condition. A Bleedle alarm sounds every five seconds until the condition is remedied.



Voices

Voice types:

- Stimulation delivery confirmation:
 - Voice - Stimulus. With “Stimulus”, delivery of current to the surgical field is announced by the word, “STIMULUS”. It may be turned on or off and has volume control.
 - Voice - Setting. The “Setting” voice announces the numeric current value of the STIMULUS setting. It also announces any new stimulus setting when you make adjustments.

Example: The system announces 0.50 mA as “Point Five”. It may be turned on or off and has volume control.

Note: Voice - Setting or Voice - Stimulus does not sound for stimulus current levels below 0.05mA.
- Activation of auto threshold:
 - Threshold increased.
 - Threshold decreased.
- Voice – Stimulated EMG Values: when selected, the system turns on annunciation of EMG responses via voice.

Tones

The Medtronic NIM Vital system uses the following tones:

- Stimulus Delivery.
- EMG Response:
 - Burst tone. Brief tone caused by electrical stimulation, direct nerve contact, irrigation, or thermal changes.
 - Train tone. Longer version of the Burst tone lasting seconds to minutes, caused by nerve excited/irritated, irrigation, drying, bumping, or anesthesia.
 - Pulse tone. Regularly repeating tone caused by electrical stimulation, tumor mapping, verifying nerve integrity.
- If the system uses the Continuous Tone, then delivery of stimulus current is accompanied by a continuous, warbled, high-low tone (referred to as “Stimulus Warble Tone”).
- If the system uses the Brief Tone, then delivery of stimulus current is accompanied by a brief warbled tone.

Note: Stimulus tones do not sound for stimulus current levels below 0.05 mA.

Other sounds

You may hear the following additional sounds from the NIM Vital system:

- Monitoring on/off sound. The two tone bo beep monitoring on sound occurs anytime monitoring is turned on such as going into monitoring from setup or closing the electrode check panel. The two tone be boop monitoring off sound occurs anytime monitoring is turned off such as returning to setup from monitoring or opening the electrode check panel.
- Incrementing probe clicks. When using the incrementing probe buttons, a click can be heard to indicate that you pressed a probe button.

Powering down the NIM Vital system

1. Press  and select Shut down from the menu, or briefly touch the white illuminated power button.

A system message appears giving you information about the patient interface box and confirms shutdown.

2. Place the patient interfaces box(es) into the cradle(s) located in the back of the NIM Vital system ensuring the patient interface box lights appear.
3. Wait for the system to complete its power down.

4. Remove the power cord from the supply receptacle to disconnect the equipment from the power.

Note: If the system alerts the user with a warning message indicating there is not enough power in the console battery, use Mains power to charge the patient interface box batteries. All stored case data (snapshots) is lost when the unit is powered off.

Visual error and informational messages

The NIM Vital system has user-friendly notifications and informational messages. It informs the user of the issue and available actions to take. The following notifications and informational message may appear:

- About
- Active Stim Only
- Advanced Settings
- Case Confirmation
- Configure Case Information
- Console Battery 1
- Console Battery 2
- Console Battery 3
- Console Battery 4
- Critical Battery
- Current Warning Level APS
- Current Warning Level
- Date Time
- Delete Profile
- Disk Space 1
- Disk Space 2
- Drive Not Found
- Edit Snapshot
- Edit Trend
- EMG Recording Failed
- End Case
- Event Threshold
- Exit Trend
- Expanded Report
- Flat Line
- Help
- High Stim
- Impedance Check 1
- Impedance Check 2
- Internal Error 1
- Internal Error 2
- Low Battery
- Low Current
- Maintenance
- Module DSP Error
- ModuleErrorDialog
- Monitoring Disabled EC
- Monitoring Disabled ESU
- Monitoring Disabled Patient Interface
- New Baseline
- New Profile
- Overcurrent
- Overwrite Quicktag
- Patient Interface Charging Failure
- Patient Interface Switch 1
- Patient Interface Switch 2
- Patient Interface Switch 3
- Patient Interface Switch 4
- Record Data
- Save High Stim
- Self Test 1
- Shut Down
- Skip Patient Interface Connection
- Snapshot Comment
- Stim Probe
- Title Comment
- Trend Recording Failed
- Planned Maintenance

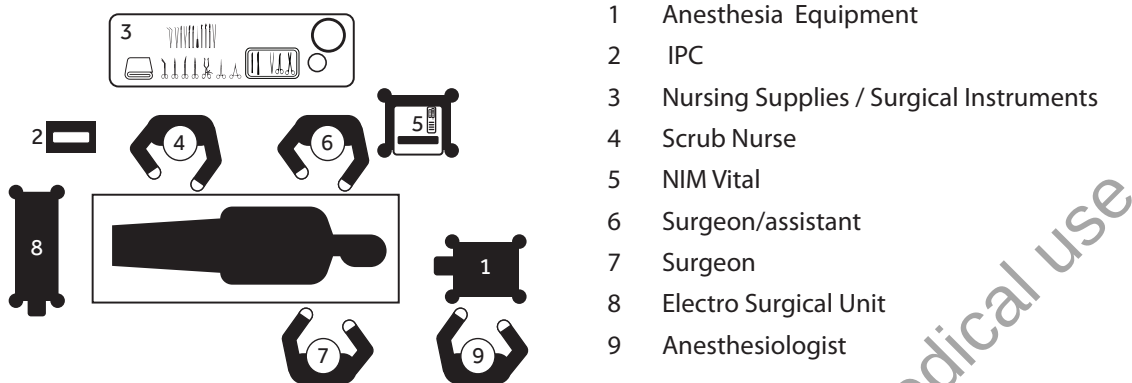
System set-up

Operating room set-up

The NIM Vital System Nerve Monitor has a few characteristics that need to be taken into consideration when setting up the operating room (OR). Some of these characteristics include, but are not limited to, external devices, traffic patterns, sterile areas, color-coding, grounding, and muting detection.

Position the unit so that it does not obstruct the power source for the purpose of disconnecting the Main voltage by the power cord. Set the NIM Vital System on a table or NIM cart located about three meters from the surgical field, but as far as possible from the electrosurgical unit. Consider traffic patterns and sterile areas. The surgeon may have additional preferences as to location and visibility.

Typical Set-up



Anesthesia requirements

All decisions regarding anesthesia are the responsibility of the attending licensed medical practitioner administering the anesthesia. Because all intraoperative monitoring discussed in this User's Guide requires that EMG activity be recorded from a muscle or muscles, it is important that the muscle(s) not be paralyzed during the surgery or at least during those parts of the surgery when the nerve(s) being monitored is (are) deemed at risk by the surgeon. It is important that the surgeon discuss these issues pre-operatively with the attending licensed medical practitioner administering the anesthesia.

Note: The use of paralyzing anesthetic agents will significantly reduce, if not completely eliminate, EMG responses to direct or passive nerve stimulation. Whenever nerve paralysis is suspected, consult an anesthesiologist.

Patient Interface setup



Prior to surgery, you must setup the patient interface box. You may use the NIM Vital system to support the process of determining which nerves to monitor and positioning the electrodes appropriately. Refer to the "View electrode placement using the Help screen" topic for additional information.

Clip the patient interface box near the surgical site within reach of the sterile electrode leads and sterile stimulator cable(s). Position it so that it is out of the way of the doctor and the scrub nurse.

Placement of the electrodes should be performed by a physician or under the direction of a licensed medical practitioner who determines the particular nerves that are at-risk with each particular patient and procedure. Place the recording electrodes in the muscles innervated by the at-risk nerves. The electrode sites should be cleaned with alcohol to remove oils from the skin. The electrode needles are inserted into the patient, taped into position, and the wires routed away from where the surgeon will be working. Usually, recording electrodes are placed before the sterile field is draped and defined. Never let the recording electrode needle leads contact one another.

Two electrodes per monitoring channel and one ground are required. The electrode pairs for each channel plug into color-coded input jacks on the patient interface. The polarity of each channel does not matter for effective monitoring unless you want the wave form inverted.

Always locate the ground and stimulus return electrodes in a non-innervated, electrically neutral area (electrically neutral areas are where the bone is close to the skin and the electrode will not contact muscle tissue [sternum]). The ground should also be located between the stimulus return and recording electrodes.

Route the white (+) stimulus return wire (monopolar) away from the channel electrode wires.

After confirming the electrodes are properly placed in the patient and connected to the patient interface box, perform an Electrode Check on the NIM Vital system. This may determine if the electrodes need to be re-inserted for better electrical contact to help optimize monitoring.

If you are using the wired patient interface box, lay the patient interface box cable out of busy traffic patterns and secure it to the floor as needed.

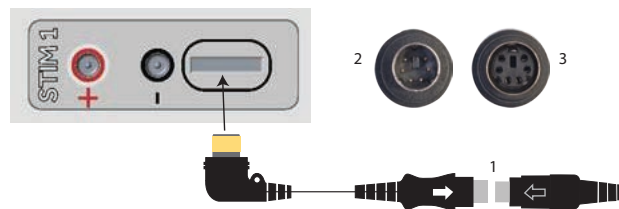
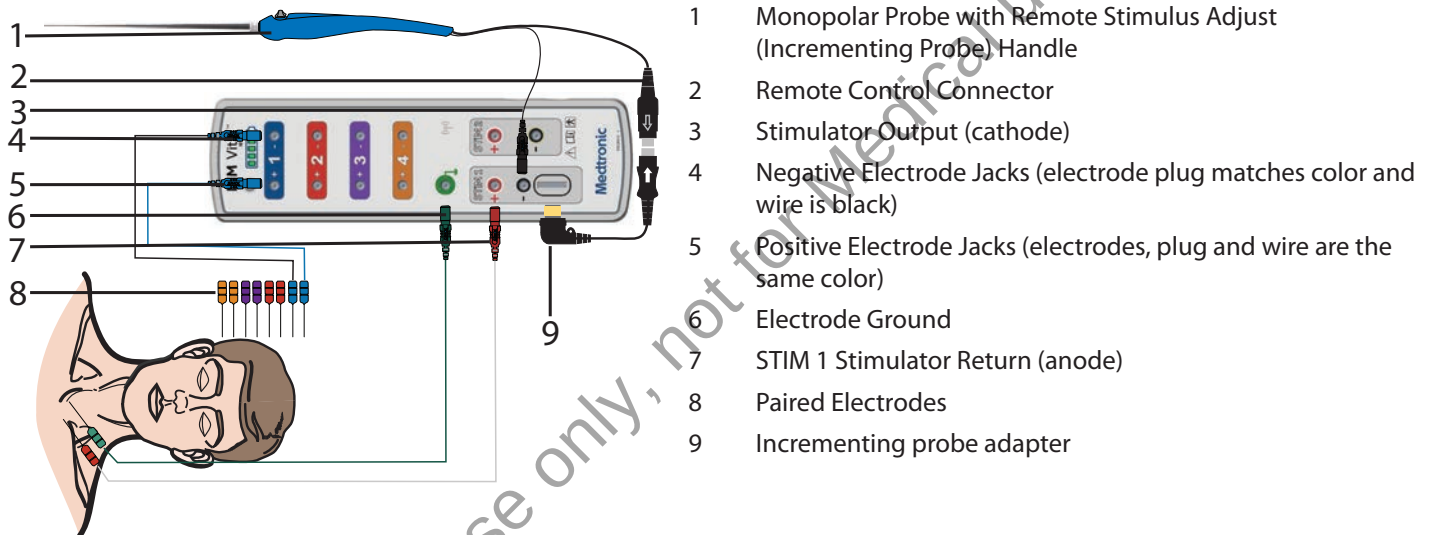
Stimulators

The NIM Vital system Stimulator output supports the use of both monopolar and bipolar stimulating probes with a range of 0-50 mA.

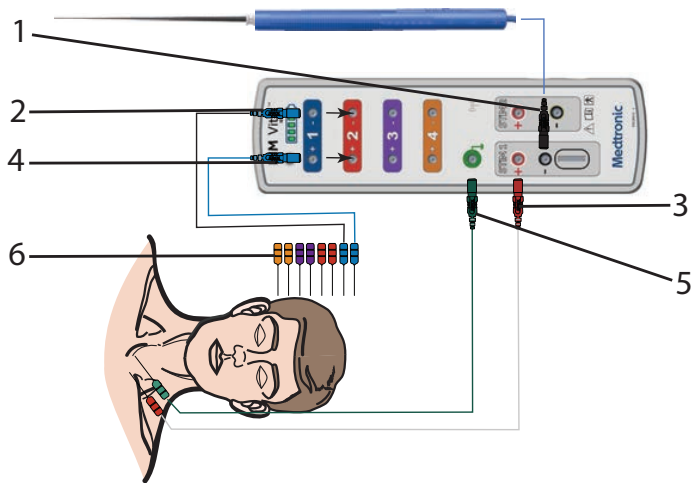
Monopolar Incrementing probe

The single use incrementing probe provides the surgeon with the means to adjust the stimulation current and print or save the monitoring screen shots from the sterile field as well as other features.

The patient interface supports one incrementing probe. The smaller plug is color-coded black and plugs into the black (-) jack on the patient interface box. The larger plug is also color-coded black and plugs into the large black (STIM CONTROL) jack on the patient interface box. If you are using the incrementing probe adapter, plug the incrementing probe into the adapter and then plug the adapter into the patient interface box. The monopolar stimulating probe delivers current to the patient and acts as the cathode. The red electrode with white wire (+) is required for monopolar stimulation. It is referred to as the stimulus return or anode. Plug the red connector of the red electrode with white wire into the white jack with a red ring (+). Route the white (+) stimulus return wire away from the channel electrode wires.



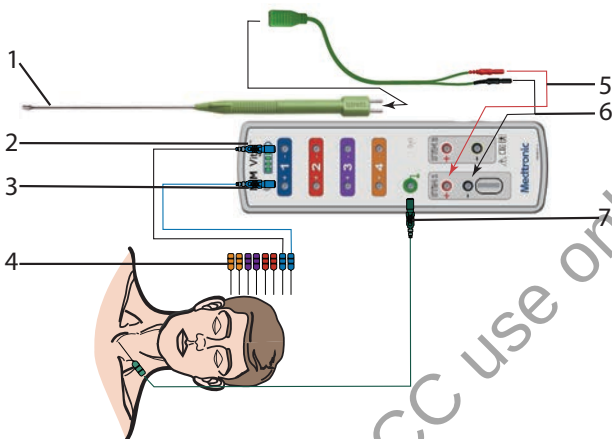
Note: The Incrementing probe connector (2) has three indentations in the connector sleeve and one-off center key that must be aligned with the incrementing probe adapter (3) or the connector may be damaged. Align white arrow (1) on side of Incrementing probe connector with the black arrow on incrementing probe adapter.

Monopolar probe with universal handle

- 1 Stimulator Output, Monopolar Probe and Universal Handle (cathode)
- 2 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 3 STIM 1 Stimulator Return (anode)
- 4 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 5 Electrode Ground
- 6 Paired Electrodes

The (PI) supports one or two monopolar probes. The handle plug is color-coded black and plugs into the black (-) jack on the PI. The monopolar stimulating probe delivers current to the patient and acts as the cathode.

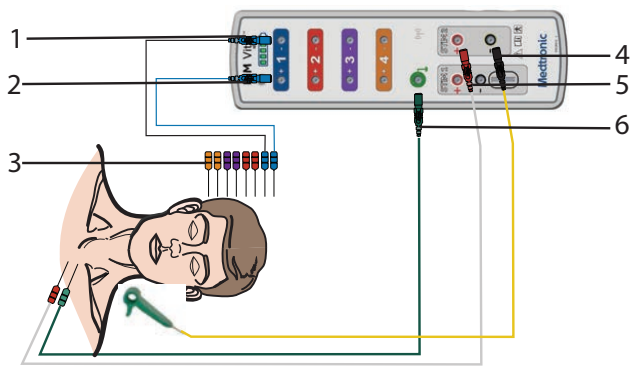
The red electrode with white wire (+) is required for monopolar stimulation. It is referred to as the stimulus return or anode. Plug the red connector of the red electrode with white wire into the white jack with a red ring (+). Route the white (+) stimulus return wire away from the channel 1-8 electrode wires.

Bipolar probe

- 1 Single Use Bipolar Probe and Handle.
- Note:** By default Monopolar (STIM 1 and STIM 2) is selected in the Type Panel (located in the Advanced Settings/Stimulation Panel). The operator should change this to Bipolar.
- 2 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 3 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 4 Paired Electrodes
- 5 STIM 1 Stimulator Return (anode)
- 6 Stimulator Output (cathode)
- 7 Electrode Ground

The PI supports one or two bipolar probes. The stimulator connection uses two different diameter pins to connect to the cable. The cable-to-patient interface uses color-coded connectors (Green wire with a red plug, connecting to the white jack (+) with a red ring, and black plug connecting to the black (-) jack).

Nervassure electrodes stimulator



- 1 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 2 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 3 Paired Electrodes
- 4 Continuous Monitoring Electrodes Stimulator Output (cathode)
- 5 STIM 2/Nervassure Electrodes Stimulator Return (anode)
- 6 Electrode Ground

The patient interface box supports one Nervassure stimulator in the STIM 2 position. The Nervassure electrodes have a yellow wire and black plug. Insert the black plug into the black (-) jack on the PI (STIM2). The Nervassure electrodes deliver current to the patient and act as the cathode.

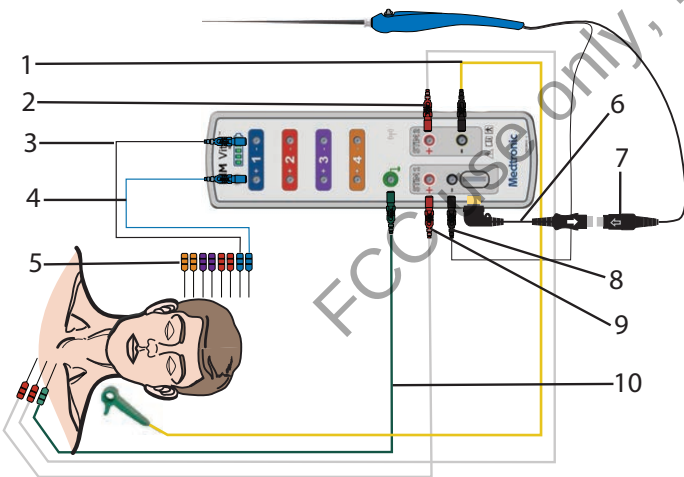
The stimulus return electrode has a white wire and red plug. Insert the red plug into the white jack with a red ring (+). The stimulus return electrode is required for stimulation and is referred to as the stimulus return or anode. Route the white (+) stimulus return wire away from the channel 1- 4 electrode wires.

Patient Interface box and stimulator combinations

Note:

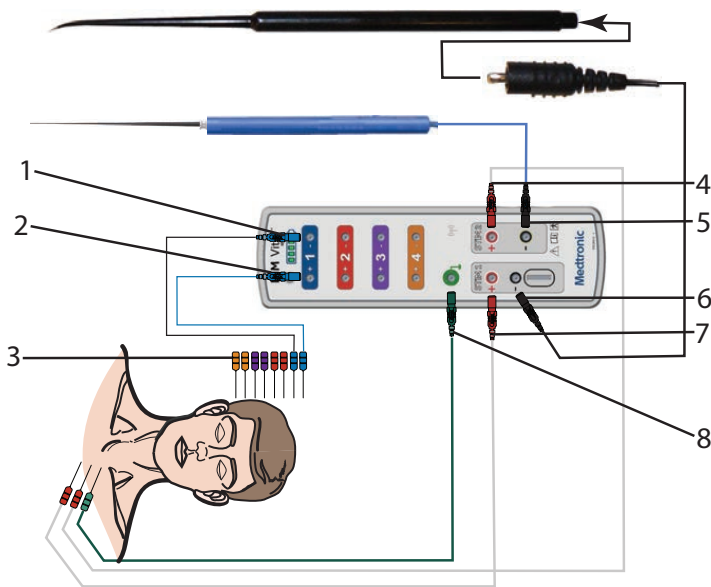
- The NIM Vital STIM 1 and STIM 2/Nervassure are wired independent of each other with each requiring an output (stimulator) and a return (red electrode with white wire).
- By default STIM 1 is on and STIM 2 is off. STIM 2 must be turned on manually (in Nervassure procedures the system turns on stim 2 when the user presses the baseline or adjust button). Refer to the "MONITORING mode" or "SETUP mode" topics.
- By default STIM 1 and 2 are Monopolar Probes and must be changed manually for Bipolar. Refer to the "Settings" topics.

Monopolar incrementing stimulator and Nervassure electrode stimulator



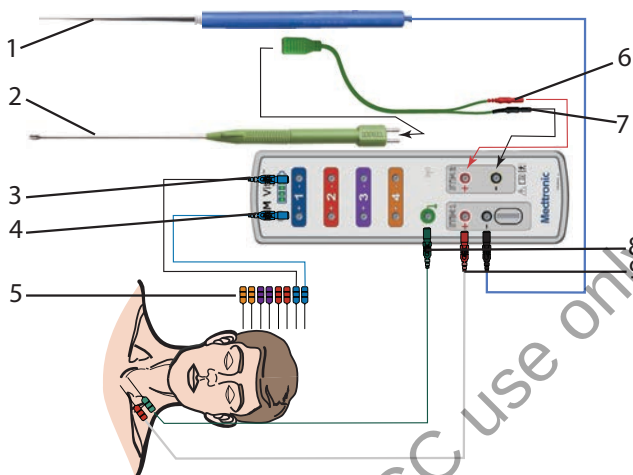
- 1 Stimulator Output, Nervassure Electrode (cathode)
- 2 STIM 2/Nervassure Stimulator Return (anode)
- 3 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 4 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 5 Paired Electrodes
- 6 Incrementing probe adapter
- 7 Remote Control Connector
- 8 Stimulator Output (cathode)
- 9 STIM 1 Stimulator Return (anode)
- 10 Electrode Ground

Monopolar probe and Stimulus Dissection probe



- 1 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 2 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 3 Paired Electrodes
- 4 STIM 2 Stimulator Return (anode)
- 5 Stimulator Output, Monopolar Probe with Universal Handle (cathode)
- 6 Stimulator Output, Stimulus Dissection Probe and Cable (cathode)
- 7 STIM 1 Stimulator Return (anode)
- 8 Electrode Ground

Bipolar and Monopolar probe



- 1 Stimulator Output, Monopolar Probe with Universal Handle (cathode)
- 2 Bipolar Probe and Handle.
- Note:** By default Monopolar (STIM 1 and STIM 2) is selected on the Type Panel (located in the Settings/ Stimulation Panel). The operator should change this to Bipolar.
- 3 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 4 Positive Electrode Jacks (electrodes, plug and wire are the same color)
- 5 Paired Electrodes
- 6 STIM 1 Stimulator Return (anode)
- 7 Stimulator Output (cathode)
- 8 Electrode Ground
- 9 STIM 2 Stimulator Return (anode)

For installing the stimulating electrode

Refer to the Instructions for Use included with your electrode set.

Surgery Notes

Please be aware of the following:

- Use of a stimulating probe is encouraged during surgery in conjunction with Nervassure monitoring.
- When using the NIM EMG endotracheal tube for Nervassure monitoring, tube movement or mucus buildup during surgery can reduce Nervassure responses requiring a new baseline.
- A decrease in the EMG amplitude (greater than the alarm limits) may occur when performing Nervassure monitoring lasting longer than four hours. You may need to acquire a new baseline if this occurs. Please note that stimulating the nerve for up to 8 hours poses no significant risk of nerve injury.

After surgery

Removal of the Nervassure electrodes is the reverse of installation. Refer to the Instructions for Use included with your electrode set.

When the case is complete

Before closing the surgical site, the surgeon should evaluate the nerve's functional integrity one more time. This can be done by stimulating the nerve both proximal and distal to the immediate dissection area as far as is accessible within the surgical field. Use the same pre- and post-surgical dissection stimulation level to compare the response.

Continue to monitor with the NIM Vital system throughout the procedure (until the incision is closed), since items such as wound dressings might exert stress or pressure on the nerve and affect its function.

When monitoring is complete

Turn off the power to the NIM Vital system when the entire procedure is completed and have the licensed medical practitioner remove the electrodes from the patient.

Contaminated single use electrodes and probes must be disposed of in an appropriate sharps biohazard container in accordance with hospital or other user facilities policy.

Managing patient interface boxes

One of the following scenarios could occur when pairing the patient interface box to the NIM Vital system:

- **NIM Vital system that has one wireless patient interface box:** after the user powers on the system, undock the patient interface box and place it on the table or NIM Vital cart. The system automatically pairs with it. **Do not undock patient interface box prior to powering on the system.**
- **NIM Vital system that has two wireless patient interface boxes:** undock patient interface box 1 and place it on the table or NIM Vital cart. If patient interface box 2 is already connected to the system, the NIM Vital console prompts you to choose which wireless patient interface box you want to use for the procedure. Select either patient interface box 1 or 2 and the NIM Vital system pairs with the patient interface box you selected.
- **NIM Vital system that has a wired patient interface box:** undock the patient interface box and place it on the table or NIM Vital cart. Since you are using a wired connection, the NIM Vital system rejects any existing wireless connection and will forget/unregister all undocked patient interface boxes. The system pairs with the wired patient interface box.
- **User decides not to use the wired patient interface box:** unplug the wired patient interface box from the receptacle on the back of the NIM Vital console. The NIM Vital system prompts the user to decide whether to switch to a wireless connection. Select to pair wirelessly and the NIM Vital system automatically pairs with the patient interface box.

If your wireless patient interface has trouble pairing with the NIM Vital system, connect it using the patient interface cable. Follow the above instructions to pair the wired patient interface box to the NIM Vital system.

If the NIM Vital system reboots, the NIM Vital system registers/remembers only the patient interface boxes that are docked or wired to it. Undocked patient interface boxes are forgotten/unregistered by the NIM Vital system.

Note: If the system alerts the user with a warning message indicating there is not enough power in the console battery, use Mains power to charge the console battery and patient interface box batteries.

Power backup

General operation

The NIM Vital System is equipped with a rechargeable battery (PN: NIM4CB01), which is installed in the rear of the console that acts as a battery backup system. The console battery serves two purposes: 1) charges the patient interface box batteries when the system is disconnected from the mains power and 2) provides battery back-up for the console if mains power is lost during use for up to five minutes.

Charging the patient interface box

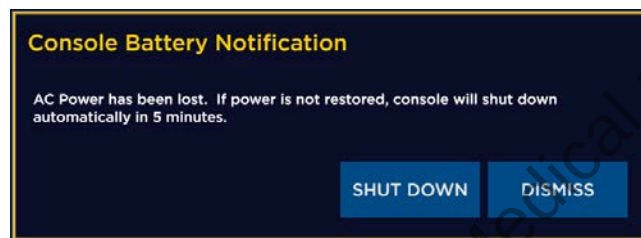
The primary purpose of the console battery is to recharge the patient Interface box batteries when the system is unplugged from the electrical wall outlet or while the system is turned on, in-use and patient interface boxes are connected to the console through the patient interface cable. The console battery is designed to fully charge two 4-channel patient interface boxes when the system is powered down. During the patient interface charging process the power button will flash until the patient interfaces are charged and the console completely shuts down and the power button will no longer flash. PI need to be docked within five minutes after removing Mains power to initiate PI charging. The system will remain in stand-by mode (flashing power button).

The secondary purpose of the console battery is to serve as a backup power supply should the system lose wall power either accidentally or intentionally such as moving the system to another part of the operating theater.

Loss of power during surgery

The secondary purpose of the console battery is to act as backup power should the system lose Mains power either accidentally or intentionally. for example, when moving the system to another area of the operating theater.

The system is designed to continue monitoring when unplugged for a minimum of five minutes to allow time for reconnection to Mains power or moving the system to another location and reconnecting to power. If the system is disconnected from mains power during use, the system displays the following caution message on the screen and an alarm sounds to indicate the system has been unplugged.



The user may clear the warning and alarm to continue using the NIM Vital during while unplugged; however, a second warning and alarm occurs after four minutes indicating that the system will shut down in one minute if mains power is not restored.

Console battery charging

The system automatically charges the console battery any time it is plugged into the mains power and adequately charges the console battery to 100% after approximately two hours of continuous power application, or if left plugged into the wall between surgical procedures.

Using the console with no battery installed

If the console battery is not installed in the NIM Vital system or has reached the end of its life, the system displays a warning message that the user may clear to continue with normal monitoring. The system still functions as a nerve monitor but does not have the backup capability and shuts down when unplugged. Additionally, the console will not be capable of recharging the patient interface boxes once the system is unplugged from the wall.

Troubleshooting

	Symptom	Cause	Solution
1	Error message appears on screen. Examples: - No communication - Self-test failure	Internal NIM communication error or malfunction	Turn NIM power button off, wait five seconds and then turn it on again. If issue persists, contact Medtronic customer service
2	Electrode impedance is too high. > 10 K Ω for subdermal electrodes. > 25 K Ω for Prass paired electrodes. > 7.5 K Ω for EMG tube. > 40 K Ω for hookwire electrode.	Electrode dislodged from patient, but not completely out. High resistance in electrode.	Insert dislodged electrode; tape down in place. Remove and replace with new electrode.
		Electrode pin not firmly inserted into patient interface.	Check connection at Patient Interface box.
3	No artifact response or sound is evoked if an electrode "Tap Test" is conducted.	The NIM artifact filter typically removes this type of artifact.	The "Tap Test" to evoke artifact is not reliable and does not confirm proper electrode or EMG tube placement and therefore not recommended.
4	Electrode impedance is too low (≤ 0.1 K Ω).	Positive and negative electrodes touching below surface of skin.	Remove and relocate electrodes.
		Extremely low impedance may be observed in a normally functioning EMG tube.	This is normal. No action required.

5	Electrode reading is (lead off): (+ or -) Off	Electrode laying on skin surface. Surface electrodes may have too high of impedance to be used which causes the symptom.	Re-insert electrode in question.
		Electrode placement insecure. Dirty electrode tip.	Remove and replace electrode in question.
		Electrode cable is broken.	Check connection to Patient Interface box.
		Electrode pin disconnected from patient interface.	Remove and replace electrode for appropriate channel with highest impedance reading first.
6	Electrode imbalance is too high. > 2K Ω (Subdermal electrodes) > 10K Ω (Prass Paired electrodes).	Dirty electrode.	Remove and replace electrode in question.
		Mismatched pair.	Remove and replace electrode in question.
		Unequal placement.	
7	Stimulus Return Impedance is shown high on the Electrode Check panel (Question mark at STIM 1, STIM 2, or ground).	No stimulus return electrode connected.	Connect the stimulus return electrode.
		Ground not connected.	Connect ground.
8	Unexpected artifact events on the NIM.	Excessive electrical noise on the patient interferes with NIM electrode measurement.	Identify and eliminate the source of the noise. Proceed to monitoring and verify stimulus delivery via stimulus current return value.
		Metal-to-metal discharge artifact.	Determine response type from waveform pattern on 50 ms screen.
		Intertwined recording electrode and stimulator wires.	Disentangle recording electrode and stimulator cables.
		Inadvertent manipulation of electrode wires, Patient Interface cable, or recording area on patient.	Check area near recording electrodes for excessive stretching from tape, drapes, etc.
9	Interference on external anesthesia equipment (ECG Monitor) from the NIM.	Check for intermittent stimulation from anesthesiologist (i.e., hand-held electrical stimulator).	Check for intermittent stimulation from anesthesiologist (i.e., hand-held electrical stimulator).
		Electrical interference from other equipment.	Move NIM Vital system away from source of interference.
			Make sure Patient Interface cable and electrode wires do not cross other electrical equipment or cables.
10	Interference on external anesthesia equipment (ECG Monitor) from the NIM.	Electrode Check automatically generates current through the electrodes during setup.	Try an alternate ECG Lead set.
		Electrode Check automatically generates current through the electrodes during monitoring when selected by the user.	Deselect Electrode Screen.
		Muting function active.	See Excessive Muting (Symptom Column).
		With Stimulator active.	Turn the NIM Stimulator to 0.0 mA when not needed.
11	Electrosurgical unit causes interference with the NIM screen and audio.	The muting filter may not be enabled.	Turn muting filter on.
		The muting filter is insufficient.	Consider using external muting detector.
		Electrosurgical grounding inadequate.	Check electrosurgical grounding pad on patient.
		NIM Vital system or Patient Interface cable too close to electrosurgical unit or its cables.	Maintain separation between electrosurgical cable and the NIM system.
12	Excessive Muting causing monitoring to be disabled (the muting message appears on the screen).	Unit receiving excessive signal.	Disconnect the muting detector completely. Turn off the muting software filter.
13	Inadequate muting causing monitoring artifact events and audio noise.	The muting filter in the software may be inadequate or turned off.	Ensure the muting filter is turned on in the software.
		If using the optional muting detector, it may be damaged, or not plugged in to the NIM.	Inspect the internal jaws for damage.
		The Muting Detector is not plugged into the NIM.	Plug the Muting Detector into the NIM.
		The electrosurgical unit's signal is too low to be muted.	Loop the electrosurgical unit cable and clip the muting detector over the doubled cable.
14	May not be using the correct Muting Detector.		
15	Rhythmic Artifact from pacemaker in safe mode.	Pacemakers – Pace Pulse is picked up by the NIM electrodes or EMG tube.	Relocate electrode ground and stimulus return to patient's shoulder (Acromion).
16	Incrementing Probe will not adjust stimulation.	Loose connector, or not plugged into the patient interface.	Check connector is properly aligned and fully seated (See System Set-Up / Patient Interface Set-Up).
17	Incrementing Probe stimulus keeps changing (run away).	Bad Incrementing Probe.	Replace Incrementing Probe or disconnect STIM CONTROL connector and manually adjust stimulus at touch screen.

Nerve Integrity Monitor

16	No EMG response to direct stimulation.	Inadequate stimulus intensity.	Increase stimulus intensity.
		Paralyzing anesthetic in use.	Eliminate paralyzing anesthetic.
		White Stimulus Return electrode (+) electrode has fallen out or is not connected.	Check stimulator cathode (-) connections.
		Stimulator probe not connected.	
		Patient Interface stimulator fuse blown.	Check fuse in STIM 1 (EMG) Patient Interface. Replace if necessary with REF 8253075 only.
		STIM 1 (EMG) Patient Interface fuse REF 8253075.	
		Not holding probe on nerve long enough.	Hold probe tip to nerve for at least 1 second.
		Nerve not contacted with flush tip.	Contact the flush tip of the probe perpendicular to the nerve.
		Volume control too low.	Check and correct volume and event threshold.
		Event threshold set too high.	
17	Unexpected EMG responses when not directly stimulating nerve.	Unexplained continuous "train" EMG response.	Identify and eliminate possible source of "train" stimulation: • Cold irrigation. • Stray heat from electrocautery bovie. • Laser heat. • Retraction on nerve or muscles being recorded. • Patient waking from anesthesia. • Nerve drying. • Ultrasonic aspirator.
		Nerve or monitoring area being stimulated or manipulated by other thermal or mechanical means.	Identify and eliminate source of inadvertent manipulation.

Patient interface troubleshooting

Symptom		Cause	Solution
1	The patient interface does not wirelessly connect to the NIM Vital system at start-up.	Patient Interface is not paired with the system.	Place the patient Interface in the dock located at the rear of console. Select a procedure and navigate to the Connection screen. Remove the patient Interface after three seconds and verify the wireless connection indicated on the console screen and the blue wireless symbol light on patient Interface changes from blinking to solid. If the wireless connection continues to fail, attach the patient Interface cable for wired operation.
		The battery charge is depleted.	Re-dock the patient Interface in the dock located at the rear of the console. Check the battery charge icon on the NIM Vital screen to verify the battery level. If low, connect the patient Interface cable for wired operation or re-dock the patient Interface in the charging cradle. Connect the patient Interface cable for wired operation and battery charging.
2	The patient interface does not work in the wireless configuration during the surgical procedure.	The battery charge is depleted. A non-typical electrical interference in the operating theater from a miscellaneous source.	Connect the patient interface cable for wired operation and battery charging.
3	The patient interface does not work in wired mode.	The patient interface cable is not fully inserted into the patient interface and/or the NIM Vital console.	Check cable connections at the patient interface and NIM Vital console ends to ensure full insertion and connection. Full insertion is indicated by a tactile click. If the condition persists contact Medtronic Customer Service.

Reprocessing and maintenance

Cleaning

The cleaning instructions detailed below apply to the NIM Vital cart, system monitor, patient interface and cable (if using a wired patient interface), muting detector and cable(s), printer and printer cable, power cords and a USB flash drive:

- Disconnect all cables from the system components.
- Clean the units by wiping them down with a soft, lint-free cloth dampened with a solution of one of the following detergents:
 - a pH-neutral (pH 6-8), enzymatic detergent
 - a mild-alkaline (pH8-11), non-enzymatic detergent

The detergent should be used at the concentration and temperature recommended by the detergent manufacturer. The temperature of the detergent solution should not exceed 40° C (104° F).

- Wipe in a single direction and away from vents and crevices to avoid introducing contaminants into the system.
- After cleaning heavily soiled areas, use another clean cloth to mitigate cross contamination.
- Continue wiping until visible organic soil has been removed.
- If contamination is suspected in areas not accessible for wiping (for example: crevices, on the inside of the Patient Interface clips), clean those areas using a brush moistened in the detergent solution until visible soil has been removed.

- Remove detergent residues from the system by wiping it down with a soft, lint-free cloth dampened with purified water.
- Dry the units by wiping them with a clean, dry lint-free cloth until visible moisture has been removed.

Disinfection

The intermediate-level disinfection instructions detailed below apply to the NIM Vital cart, system monitor, patient interface and cable (if using a wired patient interface), muting detector and cable(s), printer and printer cable, power cords and a USB flash drive.

- Prior to disinfecting the system, ensure that the system has been cleaned per the cleaning instructions above and that cables are disconnected from the system components.
- Disinfect the system by wiping its external surfaces with a soft, lint-free wipe soaked with one of the following solutions:
 - a 70% solution of isopropyl alcohol (IPA) in purified water.
 - a 0.5% solution of Accelerated Hydrogen Peroxide (AHP).
- Wipe in a single direction and away from system's crevices.
- Allow the disinfectant to remain with system's surfaces for a minimum of 10 minutes.
- If required due to air-drying, re-apply the disinfectant as described above to achieve the required minimum contact time.

Storage

Allow the NIM Vital system and accessories to thoroughly air-dry before storing them in a cool dry place. Refer to the "Technical Specifications" topic for more information.

Maintenance

Medtronic provides three ways to maintain your system to ensure optimal electrical and functional performance related to nerve detection and stimulation. System self-tests are performed by the system at boot up. System Quick Check is performed by the user. Planned maintenance is performed by Medtronic.

The maintenance schedule must comply with the policies of your institution's infection control unit and/or biomedical department.

System self-tests

The system automatically performs a series of self-tests and reports any failures on-screen at start-up. Whenever a problem is detected then a comprehensive testing should be performed by returning the console and patient interface to Medtronic Service and Repair.

System quick check

The user can complete the functional and safety testing using the Annual System Quick Check checklist page included in this manual.

Note: Refer to W30.

Annual planned maintenance

To help maintain performance and ensure optimal electrical and functional performance related to nerve detection and stimulation Medtronic recommends returning the system for planned maintenance once per year or whenever a problem is suspected; or more often as required by local statutory, hospital administration or business practice.

During the annual planned maintenance over 100 tests are performed. These include comprehensive visual, functional and electrical safety testing; and Patient Interface battery check and replacement, if necessary. Medtronic returns systems to the customer with a certificate indicating maintenance performed.

Contact Medtronic Service and Repair to schedule an annual planned maintenance.

Annual system quick check

User maintenance for the NIM Vital is limited to visual inspection before use and periodic cleaning. Annual "System Quick Check" with Simulator and System Safety Checks according to IEC/EN60601-1 is recommended. Please see Warning W6h. If the user does not have a patient simulator (CFN # 8253600), please contact Medtronic's customer service to purchase one.

Model # _____ S/N _____ Tester _____ Date _____

A. System quick check with Simulator (A. a - f) _____ (✓)

Use Patient Simulator to confirm appropriate behavior.

Refer to the Patient Simulator Instructions for Use topic to confirm the following:

- a. System Set-Up _____ (✓)
- b. Confirming Electrodes _____
- c. Electrode Lead Off _____
- d. Mechanical Stimulation _____
- e. Stimulus: Set and Measure _____
- f. Threshold Test _____

B. System safety check according to IEC/EN60601-1

Medtronic recommends System Safety Checks to be scheduled at yearly intervals.

IEC/EN60601-1 safety analysis

In accordance with local procedures, perform a complete Safety Analysis for a Class 1, Type BF Device on the NIM Console.

Utilize “Equipotential Ground” connector found on rear of console as Chassis ground.

For Patient Leakage and Mains on Applied Parts tests, a Patient Interface must be attached to the NIM Console with electrodes connected to each channel.

Ensure Ground Impedance is less than 0.252 Ωs when measured with a 25 Amp source.

High potential (Hi-Pot) testing (B. a - c) _____ (✓)

In accordance with local procedures, perform the following Hi-Pot tests on the NIM Console.

Note: Perform Test at voltages indicated and record values in space as needed.

Safety ground to Line/Neutral:

Apply Hi-Pot to Line and Neutral of Power Inlet of NIM® Console while monitoring Ground.

Applied Parts to line/neutral:

Apply Hi-Pot to Line and Neutral of Power Inlet while monitoring Applied Parts.

Precaution: use DC voltage only when performing Applied Parts Hi-Pot test. AC Hi-Pot voltage to applied parts will damage the device.

System Safety Check	Manufacturers Specifications	Recorded Value
a. Ground impedance	<0.252Ω @ 25 Amps	_____
b. Safety ground to Line/Neutral	<5.0 mA @ 1500 Vac	_____
c. Applied Parts to line/neutral	<1.0 mA @ 3535 Vdc	_____

Accessories

System description

The Medtronic NIM Universal Patient Simulator provides for testing some of the features of the NIM system without the need for patient interaction. In addition, the NIM Universal Patient Simulator is a convenient means of testing various aspects of instrument operability prior to patient application.

This section describes the NIM Patient Simulator and pertinent components of the NIM system used during a test.



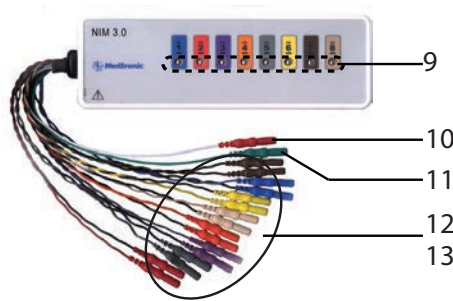
On the NIM Vital Universal Patient Simulator, there are 8 channel stimulation contact pads, one (1) for each channel. These contacts are the points for activating individual circuits. A monopolar probe is recommended for use during testing.

Simulator set-up

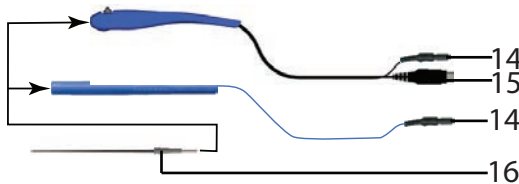
Simulator use requires prior setup of the NIM Vital unit as previously described.



- 1 Electrode ground
- 2 Auxiliary stimulator STIM 2 or Nervassure jack
Note: You cannot use the Nervassure Stimulating Electrodes with the Simulator.
- 3 Incrementing Probe control jack
- 4 Stimulator STIM 1 jack
- 5 Stimulus return jack
- 6 Positive electrode jacks
- 7 Negative electrode jacks



- 9 Simulated patient with inserted electrodes (pads)
- 10 Simulated stimulus return plug for connection to the Patient Interface
- 11 Simulated electrode ground plug for connection to the Patient Interface
- 12 Simulated negative electrodes for connection to the Patient Interface
- 13 Simulated positive electrodes for connection to the Patient Interface



- 14 Stimulus plugs for connection to the Patient Interface.
- 15 Incrementing probe control plug for connection to the Patient Interface
- 16 Probe for stimulating patient electrode pads (Simulated Events)

Follow these steps to set-up the system for Patient Simulator use:

1. Connect all channel jumper cables (simulated subdermal electrodes, ground, and STIM 1 return. You can also use STIM 1 return as the STIM 2 return) from the simulator to the corresponding patient interface. Refer to the Wiring Table topic.
2. Connect a monopolar stimulator to the STIM 1 negative (black) jack on the patient interface.

Wiring Table			
Patient Simulator to Patient Interface			
Connector	Wire	Ch. #	Connects To
Blue	Blue	1	Positive
Blue	Black	1	Negative
Red	Red	2	Positive
Red	Black	2	Negative
Purple	Purple	3	Positive
Purple	Black	3	Negative
Orange	Orange	4	Positive
Orange	Black	4	Negative
Red	White	N/A	STIM 1 / 2
Green	Green	N/A	Ground

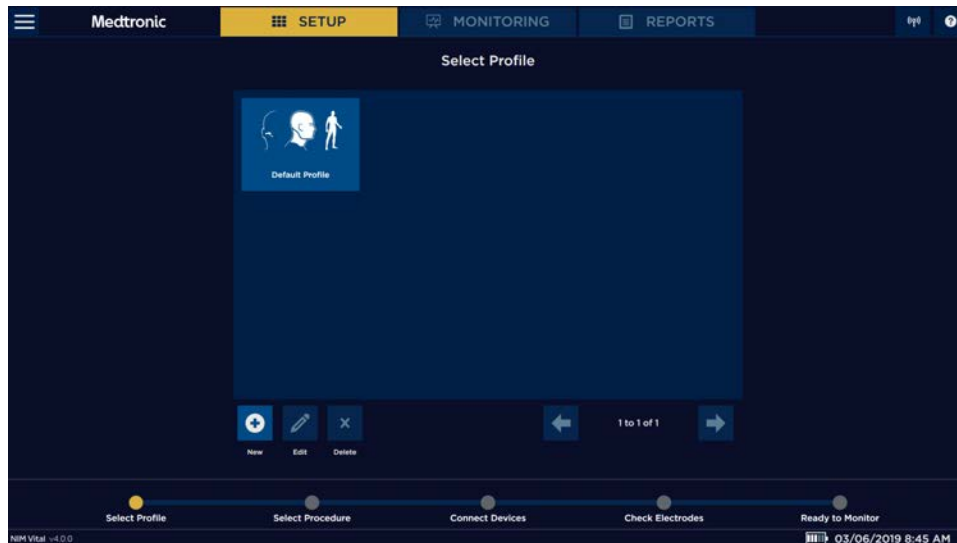
Use the patient simulator

Confirming electrodes

This check confirms that all electrode circuits are connected and functioning properly.

1. Connect Simulator and probe to the patient interface box and the patient interface box wirelessly to the NIM Vital system.
2. Turn on the power switch.

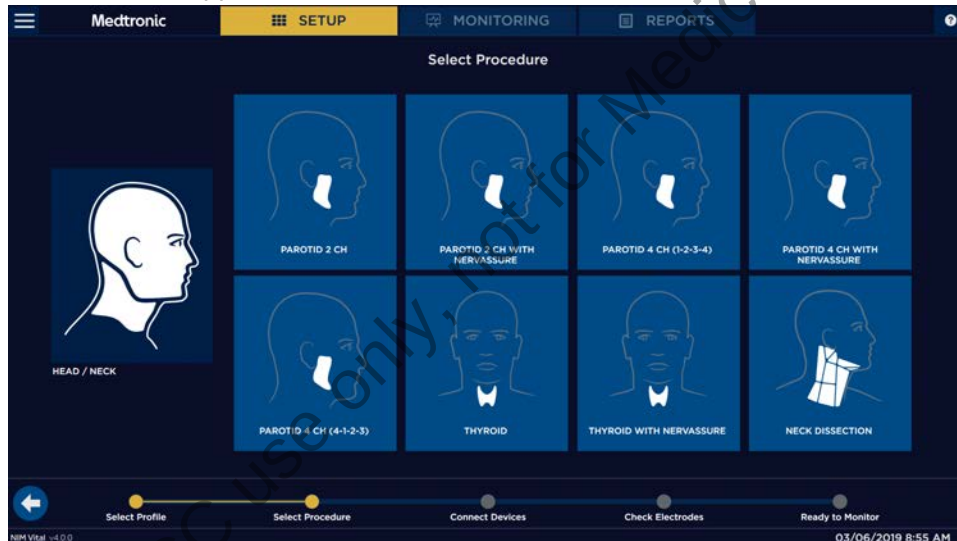
The NIM Vital performs a series of self-tests during the boot up process. After the splash screen closes the SETUP screen appears.



You can select any procedure. For this assessment the assumption is that you have setup a custom procedure (refer to the System Setup/Custom Setup for instructions) called "Stimulation Test" and named the channels Ch 1, Ch 2, CH 3, CH 4.

3. Select User Profiles/ Stimulation Test.

The Select Procedure SETUP screen appears.



4. Select a procedure.
The Connect Devices screen appears.
5. Connect the patient interface box (wired or wirelessly).
6. Press .
- The Check Electrode screen appears.
7. Press Show Details.

The Electrodes screen appears. Confirm the following:

- All channels are on.
- All channels have Subdermal selected.
- Positive and negative k Ω (impedance) for 4 channels is 5.1 k Ω or 5.6 k Ω $\pm$ 1.0 k Ω with the Patient Simulator.
- The Δ (difference) in their values is 500 Ω $\pm$ 500 Ω .
- The k Ω (impedance) of the Ground is 6.5 k Ω $\pm$ 1.0 k Ω .
- The k Ω (impedance) of the Stimulus Return is 6.2 k Ω $\pm$ 1.0 k Ω .

Note: If any of these conditions are different, check your setup. If still incorrect, contact Customer service.

Electrode lead off

This test simulates what happens when contact with an electrode is lost.

1. On the Monitoring screen, disconnect the positive lead from Channel 1 (all adjustments are at default values).

After Removal:

- Channel 1 shows a lead off message.
 - After approximately a few seconds, the system displays "Lead Off" in yellow text on a zero (0) amplitude waveform line.
2. Reconnect the electrode and confirm the NIM Vital returned to normal operation.
 3. Repeat test for all channels.

Note: If any of these conditions are different, check your setup. If still incorrect, contact Customer service.

Stimulation

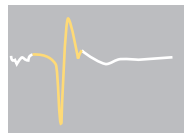
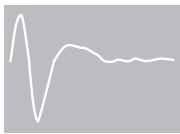
Mechanical stimulation

The positive and negative patient stimulator electrode cables are sensitive to touch (mechanical stimulation) and generate EMG visual tone responses when manipulated (tapped). These simulated responses appear as spontaneous burst-like responses.

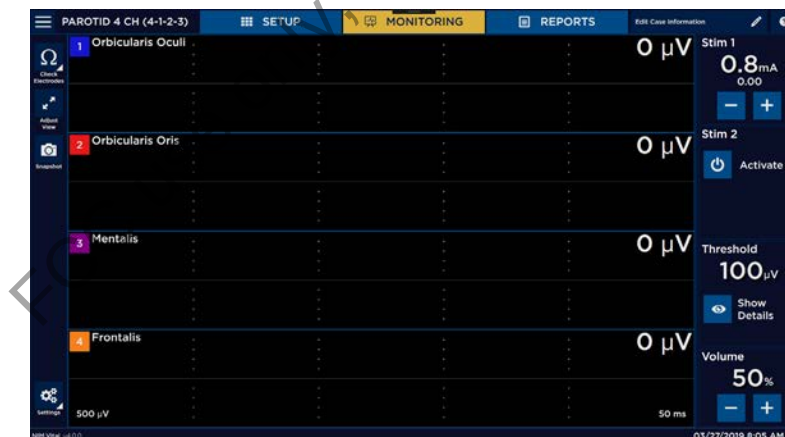
1. Start at the Monitoring screen with default settings and all electrodes connected.

Note: The Artifact Filter check box on the Settings/Display/Advanced button/MONITORING tab should be selected (On) by default. If not, turn it on (select).

2. Lightly tap the electrode connectors.
3. Observe the following:
 - You should hear single beep as each channel is tapped.
 - Alarm tones are lowest for channel 1 and highest for channel 4.
 - You should see sharp (spike like) waveforms on the screen.
 - The "Detected Artifact" appears as an orange trace.
 - Tapping multiple cables produces multiple alarms and waveforms.

		
Un-Stimulated (mechanical) Event	Stimulated (patient simulator) Event	Stimulated Event

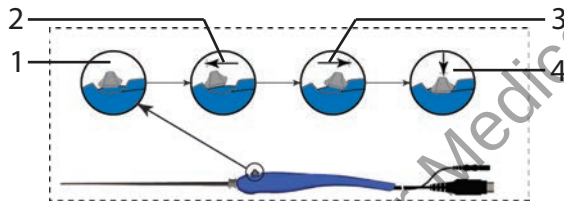
Stimulus: set and measure



1. Start at the MONITORING screen (default settings) with all electrodes connected using a monopolar probe with universal handle, or incrementing probe handle with Prass tip.
2. Check the stimulus adjustment buttons for the following:
 - The upper right of the screen should read 1.0 unless the user needs to lower it (this is the mA setting).
 - Below the mA setting is a small window reading 0.00 mA. This is the measured value.
 - Press [+] and [-] observing that the mA setting changes values.
 - Press the mA [+] until reaching a value of 3.00 mA.
 - A dialog box appears
 - Stimulus in excess of 3 mA.
 - Press **[Confirm]** to enable stimulus.

Nerve Integrity Monitor

3. Touch and hold the stimulating probe to channel 1 of the Patient Simulator and observe the following:
 - Stimulus waveform on channel 1 (Refer to the Example Stimulus and Spike Waveforms).
 - Stimulus tone sounds (steady repeating beep).
 - Raw EMG can be heard (a popping sound accompanying the stimulus tone).
 - mA Measured is $\pm 5\%$ of the mA setting.
 - The system displays the μV reading to the right and above the zero (0) amplitude line in yellow and boxed.
4. Repeat test for all channels.
5. Set mA button to 1.00 mA and Event Threshold to 100 μV (default settings for a Thyroid procedure. Other default settings may vary depending on the procedure chosen).
6. Stimulate channel 1 and observe that the stimulus tone sounds (repeating beep) and raw EMG can be heard (a popping sound accompanying the stimulus tone).
7. Increase the Event Threshold to 500 μV and stimulate channel 1 and observe the following:
 - Stimulus waveform on channel 1.
 - Stimulus tone is NOT heard.
 - Raw EMG can be heard (a popping sound).
 - mA Measured is $\pm 5\%$ of the mA setting.
 - The system displays the μV reading to the right and above the zero (0) amplitude line, the highest in a yellow box.
8. Repeat for remaining channels.
9. Move the Stimulator and STIM 1 Return to STIM 2 and repeat steps 2, 3, and 7 using any channel.



10. If a Remote (Incrementing Probe) is available, check the stimulus adjustment as shown in the 2, 3 and 4 illustration. (If all 8 channels have been tested it is acceptable to test the remote probe on any one channel).
 - 1 - Toggle button normal or at rest.
 - 2 - Increase current.
 - 3 - Decrease current.
 - 4 - The user can perform the following functions with the toggle button:
 - Momentary press saves the current screen to memory (for reports) and to a selected peripheral device (printer and/or USB flash drive) if the user selected that option in the settings area.
 - Press and hold opens a menu on the user interface with more options.

Note: If any of these conditions are different, check your setup. If still incorrect, contact Customer service.

Threshold test

1. Decrease Event Threshold to 20 μV .
2. Grasp one lead of the channel 1 electrode wire to induce artifact noise over 20 μV threshold causing continuous event tones to sound. If the artifact is not over the 20 μV level, event tones and auto threshold will not be able to be tested.
3. Select Auto Threshold located at Settings/Display/Auto Threshold.
4. Press the channel 1 electrode wire with your finger and observe the following:
 - Continuous event alarms sounding for ten seconds.
 - After ten seconds, the system announces the Threshold Increase.
 - The new threshold value appears next to the channel number.

Note: Auto Thresholds maximum is 400 μV . Holding a channel electrode wire between your thumb and forefinger, or pressing the wire too hard can generate signals greater than the maximum. In this case the threshold increases to 400 μV , but alarms continue to sound.

5. Repeat for the remaining channels.

Note: If any of these conditions are different, check your setup. If still incorrect, contact Customer service.

Cleaning

Refer to the "Cleaning and Maintenance" topic.

Storage

Allow the unit and accessories to thoroughly air-dry before storing in a cool dry place. Refer to the "Technical Specifications" topic for further information.

Troubleshooting

Should you encounter any difficulty eliciting simulated responses from the NIM Vital system patient simulator, check the following:

- Verify that the Stimulus Measured is approximately the same as the Stimulus Intensity.
- Make sure the jumper cables are connected correctly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM Vital system.
- Adjust the STIMULUS intensity on the NIM Vital system for adequate output.
- Clean the stimulator contacts of debris.
- Check the integrity of the stimulator or stimulus-dissection instrument and its connecting cable.
- Check for a blown fuse in NIM Vital system patient interface and replace with a proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM Vital system patient interface.

Customer service information

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

Troubleshooting

Should you encounter any difficulty eliciting simulated responses from the NIM Vital system patient simulator, check the following:

- Verify that the Stimulus Measured is approximately the same as the Stimulus Intensity.
- Make sure the jumper cables are connected correctly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM Vital system.
- Adjust the STIMULUS intensity on the NIM Vital system for adequate output.
- Clean the stimulator contacts of debris.
- Check the integrity of the stimulator or stimulus-dissection instrument and its connecting cable.
- Check for a blown fuse in NIM Vital system patient interface and replace with a proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM Vital system patient interface.

Customer service information

For further information regarding the use of this product or to report any problems, please contact Medtronic using the appropriate information provided on the blue and white contact information card packaged with each device; or contact your local distributor.

External display support

The NIM Vital system has the following external video port, but does not have any specific connection settings for a microscope output:

- HDMI
- Display probe

Wireless display module

The wireless display module enables users to wirelessly replicate the NIM Vital console display onto any monitor with an HDMI input port. Refer to the installation instructions packaged with the wireless display module.

NIM Vital Mute adapter (optional)

The NIM Vital mute adapter enables the NIM Vital console to be connected to an external muting detector.

1. Console Connector (below knobs) .
2. Connector to mute probe.
3. Tether.

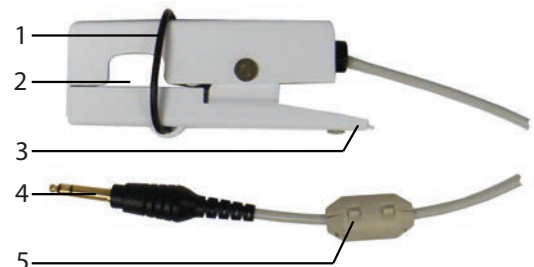


NIM Muting detector (optional)

Refer to Precaution P7 for more information.

The optional Muting Detector Probe is designed to detect the presence of electronic noise from external devices (such as electrocautery/electrosurgical unit) that may cause interference on the EMG monitor. The use of a mute probe could be considered if there is excessive noise from the electrosurgical unit.

1. Anti-slide Ring.
2. Electronic Noise Detection Area.
3. Insulating Sleeve.
4. Cable Connector.
5. Ferrite.



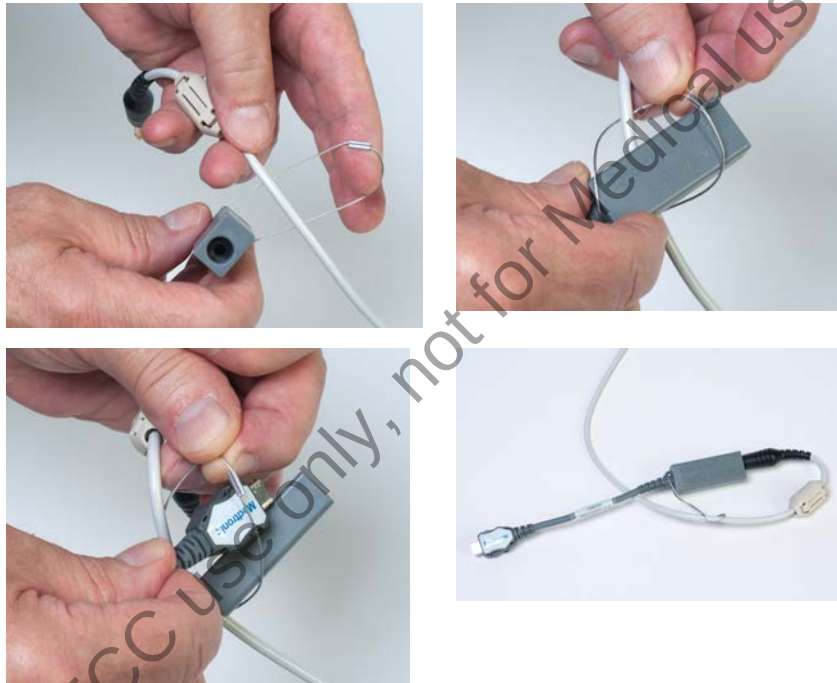
Muting Detector setup

Refer to Precaution P7.

1. Connect the mute probe adapter to the console.



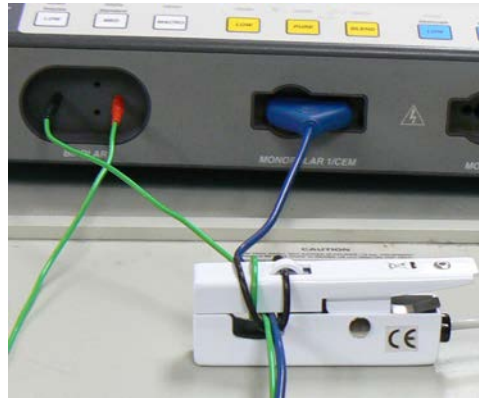
2. Connect the mute probe to the mute probe adapter.



3. Open the Muting Detector jaws and insert the cable from the electrosurgical instruments ensuring that the wire is free to move and the jaws are completely closed.
4. Route the wire straight through the clamp.



Standard Clamping



Monopolar and Bipolar (if needed) Clamping

Note: Bipolar clamping is normally not needed, but if power level is very low it may be necessary to loop the single conductor around and through the clamp. Refer to step 6 for clamping instructions.

5. Slide the cable so the probe is near the main unit of the electrosurgical instruments, not near the hand piece(s).
6. Slip the upper side of the anti-slide ring around the end of the Muting Detector to form a "U" around the cable. Pull it snugly against the probe's lower jaws (see Steps 1 & 2).

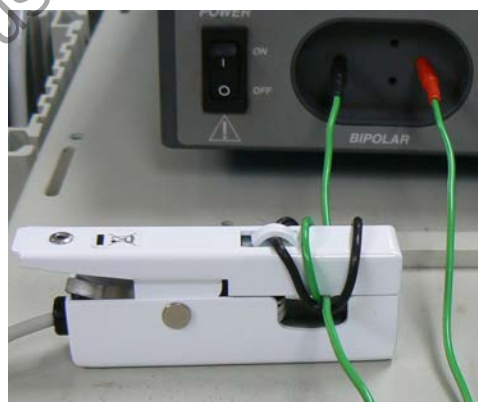


Step 1

Step 2

Note: Do not clip the Muting Detector to the grounding pad cable.

7. Secure the Muting Detector and Patient Interface cables to the floor with tape or other non-slip/trip device.



8. If necessary, for very low power levels, loop the single conductor around and through the clamp once.

Additional mute probe adapter information

To remove the mute probe adapter from the console, squeeze the two tabs on the side of the adapter to release it.

To tether the mute probe adapter to the muting detector, do the following:

1. Loop the mute probe adapter tether around the muting detector.
2. Take the end of the mute probe adapter marked with "Medtronic" and slip it through the tether, while going around the muting detector's cable.

Muting

The Muting Detector is normally clamped around the active cable of an electrosurgical instrument that would otherwise interfere with monitoring. Do not include the grounding pad cable in the jaws of the Muting Detector. It may also be connected to other equipment cables, such as electrocautery, ultrasonic debulking devices (for example, CUSA), or other external devices, which generate interfering signals. Always attach the Muting Detector close to the output jacks of the electrosurgical or other unit rather than near the hand piece the surgeon uses. More than one output cable may be clamped within the Muting Detector jaws at one time.

Monopolar electrosurgical instrument clamping

Power level for satisfactory muting performance of electrosurgical unit:

- Monopolar Electrosurgical Unit
- 5-100 W

STIM Bur Guard

The STIM Bur Guard provides stimulating current to standard Medtronic burs in both static and dynamic modes. The STIM Bur Guard locks onto any Visao handpiece, while the cable connects to a port on the IPC System or XPS 3000 (REF 1897102BF). A separate cable then connects to the NIM Patient Interface box. Wires within the STIM Bur Guard make contact with the uncoated bur and carry the stimulating current to the bur tip.

Prior to using this device, you must be familiar with the NIM Systems User's Guide, the Bur manual, the STIM Bur Guard User's Guide, and the IPC System or XPS 3000 (REF 1897102BF) User's Guide.

Compatible equipment:

- XPS 3000 Console (1897102BF)
- IPC Console

For more information related to the STIM Bur Guard system contact your local Medtronic representative.



Accessories / parts list

System components & accessories

(See Medtronic Catalog for product details **Note:** online some numbers require a dash xx-xxxxx)

P/N	Description	P/N	Description
NIM4CM01	NIM Vital Console	NIM4CC01	NIM Vital Cart
NIM4CS01	NIM Vital Storage Case	NIM4CB01	NIM Vital Battery Console
Mainframe accessories			
NIM4CPB1	NIM Vital Patient Interface (4 channel)	NIM4CAV1	NIM Vital Video/Audio Recording Adaptor Kit
NIM4CFU1	Fuse Kit, NIM4CFU1 NIM Vital Console	NIM4CC02	NIM Vital Power Isolator for Printer
8253075	FUSE KIT 8253075 NIM 3.0 INTFC 32MA	NIM4CPB2	NIM Vital Patient Interface Connector Cable
NIM4CC03	International NIM Vital Power Isolator for Printer	8220325	Muting Probe NIM
NIM4CD01	NIM Vital Wireless Display Module	NIMCAD400	NIM Incrementing Probe Adapter
8253030	Keyboard	NIM4CAM1	INTFC Adaptor Mute Probe
EMG Endotracheal Tubes			
8229506	NIM EMG Endotracheal Tube, 6 mm	8229709	NIM Trivantage EMG Endotracheal 9.0 MM ID
8229507	NIM EMG Endotracheal Tube, 7 mm	8229735	3PK NIM Trivantage 5 MM
8229508	NIM EMG Endotracheal Tube, 8 mm	8229736	3PK NIM Trivantage 6 MM
8229705	NIM Trivantage EMG Endotracheal 5.0 MM ID	8229737	3PK NIM Trivantage 7 MM
8229706	NIM Trivantage EMG Endotracheal 6.0 MM ID	8229738	3PK NIM Trivantage 8 MM
8229707	NIM Trivantage EMG Endotracheal 7.0 MM ID	8229739	3PK NIM Trivantage 9 MM
8229708	NIM Trivantage EMG Endotracheal 8.0 MM ID		
Monopolar Stimulating probes			
8225101	Standard Prass Flush-Tip Stimulator Probe, 5/Box	8225278	Ball-Tip Monopolar Stim Probe 1 mm (tips only), 10/Box
8225110	Standard Prass Flush-Tip Stim Probe (tips only), 10/Box	8225251	Ball-Tip Monopolar Stim Probe 2.3 mm (tips only), 10/Box
8225275	Ball-Tip Monopolar Stimulator Probe 1mm, 1/Box	8225277	Yingling Flex-Tip Monopolar Stimulating Probe, 5/Box
8225825	Incrementing Probe with Standard Prass Tip, 3/Box	8225051	Monopolar Stimulator Handles, 10/Box
8225276	Ball-Tip Monopolar Stimulator Probe 2.3 mm, 1/Box	8225490	Incrementing Probe, Ball Tip 1mm 3/Box

Bipolar Stimulating probes			
8225351	Concentric Bipolar Stimulating Probe, 5/Box	8225401	Side-by-Side Bipolar Stimulating Probe, 5/Box
8225451	Prass Bipolar Stimulator Probe, 5/Box		
Power cords			
1895825	Power Cord, 6 Meter, EU	1897821	Power Cord, 6 Meter, Standard, U.S.
1895824	Power Cord, 6 Meter, U.K.	1895823	Power Cord, Japan, 100 V
Automatic Periodic Stimulating electrodes			
8228052	APS Electrode, 2 mm	8228053	APS Electrode, 3 mm
Prass Paired EMG Electrodes			
8227301	25 mm, Protected Pin 2 channel, 5 Pkg/Box	8227307	38 mm, Protected Pin 2 channel, 5 Pkg/Box
8227304	18 mm, Protected Pin 2 channel, 5 Pkg/Box		
Subdermal Needle Electrodes			
8227421	Subdermal Needle Twisted Pair Electrodes 4 channel	8227103	Subdermal Needle Electrodes 12 mm
8227422	Subdermal Needle Twisted Pair Electrodes 8 channel	8227450	Paired Electrodes, Gray, Prot. Pin
8227410	Paired Subdermal Electrodes 2 channel 1set/box	8227465	Paired Subdermal Electrodes 25/box
8227411	Paired Subdermal Electrodes 4 channel 1set/box	8227466	Paired Subdermal Electrodes 25/box
8227412	Paired Subdermal Electrodes 8 channel 1set/box		
Stimulus dissection instruments			
1352401	Curved Needle	1352413	Ring Dissector, 2.0 mm, Regular
1352401	Elevator	1352415	Cable, 9 ft
1352407	Storage Case	1352415	Cable, Protected Pin, 1 Ea.
Neurotologic Stimulus Dissection Instrument Set			
1353402	Right Angled Pick, Long	1353405	Duck Bill Elevator, Wide
1353403	Curved Needle	1353409	Raspatory, Narrow Right
1353404	Duck Bill Elevator, Medium	1353415	Cable, 9.0 ft

Note: Please refer to the ENT Product and Instruments Catalog for a complete listing of available products.

Additional information can be found at www.mcatalogs.com/ent/ 68E4004 Minimization of Pacemaker Pacing Artifacts displayed on the NIM monitor screen.

Installing the optional power isolator

Figure 1

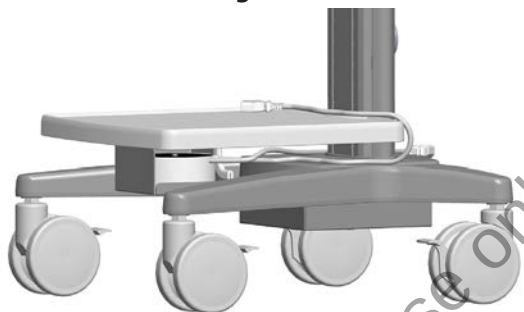


Figure 2

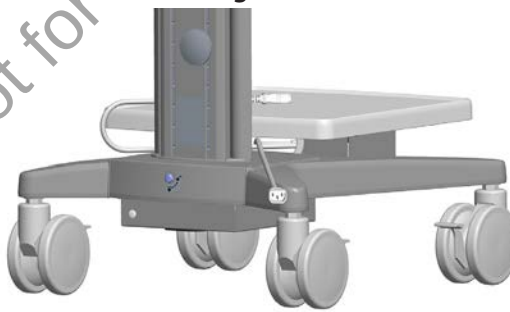


Figure 3

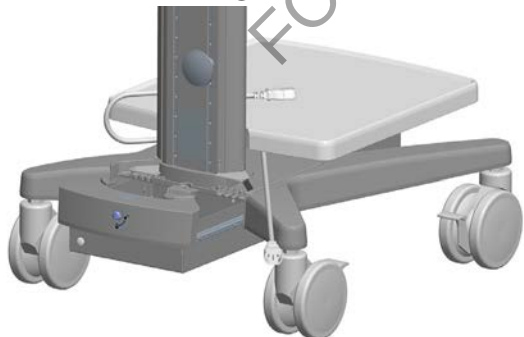
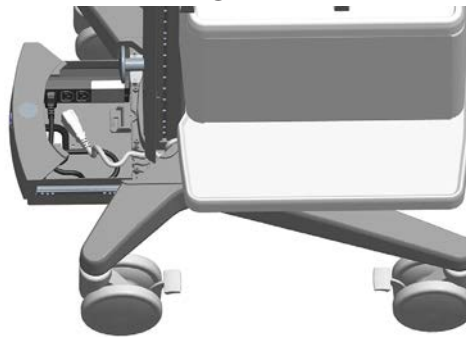


Figure 4



Medtronic does not provide printers but if you wish to install one, you need to install the optional power isolator.

You can setup the printer on the NIM Vital cart bottom shelf.

Note: "Front", "back/rear", "left" and "right" instructions assume you are facing the NIM Vital cart front where you face the upper drawer and/or the NIM Vital monitor, unless specified otherwise.

Nerve Integrity Monitor

1. Lock the castor wheels.
2. Slide the printer power isolator (Medtronic part # NIM4CC02 or NIM4CC03) into its cradle (opening on the right of the cradle) underneath the bottom shelf of the NIM Vital cart (figure figures 1 and 2), with the label side up and the two cords facing the rear of the cart.
3. Run the two cords to the rear of the cart, between the shelf and cart base (figure 3). **Note:** the user must route the printer cord (male connector) to the right of the cart spine. The user must route the power cord (female connector) to the left of the cart spine.
4. Using a counter-clockwise turn, unlock and open the drawer under the cart base at the rear of the cart.
5. Using the provided L-Key, remove the two screws and the metal plate from the cart base.
6. Open the cable duct on the cart's spine.
7. Plug the power cord into one of the two open outlets on the power strip in the drawer (figure 4).
8. Place the power cord in the left-most channel ensuring that all the slack has been pulled out of the cord and reinstall the metal plate to the cart base using the two screws.
9. Close the drawer and secure it by turning the knob clockwise.
10. Place the printer on the shelf and plug in the printer cord into the rear of the printer. See the "NIM Vital Compatible Accessories" section of the "Technical Specifications" topic for the list of compatible printers and their duty cycles, if applicable.
11. If needed, attach the optional power cord adapter that conforms to your printer's power cord type.

NIM Probes and electrodes

Probes and electrode types recommended for use with the NIM Vital system.

Probes



Monopolar Ball Tip Probe.



Monopolar Standard Press Flush Tip Probe.



Incrementing Monopolar Probe Handle.



Universal Monopolar Probe Handle.



Bipolar Side-by-Side Stimulating Probe



Bipolar Press Flush Tip Stimulating Probe

Electrodes



NIM Trivantage EMG Endotracheal Tube.



NIM EMG Endotracheal Tube. Designed to monitor both vocal cords.



Paired Subdermal Electrodes. Non-insulated high performance electrodes with 2.5 mm spacing.



Prass Paired Electrodes. The electrodes are insulated to within 5 mm of the end with 5 mm spacing. Muscle-specific single use.



Prass Paired Electrodes Small Hub. The electrodes are insulated to within 5 mm of the end with 2.5 mm spacing. Muscle-specific single use.



Subdermal Needle Electrodes. Non-insulated high performance electrodes 12 mm long with a 0.4 mm diameter.



Electrode Ground (green with green wire) and Electrode Stimulus Return (red with white wire).



Hookwire Electrode. Two small wires attached to the end of a hypodermic needle. Injected intramuscularly (then the hypodermic needle is removed). The wires are insulated to within 3 mm of the end and are designed to obtain a more specific response.



NIM Vital continuous monitoring electrodes and tools

APS (Automatic Periodic Stimulation) Probe.

Continuous, real-time monitoring of vagus nerve through low-level stimulation.

Single-use.

Fuses

Console Replacement: the console AC power is fuse protected. Have a Biomedical Engineer check the fuse if a problem is suspected. It is very important that the correct replacement fuse is used (5 x 20 mm, 2.5 Amp, time-lag, Low breaking capacity, Xomed Fuse Kit # NIM4CFU1).



Patient Interface fuse replacement

The Patient Interface has its own fuse. An LED underneath the fuse will blink white to indicate which fuse(s) need to be replaced. It is very important that the correct fuse is used – It must be Xomed Fuse Kit # 8253075 (similar 32 mA Type F 250V 5 x 20 mm fuses may not offer the same degree of protection).

1



2



3



4



5



Technical specifications

Physical dimensions - console

Size:

41 cm W x 45 cm D
42.5 cm H (Screen Open)
20.5 cm H (Screen Down for storage)
10.7 Kg

Weight:

Physical dimensions - patient interface

Size:

6.5 cm W x 7.5 cm H x 21.5 cm D

Weight:

.55 Kg

Physical dimensions - cart (NIM4CC01)

Size:

53 cm W x 101 cm H x 61 cm DP

Weight:

45 kg

Capacities:

Drawer Max. Load - 4.5 kg
Shelf Max. Load - 9.0 kg
Cart Total Max. Load - 79.5 kg

Operational environment - console, console back-up battery, patient interface with internal battery

Operating Temperature range:

10 to 33° C (Operating)

Humidity:

30-70% RH non-condensing

Atmospheric Pressure range:

700 hPa to 1060 hPa

Transport and storage environment - console, console back-up battery, patient interface with internal battery

Shock and Vibration:

Verified to Standard ISTA 2A

Ambient Temperature range:

-20°C to + 50° C

Relative Humidity range:

10 % to 100 %, including condensation

Atmospheric Pressure range:

500 hPa to 1060 hPa

Amplifier

Channels - 1 to 4:

Individually and simultaneously selectable

Input Sensitivities:

5 – 10,000 μ V peak-to-peak AC Coupled, $\pm$ 5% at 10 mV to $\pm$ 30% at 100 mV peak-to-peak AC Coupled

Sensitivity Selection:

Automatically zeroed

Bandpass:

15 Hz - 1.85 kHz ($\pm$ 3 db @ 500 Hz) EMG Display

Input Noise:

200 Hz - 1.0 kHz (-6, +3 db @ 500 Hz) Audio EMG Speaker

Input Impedance:

3-14 μ V p-p, < 5 μ V RMS @ DC - 2 KHz, inputs shorted

DC offset Rejection:

> 10 Meg Ohm

Common Mode Rejection:

$\pm$ 0.90 V DC Rejection

Channel Enable/Disable Controls:

>80 dB @ 60 Hz, balanced inputs, >66 dB @ 60 Hz, 1 K Ohm imbalance

Event Threshold Control and Display:

Dedicated function touch pads for independent channel enable/disable.

Patient Isolation Wired:

Adjustable Graduated Touch Screen with Voltage threshold displayed.

1,000 Vrms 60Hz < 100 μ A

Impedance measurement

Control:

Automatic CHECK ELECTRODE feature.

Measuring Signal:

6 μ A or 24 μ A peak-to-peak, 7.8 Hz Square wave

Measurement Range:

Electrodes:

0K to 2K Ohm $\pm$ 500 Ohm

>2K-175K Ohm $\pm$ 20%

Ground and Stim Returns < 25K.

Artifact detection and rejection

Stimulus Artifact:

Synchronized and adjustable muting and warning.

Bipolar Electrocautery Rejection:

Continuous Monitoring During Bipolar Cautery < 40 watts

Monopolar Electrocautery (ESU) Interference:

Automatic detection and muting in wired or wirefree modes.

Muting Detector Input ESU Sensitivity:

Monopolar ESU Cut / Coag

Muting Console Input Sensitivity:

Contact 5 - 100 Watts

Air-Discharge 10-100 Watts

Muting (0.6 - 2.0 Volts Vrms)

Non-Muting (<0.3 Volts Vrms)

ESU < 100 Watts Cut / Coag or

(<3.0 Vrms 100-800 KHz Sq. Wave)

Automatic detection with Channel Off Muting and Warning message.

Electrode Lead Off:

Display / touch screen

Type:

High contrast, digital, graphic color, visible in complete darkness.

Resolution:

Display Full HD - 1920H x 1080W pixels

Dedicated Function Event Touch Screen Controls:

Touch Panel - Capacitive Multi and Glove touch capable 4095H x 4095W

Vertical Display:

20, 50, 100, 200, 500, 1,000, 2,000 5K, 10K, 20K, 50K, and 100K μ V display modes.

Event Capture:

Enable/disable capture mode indicator on touch screen.

Time Scale:

25 ms, 50 ms, 100 ms or 20 s display modes.

Patient Interface

Color Coded Channel Patient Connections:

"Touchproof safety connection protected pin 1.5 mm per specification: DIN 42 802"

Internal Fuse:

Electronic limiting protection circuit and standard fuses. See Stimulator 1 and 2

"Internal Fuse".

Stimulator 1 and 2

Stimulus Type Constant:

Constant Current

Stimulus Range:

Stim 1 and Stim 2

0-3 mA, a minimum of ± 12 V
compliance (tested into a 4K load)Load Impedance Range: as long as the load impedance X
stimulation current is less than or equal to the compliance
voltage.

Stimulus Control:

Stim 1

3.1-50mA a minimum of ± 100 V
compliance (tested into a 2K load)

Stimulus Output Accuracy:

Stimulus Adjustment:

Digitally controlled, range – dependent adjustment increments of 0.01, 0.05, 0.1, .5
and 1.0 mA $\pm .01$ mA (or $\pm 10\%$ of reading at 1 K load) over Stimulus Range.Dedicated Side Control knobs and Graduated Touch Screen Control with display of
command current and delivered current.

Stimulus Measurement Accuracy:

 $\pm .02$ mA (or $\pm 10\%$ of reading at 1 K load) over Stimulus Range.**Internal Fuse:**32 mA Type F, 250 V 5 x 20 mm (**It must be Xomed #8253075, other similar
fuses may not give the same degree of protection**). Order 8253075 Fuse Kit for
replacements.**Stimulus 1 and 2 characteristics**

Waveform:

Duration (Width):

Monophasic, Bi-phasic, Alternating Polarity, or Pulse Train of square pulses

Software selectable, 50, 100, 150, 200, 250, or 1000 μ s, (Accuracy: 50 μ s $\pm$ 15 μ s, 100 μ s
- 1000 μ s $\pm$ 10% of setting)

Interpulse Interval

50 μ s, 100 μ s, 500 μ s, 1-5mSec

Interphase Delay

0, 50, 100, 500, μ s

Train Count

1, 2, 3, 4, and 5

Rise Time to 30 mA:

Less than 10 μ s

Rate STIM 1 and 2:

Software selectable 1, 4, 7, 10, or 20 Hz ($\pm 10\%$ of setting)

Rate STIM 2 Nervassure selected:

Nervassure repetition rates 1, 2, 4, 10, 30, 60, and 120 pulses per minute

Stimulus Probe:

Monopolar (standard) or bipolar

Stimulus Trigger Input:

TTL compatible remote input. Not active. For future expansion.

Audio output

Volume Adjustment:

Dedicated Side Control knob and Graduated Touch Screen Control with graphic of
Volume.

Transducers:

1 x 7.62 x 7.62 cm speaker

4 x 2.5 x 2.5 cm speakers

Piezoelectric Sounder

Baseline Audio Sound Level:

58 $\pm$ 4 dB SPL C Weighted (1 ft)

Change in Baseline with added Channels:

< $\pm$ 4 dB SPL C Weighted (1 ft)

Change in Baseline due to EMG and Tones:

> + 20 dB SPL C Weighted (1 ft)

Max Audio Sound Level:

> + 93 $\pm$ 4 dB SPL C Weighted (1 ft)

Min Audio Volume (Tone and Alarm) sounds:

> 63 dB SPL C Weighted (1 ft)

EMG & Event Tone Signals:

Continuously processed EMG and/or activity-level dependent event tones for each
channel.

Volume Preset and Limiter:

Volume Power Up Pre-set Default and a Low Volume Limiter.

"Current Delivered" Tone Signals:

Selectable options include continuous and brief warble tone, voice and voice setting.
Signal occurs when 80% of set current is measured delivered over range when greater
than (0.05) mA.

Power-Down / Power-up Tone :

Constant Power-up / Decaying Power-down Tone

Touch Screen Key Click:

Selectable ON/OFF

Connection:

3.5mm Mini Audio Female Headphone Jack

Headphone Output:

Line level

I/O - Video Output/USB Drive Output/Networking**Data output**

Connection:

3 x USB-A (3.0) , 2 x USB-C (3.0)

Networking

Ethernet:

Not active. For future expansion.

Connection:

RJ45

Video Output 1

Interface:

HD 1920 x 1080 resolution

Connection:

19 pin HDMI

Video Output 2

Interface:

HD 1920 x 1080 resolution

Connection:

20 pin DisplayPort

Wireless Remote Monitor

Interface:

HD 1920 x 1080 resolution

Connection:

Display Port or HDMI

Electrical - Mains

Input Voltage/Power:

100 - 240VAC, 250VA

Console:

100 - 240VAC, 600VA

Cart:

50/60 Hz

Frequency:

62 W Nominal; <78 W Peak (Total 72 W [62 W Console, 10 W Wireless HDMI])

Power consumption:

Nerve Integrity Monitor

Cart Auxiliary AC output Power Isolator (See Printers listed in NIM Vital Compatible Accessories):

NIM4CC02 100-127VAC, 50-60 Hz, - 200VA
NIM4CC03 220-240VAC, 50-60 Hz - 200VA

- Continuous duty cycle – 200VA
- 25% Intermittent duty cycle (Up to 5 minutes on at maximum 2X rated load then 15 minutes off)
NIM Printer Power Supply (# 8253025) 150 VA Max.

Auxiliary AC output: (For Use With Approved NIM Accessories Only):
Line Isolation:

4000 V Peak-to-Peak 60Hz dielectric withstand from Line Connections to Signal Ground

Internal Fuse:
Patient Connections:
Patient Connection Capacitance:

5 x 20mm, 5Amp, 250V, Quick-acting, Low breaking capacity,
All patient probes and electrodes are Type BF applied parts
100 pF +/- 30% @ 1kHz (All patient probes and electrodes combined to Safety GND)

Electrical - Batteries

Console Back-up Battery - Li-ion - Secondary:
Console Real Time Clock (RTC) - Primary Lithium Cell:
Patient Interface Battery - Li-ion - Secondary:

14.4V / 4750 mAh / 72Wh
3.0V / 0.600mAh / 1.8Wh (Non-user Replaceable)
7.2V / 3400mAh / 24.4Wh (Non-user Replaceable)

Classification

Type of Protection against electrical shock:
Degree of protection against electrical shock:
Ingress of water, dust, or solids IEC 60529:
Use with flammable anesthetic mixtures, with air, oxygen, and nitrous oxide:
Transportation of Batteries UN/DOT 38.3 2015:

Class I Medical Device per IEC/EN60601-1
Type BF applied parts
Console IPX1, Patient Interface IPX2
Not suitable for use in the presence of flammable anesthetic mixtures.

Battery Safety

IEC 62123-2012 I:

NIM Vital System Essential Performance as defined by IEC 60601-1:

Recommendations of the Transport of Dangerous Goods: Manual of Tests and Criteria
- Lithium Metal and Lithium Ion Batteries
Secondary cells and batteries containing alkaline or other non-acid electrolytes -
Safety requirement for portable sealed secondary cells, and for batteries made from them, for use in portable application.
Audible notification (tone, buzzer, voice) to the user if monitoring of one or more active channels is halted

AND

Audible notification (event tone, stim delivery tone) that nerve stimulus has been delivered.

NIM Vital Compatible Accessories

Audio Accessories Verified Compatible

Wireless Video Output

Wireless HDMI:
Interface:
Connection:

C2G 29329
HD 1920 x 1080 resolution
Display Port or HDMI through C2G

Printers Verified Compatible

Printer 1:

Samsung Xpress m2020w Wireless Black-and-White laser printer
- 25% Intermittent duty cycle (Up to 5 minutes on- Printing followed by 15 minutes off or Standby)
HP officejet 200 Mobile Printer Wireless Color Inkjet printer
Samsung Xpress C430W
- 25% Intermittent duty cycle (Up to 5 minutes on- Printing followed by 15 minutes off or Standby)

Printer 2:
Printer 3:

USB Drive Data Output

USB Compact Flash Memory:

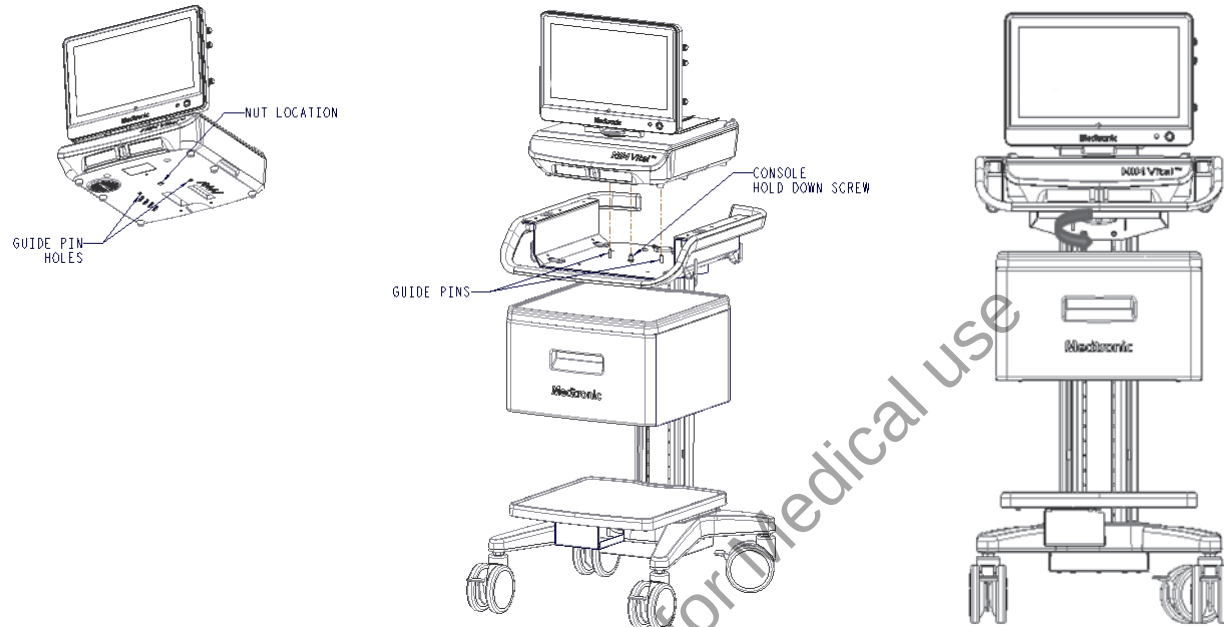
SanDisk Brand, Cruzer Mini SanDisk Brand, Cruzer Micro, Apricorn Aegis Secure Key ASK-256-26GB

The NIM Vital equipment cart

The equipment cart serves as a convenient means to operate the NIM Vital in the operating room as well as store the console and accessories when not in use.

NIM Vital lockdown

The Equipment Cart is supplied with a retaining screw with a four-arm knob which holds the NIM Vital console to the equipment cart.



1. Guide pins and a nut located on the bottom of the NIM Vital console interfaces with the console cart (illustration 1).
2. Place the NIM Vital console onto the top of the cart making sure to align the two pins on the cart with the holes in the bottom of the console (illustration 2).
3. Reach underneath the console tray and hand-tighten the securing knob (illustration 3).

NIM Vital cart repair

Repair kits for select cart components may be ordered by contacting Medtronic Service and Repair.

Channel default settings

NIM Vital (4 Channel Patient Interface)																
Procedure Name	Acoustic Neuroma 4 ch (1, 2, 3, 4)	Acoustic Neuroma 4 ch (1, 2, 3)	Acoustic Neuroma 4 ch with Nervassure	Acoustic Neuroma 2 ch	Acoustic Neuroma 2 ch with Nervassure	Cochlear Implant	Mastoid	Head/Neck				Peripheral				
Category Name	Neuro/Otology															
Ch 1 Name Electrode Type	Frontalis Subdermal	Orbicularis Oculi Subdermal						Frontalis Subdermal	Orbicularis Oculi Subdermal		Vocalis 1 Endotracheal Tube					
Ch 2 Name Electrode Type	Orbicularis Oculi Subdermal	Orbicularis Oris Subdermal						Orbicularis Oculi Subdermal	Orbicularis Oris Subdermal		Vocalis 2 Endotracheal Tube					
Ch 3 Name Electrode Type	Orbicularis Oris Subdermal	Mentalis Subdermal		Available to surgeon no default names or Electrode Type				Orbicularis Oris Subdermal	Mentalis Subdermal	Available to surgeon no default names or Electrode Type			Sternocleidomastoid Subdermal	Abductor Digitus Proximal Paired	Available to surgeon no default names or Electrode Type	
Ch 4 Name Electrode Type	Mentalis Subdermal	Frontalis Subdermal						Mentalis Subdermal	Frontalis Subdermal					Trapezius Subdermal	Abductor Hallucis Proximal Paired	
Electrode Placement Image	Yes															

Display default settings

NIM Vital												
Procedure Name	Acoustic Neuroma 4 ch	Acoustic Neuroma 2 ch	Cochlear Implant	Mastoid	Thyroid	Thyroid with Nervassure	Parotid	Neck Dissection	Glomus	Lower Extremity 4 Ch	Knee (Peroneal) 2 Ch	Ankle (Tibial Nerve) 2 Ch
Event Threshold	100 μ V											
Event Capture	Largest											
Stimulus Rejection Period	3.1 mS				2.1 mS		3.1 mS			5.0 mS		
Time Scale	50 mS				25 mS		50 mS					
Vertical Scale	500 μ V				1000 μ V		500 μ V			2000 μ V		
Detect Artifacts	Yes											
Monitoring Audio	EMG + Event Tones											
Stimulus Delivery Tone	Brief											

STIM 1 & 2 default settings

NIM Vital												
Procedure Name	Acoustic Neuroma 4 Ch	Acoustic Neuroma 2 Ch	Cochlear Implant	Mastoid	Thyroid	Thyroid with Nervassure™	Parotid	Neck Dissection	Glomus	Lower Extremity 4 CH	Knee (Peroneal) 2 CH	Ankle (Tibial Nerve) 2 CH
STIM 1 Name	STIM 1											
STIM 1 Mode	Regular											
STIM 1 Pulse Width	100 uS											
STIM 1 Current	0.8 mA				1.0 mA		0.8 mA	1.0 mA	0.8 mA	1.0 mA		
STIM 1 Warning Level	3.0 mA									12.0 mA		
STIM 1 Rate	4/sec											
STIM 2 Name	STIM 2					Vagus STIM Nervassure	STIM 2					
STIM 2 Mode	Regular											
STIM 2 ON/OFF	OFF					ON	OFF					
STIM 2 Pulse Width	100 uS											
STIM 2 Current	0.0mA				1.0 mA		0.0mA					
STIM 2 Warning Level	3.0 mA				Variable		3.0mA			12.0 mA		
STIM 2 Rate	4/sec				1/sec		4/sec					

Legal information

Contact information

For further information regarding the use of this product or to report any problems, please contact Medtronic customer service at 1 800 874 5797; or refer to the last page of this manual for address information.

Open source software disclosure

The following open source software disclosure information applies to the NIM Vital system:

- This document identifies the Open Source Software that may be separately called, executed, linked, affiliated, or otherwise utilized by this product.
- Such Open Source Software is licensed to users subject to the terms and conditions of the separate software license agreement for such Open Source Software.
- Use of the Open Source Software by you shall be governed entirely by the terms and conditions of such license.
- The source/object code and applicable license for any Open Source Software can be obtained at the following site(s): Ubuntu – <https://www.ubuntu.com/>

Guidance and manufacturer's declaration – electromagnetic emission and immunity

Environment of intended use: professional healthcare facility environment

Guidance and manufacturer's declaration - electromagnetic emissions		
The NIM Vital is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM Vital should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emission CISPR 11	Group 1	The NIM Vital uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class A	The NIM Vital is suitable for use in all establishments other than domestic establishment and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – Part I			
The NIM Vital is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM Vital should assure that it is used in such an environment.			
Immunity test	IEC/EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	
Surge IEC 61000-4-5	±1 kV line to line ±2 kV line to earth	±1 kV line to line ±2 kV line to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	0 % U_T (100 % dip in U_T) for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIM Vital requires continuous operation during power mains interruptions, it is recommended that the NIM Vital be powered from an uninterruptible power supply or a battery.
	0 % U_T (100 % dip in U_T) for 1 cycle at 0°	0 % U_T (100 % dip in U_T) for 1 cycle at 0°	
	40 % U_T (60 % dip in U_T) for 5 cycles	40 % U_T (60 % dip in U_T) for 5 cycles	
	70 % U_T (30 % dip in U_T) for 0.5 sec	70 % U_T (30 % dip in U_T) for 0.5 sec	
	0 % U_T (100 % dip in U_T) for 5 sec	0 % U_T (100 % dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunities - part II

The NIM Vital is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM Vital should assure that it is used in such an environment.			
Immunity test	IEC/EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NIM Vital, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V / m 80 MHz to 2.7 GHz 9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz Pulse modulation	3 V / m 80 MHz to 2.7 GHz 9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz Pulse modulation	Portable and mobile RF communications equipment should be used no closer to any part of the NIM Vital, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = (6/E) \sqrt{P}$ Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test levels in volt per meter (V/m), and d is the recommended separation distance in meters (m). Interference may occur in the vicinity of equipment marked with the following symbol: 
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between portable and mobile RF communications equipment and the NIM Vital							
The NIM Vital is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIM Vital can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIM Vital as recommended below, according to the maximum output power of the communications equipment.							
Rated maximum power of transmitter P(W)	Separation distance according to frequency of transmitter meters						
	380MHz-390MHz $d = 0.22\sqrt{P}$	430MHz-470MHz $d = 0.22\sqrt{P}$	704MHz-787MHz $d = 0.67\sqrt{P}$	800MHz-960MHz $d = 0.22\sqrt{P}$	1.7GHz-1.99GHz $d = 0.22\sqrt{P}$	2.4GHz-2.57GHz $d = 0.22\sqrt{P}$	5.1GHz-5.8GHz $d = 0.67\sqrt{P}$
0.01	0.03	0.03	0.07	0.03	0.03	0.03	0.07
0.1	0.07	0.07	0.21	0.07	0.07	0.07	0.21
1	0.22	0.22	0.67	0.22	0.22	0.22	0.67
10	0.7	0.7	2.12	0.7	0.7	0.7	2.12
100	2.2	2.2	6.7	2.2	2.2	2.2	6.7
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.							
NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.							

Limited warranty

- A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic NIM Vital System. This Limited Warranty is extended only to the buyer purchasing the NIM Vital System directly from Medtronic or from its affiliate or its authorized distributor or representative. The NIM Vital System may include the console (including power cable), Patient interface boxes (including patient interface cable, hereafter referred to as System Components), Wireless display module, Cart, Storage Case, Video/Audio Recording Adapter Kit (hereinafter referred to as "Accessories"), and single use electrodes and probes (hereinafter referred to as Single Use Components) and collectively referred to as the Product, unless specifically noted.
- (1) Should a System Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (one year from the date of sale of a new System Component or 90 days from the date of sale of a refurbished or used System Component), Medtronic will, in its sole discretion, either repair or replace the System Component or any portion thereof.
 - (2) Should an Attachment fail to function to Medtronic's published specifications during the term of this Limited Warranty (90 days from the date of sale of a new Attachment), Medtronic will, in its sole discretion, either repair or replace the Attachment or any portion thereof.
 - (3) Should a Single Use Component fail to function to Medtronic's published specifications prior to its "use by" date Medtronic will replace the Single Use Component.
- B. To qualify for this Limited Warranty, the following conditions must be met:
- (1) The Product must be used on or before its "Use By" or "Use Before" date, if applicable.
 - (2) The Product must be used in accordance with its labeling and may not be altered or subjected to misuse, abuse, accident or improper handling.
 - (3) Medtronic must be notified in writing within thirty (30) days following discovery of a defect, or malfunction.
 - (4) The Product must be returned to Medtronic within thirty (30) days of Medtronic receiving notice as provided for in (3) above.
 - (5) Upon examination of the Product by Medtronic, Medtronic shall have determined that: (i) the Product was not repaired or altered by anyone other than Medtronic or its authorized representative, (ii) the Product was not operated under conditions other than normal use, and (iii) the prescribed periodic maintenance and services, if applicable, have been performed on the Product.
- C. This Limited Warranty is limited to its express terms. THIS LIMITED WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED WHETHER STATUTORY OR OTHERWISE, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. In no event shall Medtronic be liable for any consequential, incidental, prospective or other similar damage resulting from a defect, failure, or malfunction of the product, whether a claim for such damage is based upon the warranty, contract, negligence or otherwise.
- D. The exclusions and limitations set out above are not intended to, and should not be construed so as to, contravene mandatory provisions of applicable law. Users may benefit from statutory warranty rights under legislation governing the sale of consumer goods. If any part or term of this Limited Warranty is held by any court of competent jurisdiction to be illegal, unenforceable, or in conflict with applicable law, the validity of the remaining portion of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid.

Transmissible Spongiform Encephalopathies (TSE)

Medtronic recommends incineration of devices that have directly or indirectly contacted patients suspected or confirmed with prions or a Transmissible Spongiform Encephalopathy (TSE) such as Creutzfeldt-Jacob disease (CJD).

Glossary

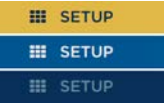
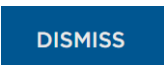
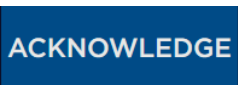
CRM	Console Radio Module.
DSP	Digital signal processor.
EIC	External Interface Controller.
Event sequence	A series of events separated from each other by less than one second.
GUI	Graphical user interface.
Nervassure	Automatic periodic stimulation.
NIM	Nerve Integrity Monitor, NIM Vital.
NIM Vital	See NIM
PI	Patient interface.
PMB	Power Management Board.
Stimulus artifact	A monitoring term for an artifact created by stimulus voltage delivered to the patient, which is picked up as feedback either internally or externally to the monitoring equipment. It is normally small and does not impact monitoring but can, under certain conditions, be displayed and sounded on the monitor.
Stimulus artifact on-screen	On the monitoring screen, the stimulus artifact appears as an event (above or below threshold) which starts directly after the stimulus on the left side of the screen and proceeds for a duration into the EMG waveform detection area. The level of the artifact is directly proportional to the stimulus delivery and cannot be EMG because nerve signals need time propagate.
Stimulus artifact sound	The audio representation of a stimulus artifact. It is a high frequency sound similar to a cymbal (ti--tchi). This sound should not be confused with an EMG sound which sounds like a drum beat.
Stimulus rejection period	Adjustable delay reading EMG after stimulation. In previous versions of the NIM, this was referred to as Stimulus Artifact or Artifact Delay.
False negative	The condition where the probe is on nerve, but you do not get an EMG tone.
Tap test	Tapping the electrode location may cause artifactual response on the NIM Vital. This test is not a reliable technique to indicate correct electrode placement/connection.

FCC use only, not for Medical use

Buttons and indicators

The “Buttons and indicators” topic contains all buttons the touch screen user interface displays and an explanation of how they work.

Globally visible

	Multi-state for tabs: (Selected, available but not selected, disabled).		Menu: Global settings.		Confirm button.
	SETUP tab.		Accept button.		Cancel button.
	MONITORING tab.				Dismiss button.
	REPORTS tab.		Warning icon.		Continue current case button.
	Click to enter patient data.		Wireless connection details.		Start new case button.
	Channel buttons.		Battery health.		Signal health.
	Wireless peripheral connection (indicator and button).		Wired peripheral connection (indicator and button).		Determining electrode check result.
	Electrode check passed.		Electrode check failed.		Show details button.
	Acknowledge button.		Edit Case Information Configuration.		Hide details button.
	Date entry button.		Indeterminate state for electrode check.		Help button.
	Save to Profile button				

SETUP

			Add new user profile button.		Modify user profile.
	Default categories button.		Go back.		Continue.
			Configure channels.		Delete user profile.

MONITORING

Nerve Integrity Monitor



Baseline button.



Freeze button.



Increase button.



Fast APS button.



Electrode check button.



Settings button.



Activate button.



Contextual help button.



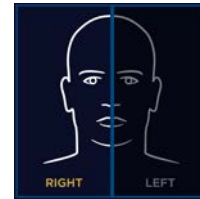
Snapshot button.



Decrease button.



Slow APS Button.



Operating side buttons (right currently selected, left currently unselected).



Restart/start new baseline button.



Next step button (baseline). Fix symbol



Quick tag buttons (green is selected showing it has been taken). The operating side is shown in a Thyroid procedure and Recall button toggles waveform recall for V1 and R1 snapshots.



Category item. Clicking will open more settings.



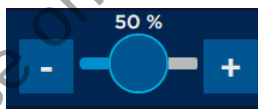
Category title. Clicking will open relevant settings.



Yellow mute when trending.



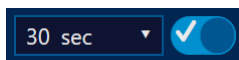
Toggle slider off/on.



Slider with plus/minus buttons for fine tuning.



Red mute when trending.



Toggle-enabled drop-down menu.



Drop-down menu.



Measure button.



Toggle-enabled sliders.



Adjust view.



Save profile.



Trend button.



Restart/Start new baseline button.



Next step button (baseline).



Channel mute icon



Print button.



Save Database button.



Save to .pdf button.



Quick Tags report button.

REPORTS

FCC use only, not for Medical use

FCC use only, not for Medical use

Symbols

SN



LOT



ACC

REF



STERILE R

STERILE

STERILE EO

EC REP



Rx Only



Serial number

Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <http://recycling.medtronic.com> for instructions on proper disposal of this product.

Do Not Use If Package Is Open Or Damaged.

Package Contents

Use By Date

Precaution

If the single use symbol is on the device label then this device is designed for single patient use only. Do not reuse, reprocess, or resterilize this product. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or create a risk of contamination of the device, which could result in patient injury, illness, or death.

Lot Number

Fuse

Accessory

Catalog Number

AC Power

Output

Is Approximately Equal To

Sterilized By Radiation. Do Not Use If Package Is Open Or Damaged.

Non-Sterile

Sterilized By Ethylene Oxide. Do Not Use If Package Is Open Or Damaged.

Authorized Representative In The European Community.

This Device Complies With Medical Device Directive 93/42/EEC

Quantity

Caution: Federal Law (U.S.A.) Restricts This Device To Sale By Or On The Order Of A Physician.

Manufacturer

Date Of Manufacture

ROHS - Environmental Friendly Use Period 50 years- China (SJ/T11364-2006).

Product does not contain any toxic or hazardous substances above permitted levels.

Symbols

ETL CLASSIFIED



Conforms To IEC/EN60601-1 and ANSI/AAMI ES60601-1 Certified To CSA C22.2 No.60601-1



Protective Earth



Equipotential



Consult Instructions for Use



Caution

Protected Against Vertical Water Drops.

IPX1

IPX2

Protects against water drops when the device is tilted up to and including 15°.



Type BF Applied Part



Manual Start/Stop



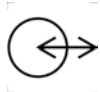
Rf Transmitter (Interference May Occur).



Follow instructions for use.



General warning sign



Input/Output



FCC Symbol - This device complies with Part 15 of the FCC Rules.



Patient Interface connector

UDI

Unique Device Identification



USB 3.0



USB 2.0



Display Port



Ethernet



Headphone



Medtronic Xomed

6743 Southpoint Drive North
Jacksonville, Florida 32216-0980
USA
medtronic.com
+1 800 874 5797



Authorized Representative in the European Community

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Europe/Middle East/Africa

Medtronic International Trading Sàrl
Route du Molliat 31
Case Postale 84
CH- 1131 Tolochenaz
Switzerland
+41 21 802 7000

Australia

Medtronic Australasia Pty Ltd
5 Alma Road
Macquarie Park, NSW 2113
Australia

Canada

Medtronic of Canada Ltd
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
+1 905 460 3800

Technical manuals

medtronic.com/manuals