



# Medtronic

## Nerve Integrity Monitor

NIM-Response® 3.0 and NIM-Neuro® 3.0



NIM-Response 3.0



NIM-Neuro 3.0

### User's Guide

**FR** Mode d'emploi **IT** Guida per l'utente **DE** Bedienungsanleitung **ES** Manual del usuario **NL** Gebruiksaanwijzing **DA** Brugsanvisning **FI** Käyttöopas **SV** Användarhandbok **PT** Guia do utilizador **EL** Οδηγός χρήστη **PL** Instrukcja obsługi **CS** Uživatelská příručka **HU** Felhasználói útmutató **TR** Kullanıcı Kılavuzu **NO** Bruksanvisning **RU** Руководство пользователя **SR** Korisnički vodič **HR** Priručnik za korisnike

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## Symbols

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                         |                                                                                                                  |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------|
| <b>SN</b>                                                                           | Serial Number                                                                                                                                                                                                                                                                                                                                                                             |                                                        | Date Of Manufacture                                                                                              |
|    | Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <a href="http://recycling.medtronic.com">http://recycling.medtronic.com</a> for instructions on proper disposal of this product.                                                                                                                       |                                                        | ROHS - Environmental Friendly Use Period - China (SJ/T11364-2006).                                               |
|    | Do Not Use If Package Is Open Or Damaged.                                                                                                                                                                                                                                                                                                                                                 | <b>ETL CLASSIFIED</b><br><br><b>Intertek</b><br>105345 | Conforms To IEC/EN60601-1 and ANSI/AAMI ES60601-1 Certified To CSA C22.2 No.60601-1                              |
|    | Package Contents                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                         |                                                                                                                  |
|    | Use By Date                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                         |                                                                                                                  |
|    | Precaution<br>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. |                                                        | Protective Earth                                                                                                 |
|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                           |                                                        | Equipotential                                                                                                    |
|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                           |                                                        | Consult Instructions for Use                                                                                     |
| <b>LOT</b>                                                                          | Lot Number                                                                                                                                                                                                                                                                                                                                                                                |                                                        | Caution                                                                                                          |
|    | Fuse                                                                                                                                                                                                                                                                                                                                                                                      | <b>IPX1</b>                                                                                                                             | Protected Against Vertical Water Drops.                                                                          |
| <b>ACC</b>                                                                          | Accessory                                                                                                                                                                                                                                                                                                                                                                                 | <b>IPX7</b>                                                                                                                             | Protected Against The Effects Of Temporary Immersion In Water.                                                   |
| <b>REF</b>                                                                          | Catalog Number                                                                                                                                                                                                                                                                                                                                                                            | <b>IPX8</b>                                                                                                                             | Rated For Water Ingress (IEC 60529)                                                                              |
|  | AC Power                                                                                                                                                                                                                                                                                                                                                                                  |                                                      | Type BF Applied Part                                                                                             |
|  | Output                                                                                                                                                                                                                                                                                                                                                                                    |                                                      | Manual Start/Stop                                                                                                |
|  | Is Approximately Equal To                                                                                                                                                                                                                                                                                                                                                                 |                                                      | Rf Transmitter (Interference May Occur).                                                                         |
| <b>STERILE</b>                                                                      | Sterilized By Radiation. Do Not Use If Package Is Open Or Damaged.                                                                                                                                                                                                                                                                                                                        |                                                      | Snapshot Option - Open Comments and Event Title Dialog Box.                                                      |
| <del><b>STERILE</b></del>                                                           | Non-Sterile                                                                                                                                                                                                                                                                                                                                                                               |                                                      | Snapshot Option - Send Snapshot or Report to Printer and Indicates a Printer is connected.                       |
| <b>STERILE EO</b>                                                                   | Sterilized By Ethylene Oxide. Do Not Use If Package Is Open Or Damaged.                                                                                                                                                                                                                                                                                                                   |                                                      | Snapshot Option - Send Snapshot or Report to USB Storage Device and Indicates a USB Storage Device is connected. |
| <b>EC REP</b>                                                                       | Authorized Representative In The European Community.                                                                                                                                                                                                                                                                                                                                      |                                                      | Follow instructions for use.                                                                                     |
|  | This Device Complies With Medical Device Directive 93/42/EEC                                                                                                                                                                                                                                                                                                                              |                                                      | General warning sign                                                                                             |
|  | Quantity                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                         |                                                                                                                  |
| <b>Rx Only</b>                                                                      | Caution: Federal Law (U.S.A.) Restricts This Device To Sale By Or On The Order Of A Physician.                                                                                                                                                                                                                                                                                            |                                                                                                                                         |                                                                                                                  |
|  | Manufacturer                                                                                                                                                                                                                                                                                                                                                                              |                                                                                                                                         |                                                                                                                  |

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## Buttons and Indicators

In this section all buttons used on the "Touch Screen User Interface" are displayed with an explanation of how they work.

|  |                                                                                                               |  |                                                                                                                                                                                           |  |                                                                                                                                                                                                   |
|--|---------------------------------------------------------------------------------------------------------------|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | Radio Button / Deselected: For option selection where choice is limited to one of two or more options.        |  | Snapshot Button: Saves current screen to memory or to selected peripheral device.                                                                                                         |  | Scroll Up/Down Buttons: Used to scroll through selected events                                                                                                                                    |
|  | Radio Button / Selected                                                                                       |  | Activate Button: Activates STIM 2 stimulus adjustment buttons.                                                                                                                            |  | Restore Button: Used to restore factory defaults.                                                                                                                                                 |
|  | Check Box: Deselected For option selection where choice is to enable or disable a single or multiple options. |  | Baseline Button: Initiates an APS™ baseline acquisition sequence                                                                                                                          |  | Mute Button: Used to mute channel.                                                                                                                                                                |
|  | Check Box: Selected                                                                                           |  | Electrode Check Button: Opens Electrode Status Panel                                                                                                                                      |  | Unmute Button: Used to unmute channel.                                                                                                                                                            |
|  | EMG Audio and Event Tones Check Boxes: One or both must be selected. Both cannot be deselected.               |  | Delete/Close Button: Closes "Delete Procedure" dialog box Opens "Delete a Custom Procedure" dialog box                                                                                    |  | APS™ Visual Alarm Indicator and Mute Button Automatic On/Off Indicator Button. Only displayed when an APS™ alarm limit has been reached and APS™ alarm tone sounds. Also used to mute APS™ alarm. |
|  | Red X: Indicates a failed test.                                                                               |  | Global Settings Button: Global Settings allows the user to select screen language, date/time format and the Diagnostic Mode, as well as set system date/time and Restore Factory Defaults |  | APS™ Alarm Button - Used to unmute APS™ alarm                                                                                                                                                     |
|  | Green Check: Indicates a successfully passed test.                                                            |  | Information Button: Opens Information Screen to enter: Surgeon's Name Patient's Name Notes                                                                                                |  | Channels Button: Opens a drop-down menu used to name channels.                                                                                                                                    |
|  | Orange Check: Indicates an Active Channel.                                                                    |  | Fast Rate Button: Selects APS™ Pulse Fast Rate                                                                                                                                            |  | Channel Buttons Channels can be turned On, Off or Muted                                                                                                                                           |
|  | Select Button: Option Button See associated text indicating option.                                           |  | Normal Rate Button: Selects APS™ Pulse Normal Rate                                                                                                                                        |  | Decrease/Increase Buttons and Setting Display Used to make adjustments to the subject as defined in the open panel.                                                                               |
|  | Help Button: Opens Help Screen for Electrode Placement & Sound Samples                                        |  | Next Button: Opens the next screen or graphic display                                                                                                                                     |  | Multi State Buttons (Set-Up used as an example): Gray = Inactive (not selectable) Blue = Selectable Orange = Selected                                                                             |
|  | Increase Button: Increases value/Setting                                                                      |  | Previous Button - Opens the previous screen or graphic display                                                                                                                            |  | Monitoring Button: Opens the Main/Monitoring Screen                                                                                                                                               |
|  | Decrease Button: Decreases value/Setting                                                                      |  | Yes Button: Accept/Keep                                                                                                                                                                   |  | Reports Button: Opens the Reports Screen                                                                                                                                                          |
|  | Monitor Button: Opens Monitoring Screen                                                                       |  | No Button: Do not Accept/Keep                                                                                                                                                             |  | Program Loading Indicator                                                                                                                                                                         |
|  | Measure Button: To view details of the event waveform.                                                        |  | Accept Button: Function as indicated.                                                                                                                                                     |  |                                                                                                                                                                                                   |
|  | Advanced Settings Button Opens: Audio, Monitoring, Stimulation, Microscope, and APS™ Panels.                  |  | Repeat Button: Function as indicated.                                                                                                                                                     |  |                                                                                                                                                                                                   |
|  | Display Button: Opens panel for adjusting amplitude and time scales.                                          |  | Cancel Button: Function as indicated.                                                                                                                                                     |  |                                                                                                                                                                                                   |
|  | Save Button: Sends selected information to USB mass storage device.                                           |  | Show Details Button: Used to show impedance readings                                                                                                                                      |  |                                                                                                                                                                                                   |
|  | Print Button: Used in Reports Section to print reports                                                        |  | Hide Details Button: Used to hide impedance readings                                                                                                                                      |  |                                                                                                                                                                                                   |
|  | Freeze Button: Freezes entire screen (all channels)                                                           |  | OK Button: Used to close panels                                                                                                                                                           |  |                                                                                                                                                                                                   |
|  |                                                                                                               |  | Select All Button- Used to select all events in memory                                                                                                                                    |  |                                                                                                                                                                                                   |
|  |                                                                                                               |  | Deselect All Button: Used to deselect all events in memory                                                                                                                                |  |                                                                                                                                                                                                   |

## Glossary

|                           |                                                                                                                                               |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| APS                       | Automatic Periodic Stimulation.                                                                                                               |
| DSP                       | Digital Signal Processor.                                                                                                                     |
| Event Sequence            | A series of events separated from each other by less than one second.                                                                         |
| FCU                       | Foot Control Unit.                                                                                                                            |
| GUI                       | Graphical User Interface.                                                                                                                     |
| NIM                       | Nerve Integrity Monitor.                                                                                                                      |
| NIM 3.0                   | NIM-Neuro 3.0 or the NIM-Response 3.0                                                                                                         |
| 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. |

## Indications for use

The NIM® 3.0 is intended for locating and identifying cranial and peripheral motor and mixed motor-sensory nerves during surgery, including spinal cord and spinal nerve roots. The APS™ electrode is an accessory intended for providing automatic periodic stimulation to nerves when used with the Medtronic Nerve Monitoring Systems.

Indications for NIM 3.0 EMG Monitoring Procedures include:

Intracranial, Extracranial, Intratemporal, Extratemporal, Neck Dissections, Thoracic Surgeries, and Upper and Lower Extremities

Indications for Spinal procedures which may use NIM 3.0 EMG monitoring include:

Degenerative Treatments, Pedicle Screw Procedures, Fusion Cages, Rhizotomy, Orthopedic Surgery, Open and Percutaneous Lumbar and Cervical Surgical Procedures, and Thoracic Surgical Procedures.

## Device description

The NIM-Neuro 3.0 is an eight-channel and the NIM-Response 3.0 is a four-channel EMG monitor for intraoperative use during surgeries in which a nerve is at risk due to unintentional manipulation. The NIM 3.0 System records electromyographic (EMG) activity from muscles innervated by the affected nerve. The monitor will assist early nerve identification by providing the surgeon with a tool to help locate and identify the particular nerve at risk within the surgical field. It will continuously monitor EMG activity from the muscles innervated by the nerve at risk to minimize trauma by alerting the surgeon when a particular nerve has been activated. The monitor utilizes touch screen and color graphic user interface (GUI) along with the audio feedback to increase the usability of the device.

## Contraindications

The NIM 3.0 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-Neuro 3.0 and NIM-Response 3.0 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 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-Neuro/Response 3.0 EMG Monitor.
  - a. EMG amplitude may be affected by anesthesia regimen used. Consult anesthesiologist if EMG changes are observed.
- W3 Surgical Identification of exposed Neural structures is key to their preservation. Failure to use Nerve Stimulation Probe may contribute to unintended surgical nerve damage or resection.
- W4 To avoid the risk of fire or explosion, do not use the NIM 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:
  - a. Do not activate the electrosurgical instruments (ESU) while stimulator is in contact with tissue.
  - b. Do not leave stimulating electrodes or probes in surgical field.
  - c. Do not store 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 interface boxes 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 NIM-Neuro/Response 3.0 Console before cleaning the unit to avoid electrical macro shock.
- W8 Achieve electrical grounding reliability with proper connections. Connect the NIM-Neuro/Response 3.0 Console to hospital grade receptacles only.
- W9 DO NOT use any parts other than Medtronic Xomed, Inc. components as damage or substandard performance could result.
- 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-Neuro/Response 3.0 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 NIM System.
- W13 All service must be performed by Medtronic qualified personnel only.
- W14 Direct stimulator contact may disrupt the operation of active implanted devices. Consult medical specialist before use.
- W15 Electrocardiogram monitoring artifacts may be caused by 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 NIM operation, such as, but not limited to decreased accuracy.

- W17 Repair and/or modification to the 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 while using the NIM Stylus, the user must maintain good sterility practices.
- W19 False negative responses (failure to locate nerve) may result from:
- a. Shorted EMG electrode or cabling (conductive parts of applied needle electrodes or cables contacting each other).
  - b. Patient Interface fuse blown (32 mA, 250 V. Xomed Part No.: 8253075).
  - c. Patient Interface defective.
  - d. Inadequate stimulus current.
  - e. 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.
  - f. Inadvertent simultaneous current delivery from both Stimulator (Patient Interface) probe outputs. This may result in current shunting, division between the stimulator probes.
  - g. Shorted internal amplifier (characterized by baseline activity of  $< 3 \mu\text{V p-p}$ ).
- W20 Stimulator current may cause involuntary patient movement resulting in patient injury.
- W21 Anesthetic agents used may have an effect on the EMG amplitude.
- W22 Be careful not to damage vascular structures when preparing the nerve for the installation of the APS Electrode.
- 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 electrode impedance is high, discontinue use and replace.
- W24 Remove APS electrode from patient prior to using external defibrillator to prevent thermal injury to patient at APS electrode site.
- W25 Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.
- W26 Operation in close proximity to a shortwave or microwave therapy equipment may produce instability in the electrical stimulator output.
- W27 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 attention is required for stimulus levels which exceed default settings or conditions resulting in levels higher than 2 mA RMS/cm<sup>2</sup>.

## Precautions

- P1 Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this Guide.
- P2 Portable and mobile RF 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-Neuro/Response 3.0 should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NIM-Neuro/Response 3.0 should be observed to verify normal operation in the configuration in which it will be used.
- P5 Loud extraneous monitoring noise is caused by activation of electrosurgical unit. Muting Detector must be properly attached to the active electrosurgical lead.
- P6 Inability to deliver stimulus current flow may be caused by inadvertent simultaneous current delivery from both STIM probe outputs. This may result in current shunting, division between the stimulator probes.
- P7 Avoid accidental contact between 'PATIENT APPLIED PARTS' and other conductive parts including those connected to protective earth.
- P8 The NEW Muting Probe (Ref - 8220325) is compatible with previous versions of the NIM. However, previous versions of the Muting Probe are NOT compatible with the NIM 3.0 System.

## When the System Arrives

### Unpacking and Inspection

Check off the contents of the box against packing slip. If incomplete or damaged, notify Customer Care.

If container is damaged, or cushioning material shows stress, notify carrier and Customer Care. Keep shipping materials for carrier inspection.

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

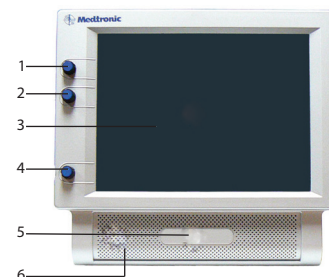
### Software

Software information (manufacturer, version, and release date) is contained on a card packaged with the system. Save this card for future reference.

## Components

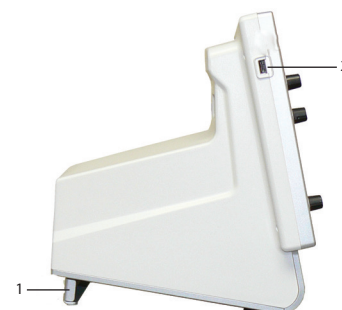
### Console Front

- 1 - STIM 1 stimulus adjustment.
- 2 - STIM 2 stimulus adjustment.
- 3 - Touchscreen. The Touch Screen displays EMG waveforms and controls many of the functions of the NIM 3.0.
- 4 - Volume adjustment.
- 5 - Product name.
- 6 - The Speaker provides audio alarms, acoustic EMG monitoring, and voice prompts.



### Console Left Side

- 1 - Anti-Glare Stand. Use this device to change the viewing angle of the NIM® 3.0 screen. It is shown in the tilted (up) position.
- 2 - USB Out. The USB Out is an industry standard USB type connector that you can use with mass storage devices.



### Console Rear

- 1 - Carry Handle for transporting unit.
- 2 - Potential equalization terminal. Can be used to equalize ground potentials between O.R. instruments.
- 3 - Accessory Power Outlet. Use this power outlet with the NIM 3.0 printer power device **only**.
- 4 - Fuse Access. The AC power fuses are located on the back of the units.
- 5 - Power Switch. The power switch turns power on or off.
- 6 - Power Connector. The power cord plugs into the back of the NIM 3.0 System console. The input fuses and accessory output is in the power entry module. Plug the power cord into the A/C power outlet.
- 7 - Anti-Glare Stand. Use this device to change the viewing angle of the NIM 3.0 screen. It is shown in the tilted up position.
- 8 - Patient Interface Connector. The patient interface connector is a 44-pin D-sub.
- 9 - RCA Audio Jack. An RCA audio jack is provided to output an audio signal that you can overlay onto a video signal when using industry standard recording devices. The output is audio line level (1 Vp-p).
- 10 - Handswitch connector. Used for APS procedures only.
- 11 - Muting Detector Input. Near-field radio frequency detector.
- 12 - Mini Jack. Standard configuration used for private listening through Stereo Headphones.
- 13 - For future use.
- 14 - Surgeon Mini Screen Port. Output connection to Surgeon Mini Screen or video recorder.
- 15 - USB Out. The USB Out is an industry standard USB type connector (two port) that you can use with mass storage devices/printer/keyboard.
- 16 - VGA Output. Only used to connect NIM-Neuro 3.0 System to microscope.



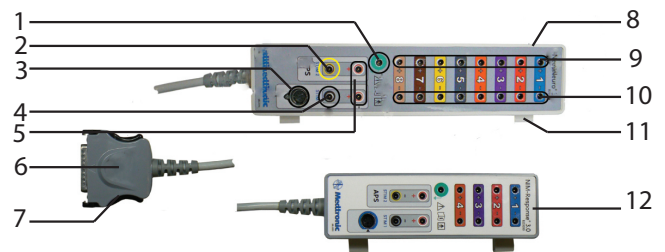
**Note: Microscope VGA output not active on NIM-Response 3.0 System.**

### Important:

Intraoperative use of the VGA Out and RCA Phone Jack requires special considerations to remain compliant with IEC/EN60601-1. Contact Medtronic Xomed for recommendations if intraoperative use of the VGA Out, RCA Phone Jack.

## 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® 3.0.
- 4 - Stimulus (out) Jack.
- 5 - Stimulus Return.
- 6 - Patient Interface to console connector.
- 7 - Connector release.
- 8 - The Patient Interface fuses are for Stimulator Output and specifically tested for ECU protection.
- 9 - Positive Electrode Jacks. Positive electrodes have matching color-coded wires and plugs.
- 10 - Negative Electrode Jacks. Negative electrodes have black wires and color-coded plugs.
- 11 - Patient Interface Clips.
- 12 - NIM-Response® 3.0 Patient Interface shown for reference only.

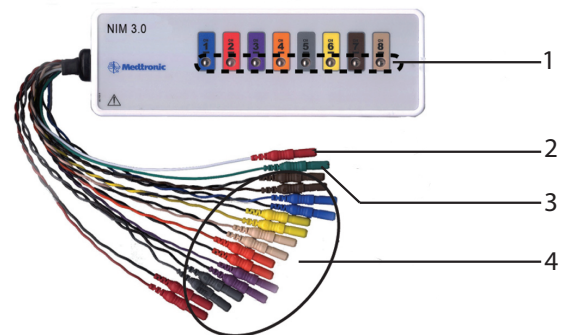


**Note:** Use Xomed 11270048 Fuse, 5 x20 mm, 32 mA, 250 V. Order 8253075 Fuse Kit for replacements.

## Patient Simulator

Use the Patient Simulator for troubleshooting and demonstrating the system without the need for patient interaction.

- 1 - Stimulator pads (Simulated Events).
- 2 - Stimulator return (anode) plug.
- 3 - Electrode ground plug.
- 4 - Simulated subdermal electrode plugs.



## Stimulator Probes/Handles

The Stimulator Probes and Handles carry stimulus current from the console via the Patient Interface, to the patient.

### Monopolar

#### Ball Tip Probe

- 1 - Stimulus to Patient Contact Area
- 2 - Insulated Sleeve
- 3 - Probe Base



#### Standard Prass Flush Tip Probe

- 1 - Stimulus to Patient Contact Area
- 2 - Insulated Sleeve
- 3 - Probe Base



#### Incrementing Monopolar Probe Handle

The Incrementing Probe provides the ability to adjust the stimulus and to print or save events from within the surgical site.

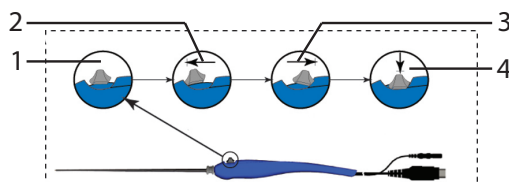
- 1 - Toggle Button
- 2 - Probe Jack
- 3 - Stimulus Plug
- 4 - Toggle Button Control Plug



### Incrementing Probe Stimulus Adjustments

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

**Note:** If the incrementing probe handle malfunctions, immediately disconnect the Toggle Button Control Plug from the Incrementing Probe jack from the Patient Interface and use console touch screen buttons to adjust stimulus current.



1 - Toggle button normal or at rest.

2 - Increase current.

3 - Decrease current.

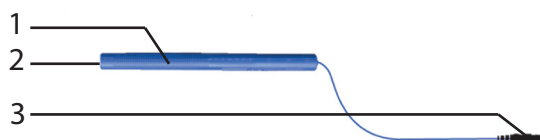
4 - Press and hold saves current screen to memory (for Reports) and to selected peripheral device (Printer and/or USB flash drive).

### Universal Monopolar Probe Handle

1 - Handle.

2 - Probe Jack.

3 - Stimulus Plug.



### Bipolar

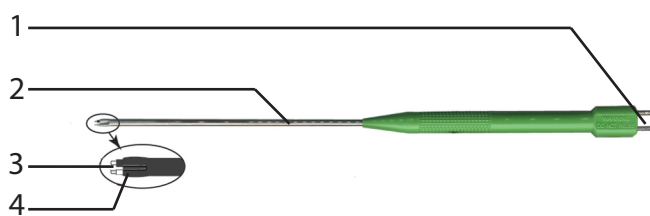
#### Side-by-side Stimulating Probe

1 - Cable Connection.

2 - Stainless Steel Tubing.

3 - Stimulus to Patient Contact Area.

4 - Insulating Sleeve.



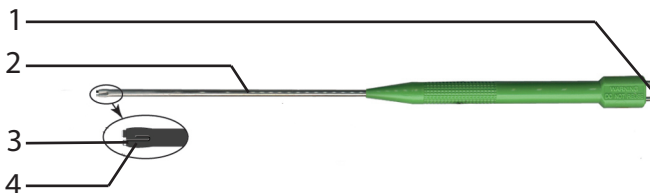
#### Prass Flush Tip Stimulating Probe

1 - Cable Connection.

2 - Stainless Steel Tubing.

3 - Stimulus to Patient Contact Area.

4 - Insulating Sleeve.



### Muting Detector

Refer to Precaution P8 for more information.

The 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.

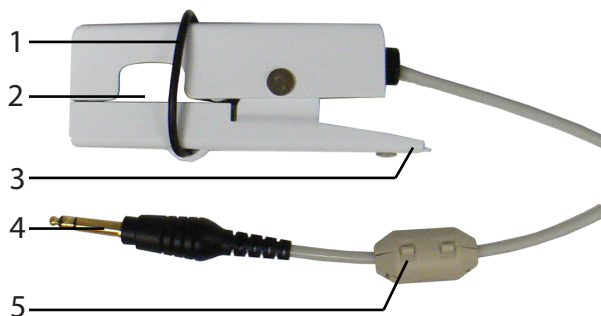
1 - Anti-slide Ring.

2 - Electronic Noise Detection Area.

3 - Insulating Sleeve.

4 - Cable Connector.

5 - Ferrite.

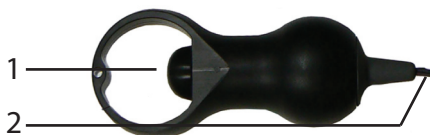


### APS Electrode Handswitch

The APS electrode handswitch cycles through the APS functions (Off, Slow, Fast).

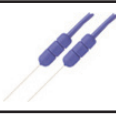
1 - Thumb Switch.

2 - Cable.



## Electrodes

Electrode types recommended for use with the NIM® 3.0 System

|                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    | EMG Endotracheal Tube. Contact electrodes designed to monitor both vocal cords.                                                                                                                                                                                                                                                                                                       |
|    | 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.                                                                                                                              |
|    | Paired Subdermal Electrodes. Non-insulated high performance electrodes with 2.5 mm spacing.                                                                                                                                                                                                                                                                                           |
|    | Press Paired Electrodes. The electrodes are insulated to within 5 mm of the end with 5 mm spacing. Muscle-specific single use.                                                                                                                                                                                                                                                        |
|    | Press 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).<br>Always locate these 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). Ground should also be located between the stimulator and monitoring electrodes. |
|  |                                                                                                                                                                                                                                                                                                                                                                                       |
|  | APS (Automatic Periodic Stimulation) Electrode.<br>Continuous, real-time monitoring of vagus nerve through low-level stimulation.<br>Single-use.                                                                                                                                                                                                                                      |

## Power Cords

|         |                                   |
|---------|-----------------------------------|
| 1897821 | Power Cord, 6 Meter, 115 V        |
| 1895820 | Power Cord Standard, U.S.         |
| 1895822 | Power Cord, 6 Meter, Europe, U.K. |
| 1895823 | Power Cord, Japan, 100 V          |



Additional information can be found at [www.mcatalogs.com/ent/](http://www.mcatalogs.com/ent/).

## Splash Screen



## Self Test

The system automatically performs an internal integrity check each time you turn the NIM-Response 3.0 ON. Refer to the Maintenance Schedule topic for more information.

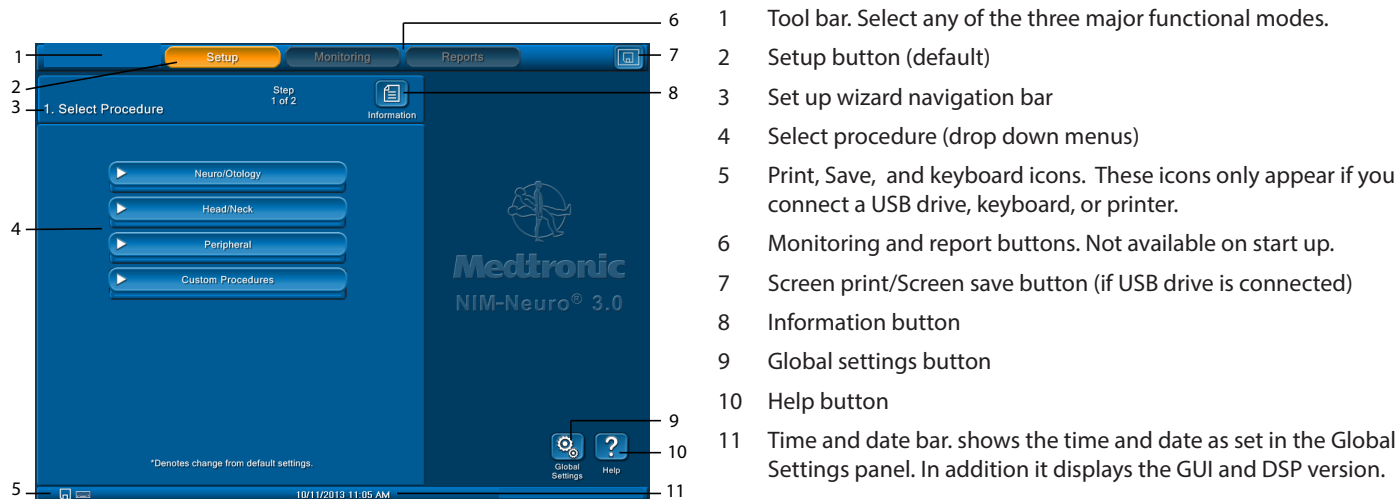
Once the NIM-Response 3.0 powers-up, the system briefly displays a series of messages. Then the console does a series of self-tests on the hardware.

## Setup Mode

### Select Procedure Step 1 of 2 Screen

The Setup screen is the default screen. You must select an existing procedure or begin a new (custom) procedure from the default screen.

Optional: You may enter/change the date, time, language, or data fields via the Global Setting button.



1. Select one of the following procedures by touching it on the screen.

- Neuro/Otology
- Head/Neck
- Peripheral
- Custom Procedures

The system opens a drop down menu which includes a selection of pre-defined procedures.

2. From the drop down menu, select one of the pre-defined procedures by touching it.

The Place Electrodes screen appears.

3. Place the electrodes according to the diagram.

4. Do one of the following:

- Go directly to monitoring either by pressing the Monitoring selection on the top toolbar, or by pressing **Monitor**.
- Access the summary of electrode impedance by pressing .

## Global Settings

You can access the Global Settings panel by pressing the Global Settings button in any of the Setup Mode screens.



1 Global Settings screen

2 Language tab

3 Date/Time tab. Select how the system displays the date/time. The default format is language sensitive.

4 Data Fields for Case Information tab

5 Blank data fields. Enables you to name two fields which will appear on the Case Information screen.

6 Diagnostic Mode. Not for end users. This selection should only be used under the direct supervision of Medtronic Xomed personnel.

7 Enable DB Saving check box (default is unchecked). Turns on the .db option in Reports Mode.

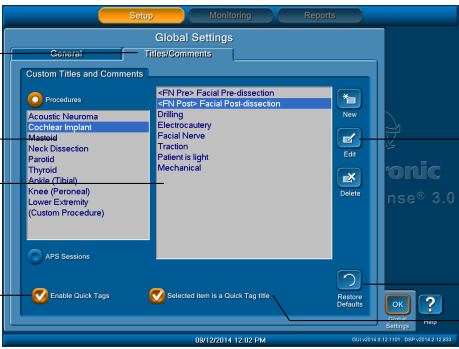
8 Set Date and Time button. Opens a data entry key pad for setting date and time.

9 Restore Defaults button. Restores all settings, including procedure settings, to their defaults.

10 OK button closes the Global Settings screen.

### Add/Maintain Custom Titles and Comments on The Global Settings Screen

This 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 are grouped by procedure type as selected by the radio buttons on the left.



1 Title/Comments tab

2 List box containing procedure names

3 List box containing pre-defined titles for the selected procedure

4 Enable Quick Tags check box

5 New, Edit, and Delete buttons

6 Restore Defaults button

7 Selected item is a Quick Tag title check box

1. Select the Titles/Comments tab on the Global Settings screen.
2. Select a procedure from the list box on the left of the Custom Titles and Comments panel. A list of titles for the selected procedure appears in the list box to the right.
3. Do any of the following:
  - Press  to create a custom title/procedure. Use the on screen or attached keyboard to type a title or comment.
  - Select a title, press , and then edit the existing procedure.
  - Select a title, press . The system deletes the title.
4. Press .

The system saves your settings.

## Quick Tags



- 1 Title/Comment text box. By default, the procedure title you selected on the Titles/Comments tab appears.
- 2 Abbreviation text box
- 3 Example of the Quick Tag you created.

You can use the Enable Quick Tags check box to type an abbreviation of the title that appears on a quick tag button on the tool bar at the bottom 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” check box. Once you have selected from the drop down menu, type an abbreviation for the title of the button using the pop-up that appears.

1. Refer to the Add/Maintain Custom Titles and Comments on The Global Settings Screen topic to select a title.
2. Select the Enable Quick Tags check box.
3. Select the Selected item is a Quick Tag title check box.

The Edit Title/Comment Abbreviation pop up appears with the title/comment name in the Title/Comment box.

4. Press the Abbreviation box.

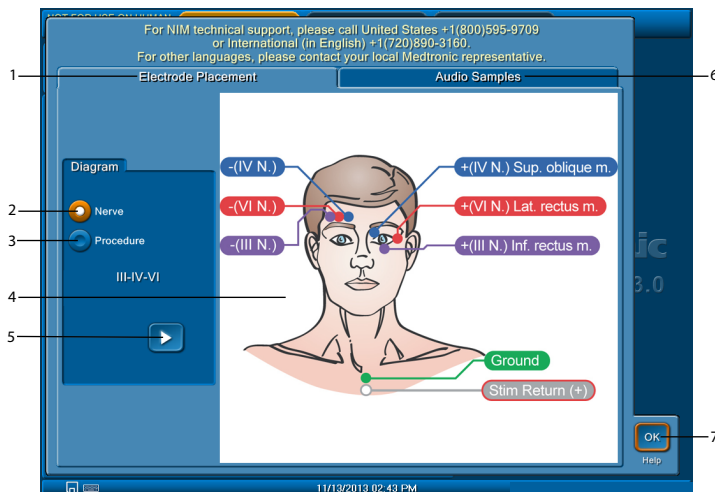
The Abbreviation pop appears with the choice to use an on screen keyboard, or use your attached keyboard.

5. Type the abbreviation you want to use for your quick tag and press .

The Abbreviation pop up disappears and the system returns you to the Edit Title/Comment Abbreviation pop up with an example of how your quick tag button will appear on the Monitoring screen.

## Help

The Help screen displays help graphics for locating electrodes or sample audio sounds.



- 1 Electrode Placement tab. Selects help graphics for locating electrodes.
- 2 Diagram/Nerve radio button. Selects help graphics by nerve number/name.
- 3 Diagram/Procedure radio button. Selects help graphics by Procedure.
- 4 Graphics display area
- 5 Previous/Next buttons. Use these buttons to change graphics.
- 6 Audio Samples tab. Contains three sample sound buttons (pulse, train, burst).
- 7 OK button. Closes Help screen.

You can use the Help screen to view electrode placement graphics to aid in 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. On the Setup screen, press .

The Help screen appears with the Electrode Placement tab showing.

2. On the Diagram panel, select one of the following:
  - Nerve – to view electrode placement by nerve number/name.
  - Procedure – to view electrode placement by procedure.

3. Use  or  to move through available placement help graphics.
4. Place electrodes according to the appropriate help graphic.
5. Press  to return to the Setup screen.

## Listen to Audio Samples

You can use the Audio Samples tab on the help screen to hear three types of audio alarms.

1. On the Setup screen, press .

The Help screen appears with the Electrode Placement tab showing.

2. Select the Audio Samples tab.
3. Select any of the following audio samples:

- Pulse
- Train
- Burst

4. Press  to return to the Setup screen.

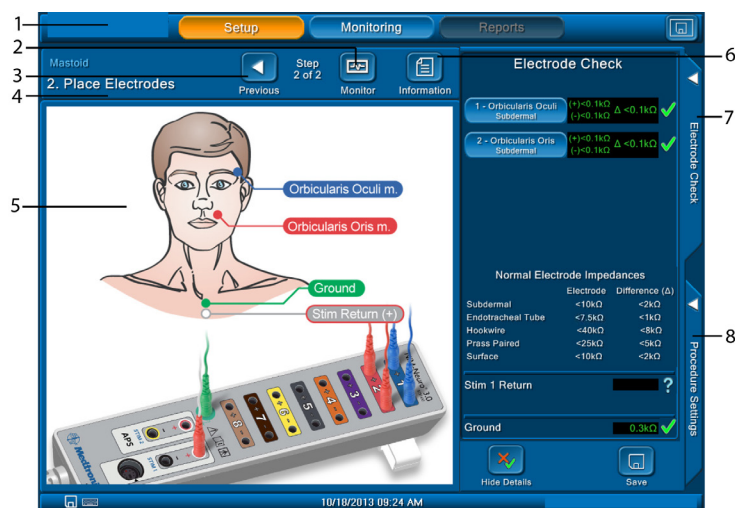
## Place Electrodes Step 2 of 2 Screen

The system automatically opens this screen after you select a factory installed procedure.

The Place Electrodes Step 2 of 2 screen assists you with electrode location. When the system runs an electrode check, this screen shows the electrodes the system is testing.

**Note:** If you make changes to the procedure and want to save them, then you must make the changes before selecting the Monitor or Monitoring button.

- Note:**
- You can bypass this screen by selecting the Monitor or Monitoring button.
  - If you bypass the 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 opened this screen, any printed report will show a failure of the impedance values of the disconnected item(s).



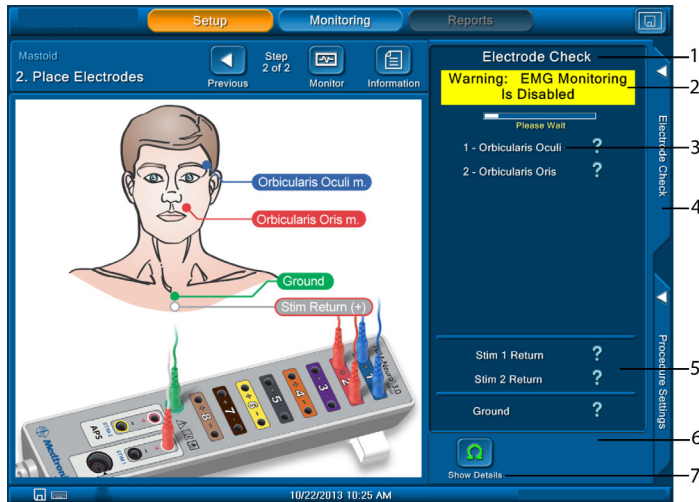
- 1 Tool Bar. Allows selection of available functional modes.
- 2 Monitor button opens the Monitoring screen. **Note:** If you make changes in the Electrode Check panel, the Procedure Settings panel, or one of the Procedure Settings/Advanced Settings Tabs, a dialog box opens asking if you wish to save your changes.
- 3 Previous arrow button. Returns you to the Select Procedure screen.
- 4 Setup wizard navigation bar
- 5 Electrode Placement Graphic. Shows electrode placement for the patient and patient interface.
- 6 Information button opens the Case Information screen.
- 7 Electrode Check tab. Closes/Opens Electrode Check panel.
- 8 Procedure Settings tab. Opens/Closes Procedure Settings Panel.

## Electrode Check

The Electrode Check screen checks the integrity of the patient to Patient Interface connections. It is the only screen where you can adjust the electrode type in use.

## Electrode Check Panel

You can access this panel from two (2) locations: In Setup Mode with Place Electrodes screen (shown below), or from the Monitoring screen by pressing control panel tab and Electrode Check button.



1 Electrode Check Panel typically appears in Setup Mode with Place Electrodes Screen. You can open/close the Electrode Check Panel using the Electrode Check tab.

2 The system disables monitoring when the Electrode Check panel is open.

3 Electrode status field:

- Progress bar. Appears while the system tests electrodes.
- Question Marks. Question marks appear while the system runs the electrode test and are replaced with pass (green check mark) or fail (red x mark) once the system has completed the test.

4 Closes Electrode Check panel.

5 STIM 1, STIM 2, and Ground status fields.

### 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 2 appears after you turn it on using the Activate button located on the main screen, or by selecting the STIM 2 or APS™ check box on the Procedure Settings/Stimulation Panel.
- STIM 1, STIM 2, Ground - If a question mark appears after the system has completed the test, no channel electrode or ground was connected so the system reads that as 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.

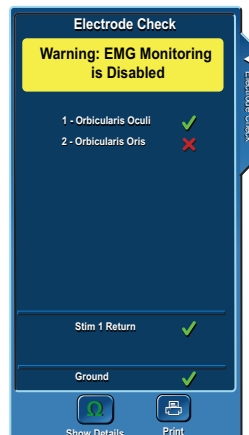
6 Print or Save button appears in this area. Sends monitoring electrodes, ground, and STIM 1 and 2 return impedance values to the printer or USB drive.

**Note:** Print button appears only if a printer is connected. The Save button appears if a USB device is connected.

7 Show Details button. Refer to the Electrode Check Show Details Panels topic.

## Electrode Check Panel Pass/Fail

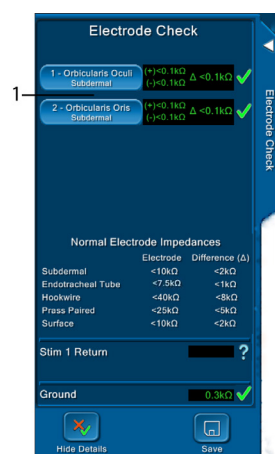
The system measures impedance values of the electrodes to the patient to confirm the integrity of the connection.



This screen shows that channel 1, stimulus return, and ground electrodes have passed where channel 2 has failed.

## Electrode Check Show Details Panel

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

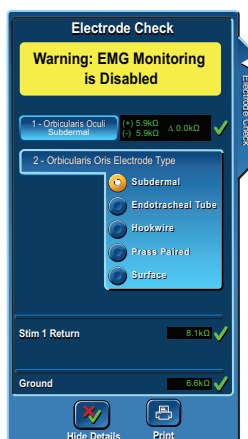


1 Electrode Type Button.

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

## Electrode Type Panel

Use the Radio Buttons on the Electrode Type screen to select the type of electrode you want to use.



## Electrode Troubleshooting Guide

| Symptom                                                                                                | Cause                                                                                                                                                                          | Solution                                                                                                                                |
|--------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Electrode impedance is too high.<br>> 10 KΩ for subdermal electrodes<br>> 7.5 KΩ for endotracheal tube | Electrode dislodged from patient, but not completely out.<br>High resistance in electrode.<br>Electrode pin not firmly inserted into patient interface.                        | Insert dislodged electrode; tape down in place.<br>Remove and replace with new electrode.<br>Check connection at Patient Interface box. |
| Electrode impedance $\leq 0.1$ KΩ                                                                      | Positive and negative electrodes touching below surface of skin.<br>Extremely low impedance, particularly in EMG tubes.                                                        | Remove and relocate electrodes.                                                                                                         |
| Electrode reading is (+ or -) Off<br>or<br>$\Delta = = =$                                              | Electrode laying on skin surface.<br>Electrode placement insecure.<br>Dirty electrode tip.<br>Electrode cable is broken.<br>Electrode pin disconnected from patient interface. | Re-insert electrode in question.<br>Remove and replace electrode in question.<br>Check connection to Patient Interface box.             |
| Question mark at STIM 1/2, and Ground in Electrode Check Panel                                         | No electrode connected.<br>Ground not connected.                                                                                                                               | Connect at least one electrode.<br>Connect ground.                                                                                      |

## Case Information

The Enter Case Information screen opens when you press the Information button. Use this screen to enter data into preselected data fields. Refer to the Global Settings topic for data field selection.



- 1 Tool Bar. Select any of the three major functional Modes.
- 2 Setup Wizard Navigation Bar. The Previous and Monitor buttons are located here. Refer to the Buttons and Indicators topic for more information.
- 3 Case Information. Press any of the information fields to open the keyboard for data entry.
- 4 Procedure Settings Tab. Opens Procedure Settings panel.
- 5 Global Settings and Help Buttons. Refer to the Global Settings topic for more information.

1. On the Setup screen, Press .

The Enter Case Information screen appears.

2. Press the Surgeon box and type the surgeon information using the on screen or attached keyboard.

3. Press .

4. Repeat steps 2 and 3 for the following information:

- Patient ID
- Patient Name
- Patient DOB
- Monitoring Professional
- Notes

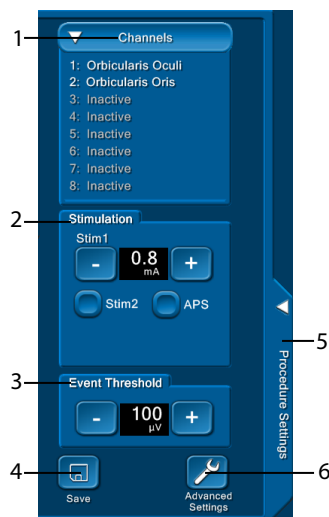
5. Press .

The system returns you to the Setup screen.

## Procedure Settings Panel

You can only access the Procedure Settings panel through the Setup Mode.

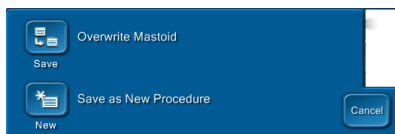
**Note:** You can save your changes on this panel (save to a new or existing procedure). You can review and/or change the monitoring settings for the procedure.



- 1 Channels. Add, remove, or change the names of the channels.
- 2 Stimulation Panel. Adjust STIM 1 stimulus and STIM 2 or APS stimulus (if selected).



- 3 Event Threshold Panel. Adjust the event threshold, which has a range from 20  $\mu$ V to 2500  $\mu$ V.
- 4 Save Button



- Opens save option panel.
  - Save option panel gives you the option to overwrite the existing procedure, create a new procedure, or cancel.
- 5 Procedure Settings tab. Opens/closes Procedure Settings panel.
  - 6 Advanced Settings Button

1. Press the Channels button to access a drop down list of channels.



2. Press an active channel to inactivate that channel. Press an inactive channel to open the Muscle Name keyboard.
3. Use the Scroll buttons to locate an existing muscle group.
4. Highlight the muscle name by touching the screen or type the new muscle name.
5. Press **OK**

The system saves the muscle name and exits.

## Advanced Settings

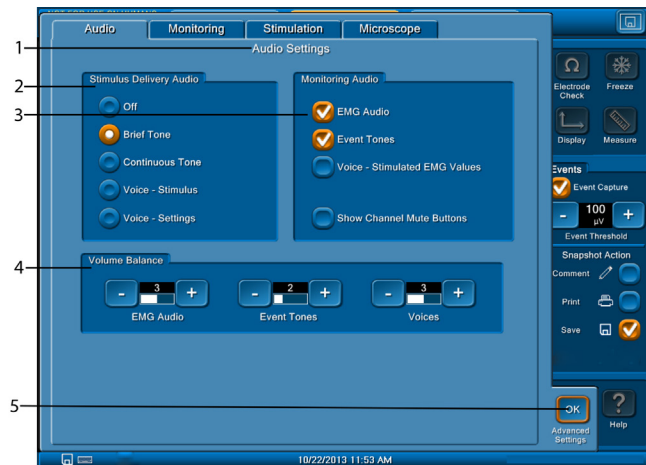
Advanced Settings function:

- You can use Advanced Settings adjustments made during the Setup Mode (Procedure Settings Panel) for the current or saved session.
- Advanced Settings adjustments made in the Monitoring Mode (Control Panel) are only effective for the current session and cannot be saved.

When you press the Advanced Settings button, the system opens a screen with tabs that enable access to the functions described.

## Audio Tab

Refer to the Audio – Understanding What You Hear topic for more information on the Audio tab.



- 1 Audio Settings. Configures system to determine what sounds will be heard during monitoring and balance between various sounds.  
**Note:** If APS is active, the Event Tones volume balance will control the APS volume balance.
- 2 Stimulus Delivery Audio panel
- 3 Monitoring Audio panel
- 4 Volume Balance panel. You can adjust Sound levels using the + and – buttons for EMG Audio, Event Tones and Voices. A numeric value and white bar graph indicate the setting relative to full scale (scale is 1 to 5).
- 5 OK button. Closes the Advance Settings panel.

Additional options for the Stimulus Delivery Audio panel (2):

- 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 (3). 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.

**Note:** If you selected “Voice – Stimulated EMG Values” in Advanced Settings/Audio, the NIM announces the value of the highest channel in the last or largest event in a sequence (one second after the sequence ends). The system rounds the actual value appropriately for annunciation. For example, the 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 8. 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.

## Monitoring Tab



- 1 View Scale. Refer to the Control Panel Display Button.
- 2 Measurement Cursor Position panel.
- 3 Waveform Filters panel
- 4 Event Capture panel
- 5 Sequence Display panel
- 6 Latency panel
- 7 Snapshot panel
- 8 OK button. Closes the Advanced Settings panel.

In the Measurement Cursor Position panel (2), you can select the following measurement start positions:

- Peak Amplitude - selects the largest peak value
- Latency - places the cursor where the response to a stimulation begins.  
If you selected the Auto Threshold check box in the Event Capture panel (4) and the Event Tones are continuous for 10 seconds:
- Auto Threshold automatically calculates a new Event Threshold (to a maximum of 400  $\mu$ 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  $\mu$ V generates Event Tones.
- Additionally, if you selected the Voice setting, it announces the amount of threshold increase.
- The Event Threshold returns to the original value after 10 – 20 seconds of no, or decreased, event activity.

In the Sequence Display box (5), the Last box is selected by default. The following happens:

- If Last and Event Capture (see Control Panel) are selected, the most recent event appears until replaced with a new or more recent event.
- If Largest Overall and Event Capture (refer to the Control Panel topic) are selected, and multiple events occur over a period of 4 seconds, 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 4 second series of events.

**Note:** Neither Event Capture nor Largest are available when the x-axis time scale is set to 20 seconds (it is only available in the 50ms time scale).

On the Latency panel (6), you can do the following:

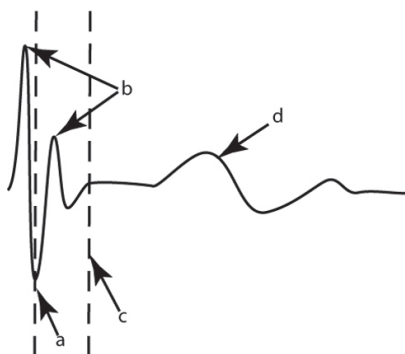
- Control whether the system shows latency values in non-APS stimulated waveform sweeps using the Display Latency check box.
- Control whether the system measures latency to the onset of the response, or to the highest peak EMG value of the response using the Onset or Peak check boxes.
- If you selected Display Latency in Advanced Settings, then for every stimulation pulse that causes a response greater than 20  $\mu$ 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 Snapshot panel (7), you can do the following:

- Choose the default snapshot actions using the Comment, Print, and/or Save check boxes. You can select more than one action.
- Select the Probe Saves Snapshot check box 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 checked, 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.
  - When the desired title is selected, the center button moves the selected item into the Event Title, save/print the snapshot and close the title/comment box.

### Stimulus Artifact Example

This is an adjustable delay allowing the small amount of electronic noise caused by stimulation (Stimulus Artifact) to stabilize before reading EMG data.



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

**Note:** In previous versions of the NIM, Stimulus Rejection Period was referred to as Stimulus Artifact or Artifact Delay.

### Special Note on Recognizing Artifact

The NIM® 3.0 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® 3.0 System cannot differentiate.

Examples:

- A transcutaneous stimulator used by the anesthesiologist might generate an audible signal.
- Any external nerve locator/stimulator not synchronized (Muting Detector) with the NIM® 3.0 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.

- The pace pulse generated by pacemakers may be detected and displayed by the NIM® 3.0 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® 3.0 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.

There are two types of Waveform Filters (3):

- Artifact Filter: Selecting this Check Box enables the detection of artifact as "Spiked Waveforms".
- Low Frequency 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 this Check Box 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.

## Stimulation Tab

### Important Note on Stimulator Adjustments

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 smallest amount of stimulus 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 motor evoked potentials. The best guideline for setting the stimulus intensity level is to use the lowest amount that produces an EMG event.

The surgeon should be aware:

- That STIMULUS is continuously being applied to the STIMULATOR probe and/or the APS.
- 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 APS).

**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 , a dialog box opens:

- Stimulus in excess of the current warning level (usually 3 mA).
- Press **OK** to allow stimulus

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



- 1 Name/text field
- 2 Type Panel. Use this panel to select either the monopolar or bipolar probes. Monopolar is the default. If you are using bipolar probes, you must change the probe type at this location.
- 3 Pulse Width panel. Use this panel to make adjustments to the stimulus pulse width.
- 4 Rate panel. Use this panel to make adjustments to the stimulus rate.
- 5 Current Warning Level. Use this box to adjust the maximum stimulator current setting before a warning dialog appears.  
**Note:** Use this area if you accessed this screen from Setup/Procedure Settings/Advanced Settings. No adjustment is available if you accessed this screen from Monitoring/Control Panel/Advanced Settings.
- 6 Rejection Period panel
- 7 Reject Stim Pulse Artifacts check box
- 8 OK button. Closes the Advance Settings panel.

**Note:** If you are using an APS procedure, you should make all adjustments to STIM 2 using the APS Tab except for the Name/text field (1) in the Stimulator 2 panel section. If you are using a monopolar or bipolar probe, make your adjustments on the Stimulator 2 panel as you did with STIM 1.

1. In the Stimulator 1 or 2 box, press the text field to open the Stimulator 1 or 2 Name keyboard.

2. Use the Scroll buttons to locate an existing probe.

3. Highlight (touch the screen) the probe name.

4. Press **OK**, or type the new name.

The system saves the probe name and exits.

5. Repeat for Stimulator 2 panel.



The following is an example of a pulse width and rate adjustment performed on the Pulse Width (3) and Rate (4) panels.



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

**Note:** If you selected an APS procedure, then the Stimulator 2 Panel/Rate adjustment will be located on the APS Tab.

Use the Rejection Period panel (6) to do the following:

- Adjust the rejection period using the Rejection Period + or - buttons.
- Suppress the stimulus pulse artifacts during monitoring by selecting the Reject Stim Pulse Artifacts check box (7).

### Microscope Tab (available on the NIM-Neuro 3.0 only)

**Note:** When the “Display Overlay” check box is not checked, the system does not display all other parts of the panel.

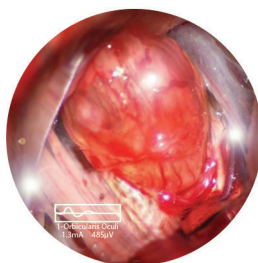
The following graphic shows all default settings.

**Note:** Not all video input microscopes are compatible with the NIM® 3.0 System. Contact Customer Care at 1(800)874-5797 for specifics.



- 1 Overlay Mode panel
- 2 Overlay Position panel
- 3 Resolution panel
- 4 Overlay Training panel
- 5 Overlay Format panel
- 6 OK button. Closes the Advance Settings panel.

Use the Display Overlay selection on the Overlay Mode panel (1) to activate the microscope overlay video output.



Example

- You can select between displaying any event or events resulting from stimulation.

Use the Overlay Position panel (2) to select where the system displays the overlay.

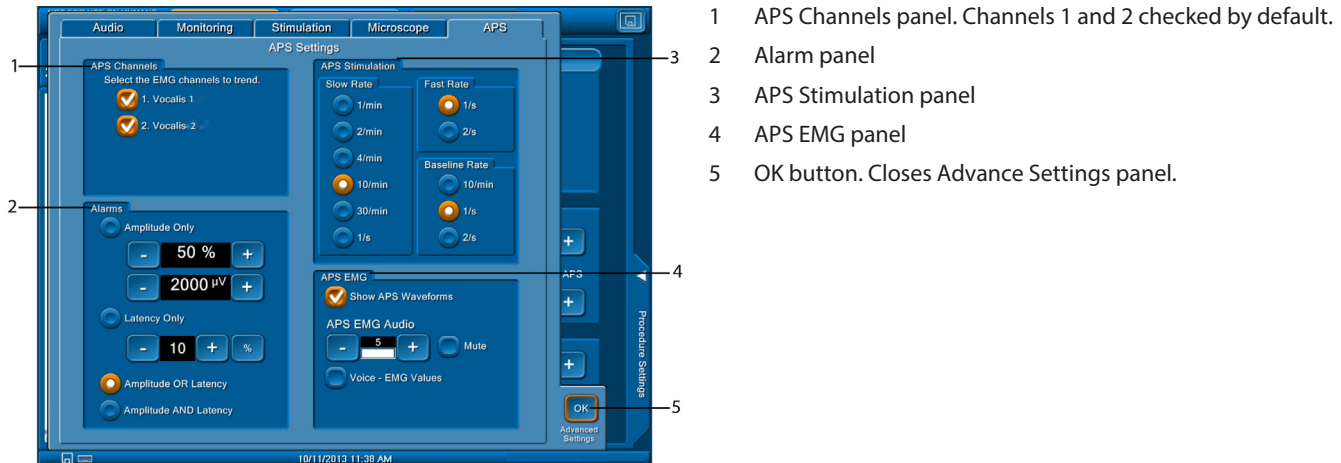
- Location is fine tunable at plus or minus 60 pixels using the horizontal or vertical offset adjustment.

The resolution (3) should be set to the value specified by the microscope manufacturer.

Use the Overlay Training panel (4) to display an event until replaced with a new event, or have the display turn off after a selected period of time.

Select the Largest Channel radio button on the Overlay Format panel (5) to select where the system displays show data only or data and waveform. Example shows data with waveform.

### APS Tab (Automatic Periodic Stimulation)



Use the Alarm panel (2) to customize the following alarm settings:

- 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 $\mu$ V). You can also set an absolute alarm limit in this area.  
Absolute alarm limit example: If the baseline amplitude is 3000  $\mu$ V, the amplitude percentage limit is 50% (1500  $\mu$ V), and Amplitude Absolute limit is 1000  $\mu$ V, then a signal of 1400  $\mu$ V would not cause an alarm because although the signal has decreased more than 50%, it is still above the absolute limit.
- 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 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 limits 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).
  - msec – 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).

Use the APS Stimulation panel (3) to select a "Slow Rate" and "Fast Rate". You may switch between these rates when in monitoring. The default settings for this panel are:

- Slow Rate 10/min (10 per minute)
- Fast Rate 1/sec (1 per second).
- Baseline Rate. You can select the rate at which baseline acquisition occurs from the following values:
  - 10/min
  - 1/sec
  - 2/sec

**Note:** The Pulse Width adjustment for APS is found on the Stimulation Tab Stimulator 2 panel.

### Create a Baseline Measurement for an APS Procedure

You must take a baseline measurement using the Baseline button on the Monitoring screen before you can perform APS trending.

**Note:** When at least one channel gets a good baseline and any other channel has a median amplitude above the event threshold, the system continues the baseline stimulation pulses for up to 20 more pulses to enable those channels to meet the criteria before stopping.

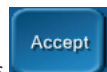


1. On the Monitoring screen, press .

The Establishing APS Baseline screen appears displaying the baseline test results.



2. If you received a baseline failure (the system displays the reason for the failure in the gray box), Press to perform a new baseline test.



3. Press .

The system closes the Establishing APS Baseline window, saves your baseline, and returns you to the Monitoring screen.

On the APS EMG panel, the Show APS Waveforms check box is selected by default. The system shows the waveforms from APS stimulation on the Monitoring Screen as blue with EMG response in white. Press the Mute APS EMG Audio to mute the APS EMG Audio (pop, pop, pop sound).

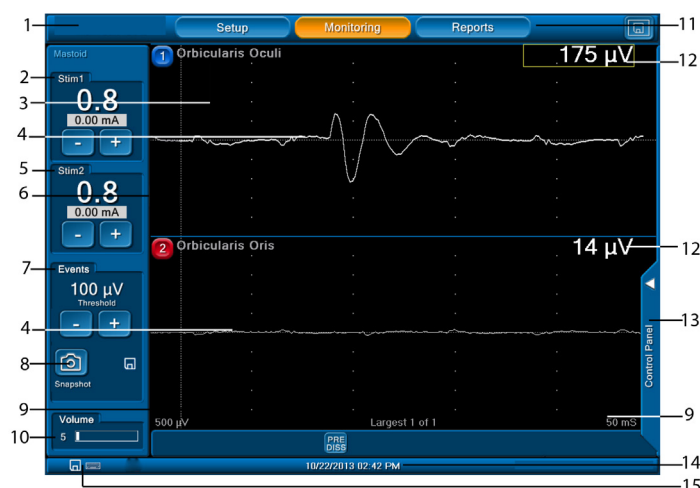
On the APS EMG panel you can control the following audio selections:

- Mute the APS EMG Audio using the Mute check box. If you select the Mute check box, then the EMG audio is muted for the sweeps initiated by a APS stimulation pulse. If you deselect the Mute check box, then the volume of the EMG audio for APS sweeps is controlled by the +/- adjustment provided.
- Voice - EMG Values – If you select this check box, then the NIM periodically announces the last APS EMG value audibly. Use the radio buttons to select the frequency of annunciation.

## Monitoring Mode

Access the Monitoring screen by selecting the Monitor or Monitoring button. The Monitoring screen appears during surgery and shows all EMG activity.

**Note:** APS is not shown.



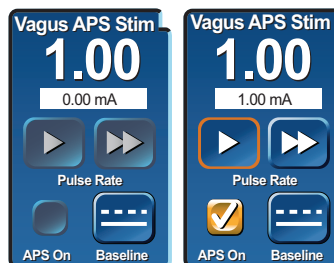
- |   |                                                                       |    |                                                                                                                                                                |
|---|-----------------------------------------------------------------------|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Tool bar                                                              | 9  | Scale. Displays screen scale settings.                                                                                                                         |
| 2 | STIM 1 panel                                                          | 10 | Volume panel                                                                                                                                                   |
| 3 | Channel label. Displays the channel number and nerve being monitored. | 11 | Setup, Monitoring, and Reports buttons                                                                                                                         |
| 4 | Trace. Displays stimulus nerve activity/inactivity.                   | 12 | Amplitude                                                                                                                                                      |
| 5 | STIM 2 panel                                                          | 13 | Control Panel tab                                                                                                                                              |
| 6 | Artifact Delay. Shows where artifact ends and EMG begins.             | 14 | Date, Time, GUI, and DSP version                                                                                                                               |
| 7 | Events panel                                                          | 15 | Print and Save icons. The system automatically displays these icons (on all screens with time and date bars) only if you connect a USB drive and/or a printer. |
| 8 | Snapshot button                                                       |    |                                                                                                                                                                |

The STIM 1 panel (2) displays the following settings:

- Stimulation setting (large numbers)
- Measured value (in the small window)
- Adjustment buttons for the STIM 1 current settings.

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.

If an APS procedure has been selected then the APS STIM Panel appears:



- The APS On, check box, Slow Rate, and Fast Rate buttons will be inactive (gray) until after the APS Baseline has been established.
- Refer to the APS Tab section in the Setup Mode topic for how to establish a baseline.

The Events panel displays the Event Threshold settings and enables you to adjust the setting level (in 5 µV increments).

- EVENT THRESHOLD is used to define where EMG activity becomes significant.
- EMG activity exceeding this "THRESHOLD" is defined as an "EVENT" and results in Event Tones (alarms) sounding.
- Set "Event Threshold" by pressing plus/minus buttons to increase or decrease the value as desired. Setting is displayed in micro-Volts.

**Note:** Event Threshold adjust buttons are unavailable for APS monitoring. See Control Panel to adjust Event Threshold.

Use the Snapshot Button to save the current screen to memory (for reports), or to a selected peripheral device:

- Comments Icon Snapshot Option. Refer to the Control Panel topic for additional information.
- Print and Save Icon Snapshot Option. The system displays these icons automatically if a USB drive and/or a Printer are connected and you selected those devices on the Control Panel - Snapshot Action. Refer to the Control Panel topic for additional information.

**Note:** Snapshots (print or save) show event information only and do not include the impedance values of the electrode, ground, or STIM 1/2.

The Volume panel displays an adjustable volume setting.

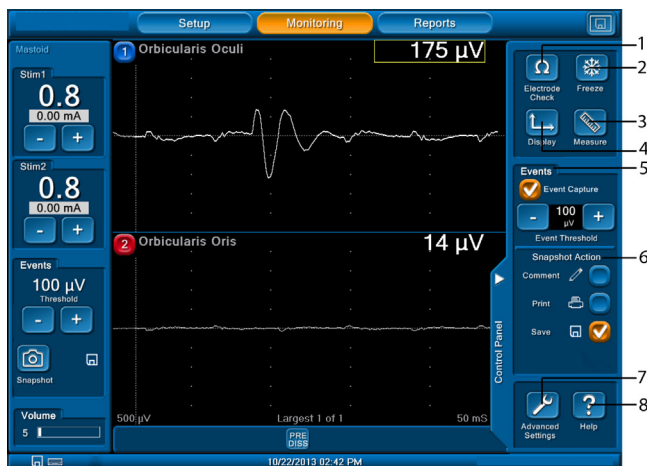
You can adjust Sound levels using the volume knob on the console's front panel (see Console Front, Item C). A numeric value and white bar graph indicate the setting relative to full scale. The default setting is 50.

The amplitude (12) 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  $\mu\text{V}$  or higher), the system displays the "Out of Range" message.

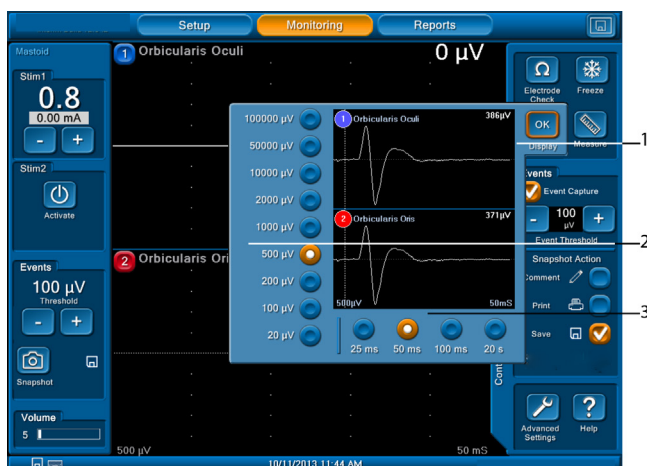
## Control Panel

Use the Control Panel to access additional settings and monitoring features.



- 1 Electrode Check button
- 2 Freeze button. When you press the Freeze button, the system displays the screen content, unchanged, until you press the Freeze button again. The Freeze button enables you to view an event over an extended period.
- 3 Measure button. Displays a cursor to view details of an event waveform.
- 4 Display button
- 5 Events panel. Select Event Capture box and the system captures and holds EMG activity that exceeds the Event Threshold setting.
- 6 Snapshot Action panel
- 7 Advanced Settings button. Opens Advanced Settings. See Set-Up Mode/Advanced Settings for information. Adjustments made to the Advanced Settings in the Monitoring Mode (Control Panel) are effective only for the current session and CANNOT be saved.
- 8 Help button. Press the Help button to view an abbreviated assistance on the Monitor Display.

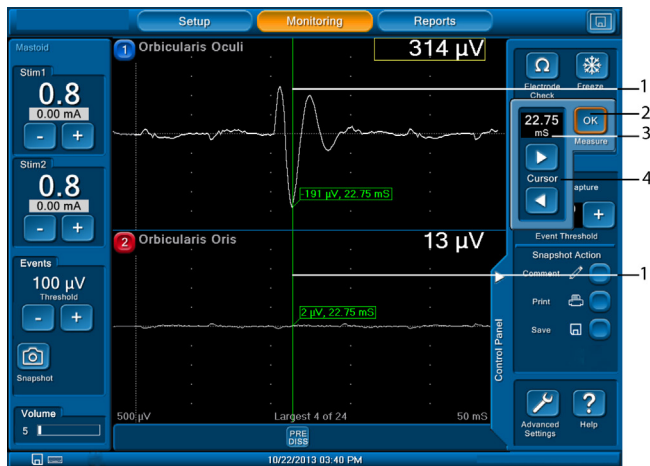
Press the Display button (1) to open the Scale Panel.



- 1 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.
  - 2 Time scale is represented by the horizontal portion of the EMG display and is adjustable (refer to the Advanced Settings / Monitoring Tab). 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.
  - 3 OK Button, closes Scales panel.
- Note:** Changing either scale only affects how the data appears on the screen. It does not modify the sensitivity of the unit.

The following buttons are available on the Events/Snapshot Action panel (6) :

- Comments. Opens comments panel enabling comments and Event Titles (you may enter titles via keyboard or select them from a customized list) you wish to add 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 Add/Maintain Custom Titles and Comments on the Global Settings Screen 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 if you selected it when you press the Snapshot button.
- Save. Sends captured event to the USB mass storage device with comments if you selected it when you pressed the Snapshot button.



- 1 When you activate the Measure button, the on screen cursor (green) shows the amplitude ( $\mu\text{V}$ ) 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.
- 2 When you press the OK button, the system turns off the cursors and displayed values.
- 3 The system displays the time.
- 4 Cursor Position buttons move the vertical (green line) cursor left or right in increments of 0.25 mS.

## The APS® Monitoring Screen

APS is a process wherein a nerve at risk is continuously being stimulated. This stimulation 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)

The plotted chart displays peak-to-peak values for EMG amplitude and latency responses for each stimulation pulse delivered. Every turquoise dot represents a single EMG amplitude response. Each blue dot represents a latency response. A red dot is an out of limit condition resulting in an alarm sounding.

If a measurement falls outside the limit values, the dots appear red-colored and the console issues an audible alarm to alert you depending on what alarm settings you selected on the Advanced Settings screen. Alarm mute buttons appear when in an alarm state, enabling you to mute the audible alarms.

## Mute an APS® Alarm

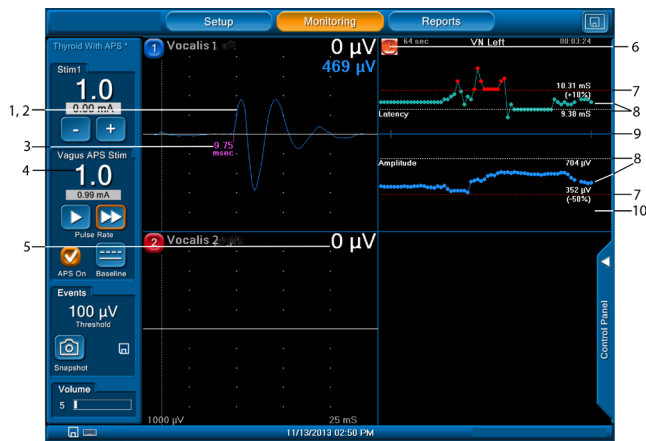
When a plotted point falls outside the set alarm limit, the system displays an alarm button on screen. You can mute this APS alarm on the Monitoring screen using the alarm button.

1. Press

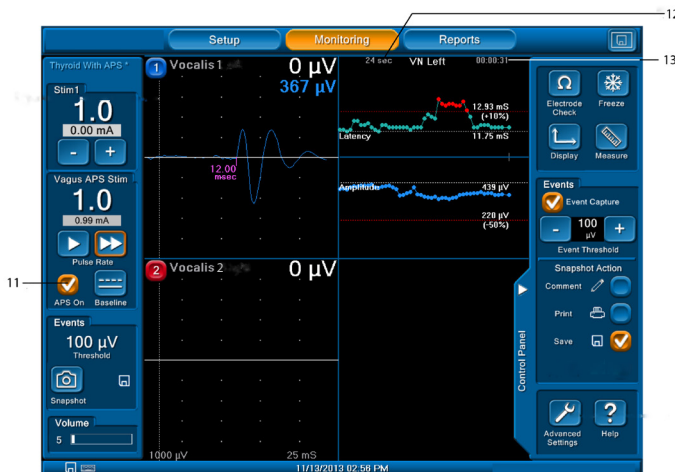
The system mutes the alarm and displays

2. To unmute the alarm, press

If a subsequent plotted point falls inside the alarm limit, the muted button turns green. If the plotted point then falls outside the alarm limit, the muted button turns back to red. The mute button continues to change between red and green until you turn off the mute button.



- 1 APS Waveform. Appears as a Blue Trace on all channels if Show APS Waveforms is on (default) in Advanced Settings APS tab.
- 2 EMG Waveform. Appears as a White Trace on all channels.
- 3 APS Latency value.
- 4 APS stimulation level.
- 5 Values. The system displays the EMG measured values in white with the largest value boxed in yellow.
- 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.
- 8 Baselines. The system displays the Latency and Amplitude as white dotted lines.
- 9 Trend lines. The system displays Latency as a series of turquoise dots and displays Amplitude as a series of blue dots.
- 10 Latency and Amplitude are separated by a scaled line. This line is the time base as shown at top left of screen (L). The scale marks are one minute apart.
- 11 Values. The system shows the alarm (if sounded) at the Limit Lines and shows the measured value of the last pulse at the Baselines.



- 11 APS ON check box. Use this check box to pause/continue APS stimulation once the session has started.
- 12 Time Base.
- 13 Session duration

If the APS button is turned OFF:

- The APS portion of the screen (right side) closes and the system adds an APS tab to the control panel tab. You can open and close the inactive APS screen using this tab.
- APS monitoring resumes once you select the APS check box.

## The Reports Mode

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

The Report Mode enables you to quickly compose and print/save three general types of reports; Event Records, Log Files and APS Records. The system provides report templates to simplify creating reports.

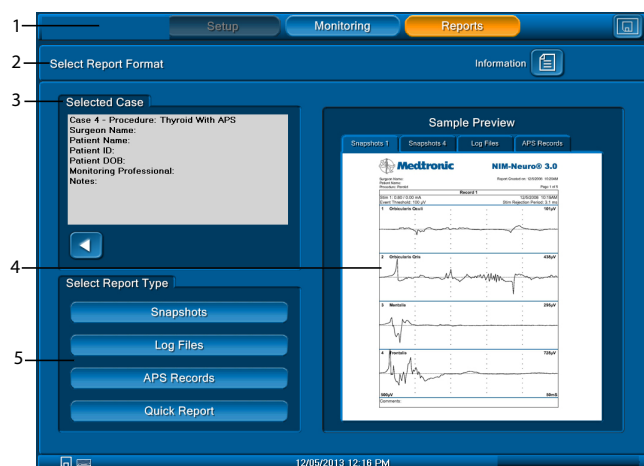
The Reports Mode can be active while audio monitoring continues in the background. The system saves all work performed in Reports mode if you exit Reports and return to Monitoring. For example, you can start a report midway through a monitoring session. When you return to Monitoring to complete the session,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

There are three steps in the process:

- Select Report Format
- Specify Report Content
- Create Report

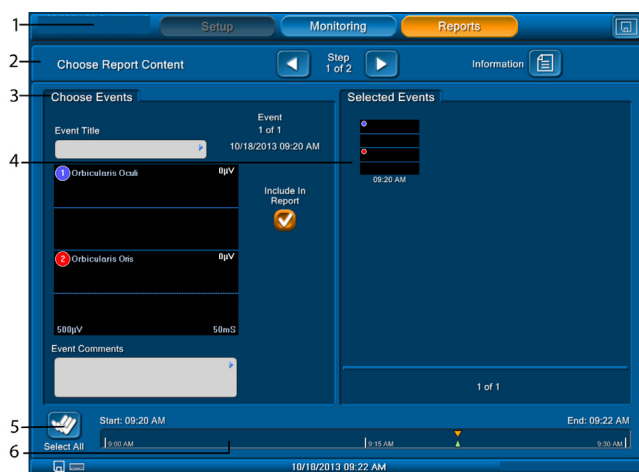
## Select Report Format

The Reports screen is used by Snapshots, Log Files, and APS Records.



- 1 Tool Bar. Selects any of the three major functional modes.
- 2 Active Screen Bar. The system displays the Next button after you select a report type.
- 3 Select Case panel. Select a case from multiple cases. The system displays Next and/or Previous button(s) if more than one case is in memory.
- 4 Sample display area of selected report type.
- 5 Select Report Type panel. Select from available report types.

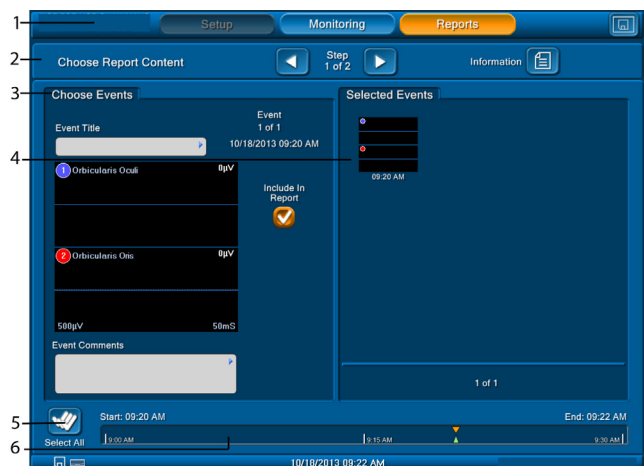
## Snapshots/Event Reports



After you select the Report Type (Snapshots), the Choose Report Content screen appears. Press the Next button on the Active Screen Bar to open the Create Report screen.

## Choose Report Content

APS reports and Snapshot reports are very similar. The differences are noted in the following.



- 1 Tool Bar. Select any of the major functional Modes (Setup not available in Reports).
- 2 Active Screen bar
- 3 Choose Events tab (on the APS Reports screen, the Choose Events panel appears as Choose Sessions panel).
- 4 Selected Events tab. Shows the collection of events the system includes on the report.
- 5 Select All button. Use this button to move all events to the Selected Events panel (on the APS Reports screen there is no Select All button).
- 6 Time-Line panel (on the APS Reports screen there is no time line panel).

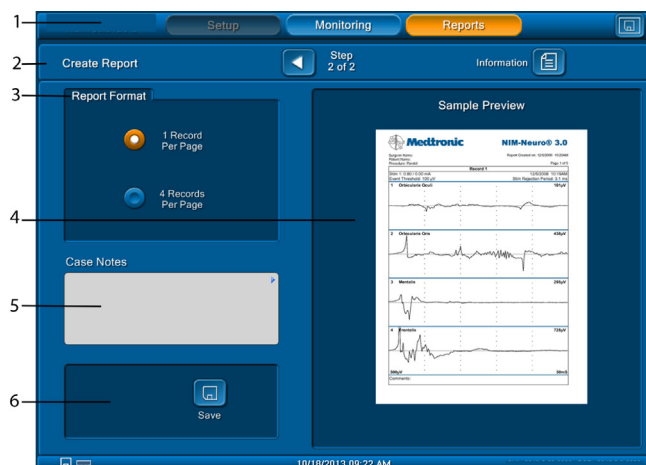
Use the Choose Events tab (3) to:

- Scroll through each captured event (to capture an event, press the Snapshot Button) with the Previous and Next buttons.
- When the system displays an event, you may enter or modify an Event Title or Comment.
- You can move the displayed event to the Selected Events panel by selecting the check box. The system displays Events in the report in the order you selected them.

- Graphically show all the captured events and time.
- The events you selected to appear on a report appear orange and not-selected events are white.

## Generate Snapshots/Events Report Format

Choose a report format and generate (print or save) the report. Depending on the report type, this step takes on different looks.

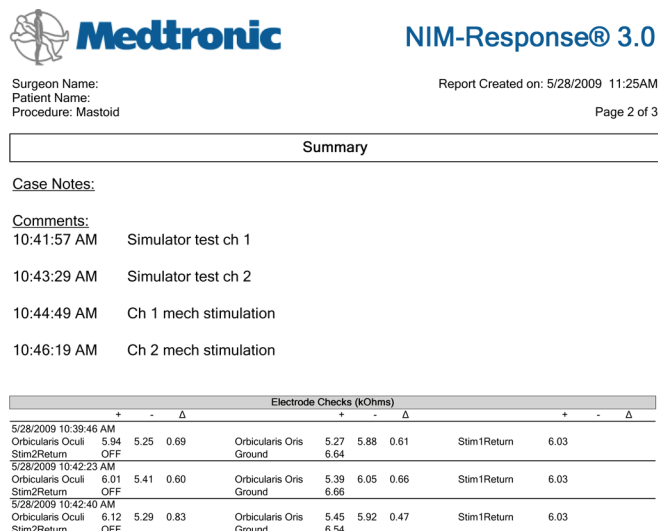
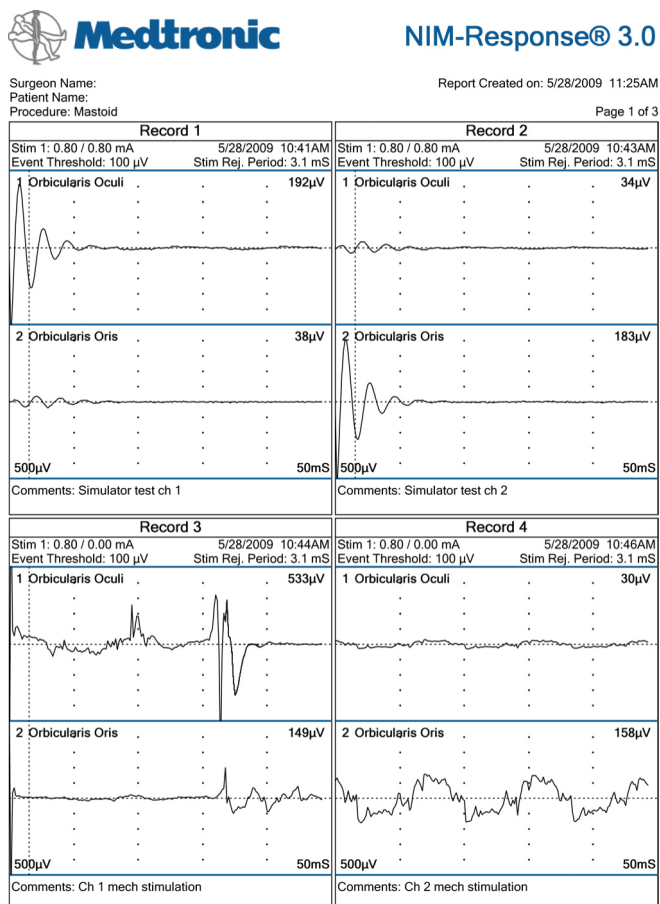


- 1 Tool Bar. Select any of the major functional Modes (Setup not available in Reports).
- 2 Active Screen Bar
- 3 Report Format panel. Select one record per page or four records per page.
- 4 Sample Preview area. Displays an example of the report type selected.
- 5 Case Notes box. Add notes to the Report Summary page.
- 6 Report Options panel

On the Report Options panel (6):

- Print button sends the report to the attached printer.
- Save button sends the report to the attached USB mass storage device. Saves the formatted report as a .pdf on the USB drive. The system formats the filenames with the report type, year, month, day and time. For example, EventReport\_20090528112530.pdf.
- Reports are located in a Case Folder titled:
  - date and patient ID or
  - date and patient name or
  - with no patient ID or name, the system uses date and sequential case.

## Snapshots/Events Reports .pdf Image Example



**Note:** Record 1 and 2 are “Stimulated” events with STIM 1 set value and measured current both showing 0.80mA (printout format is set value/measured current. Record 3 and 4 are Non-Stimulated events with STIM 1 set value showing 0.80mA, and measured current showing 0mA (STIM 1: 0.80/0.00mA). Since no measured current is shown, events are non-stimulated.

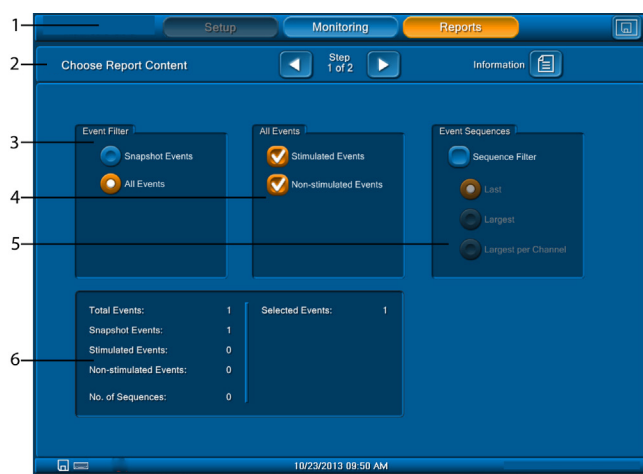
**Note:** Enter Case Notes using the Case Notes text boxes. You entered comments when you pressed the Snapshot button, or when you created the report.

## Select the Log File

The procedure for selecting a log file is the same as the procedure for selecting a report. Refer to the Select Report Format topic for more information.

## Construct the Log File

The system maintains a log file that contains data for all events (not only Snapshot Events) throughout the case. The system creates an event in the Log File when the EMG value exceeds the Event Threshold value. You can use the data in this file to construct Log File Reports or you can export the data in comma-delimited format for off-line analysis. For a Log File Report, this wizard step enables you to select event data using data filters.



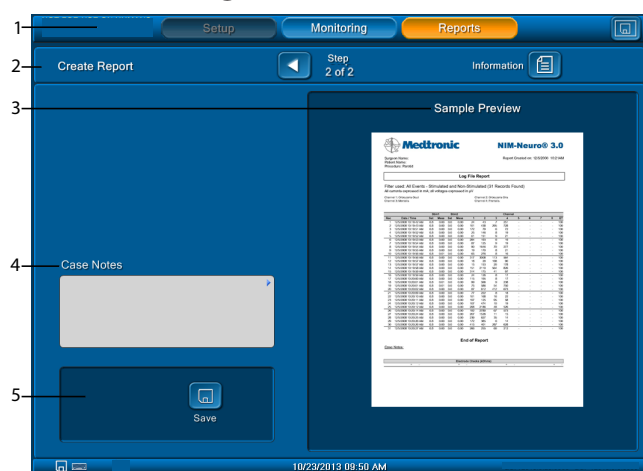
- 1 Tool Bar. Select any of the major (Setup not available in Reports) functional Modes.
- 2 Active Screen Bar
- 3 Event Filter. Choose Events captured using Snapshot or All Events.
- 4 All Events. Additional filter criteria that enables you to select Stimulated Events, Non-Stimulated Events, or both.  
**Note:** The All Events panel is visible only if you press the All Events button.
- 5 Event Sequences panel
- 6 Status box. Shows statistics about the logged events, including the number of events that the system includes in the Report (Selected Events).

An Event Sequence (5) is a series of events separated from each other by less than one second.

When you select the Sequence Filter (5) you can sort event sequences by Last or Largest:

- Last. When selected, the system includes only the last event in a sequence on the report. This is the default when you press the Sequences button.
- Largest. When selected, the system includes only the event that contains the greatest value within a sequence on the report.

## Generate the Log File



- 1 Tool Bar. Select any of the major functional Modes (Setup not available in Reports).
- 2 Active Screen Bar
- 3 Sample Preview panel shows an example of the report type prior to saving or printing.
- 4 Case Notes. Add notes to the Report Summary page.
- 5 Report Options

The following Report Options (5) are available:

- Print button sends the report to the attached printer as a pdf image.
- Save button opens a dialog box enabling you to send the report to the attached USB mass storage device.
- Save the formatted report to a .pdf image file, .csv data file, or a .db database file on the inserted USB drive. The system formats the filenames with the date and time, report type and appropriate extension. For example, LogReport\_20090618081932.pdf would be a Log Report Image created 2009 June 18 at 08:19:32.
- Reports are located in a Case Folder titled:
  - date and patient ID or
  - date and patient name or
  - with no patient ID or name, the system uses date and sequential case number.



## NIM-Response® 3.0

Surgeon Name: John Cutter  
Patient Name: Jane Doe  
Procedure: Thyroid

Report Created on: 6/18/2009 8:19:AM

### Log File Report

Filter used: All Events - Stimulated and Non-Stimulated (19 Records Found)  
All currents expressed in mA; all voltages expressed in  $\mu$ V

Channel 1: Vocals 1

Channel 2: Vocals 2

| Rec | Date / Time          | Stim1 |      | Stim2 |      | Channel |     |   |   | ET  |
|-----|----------------------|-------|------|-------|------|---------|-----|---|---|-----|
|     |                      | Set   | Meas | Set   | Meas | 1       | 2   | 3 | 4 |     |
| 1   | 6/18/2009 8:15:50 AM | 1.00  | 1.01 | 0.00  | 0.00 | 359     | 49  | - | - | 100 |
| 2   | 6/18/2009 8:16:04 AM | 1.00  | 1.00 | 0.00  | 0.00 | 46      | 358 | - | - | 100 |
| 3   | 6/18/2009 8:16:34 AM | 1.00  | 0.05 | 0.90  | 0.90 | 333     | 41  | - | - | 100 |
| 4   | 6/18/2009 8:16:48 AM | 1.00  | 0.05 | 0.90  | 0.91 | 42      | 323 | - | - | 100 |
| 5   | 6/18/2009 8:16:59 AM | 1.00  | 0.05 | 0.90  | 0.01 | 11      | 102 | - | - | 100 |
| 6   | 6/18/2009 8:16:59 AM | 1.00  | 0.00 | 0.90  | 0.00 | 12      | 104 | - | - | 100 |
| 7   | 6/18/2009 8:17:01 AM | 1.00  | 0.00 | 0.90  | 0.00 | 9       | 109 | - | - | 100 |
| 8   | 6/18/2009 8:17:08 AM | 1.00  | 0.00 | 0.90  | 0.00 | 133     | 31  | - | - | 100 |
| 9   | 6/18/2009 8:17:14 AM | 1.00  | 0.05 | 0.90  | 0.01 | 253     | 38  | - | - | 100 |
| 10  | 6/18/2009 8:17:19 AM | 1.00  | 0.05 | 0.90  | 0.01 | 68      | 140 | - | - | 100 |
| 11  | 6/18/2009 8:17:21 AM | 1.00  | 0.00 | 0.90  | 0.00 | 32      | 106 | - | - | 100 |
| 12  | 6/18/2009 8:17:22 AM | 1.00  | 0.00 | 0.90  | 0.00 | 34      | 108 | - | - | 100 |
| 13  | 6/18/2009 8:17:22 AM | 1.00  | 0.00 | 0.90  | 0.00 | 145     | 36  | - | - | 100 |
| 14  | 6/18/2009 8:17:23 AM | 1.00  | 0.00 | 0.90  | 0.00 | 150     | 35  | - | - | 100 |
| 15  | 6/18/2009 8:17:25 AM | 1.00  | 0.00 | 0.90  | 0.00 | 25      | 139 | - | - | 100 |
| 16  | 6/18/2009 8:17:26 AM | 1.00  | 0.00 | 0.90  | 0.00 | 40      | 293 | - | - | 100 |
| 17  | 6/18/2009 8:17:29 AM | 1.00  | 0.00 | 0.90  | 0.00 | 38      | 137 | - | - | 100 |
| 18  | 6/18/2009 8:17:30 AM | 1.00  | 0.05 | 0.90  | 0.01 | 250     | 112 | - | - | 100 |
| 19  | 6/18/2009 8:17:31 AM | 1.00  | 0.00 | 0.90  | 0.00 | 174     | 46  | - | - | 100 |

End of Report

Case Notes:  
None

| Electrode Checks (kOhms) |      |      |          |          |      |      |          |             |      |
|--------------------------|------|------|----------|----------|------|------|----------|-------------|------|
|                          | +    | -    | $\Delta$ |          | +    | -    | $\Delta$ |             | +    |
| 6/18/2009 8:13:11 AM     |      |      |          |          |      |      |          |             |      |
| Vocals 1                 | 5.86 | 5.23 | 0.63     | Vocals 2 | 5.22 | 5.84 | 0.62     | Stim1Return | 5.96 |
| Stim2Return              | 5.95 |      |          | Ground   | 6.49 |      |          |             |      |
| 6/18/2009 8:15:28 AM     |      |      |          |          |      |      |          |             |      |
| Vocals 1                 | 5.86 | 5.23 | 0.63     | Vocals 2 | 5.22 | 5.84 | 0.62     | Stim1Return | 5.96 |
| Stim2Return              | 5.95 |      |          | Ground   | 6.49 |      |          |             |      |
| 6/18/2009 8:18:10 AM     |      |      |          |          |      |      |          |             |      |
| Vocals 1                 | 5.85 | 5.14 | 0.71     | Vocals 2 | 5.20 | 5.77 | 0.57     | Stim1Return | 5.99 |
| Stim2Return              | 6.01 |      |          | Ground   | 6.49 |      |          |             |      |

Log Reports pdf Image Example

## APS Reports

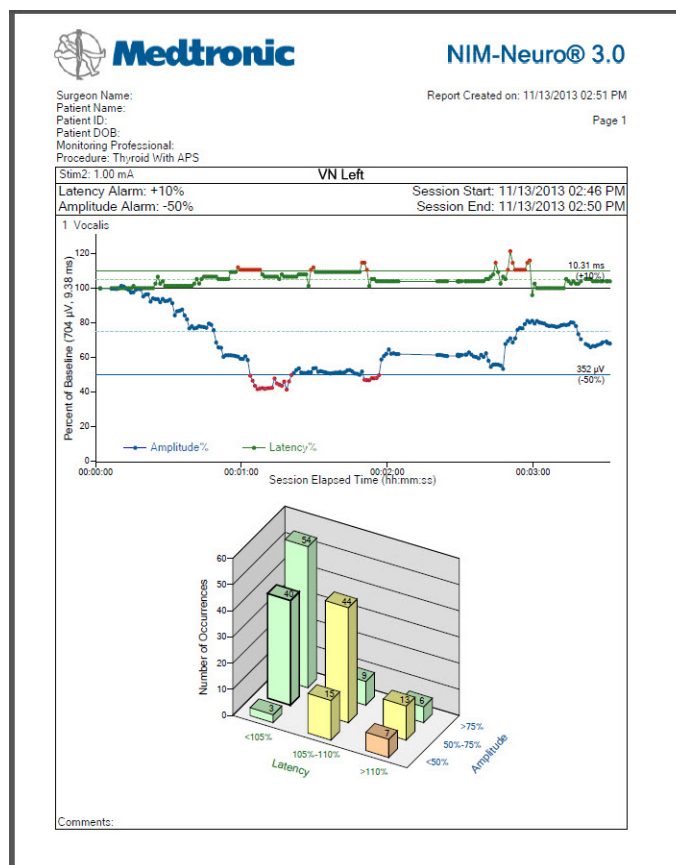
Refer to the Select Report Format topic and select/press APS Reports.

**Note:** Functionally APS Reports and Snapshot Reports use all the same screens/Panels with the same function. Refer to the Snapshots/Event Reports topic for instructions.



Log Reports .csv (in Excel) Example

## APS Reports .pdf Image Example



## Creating a Report

### Snapshots Report

1. Refer to the Select Report Format topic and select/press Snapshots.

The Choose Report Content (Snapshots) screen opens.

2. In the Choose Events panel:

- Select an event you wish to copy to the report using the Next and Previous buttons.
  - Press the blue arrow in the white Event Title box to title the event or modify an existing title.
  - Press the blue arrow in the white Event Comments box to enter comments about the event or modify an existing comment.
  - Press the Include in Report Check Box.
  - The selected event appears on the Selected Events panel.
- or

Press the Select All Button to move all events to the Selected Events panel. You may still use the Next and Previous buttons to move through the selected events and enter/modify event titles and comments as needed.

3. Press the Next button on the Active Screen Bar.

The Create Report (Event Records) screen opens.

4. Select one(1) or four(4) from the Report Format panel using the radio buttons.
5. Press the blue arrow in the white Case Notes box to enter comments.

**Note:** Event Title and Event Comments appear at the top and bottom of the event where they were entered and in the Summary section of the report. Case Notes only appear in the Summary section.

6. Press the Print and Save button to open a dialog box enabling you to send the report to the attached USB mass storage device.



- Save the formatted report to a .pdf image file, .or csv data file.

## Log Files

1. Refer to the Select Report Format topic and select Log Files.

The Choose Report Content (Log Files) screen opens.

2. In the Event Filter panel:

- Select the Snapshot Events Radio button and only events that were saved when you pressed the Snapshot button on the Main Screen will be available in the Log File Report, or
- Select the All Events Radio button.

The All Events, and Event Sequences panels open.

- All Events. The system selects Stimulated and Non-Stimulated Events by default. You can adjust these settings to any combination of the two.
- Event Sequences. Select Off (default) if you need to select between Last (default) and Largest.

3. Press the Next button on the Active Screen Bar.

The Create Report (Log Files) screen opens.

4. Press the blue arrow in the white Case Notes box to enter case comments. Case Notes are located between the End of Report and Electrode Check sections of the Log File.

5. Press Print and/or Save.

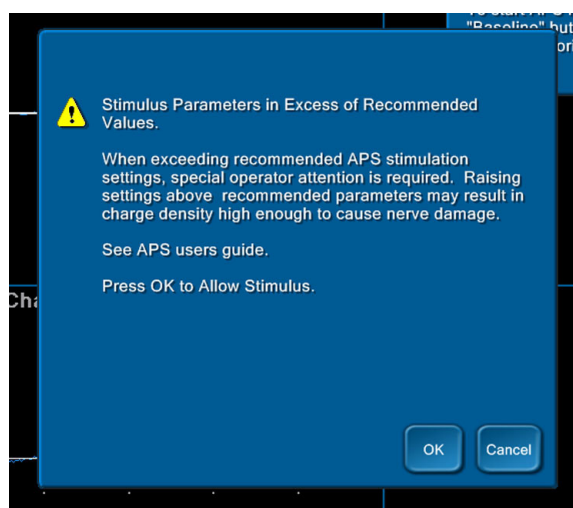
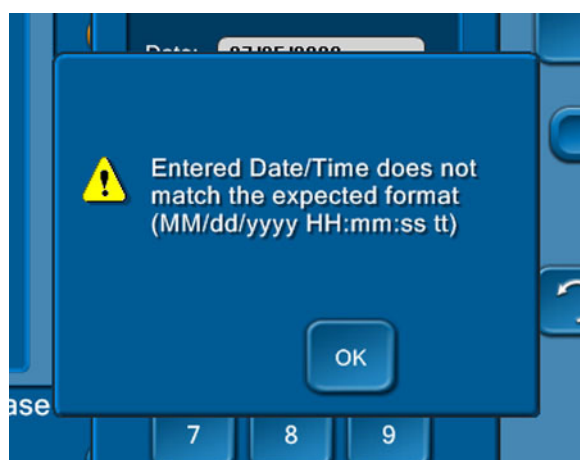
## Quick Reports

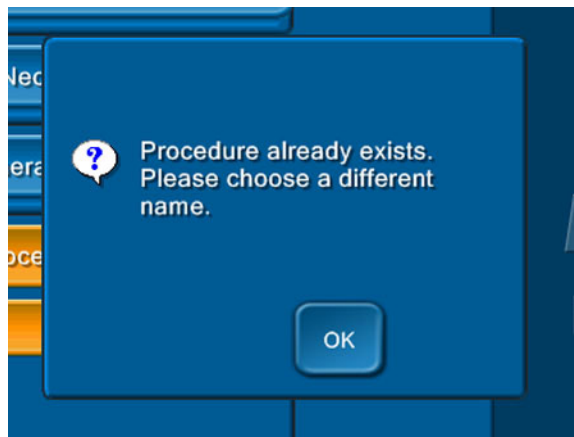
The Quick Reports feature enables you to create a report with certain default features without needing to specify report content each time. The system saves all settings you select on the Quick Report screen as the default. Some of the group boxes may not be visible (for example, if it is not an APS procedure, the APS box does not appear). Also, if Enable DB Saving is OFF in Global Settings, the Database box does not appear.

## Special Functions and Features

### Visual Alarms and Warnings

The operator may encounter the following warnings and should respond appropriately.





## Audio – Understanding What You Hear

The NIM 3.0 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 three distinct alarms:

- **BEEP Alarm.** The system uses a high-pitched, repetitive beep to register failure of internal microprocessor hardware. If you hear it at any time other than at power up, stop using the NIM 3.0 System and contact Medtronic. Refer to the Customer Care section for further information.
- **Bleedle Alarm.** This is a three-note alarm (Blee-Dle Deet) that you cannot disable. It repeats until you remedy the responsible condition. You will hear the alarm once under the following conditions:
  - Check Electrode
  - Muting
  - Power Up
- **APS alarm.** The system uses a single beep alarm to notify you when a plotted point falls outside the alarm limit. If a second consecutive plotted point falls outside the alarm limit, the system sounds a two beep alarm. If a third consecutive plotted point falls outside the alarm limit, the system sounds a three beep alarm and continues to sound three beeps until the condition is remedied. Refer to the Muting and Muting conditions topics for more information on these two conditions.
- **Voice Alarms.** You can select two voice alarms that work in unison with the bleedle alarm. You can turn them on or off and control the volume. These alarms are Check Electrodes and Muting. Refer to the System Setup topic for more information.

### Voice Annunciation

Voice annunciation types:

- Stimulation delivery confirmation
- Numeric stimulator current values
- Activation of auto threshold
- Annunciation. When you select Voice – Stimulated EMG Values, the system turns on annunciation of EMG responses via voice.

### Threshold / Voice

The system uses these voices as part of the Auto Threshold feature when you make automatic adjustments. Refer to the Auto Threshold topic for more information.

The NIM 3.0 System has two (2) Threshold voices:

- Threshold increased
- Threshold decreased

### Help / Voices

The system announces “Check electrodes” when it loses contact with an electrode.

### Stimulus Delivery Audio

#### Tone

The stimulus tone announces the delivery of current to the patient.

- 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.

## Voice

The stimulus voice announces the delivery of current to the surgical field by voice.

- 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 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.

Other EMG Responses (Samples are available in the Help Screen topic):

- Burst - Brief tone. Caused by electrical stimulation, direct nerve contact, irrigation, or thermal changes.
- Train Tones lasting seconds to minutes. Caused by nerve excited/irritated, irrigation, drying, bumping, or anesthesia.
- Pulse - Repeated tones. Caused by electrical stimulation, tumor mapping, verifying nerve integrity.

## 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

### Muting Conditions

Check Electrode:

- As soon as contact with an electrode is lost after removal.
- The channel shows a background noise waveform.
- After approximately 30 seconds, the system displays Electrode Off in yellow text on a zero (0) amplitude waveform line.
- The system mutes the channel until connection is restored.

### Muting from External Source:

As soon as the Muting Detector senses current flow, the dialog box “Monitoring/WARNING EMG MONITORING IS DISABLED/Muting from external source” appears and the system becomes mute. After 20 to 30 seconds, the bleedle alarm sounds followed by the “Muting” voice. The bleedle alarm repeats every 20 to 30 Seconds until you remedy the condition.

### 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.



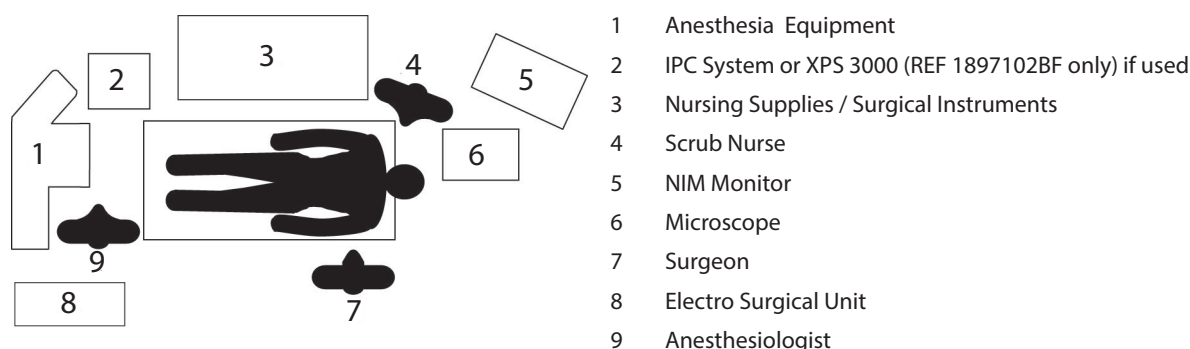
## System Set-Up

### Operating Room Set-Up

The NIM 3.0 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.

Set the NIM 3.0 System on a table or 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 further preferences as to location and visibility.

## Typical Set-Up (shown with IPC®)



## 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.

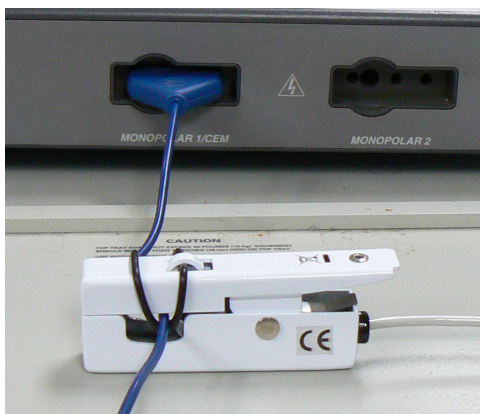
Note the following Contraindications for Use:

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.

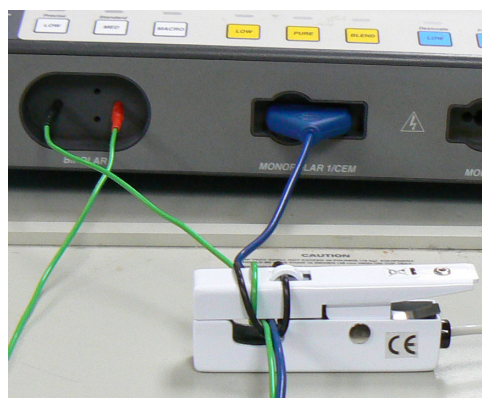
## Muting Detector Set-Up

Refer to Precaution P8.

1. 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.
2. Route the wire straight through the clamp.



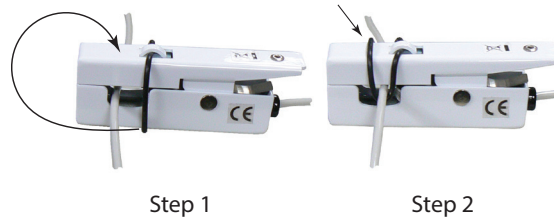
Standard Clamping



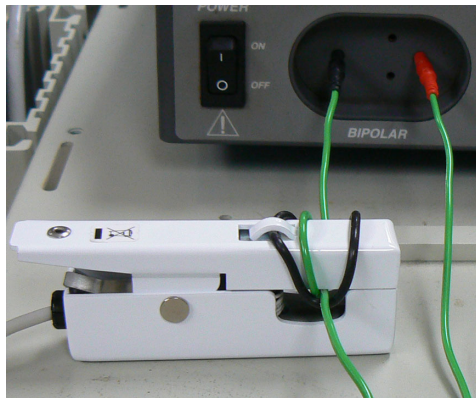
Monopolar and Bipolar (if needed) Clamping

**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 instruction seven for clamping instructions.

3. Slide the cable so the probe is near the main unit of the electrosurgical instruments, not near the hand piece(s).
4. 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).



5. Do not clip the Muting Detector to the grounding pad cable.
6. The Muting Detector and Patient Interface cables should be secured to the floor with tape or other non-slip/trip device.



7. For very low power levels it may be necessary to loop the single conductor around and through the clamp once.

## Patient Interface Set-Up

Prior to surgery, you must setup the Patient Interface and Stimulator. This may be done prior to turning on the NIM 3.0 System, or you may use the NIM 3.0 System to support the process of determining which nerves to monitor and positioning the electrodes appropriately (refer to Electrode placement in the Special Functions and Features topic).

Clip the Patient Interface 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 electrodes should be performed by or under the direction of a licensed medical practitioner who determines the particular nerves that are at-risk with each particular patient and procedure. The physician then places 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 electrode 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.

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

If/when wires must cross, they should cross at right angles. Never run other operating room cords/cables parallel to any of the NIM 3.0 System wires.

Verify the electrodes are properly inserted by turning on the NIM 3.0 System and looking at the Electrode screen. This may determine if electrodes need to be re-inserted for better electrical contact to help optimize monitoring.

Lay the Patient Interface cable out of busy traffic patterns and secure it to the floor as needed.

## Patient Interface and Single Stimulators

The NIM 3.0 System Stimulator output supports the use of both monopolar and bipolar stimulating probes with a range of 0-30 mA.

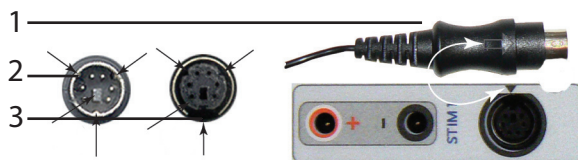
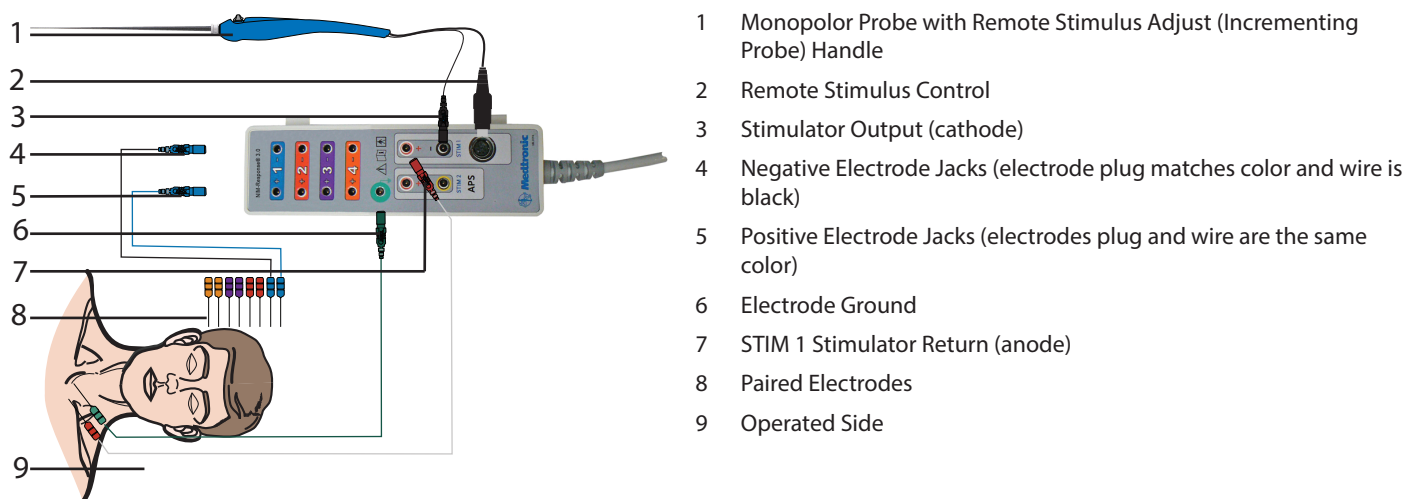


**Note:** The NIM-Neuro 3.0 Patient Interface shown here is for reference only. The NIM-Response 3.0 Patient Interface is used in the illustrations in this section. ALL connections are the same.

### Monopolar Incrementing Probe

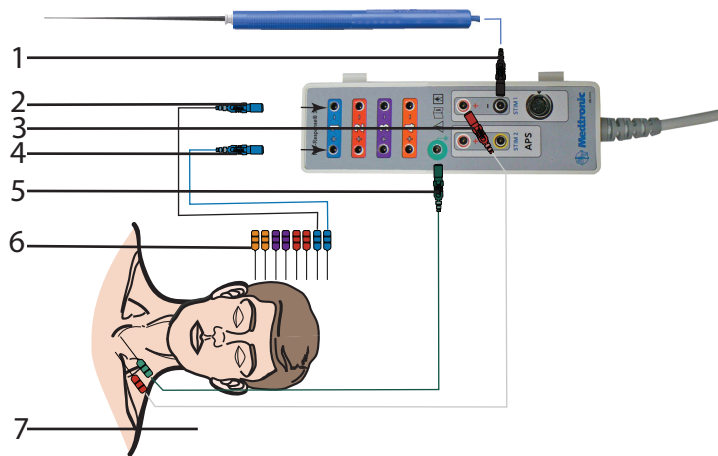
The (single use) Incrementing Probe provides the surgeon with the means to adjust the stimulation current and print or save the monitoring screen at the surgical site.

The patient interface supports one incrementing probe. The smaller plug is color-coded black and plugs into the black (-) jack on the patient interface. The larger plug is also color-coded black and plugs into the large black (STIM CONTROL) jack on the patient interface. 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 Patient Interface connection (3) or the connector may be damaged. Align arrow (1) on side of Incrementing Probe connector with key symbol on Patient Interface.

## Monopolar Probe with Universal Handle

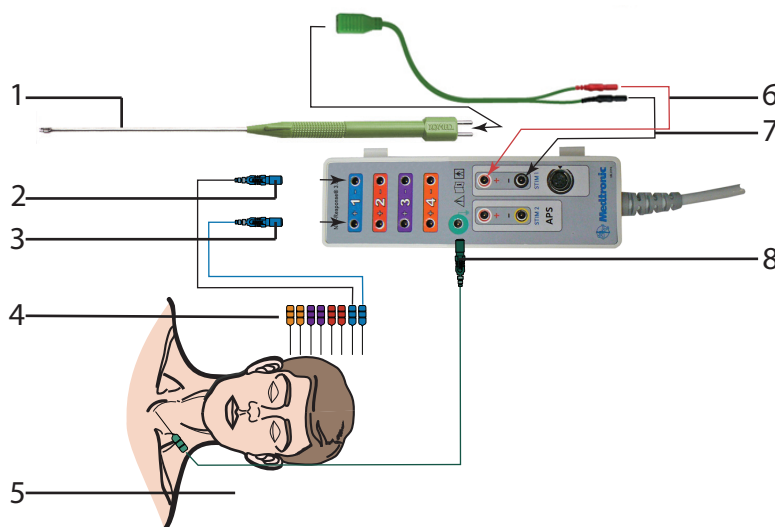


- 6 Paired Electrodes
- 2 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 4 Positive Electrode Jacks (electrodes plug and wire are the same color)
- 5 Electrode Ground
- 3 STIM 1 Stimulator Return (anode)
- 1 Stimulator Output, Monopolar Probe and Universal Handle (cathode)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

The patient interface supports one or two single use probes. The handle plug is color-coded black and plugs into the black (-) jack on the patient interface. 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.

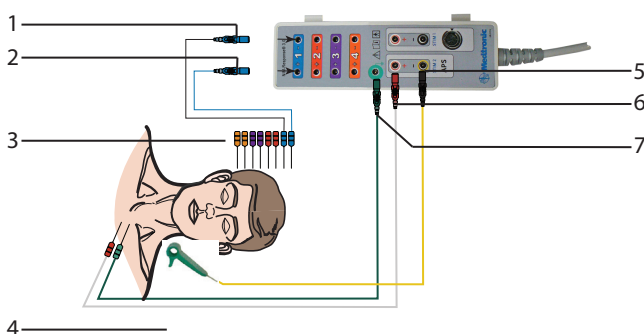
## Bipolar Probe



- 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 Operated Side
- 6 STIM 1 Stimulator Return (anode)
- 7 Stimulator Output (cathode)
- 8 Electrode Ground

When bipolar stimulation is required, you can only use one probe. 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).

## APS Electrode Stimulator



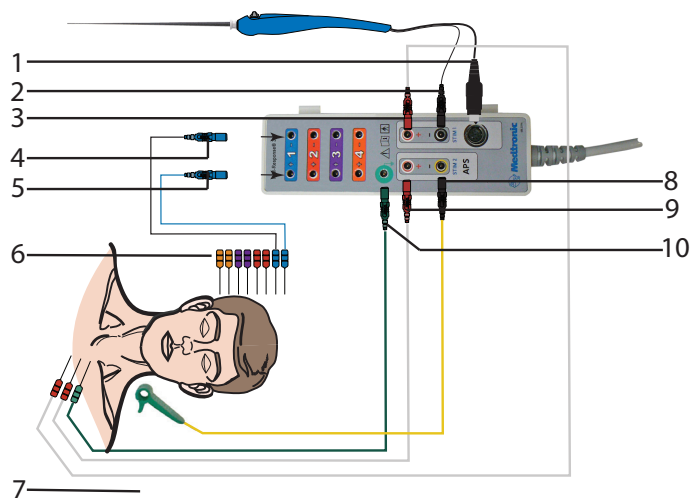
- 1 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 2 Positive Electrode Jacks (electrodes plug and wire are the same color)
- 3 Paired Electrodes
- 4 Operated Side
- 5 APS Electrode Stimulator Output (cathode)
- 6 STIM 2/APS Stimulator Return (anode)
- 7 Electrode Ground

## Patient Interface and Stimulator combinations

### Note:

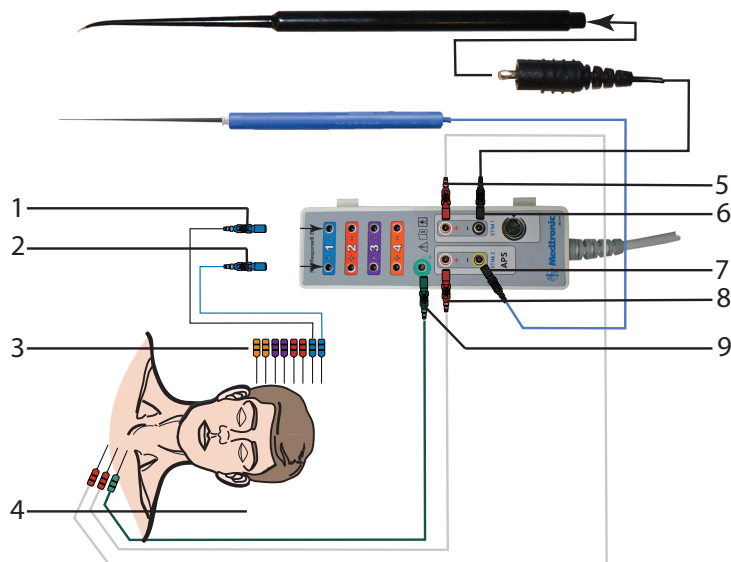
- In previous versions of the NIM® STIM 1 and STIM 2 were wired in parallel (any signal applied to one was applied to both). The NIM® 3.0 STIM 1 and STIM 2/APS™ are wired independent of each other with each requiring an output (stimulator) and a return (red electrode with white wire).
- By default STIM 1 is on and STIM 2 is off (except for procedure “Thyroid with APS”). STIM 2 must be turned on manually. Refer to the Monitoring Mode or Setup Mode topic.
- By default STIM 1 and 2 are Monopolar Probes and must be changed manually for Bipolar. Refer to the Advanced Settings topics.

### Monopolar Incrementing Stimulator and APS Electrode Stimulator



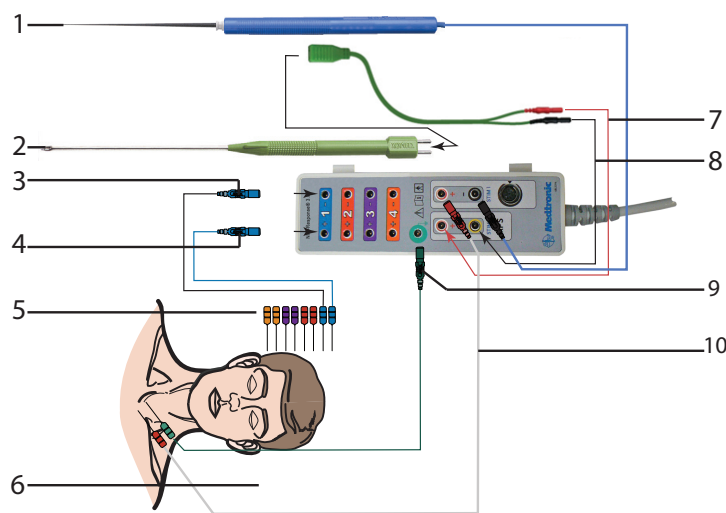
- 1 Remote Stimulus Control
- 2 Stimulator Output (cathode)
- 3 STIM 1 Stimulator Return (anode)
- 4 Negative Electrode Jacks (electrode plug matches color and wire is black)
- 5 Positive Electrode Jacks (electrodes plug and wire are the same color)
- 6 Paired Electrodes
- 7 Operated Side
- 9 STIM 2/APS Stimulator Return (anode)
- 8 Stimulator Output, APS Electrode (cathode)
- 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 Operated Side
- 5 STIM 1 Stimulator Return (anode)
- 6 Stimulator Output, Stimulus Dissection Probe and Cable (cathode)
- 7 Stimulator Output, Monopolar Probe with Universal Handle (cathode)
- 8 STIM 2 Stimulator Return (anode)
- 9 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 in the Type Panel (located in the Advanced 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 Operated Side
  - 7 STIM 1 Stimulator Return (anode)
  - 8 Stimulator Output (cathode)
  - 9 Electrode Ground
  - 10 STIM 2 Stimulator Return (anode)

## Monitor Set-Up

The NIM® 3.0 System has a large number of user selectable characteristics used during a typical setup procedure. This section addresses the three most common types of setup procedures:

- Basic setup. Basic information used by all programs. For example, time and date.
- Standard setup that uses a factory loaded program.
- Custom setup. This setup enables the surgeon to define the surgery being performed and the nerves to be monitored.

### Basic Setup All Procedures

Refer to the Setup Mode 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 **Global Settings**.
4. Select Language (English is default).
5. Select Time/Date Format.
6. Press **Set Date and Time**.  
The keypad appears.
7. Touch the Date text field and use the keypad to type the date.
8. Touch the Time text field and use the keypad to type the time.
9. Select AM or PM (if formatted for AM/PM).
10. Do one of the following:
  - Press **Clear** to clear the selected text field.
  - Press **Apply** and the system saves the new time and date.
  - Press **X** to exit the keypad.
11. In the Data Fields for Case Information panel there are six (6) selectable, predefined text fields and two (2) user-defined text fields.
  - Select any combination of Data Fields.
  - Press the text field (<title>) to open the keyboard and type a title for the user-defined text field.
12. Press **OK** to close the Global Settings panel.

### Standard Setup

Refer to the Setup Mode and Patient Interface Setup topics for more information while performing a standard setup.

1. On the Select Procedure screen, do the following:
  - Press Neuro/Otology, Head/Neck, or Peripheral to expand the drop-down menus of predefined procedures.
  - Select the procedure.
 The Place Electrode screen appears. If the patient interface is not connected then connect it now (refer to the Console Rear topic).

2. Do both of the following:

- Connect the electrodes according to the graphic display (both patient interface and patient).
- Connect the stimulation probe (refer to the Patient Interface Setup topic).

3. Review the Check Electrodes panel to ensure all electrodes including STIM 1/2 and ground have green check marks. If not, refer to the Electrode Troubleshooting Guide topic.

4. To change electrode type, do the following:

- Press **Show Details**. Each channel shows a button with the muscle group being monitored and the electrode type.
- Press the channel button. A drop-down menu appears showing the available electrodes.
- Select the electrode and the menu closes.

5. Press **Next** on the Place Electrodes tool bar.

The Enter Case Information screen appears.

6. Do the following:

- Press the text field to activate the keyboard.
- Type text and press **OK**.
- Complete all text fields.

7. Press **Monitor** or the Monitoring button.

## Custom Setup

Refer to the Setup Screens, Panels, and Patient Interface Setup topics for more information while performing a custom setup.

1. Press **Custom Procedure** on the Select Procedure screen.

The drop-down menu appears

2. Press **New**.

The Keyboard appears.

3. Type the name of the custom procedure and press **OK**.

The system saves the new procedure as a button on the Custom Procedure drop-down menu.

4. Press the new procedure button.

The Place Electrode screen appears.

5. Do the following:

- If patient interface is not connected then connect it now (refer to the Console Rear topic for more information).
- Connect the electrodes according to the surgeon's directions. **Note:** The graphic display appears blank for the custom setup.
- Connect stimulation probe (Refer to the Patient Interface Setup topic).

6. Review the Check Electrodes panel.

- To change the electrode type:
    - Press **Show Details**. Each channel shows a button with 1-Channel 1, 2-Channel 2 etc. and the electrode type as subdermal.
    - Press the numbered channel button. A drop-down menu appears showing available electrodes.
- When you select the electrode the menu closes.

All electrodes including STIM 1/2 and ground have green check marks. If not, refer to the Electrode Troubleshooting Guide topic.

7. Press the **Check Electrode** tab.

The electrode panel closes.

8. Press the **Procedure Settings** tab.

The Procedure Settings panel appears.

9. To assign muscle group names to the channels, do the following:

- Press **Channels**. **Note:** You can only name channels when they are inactive. Press any active channel once to inactivate it.
- Press **Inactive** and the keyboard appears.
- Type the channel name.
- Press **OK**.
- When all channels are complete, press **Channels** to close the drop-down menu.

**Note:** You may choose to save this procedure at this point, or refer to the Additional Settings topic for more information.

## Additional Settings

If your changes to Stimulus, Event Capture, Audio Settings, Monitoring Settings, Stimulation Settings, Microscope Settings, or APS Settings are a permanent part of a custom procedure, you must use the Additional Settings panel which you can access through Procedure Settings/Advanced Settings button.

When you access Advanced Settings from the Control Panel tab, you cannot save your changes. The system only uses the changes in the current session.

When you press Advanced Settings, the system opens a screen with tabs that enable access to the functions described in the Setup Mode/Advanced Settings topic.

## For Installing the Stimulating Electrode

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

## APS Monitoring

1. Press **Baseline** (located on the left side of the Monitoring screen).

If an APS session is in progress, a pop-up window appears with the following selections available:

- Stop the current session and continue a previous session (old baseline)  
**Note:** If there has been at least one APS session prior to the current session, you can choose to “Stop the current session and continue a previous session.”
- Start a new session (new baseline)
- Continue the current session (the current session time appears underneath this selection).

If there is no APS session in progress or if “Start a new session” is chosen, then the NIM begins a process used to establish baseline amplitude and latency values for the trend graph.

**Note:** The APS channel you selected appears on the right half of the monitoring screen. If you did not select a channel then the system displays all channels showing a baseline and limit lines on the right half of the monitoring screen. All channels selected is the default (up to 4 max).

The baseline appears as a white line and the trend limit as a red line for both the EMG amplitude and latency values.

Each APS stimulation pulse results in a blue dot (EMG) or turquoise dot (latency) on the baseline.

Should a stimulation pulse occur at or outside a trend limit line, the system places a red dot at the location and an alarm sounds. The alarm draws attention to any condition which prevents proper monitoring. Do not ignore alarms. You must assume that the system has stopped valid monitoring and determine immediately why the alarm sounded. Make required adjustments to resume valid monitoring or address the situation.

## Changing APS Settings

1. Select **APS ON** (The system changes the check box from orange with white check mark to blue with no check mark):
  - APS monitoring stops.
  - The system changes the Advanced Settings button from grey to blue.
2. Press **Advanced Settings**. Refer to the Setup Mode/Advanced Settings topic for more information.
3. Adjust the Event Threshold using the Monitoring Mode topic for instructions.
4. Acquire a new baseline using the APS Monitoring topic for instructions.

## Surgery Notes

- Use of a stimulating probe is encouraged during surgery in conjunction with APS monitoring.
- When using the NIM® EMG endotracheal tube for APS monitoring, tube movement or mucus buildup during surgery can reduce APS responses requiring the need to acquire a new baseline.
- A decrease in the EMG amplitude (greater than the alarm limits) may occur when performing APS 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 (APS Electrode) 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 lowest level of stimulation that produces a response.

Continue to monitor with the NIM 3.0 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 3.0 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.

## Power Disconnection

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

**Note:** All stored data (Snapshots) is lost when unit is powered off.

## **Cleaning and Maintenance**

### **Cleaning (after each use)**

The patient simulator, patient interface and cable, Muting Detector and cable(s), printer, printer cable, power cords, headphones, USB compact flash, and the NIM-Neuro 3.0 System monitor

- Disconnect all cables from the rear of the monitor.
- DO NOT immerse or sterilize the units.
- Wipe down the units with a cloth dampened with a neutral enzymatic detergent, pH 6.0-8.0 or phenol based disinfectant.
- Do not use alcohol, other solvents, or abrasive cleaners.
- Dry the units with a clean, non-abrasive cloth.

### **Storage**

Allow the NIM 3.0 System and accessories to thoroughly air-dry before storing them in a cool dry place. Refer to the Technical Specifications for further information.

### **Maintenance**

Medtronic Xomed is committed to providing the highest standards of workmanship in manufacturing its products. Your NIM 3.0 System requires minimal maintenance and calibration. However, Medtronic Xomed recommends preventative maintenance and screen calibration scheduled at yearly intervals.

Comprehensive testing and calibration should be performed by returning the entire system, including the patient interface and Muting Detector to Medtronic Xomed Customer Care. Contact them directly for details on how to return your product.

### **Maintenance Schedule**

An effective maintenance schedule should be established for your monitoring equipment and reusable supplies. This should include inspection of NIM operation; components, for physical damage; connectors and cables, for wear; as well as general cleaning on a regular basis.

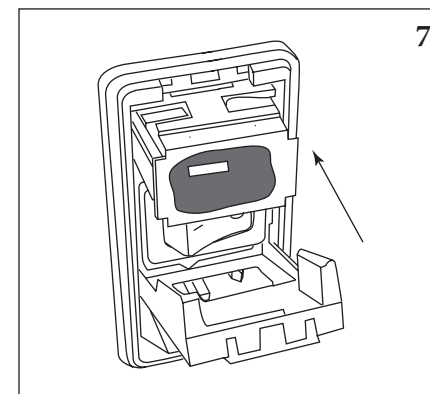
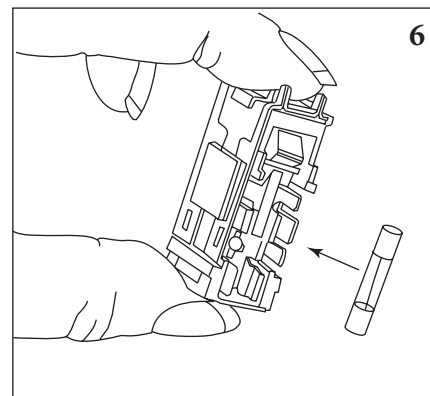
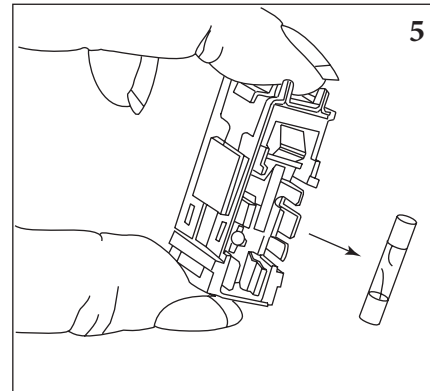
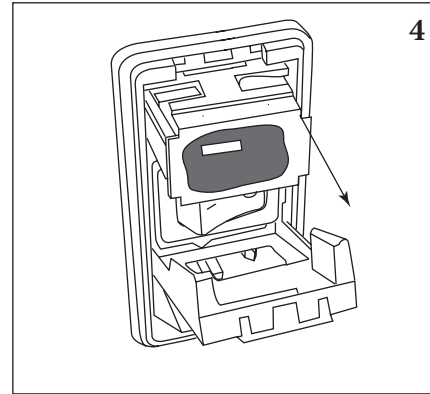
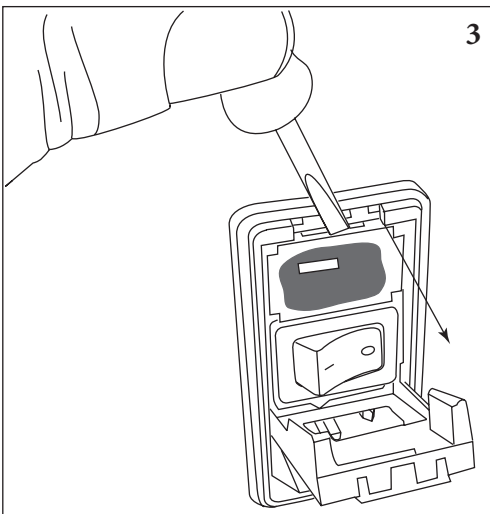
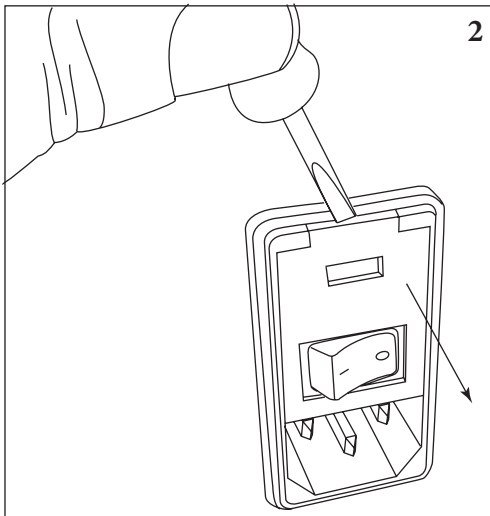
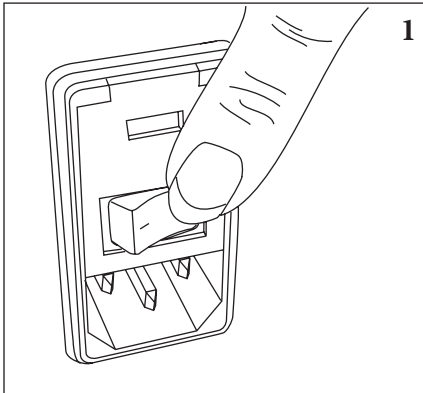
The NIM Monitoring system does not routinely require wear-out components or technical maintenance other than basic performance and safety inspections. Also, on power up, the system automatically performs a series of self-tests and reports any failures on screen. Whenever a problem is detected then a comprehensive testing and calibration should be performed by returning the entire system, including the patient interface and Muting Detector to Medtronic Xomed, Inc. Service and Repair.

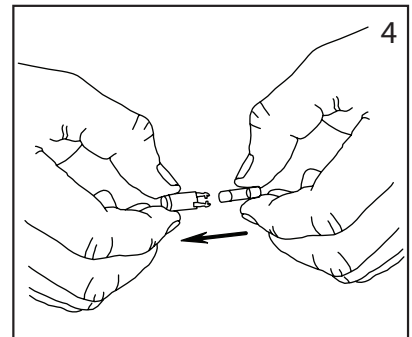
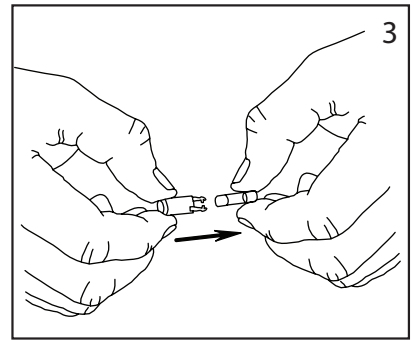
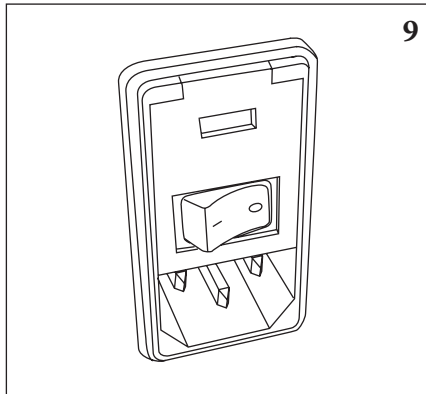
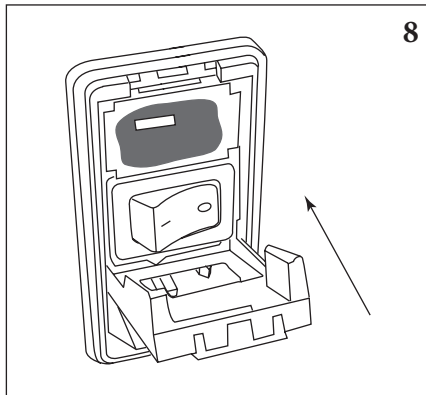
Medtronic, Inc. recommends that preventive maintenance including performance tests, Annual System Quick Check and safety checks should be performed at least once per year or whenever a problem is suspected or more often as required by local statutory, hospital administration or business practice. The maintenance schedule frequency must comply with the policies of your institution's infection control unit and/or biomedical department.

## Fuses

### Console Replacement

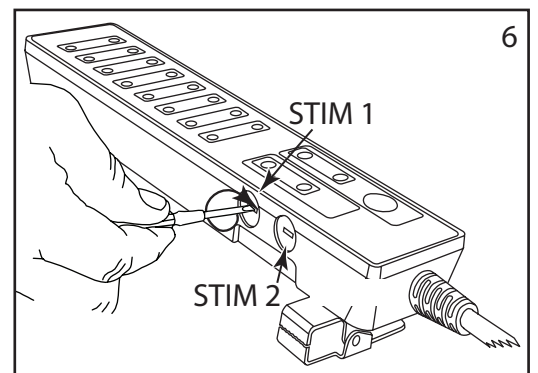
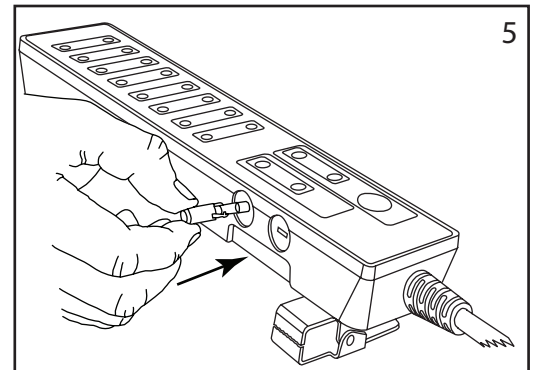
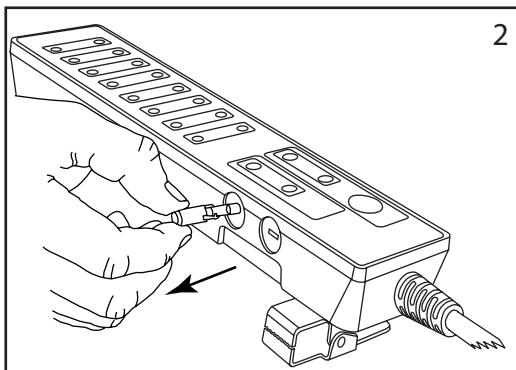
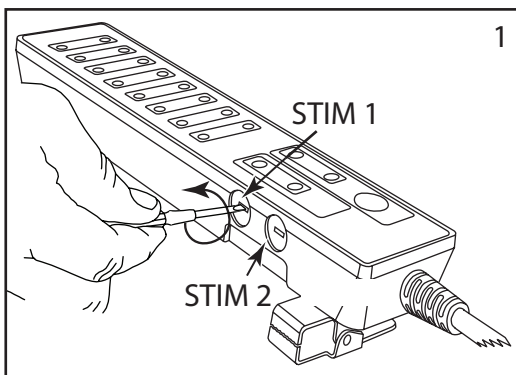
The console AC power is fuse protected. Have a Biomedical Engineer check the fuse if a problem is suspected. It is very important that the correct replacement fuse is used (5 x 20 mm, 2.5 Amp, time-lag, Low breaking capacity, Xomed Fuse Kit # 8253070).





### Patient Interface Replacement

The Patient Interface has its own fuse. 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).



## Troubleshooting

| Symptom                                                                                                                                          | Cause                                                                                                                            | Solution                                                                                                                                                                    |
|--------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| "No communication with knobs" error message appears during transition to monitoring.                                                             | Internal NIM communication error.                                                                                                | Turn NIM power button off and then turn it on again.                                                                                                                        |
| "High temperature alarm" error message appears on screen.                                                                                        | Internal NIM temperature exceeding normal limits.                                                                                | Turn NIM power off and contact Medtronic custom service.                                                                                                                    |
| No visual display or audio alarms at power-up.                                                                                                   | Power cord not connected to outlet or to the NIM® 3.0 system. Power switch not turned on.                                        | Plug in power cord.<br>Turn power switch on.                                                                                                                                |
| Electrode impedance is too high.                                                                                                                 | Electrode dislodged from patient, but not completely out.                                                                        | Insert dislodged electrode; tape down in place.                                                                                                                             |
| > 10 K $\Omega$ for subdermal electrodes.                                                                                                        | High resistance in electrode.                                                                                                    | Remove and replace with new electrode.                                                                                                                                      |
| > 25 K $\Omega$ for Prass paired electrodes.                                                                                                     |                                                                                                                                  |                                                                                                                                                                             |
| > 7.5 K $\Omega$ for EMG tube.                                                                                                                   | Electrode pin not firmly inserted into patient interface.                                                                        | Check connection at Patient Interface box.                                                                                                                                  |
| > 40 K $\Omega$ for hookwire electrode.                                                                                                          |                                                                                                                                  |                                                                                                                                                                             |
| Use of "Tap Test" (checking if NIM is connected and monitoring) near electrodes to evoke artifact is not reliable. It will not evoke a response. | Low Noise Electrodes, Twisted Pair, Paired Subdermal, and Prass Paired electrodes artifacts are eliminated or too low to detect. | Increase sensitivity of "Tap Test" to evoke artifact by decreasing threshold and increasing volume for test.                                                                |
| Electrode impedance $\leq 0.1$ K $\Omega$                                                                                                        | Positive and negative electrodes touching below surface of skin.                                                                 | Remove and relocate electrodes.                                                                                                                                             |
|                                                                                                                                                  | Extremely low impedance, particularly in EMG tubes.                                                                              | Use "tap test" near electrodes to evoke EMG or artifact (increase threshold, decrease volume for test). "Tap Test" does not confirm proper electrode or EMG tube placement. |
|                                                                                                                                                  |                                                                                                                                  | If activity is noted on channel in question, proceed.                                                                                                                       |
| Electrode reading is:<br>(+ or -) Off<br>or<br>$\Delta = = =$                                                                                    | Electrode laying on skin surface.                                                                                                | Re-insert electrode in question.                                                                                                                                            |
|                                                                                                                                                  | Electrode placement insecure.                                                                                                    |                                                                                                                                                                             |
|                                                                                                                                                  | Dirty electrode tip.                                                                                                             | Remove and replace electrode in question.                                                                                                                                   |
|                                                                                                                                                  | Electrode cable is broken.                                                                                                       |                                                                                                                                                                             |
| Electrode difference is greater than 2K $\Omega$ (Subdermal electrodes) or 10K $\Omega$ (Prass Paired electrodes).                               | Electrode pin disconnected from patient interface.                                                                               | Check connection to Patient Interface box.                                                                                                                                  |
|                                                                                                                                                  | Dirty electrode.                                                                                                                 | Remove and replace electrode for appropriate channel with highest impedance reading first.                                                                                  |
|                                                                                                                                                  | Mismatched pair.                                                                                                                 |                                                                                                                                                                             |
| Question mark at STIM 1/2, and Ground in Electrode Check Panel                                                                                   | Unequal placement.                                                                                                               | Remove and replace electrode in question.                                                                                                                                   |
|                                                                                                                                                  | No channel electrode connected.                                                                                                  | Connect at least one channel electrode.                                                                                                                                     |
| Interference on anesthesia equipment (EKG Monitor).                                                                                              | Ground not connected.                                                                                                            | Connect ground.                                                                                                                                                             |
|                                                                                                                                                  | Measuring current on NIM® EMG Electrodes.                                                                                        | Try an alternate EKG Lead set.                                                                                                                                              |
|                                                                                                                                                  | Electrode Check (Electrode Screen selected).                                                                                     | Deselect Electrode Screen.                                                                                                                                                  |
|                                                                                                                                                  | Muting function active.                                                                                                          | See Excessive Muting (Symptom Column).                                                                                                                                      |
| Incrementing Probe will not adjust stimulation.                                                                                                  | With Stimulator active.                                                                                                          | Turn the NIM® Stimulator to 0.0 mA when not needed.                                                                                                                         |
| Stimulus keeps changing (run away).                                                                                                              | Loose connector.                                                                                                                 | Check connector is properly aligned and fully seated (See System Set-Up / Patient Interface Set-Up).                                                                        |
| Electrosurgical interference.                                                                                                                    | Bad Incrementing Probe.                                                                                                          | Replace Incrementing Probe or disconnect STIM CONTROL connector and manually adjust stimulus at touch screen.                                                               |
|                                                                                                                                                  | Muting Detector Probe not connected.                                                                                             | Check Muting Detector Probe connections.                                                                                                                                    |
|                                                                                                                                                  | Muting Detector Probe input insufficient.                                                                                        | Loop the unit cable through muting detector.                                                                                                                                |
|                                                                                                                                                  | Electrosurgical grounding inadequate.                                                                                            | Check electrosurgical grounding pad on patient.                                                                                                                             |
|                                                                                                                                                  | Source of interference unidentified.                                                                                             | Identify source of interference; then eliminate or separate from the NIM® 3.0 system.                                                                                       |
|                                                                                                                                                  | NIM® 3.0 system or Patient Interface cable too close to electrosurgical unit or its cables.                                      | Maintain separation between electrosurgical cable and the NIM® system.<br>For less coupling, coil up the Muting Detector Probe next to the NIM® 3.0 system.                 |
| Excessive Muting.                                                                                                                                | Unit receiving excessive signal into the Muting Detector Probe or electrode leads.                                               | Disconnect the muting detector completely.                                                                                                                                  |
| Rhythmic Artifact.                                                                                                                               | Pacemakers – Pace Pulse.                                                                                                         | Relocate electrode ground and stimulus return to patients shoulder (Acromion).                                                                                              |
| Inadequate muting.                                                                                                                               | Signal from electrosurgical unit inadequate to cause muting.                                                                     | Loop the electrosurgical unit cable and clip the muting detector over the doubled cable.                                                                                    |

|                                                           |                                                                                                     |                                                                                                                                                                                                                                  |
|-----------------------------------------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| No response to direct stimulation.                        | Inadequate stimulus intensity.                                                                      | Increase stimulus intensity.                                                                                                                                                                                                     |
|                                                           | Paralyzing anesthetic in use.                                                                       | Eliminate paralyzing anesthetic.                                                                                                                                                                                                 |
|                                                           | White Stimulation (+) electrode has fallen out or is not connected.                                 | Check that Stimulus Measure is approximately the same value as the Stimulus setting. Re-insert electrode in question.                                                                                                            |
|                                                           | Probe (electrode) not connected.                                                                    | Check stimulator anode (+) and cathode (-) connections.                                                                                                                                                                          |
|                                                           | Patient safety fuse blown.                                                                          | Check fuse in STIM 1 (EMG) Patient Interface. Replace if necessary.                                                                                                                                                              |
|                                                           | 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.                                                                                | Check stimulator tip for obstruction. Replace if necessary. Check location of stimulation.                                                                                                                                       |
|                                                           | Volume control too low.                                                                             | Check and correct all settings volume, event threshold, stimulus intensity.                                                                                                                                                      |
|                                                           | Event threshold set too high.                                                                       |                                                                                                                                                                                                                                  |
| Unexpected responses when not directly stimulating nerve. | Excessive current shunting in surgical field.                                                       | Remove fluids from surgical stimulating area.                                                                                                                                                                                    |
|                                                           | No electrodes in innervated muscle tissue. Nerve not stimulated.                                    | Place channel electrodes in muscle to be monitored.                                                                                                                                                                              |
|                                                           |                                                                                                     | "Tap Test" does not confirm proper electrode or EMG tube placement.                                                                                                                                                              |
|                                                           |                                                                                                     | Check EMG tube placement if applicable.                                                                                                                                                                                          |
|                                                           | Unexplained continuous "train" EMG response.                                                        | Identify and eliminate possible source of "train" stimulation:<br>Cold irrigation.<br>Laser heat.<br>Retraction on nerve or muscles being recorded.<br>Patient waking from anesthesia.<br>Nerve drying.<br>Ultrasonic aspirator. |
|                                                           |                                                                                                     | Identify and eliminate source of inadvertent manipulation.                                                                                                                                                                       |
|                                                           | 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.                                                                                                                                            |
|                                                           | Electrical interference from other equipment.                                                       | Check for intermittent stimulation from anesthesiologist (i.e., hand-held electrical stimulator).                                                                                                                                |
|                                                           |                                                                                                     | Move NIM® 3.0 system away from source of interference.<br>Make sure Patient Interface cable and electrode wires do not cross other electrical equipment or cables.                                                               |

## Technical Specifications

### Physical Dimensions

Size:

30 cm W x 33 cm H x 27 cm D

Weight:

6.8 Kg

### Operational Environment

Operating Temperature range:

10 to 40 °C (Operating)

Humidity:

30-70% RH non-condensing

Atmospheric Pressure range:

700 kPa to 1060 kPa

Mode of Operation:

Continuous duty

### Transport and Storage Environment

Shock and Vibration:

Verified to Standard ISTA 2A

Ambient Temperature range:

- 40 °C to + 70 °C

Relative Humidity range:

10 % to 100 %, including condensation

Atmospheric Pressure range:

500 kPa to 1060 kPa

### Amplifier

NIM-Response® 3.0 Ch. 1-4 NIM-Neuro® 3.0 1-8:

Individually and simultaneously selectable

Input Sensitivities:

5 – 100,000 µV peak-to-peak AC-coupled

Sensitivity Selection:

Automatically zeroed

Bandpass:

Input Noise:

Input Impedance:

DC offset Rejection:

Common Mode Rejection:

Channel Enable/Disable Controls:

Event Threshold Control and Display:

Patient Isolation:

## Impedance Measurement

Control:

Measuring Signal:

Measurement Range:

## Artifact Detection and Rejection

Stimulus Artifact:

Bipolar Electrocautery Rejection:

Electrocautery (ESU) Interference:

Muting Detector Input ESU Sensitivity:

Muting Console Input Sensitivity:

Muting Detector Input ESU Immunity:

Electrode Lead Off:

## Display / Touch Screen

Type:

Resolution:

Dedicated Function Event Touch Screen Controls:

Vertical Display:

Event Capture:

Time Scale:

## Patient Interface

Neuro - 8 channels/Response - 4 channels:

Low Cable Triboelectric:

Internal Fuse:

## Stimulator 1 and 2

Stimulus Type Constant:

Stimulus Range:

Load Impedance Range:

Stimulus Control:

Stimulus Output Accuracy:

Stimulus Adjustment:

Stimulus Measurement Accuracy:

Internal Fuse:

## Stimulus 1 and 2 Characteristics

Waveform:

Duration:

Rise Time to 30 mA:

Rate STIM 1 and 2:

Rate STIM 2 APS™ STIM repetition rates:

Stimulus Probe:

Stimulus Trigger Input:

## Audio Output

Transducers:

Baseline Audio Sound Level:

Change in Baseline with added Channels:

Change in Baseline due to EMG and Tones:

Max Audio Sound Level:

EMG & Event Tone Signals:

Volume Preset and Limiter:

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

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

3-14  $\mu$ V p-p, < 5  $\mu$ V RMS @ RMS - 4 Hz, inputs shorted

> 10 Meg Ohm

$\pm 1.00$  VDC Rejection

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

Dedicated function touch pads for independent Ch. enable/disable.

Adjustable Graduated Touch Bar with Voltage threshold displayed.

1,000Vrms 60Hz < 100  $\mu$ A

Automatic CHECK ELECTRODE feature.

10mV peak-to-peak, 800 Hz Sinewave.

0-200KOhm  $\pm 20\%$  or  $\pm 100$ Ohm.

Synchronized and adjustable muting.

Continuous Monitoring During Bipolar Cautery < 40 watts

Automatic detection and muting.

ESU Cut / Coag Contact 5 - 100 Watts Air-Discharge 10-100 Watts

Muting (0.6 - 2.0 Vrms) Non-Muting (<0.3 Vrms)

ESU < 100 Watts Cut / Coag or (<3.0 Vrms 100-800 KHz Sq. Wave)

Automatic detection, muting and warning.

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

Display 1024 H x 768 W pixels, Touch Panel 256 H x 256 W

For Amplitude, Time Display and Capture.

20, 100, 500, 1000, 2000, 10,000, 50 K, and 100 K $\mu$ V display modes.

Enable/disable capture mode indicator on touch screen.

25 mS, 50 mS, 100 mS or 20 S display modes.

"Color coded channel connections - touchproof 1.5 mm protected pin safety connection per DIN 42 802."

< 100  $\mu$ V from a 0.5J impact

See Stimulator 1 and 2 "Internal Fuse"

Constant Current

0-30 mA, a minimum of 80 volts compliance (80 V- 10 %) tested into a 1K Ohms load

100 - 10K Ohms (0 - 3 mA): Compliance 10 V (3.5 - 30 mA): Compliance 80 V  
As long as the load impedance X stimulation current is less or equal the compliance voltage

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 1K Ohms load) over Stimulus Range.

Graduated Touch Screen Control with display of command current and delivered current.

$\pm .02$  mA (or  $\pm 10\%$  of reading at 1K Ohm load) over Stimulus Range.

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.

Monophasic, square pulse, no DC component

Software selectable, 50, 100, 150, 200 or 250  $\mu$ s ( $\pm 10\%$  of setting)

Less than 10  $\mu$ s

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

(Slow) 1, 2, 4, 8, 10 per minute, (Fast) 1, 2 Hz ( $\pm 10\%$  of setting) (APS™ feature NOT available on the NIM-Pulse® 3.0)

Monopolar (standard) or bipolar

TTL compatible remote switch for Selection of APS™: OFF, SLOW, and FAST repeating sequence (NOT for NIM-Pulse® 3.0)

Built-in 7.62 x 7.62 cm speaker and Piezoelectric Sounder

63  $\pm 4$  dB SPL C Weighted (30.5 cm)

<  $\pm 4$  dB SPL C Weighted (30.5 cm)

> + 20 dB SPL C Weighted (30.5 cm)

102  $\pm 4$  dB SPL C Weighted (30.5 cm)

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

Volume Power Up Pre-set Default and a Low Volume Limiter. Volume Presets for Main, Tones, Voices, and EMG Volumes

“Current Delivered” Tone Signals:

Power-Down / Power-up Tone :

Touch Screen Key Click:

Connection:

Headphones:

Headphone Output:

## Video, Audio, and other Accessories Verified Compatible

Headphones:

Audio Amplifier:

Audio Extension Cable:

Remote Monitor:

Keyboard:

## I/O - Printer Output / Flash Drive/Keyboard

### Connection

### Printer Verified Compatible

Printer:

Power Isolator:

## Data Output Verified Compatible

USB Compact Flash Memory

## Video Output

### Microscope Overlay

Interface:

Connection:

### Remote Monitor

Interface:

Connection:

## Electrical

Input Voltage:

Frequency:

Total Power Consumption:

Auxiliary AC output (For Use With Approved NIM®

Accessories Only):

Line Isolation:

Internal Fuse:

Patient Connections:

Patient Isolation:

Patient Connection Capacitance:

Signal occurs when 80% of set current is measured over range of 0.05-30 mA.

Constant Power-up / Decaying Power-down Tone

Selectable ON/OFF

RCA Phone Jack

Plug: 3.5 mm stereo nickel plated

Impedance: @1KHZ is 25 ohms or greater SPL 107 +/- 4dB

60 to 83 dB ± 6 dB SPL C- Weighted

Radio Shack Headphones P/N 33-1223 (Sennheiser P/N HD497)

Radio Shack Volume Amplifier P/N 33-1109

Radio Shack 4.8768m Shielded Audio cable P/N 42-2493

8.4" TFT - Mini-Screen with Cable (Medtronic 8253010)

Medical Grade Keyboard (Medtronic 8253030)

USB 2.0

Canon Pixma Model MG7520 (Medtronic 8253250)

Power Isolator 100-120VAC 50/60 Hz 8253120

Power Isolator 230 VAC 50/60 Hz 8253230

SanDisk Brand Cruzer Mini SanDisk Brand Cruzer Micro

2GB/4GB Transcend Brand USB flash drives

Resolution 640x480 (VGA), 800x600 (SVGA) and 1024 x 768 (XVGA)

15-pin HD

XVGA Compatible, 1024 x 768 resolution

MDR “Mini D Ribbon”

100V, 120V / 230V

50/60 Hz

62 W Nominal <78 W Peak (Total 33 W Console, 10 W Printer, and 19 W Mini-Screen)

Power Isolator 100-120VAC 50/60 Hz 8253120

Power Isolator 230 VAC 50/60 Hz 8253230

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

5 x 20 mm, 2.5 Amp, 250V, Time-lag, Low breaking capacity, Xomed Part # 11270068. Order 8253070 Fuse Kit for replacements.

All patient probes and electrodes are Type BF applied parts

90-264 Vrms 50-60 Hz < 100µA (Mains on applied part N.C.)

140 pF +/- 30 % @ 1 kHz (All patient probes and electrodes combined to Safety GND)

## Classifications

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:

Class I Medical Device per IEC/EN60601-1

Type BF applied parts

IPX1

Not suitable for use in the presence of flammable anesthetic mixtures.

## Accessories / Parts List

### System Components & Accessories

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

| P/N                   | Description                                                    | P/N     | Description                                                   |
|-----------------------|----------------------------------------------------------------|---------|---------------------------------------------------------------|
| 8253401               | NIM-Neuro® 3.0 Mainframe                                       | 8253001 | NIM-Response® 3.0 Mainframe                                   |
| 8253402               | International NIM-Neuro® 3.0 Mainframe                         | 8253002 | International NIM-Response® 3.0 Mainframe                     |
| Mainframe Accessories |                                                                |         |                                                               |
| 8253410               | NIM-Neuro® 3.0 Patient Interface Box                           | 8253200 | Patient Interface Box, Response® 3.0                          |
| 8253070               | Fuse Kit, NIM® 3.0 Mainframe, 2.5 Amp                          | 8253600 | NIM® 3.0 Universal Patient Simulator                          |
| 8253075               | Fuse Kit, NIM® 3.0 Patient Interface, 32 mA                    | 8253027 | Printer Package, NIM® 3.0 System                              |
| 8253250               | NIM 3.0 Printer - Canon Pixma MG7520                           | 8253120 | NIM 3.0 Printer AC-AC Pwr Isolator 100-120VAC 50/60 Hz        |
| 8253252               | NIM 3.0 Printer Ink Tank (Black) Canon CLI-251BK XL            | 8253230 | NIM 3.0 Printer AC-AC Pwr Isolator 230 VAC 50/60 Hz           |
| 8253253               | NIM 3.0 Printer Ink Tank (Gray) Canon CLI-251GY XL             | 8253251 | NIM 3.0 Printer Ink Tank (Pigmented BLK) Canon PGI-250PGBK XL |
| 8253254               | NIM 3.0 Printer Ink Tank (CMY-3 color pack) Canon CLI-251BK XL |         |                                                               |

|                                        |                                                          |         |                                                          |
|----------------------------------------|----------------------------------------------------------|---------|----------------------------------------------------------|
| 8253010                                | Surgeon Mini Screen                                      | 8253030 | Keyboard                                                 |
| 8253080                                | Cable to Surgeon Mini Screen                             | 8253015 | Cable to Microscope                                      |
| 8220325                                | NIM® Muting Detector                                     | 8253085 | Video/Audio Recording Adaptor Kit, NIM® 3.0              |
| <b>EMG Endotracheal Tubes</b>          |                                                          |         |                                                          |
| 8229306                                | EMG Endotracheal Tube Reinforced 6 mm                    | 8229707 | NIM Trivantage 7.0 MM ID                                 |
| 8229307                                | EMG Endotracheal Tube Reinforced 7 mm                    | 8229708 | NIM Trivantage 8.0 MM ID                                 |
| 8229308                                | EMG Endotracheal Tube Reinforced 8 mm                    | 8229709 | NIM Trivantage 9.0 MM ID                                 |
| 8229506                                | NIM® EMG Endotracheal Tube, Reinforced Contact Tube 6 mm | 8229735 | 3PK NIM Trivantage 5 MM                                  |
| 8229507                                | NIM® EMG Endotracheal Tube, Reinforced Contact Tube 7 mm | 8229736 | 3PK NIM Trivantage 6 MM                                  |
| 8229508                                | NIM® EMG Endotracheal Tube, Reinforced Contact Tube 8 mm | 8229737 | 3PK NIM Trivantage 7 MM                                  |
| 8229705                                | EMG NIM Trivantage 5.0 MM ID                             | 8229738 | 3PK NIM Trivantage 8 MM                                  |
| 8229706                                | NIM Trivantage 6.0 MM ID                                 | 8229739 | 3PK NIM Trivantage 9 MM                                  |
| <b>Monopolar Stimulating Probes</b>    |                                                          |         |                                                          |
| 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                   |
| <b>Bipolar Stimulating Probes</b>      |                                                          |         |                                                          |
| 8225351                                | Concentric Bipolar Stimulating Probe, 5/Box              | 8225401 | Side-by-Side Bipolar Stimulating Probe, 5/Box            |
| 8225451                                | Prass Bipolar Stimulator Probe, 5/Box                    |         |                                                          |
| <b>Power Cords</b>                     |                                                          |         |                                                          |
| 1897821                                | Power Cord, 6 Meter, 115 V                               | 1895820 | Power Cord Standard, U.S.                                |
| 1895822                                | Power Cord, 6 Meter, Europe, U.K.                        | 1895823 | Power Cord, Japan, 100 V                                 |
| <b>APS Electrodes</b>                  |                                                          |         |                                                          |
| 8228052                                | APS™ Electrode, 2 mm                                     | 8253054 | APS™ Electrode Handswitch, NIM-Response®/NIM-Neuro® 3.0  |
| 8228053                                | APS™ Electrode, 3 mm                                     |         |                                                          |
| <b>Prass Paired EMG Electrodes</b>     |                                                          |         |                                                          |
| 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                |         |                                                          |
| <b>Subdermal Needle Electrodes</b>     |                                                          |         |                                                          |
| 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           |         |                                                          |
| <b>EMG Hookwire Electrodes</b>         |                                                          |         |                                                          |
| 8226326                                | EMG Paired Hookwire Electrode, Protected Pin             | 8226626 | EMG Single Hookwire Electrode, Protected Pin, 6/Box      |
| <b>Stimulus Dissection Instruments</b> |                                                          |         |                                                          |
| 1352400                                | Stimulus-Dissection Instrument Set, 1 Set                | 1353400 | Neurotologic Stimulus-Dissection Instrument Set, 1 Set   |
| 1352415                                | Cable, Protected Pin, 1 Ea.                              |         |                                                          |
| <b>Storage Case/ Stand</b>             |                                                          |         |                                                          |
| 8253020                                | Cart, NIM® 3.0 System                                    | 8253035 | Storage/Carrying Case                                    |

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

Additional information can be found at [www.mcatalogs.com/ent/](http://www.mcatalogs.com/ent/)

68E4004 Minimization of Pacemaker Pacing Artifacts displayed on the NIM® monitor screen.

## Annual System Quick Check

### Preventive and Corrective Maintenance

User maintenance for the NIM® 3.0 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.

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 Xomed 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  $\Omega$ s 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              | <0.252 $\Omega$ @ 25 Amps    | _____          |
| b. Safety ground to Line/Neutral | <5.0 mA @ 1500 Vac           | _____          |
| c. Applied Parts to line/neutral | <1.0 mA @ 3535 Vdc           | _____          |

Perform an operational check using the Patient Simulator and the Patient Interface. Please see the NIM® 3.0 and Patient Simulator User Guides for details.

# Patient Simulator Instructions for Use

## Introduction

Important Notice:

This Patient Simulator Guide covers the NIM-Neuro® 3.0 , and NIM-Response® 3.0.

## System description

The Medtronic Xomed NIM® 3.0 Universal Patient Simulator provides for testing some of the features of the NIM® 3.0 system without the need for patient interaction. In addition, the NIM® 3.0 Universal Patient Simulator is a convenient means of testing various aspects of instrument operability prior to patient application.

This section describes the NIM® 3.0 Patient Simulator and pertinent components of the NIM® 3.0 system used during a test.

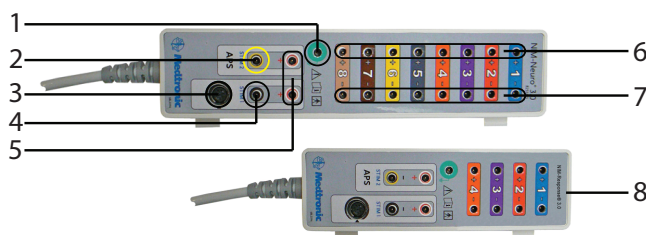


On the NIM® 3.0 Universal Patient Simulator, there are 8 channel stimulation contact pads, one (1) for each channel. These contacts are the points for activating individual circuits. A monopolar probe is recommended for use during testing.

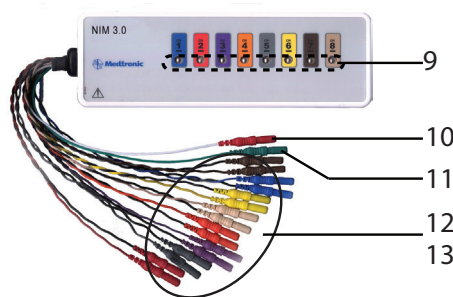
## System Set-Up

### Simulator Set-Up

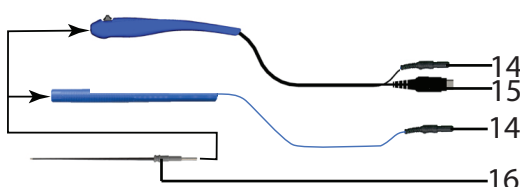
Simulator use requires prior setup of the NIM® 3.0 unit as previously described.



- 1 Electrode ground
- 2 Auxiliary stimulator STIM 2 or APS jack
- Note:** You cannot use the APS Stimulating Electrode 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
- 8 NIM-Response 3.0 Patient Interface shown for reference only.



- 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 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<br>Patient Simulator to Patient Interface |        |       |             | NIM-Response® 3.0 |    | NIM-Neuro® 3.0 |    |
|--------------------------------------------------------|--------|-------|-------------|-------------------|----|----------------|----|
| Connector                                              | Wire   | Ch. # | Connects To | Yes               | No | Yes            | No |
| Blue                                                   | Blue   | 1     | Positive    | x                 |    | x              |    |
| Blue                                                   | Black  | 1     | Negative    | x                 |    | x              |    |
| Red                                                    | Red    | 2     | Positive    | x                 |    | x              |    |
| Red                                                    | Black  | 2     | Negative    | x                 |    | x              |    |
| Purple                                                 | Purple | 3     | Positive    | x                 |    | x              |    |
| Purple                                                 | Black  | 3     | Negative    | x                 |    | x              |    |
| Orange                                                 | Orange | 4     | Positive    | x                 |    | x              |    |
| Orange                                                 | Black  | 4     | Negative    | x                 |    | x              |    |
| Gray                                                   | Gray   | 5     | Positive    |                   | x  | x              |    |
| Gray                                                   | Black  | 5     | Negative    |                   | x  | x              |    |
| Yellow                                                 | Yellow | 6     | Positive    |                   | x  | x              |    |
| Yellow                                                 | Black  | 6     | Negative    |                   | x  | x              |    |
| Brown                                                  | Brown  | 7     | Positive    |                   | x  | x              |    |
| Brown                                                  | Black  | 7     | Negative    |                   | x  | x              |    |
| Tan                                                    | Tan    | 8     | Positive    |                   | x  | x              |    |
| Tan                                                    | Black  | 8     | Negative    |                   | x  | x              |    |
| Red                                                    | White  | N/A   | STIM 1 / 2  | x                 |    | x              |    |
| Green                                                  | Green  | N/A   | Ground      | x                 |    | x              |    |

## System Assessment Confirming Electrodes

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

1. Connect simulator and probe to patient interface and patient interface to the NIM® 3.0.
2. Turn on the power switch.

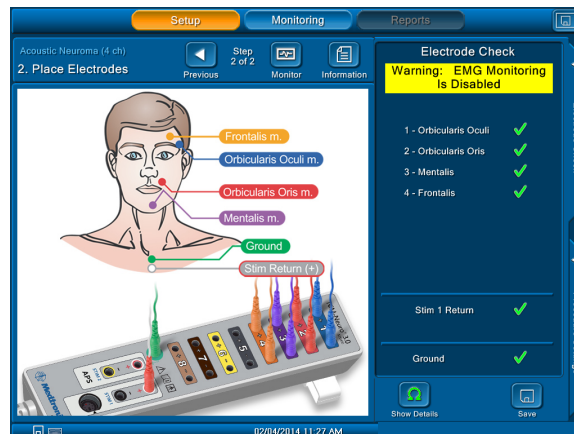
The NIM® 3.0 performs a series of self tests during the boot up process (this process takes about 40 seconds).. After the splash screen closes the Setup screen appears.



You can use any procedure. For this procedure we assume 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, etc. (4 channels for NIM-Response® 3.0 and 8 channels for the Neuro are shown).

## 3. Select Custom Procedure/Stimulation Test.

The Setup Step 2 of 2 screen appears.



4. If the Electrode Check panel is closed, press the Electrode Check tab. If the Electrode Check panel is open, proceed to step 9.

5. Press **Show Details**.



The Electrodes screen appears. Confirm the following:

- All channels are on.
- All channels have Subdermal selected.
- Positive and negative kΩ (impedance) of all 8 or 4 channels is  $5.1\text{ k}\Omega$  or  $5.6\text{ k}\Omega \pm 1.0\text{ k}\Omega$  with the Patient Simulator.
- The  $\Delta$  (difference) in their values is  $500\text{ }\Omega \pm 500\text{ }\Omega$ .
- The kΩ (impedance) of the Ground is  $6.5\text{ k}\Omega \pm 1.0\text{ k}\Omega$ .
- The kΩ (impedance) of the Stimulus Return is  $6.2\text{ k}\Omega \pm 1.0\text{ k}\Omega$ .
- The “Monitoring is Disabled” warning is on.

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

### 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 background noise waveform.
- There is a continuous noise. This is due to ambient electronic noise being picked up by the disconnected electrode.

After approximately 30 seconds, the system displays “Electrode Off” in yellow text on a zero (0) amplitude waveform line.

2. Reconnect the electrode and confirm the NIM® 3.0 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 Care.

## 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.

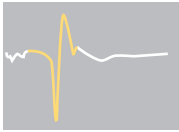
1. Start at the Monitoring screen with default settings and all electrodes connected.

**Note:** The Detect Artifacts check box on the Advanced Settings 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 8.
- 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 Monitor 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 left of the screen should read 0.8 (this is the mA setting).
- Below the mA setting is a small window reading 0.00 mA. This is the measured value.
- Press the Minus and Plus buttons observing that the mA setting changes values.
- Press the mA + button until reaching a value of 3.00 mA.
  - A dialog box appears
  - Stimulus in excess of 3 mA
  - Press **OK** to enable stimulus.

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  $\mu V$  reading is displayed 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  $\mu V$ .

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).

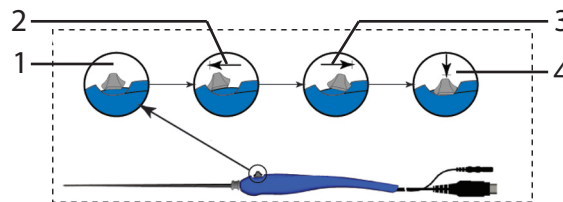


7. Increase the Event Threshold to 500  $\mu\text{V}$  and stimulate channel 1 and observe the following:

- 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  $\mu\text{V}$  reading is displayed 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 - Press and hold saves current screen to memory or to selected peripheral device (Printer or USB flash drive) if it has been enabled.

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

### Threshold Test

1. Decrease Event Threshold to 20  $\mu\text{V}$ .

2. Grasp one lead of channel 1 electrode wire to induce artifact noise over 20  $\mu\text{V}$  threshold causing continuous event tones to sound. If artifact is not over the 20  $\mu\text{V}$  level, event tones and auto threshold will not be able to be tested.

3. Select **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
- event tones no longer sound
- the new threshold value appears next to the channel number.

**Note:** Auto Thresholds maximum is 400  $\mu\text{V}$ . 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  $\mu\text{V}$ , 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 Care.

### 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-Neuro® 3.0 System Patient Simulator, check the following:

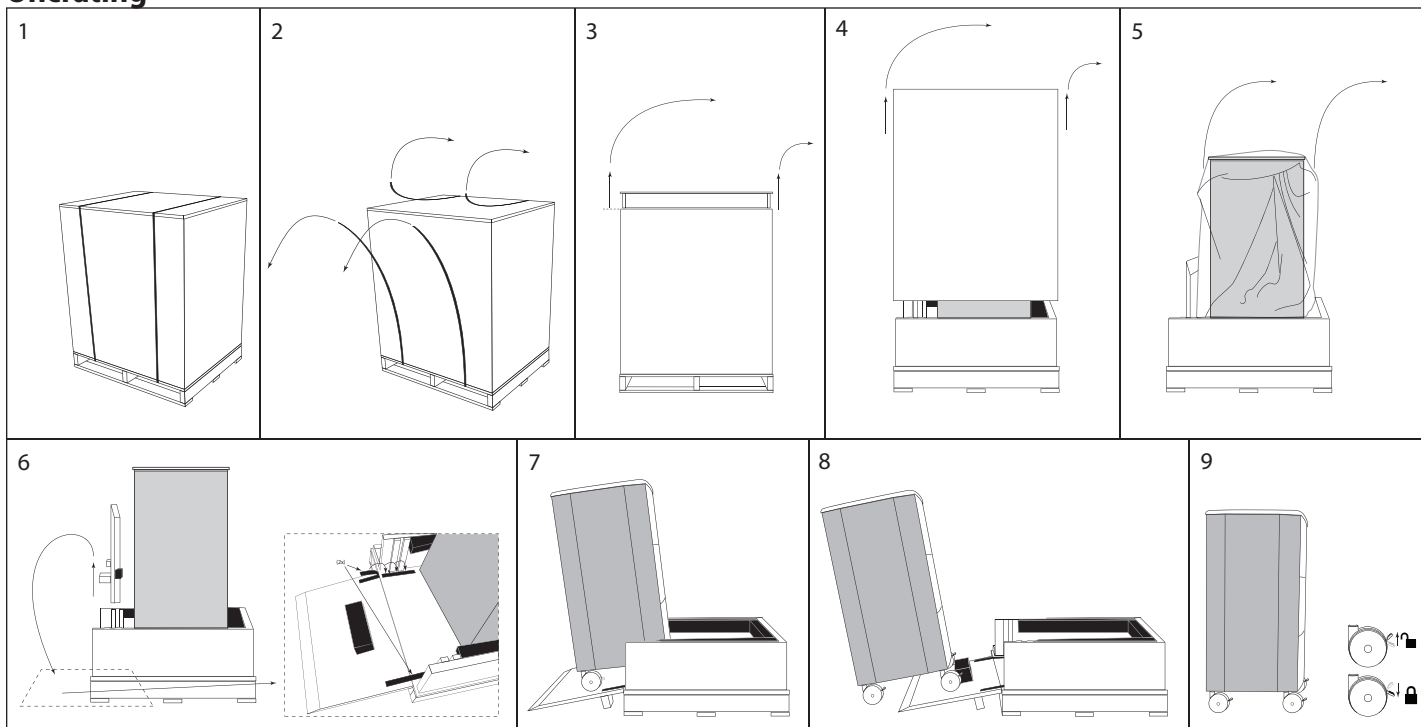
- Verify that the Stimulus Measured is approximately the same as the Stimulus Intensity.
- Make sure the jumper cables are connected correctly between the SIMULATOR and PATIENT INTERFACE.
- Adjust the EVENT THRESHOLD setting on the NIM-Neuro® 3.0 System.
- Adjust the STIMULUS intensity on the NIM-Neuro® 3.0 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 blown fuse in NIM-Neuro® 3.0 System Patient Interface and replace with proper valued fuse (shown near fuse box).
- Check for proper closure of fuse holder in the NIM-Neuro® 3.0 System Patient Interface.

## The NIM® 3.0 Equipment Cart

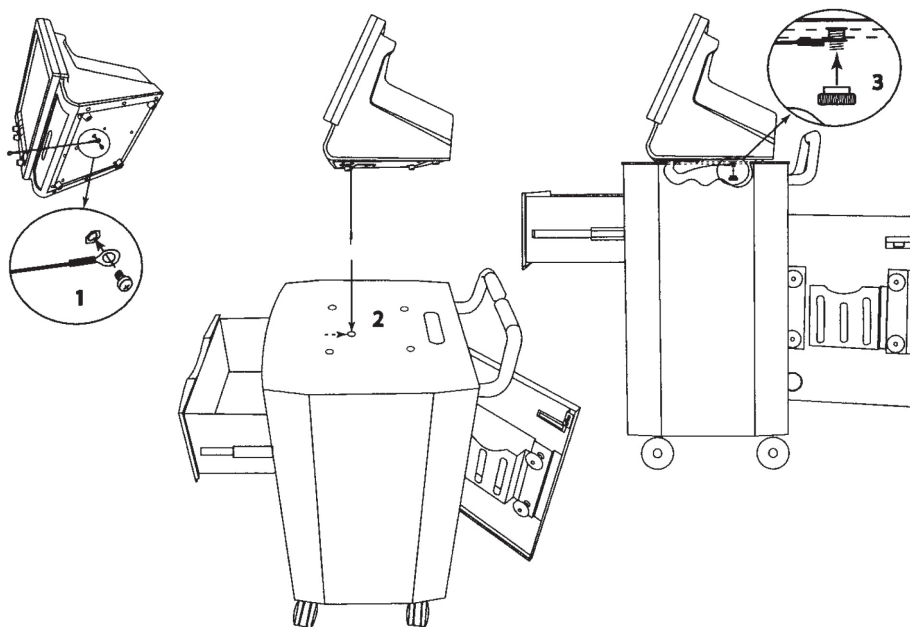
The equipment cart serves as a convenient means to operate the NIM® 3.0 in the operating room as well as store the console and accessories when not in use.

### Uncrating



### NIM® 3.0 Tether

The Equipment Cart is supplied with a tether that needs to be installed.



1. Remove parts from the bag and use a phillips screwdriver to attach the tether to the bottom of the NIM® 3.0 (illustration 1).
2. Open the rear door and pull the top drawer out about half way, then insert the tether through the hole in the top of the cart (illustration 2).
3. Reach in through the rear door and locate the stud in the top plate and secure the tether to the stud using the knurled nut (illustration 3).

## Channel Default Settings

| NIM-Response® 3.0         |                             |                                                         |                  |                             |                                                         |                             |                     |                                                         |                               |                                 |                                                         |                           |
|---------------------------|-----------------------------|---------------------------------------------------------|------------------|-----------------------------|---------------------------------------------------------|-----------------------------|---------------------|---------------------------------------------------------|-------------------------------|---------------------------------|---------------------------------------------------------|---------------------------|
| Procedure Name,           | Acoustic Neuroma 4 Ch       | Acoustic Neuroma 2 Ch                                   | Cochlear Implant | Mastoid                     | Thyroid                                                 | Thyroid with APS™           | Parotid             | Parotid (2Ch)                                           | Neck Dissection               | Lower Extremity 4 Ch            | Knee (Peroneal) 2 Ch                                    | Ankle (Tibial Nerve) 2 Ch |
| Category Name,            | Neuro / Otology             |                                                         |                  |                             |                                                         |                             |                     |                                                         |                               |                                 |                                                         |                           |
| Ch 1 Name Electrode Type  | Orbicularis Oculi Subdermal |                                                         |                  | Vocalis 1 Endotracheal Tube |                                                         | Orbicularis Oculi Subdermal |                     | Vocalis 1 Endotracheal Tube                             |                               | Peroneus Longus Prass Paired    |                                                         |                           |
| Ch 2 Name Electrode Type  | Orbicularis Oris Subdermal  |                                                         |                  | Vocalis 2 Endotracheal Tube |                                                         | Orbicularis Oris Subdermal  |                     | Vocalis 2 Endotracheal Tube                             |                               | Tibialis Ant. Prass Paired      |                                                         |                           |
| Ch 3 Name Electrode Type  | Mentalis Subdermal          | Available to surgeon no default names or Electrode Type |                  |                             | Available to surgeon no default names or Electrode Type |                             | Mentalis Subdermal  | Available to surgeon no default names or Electrode Type | Sternocleidomastoid Subdermal | Abductor Digniti Prass Paired,  | Available to surgeon no default names or Electrode Type |                           |
| Ch 4 Name Electrode Type  | Frontalis Subdermal         |                                                         |                  |                             |                                                         |                             | Frontalis Subdermal |                                                         | Trapezius Subdermal           | Abductor Hallucis Prass Paired, |                                                         |                           |
| Electrode Placement Image | Yes                         |                                                         |                  |                             |                                                         |                             |                     |                                                         |                               |                                 |                                                         |                           |

| NIM-Neuro® 3.0                 |                                                         |                                                         |                  |                             |                                                         |                                                         |                                                         |                     |                               |                 |                                                         |                      |                                                         |                                |
|--------------------------------|---------------------------------------------------------|---------------------------------------------------------|------------------|-----------------------------|---------------------------------------------------------|---------------------------------------------------------|---------------------------------------------------------|---------------------|-------------------------------|-----------------|---------------------------------------------------------|----------------------|---------------------------------------------------------|--------------------------------|
| Procedure Name,                | Acoustic Neuroma 4 Ch                                   | Acoustic Neuroma 2 Ch                                   | Cochlear Implant | Mastoid                     | Glomus                                                  | Thyroid                                                 | Thyroid with APS™                                       | Parotid             | Parotid (2Ch)                 | Neck Dissection | Lower Extremity 4 Ch                                    | Knee (Peroneal) 2 Ch | Ankle (Tibial Nerve) 2 Ch                               |                                |
| Category Name,                 | Neuro / Otology                                         |                                                         |                  |                             |                                                         |                                                         |                                                         |                     |                               |                 |                                                         |                      |                                                         |                                |
| Ch 1 Name Electrode Type       | Orbicularis Oculi Subdermal                             |                                                         |                  |                             |                                                         | Vocalis 1 Endotracheal Tube                             | Orbicularis Oculi Subdermal                             |                     | Vocalis 1 Endotracheal Tube   |                 | Peroneus Longus Prass Paired                            |                      |                                                         | Abductor Digniti Prass Paired  |
| Ch 2 Name Electrode Type       | Orbicularis Oris Subdermal                              |                                                         |                  |                             |                                                         | Vocalis 2 Endotracheal Tube                             | Orbicularis Oris Subdermal                              |                     | Vocalis 2 Endotracheal Tube   |                 | Tibialis Ant. Prass Paired                              |                      |                                                         | Abductor Hallucis Prass Paired |
| Ch 3 Name Electrode Type       | Mentalis Subdermal                                      | Available to surgeon no default names or Electrode Type |                  |                             | Mentalis Subdermal                                      | Available to surgeon no default names or Electrode Type |                                                         | Mentalis Subdermal  | Sternocleidomastoid Subdermal |                 | Abductor Digniti Prass Paired,                          |                      | Available to surgeon no default names or Electrode Type |                                |
| Ch 4 Name Electrode Type       | Frontalis Subdermal                                     |                                                         |                  |                             | Frontalis Subdermal                                     |                                                         |                                                         | Trapezius Subdermal |                               |                 |                                                         |                      |                                                         |                                |
| Ch 5 Name Electrode Type       | Available to surgeon no default names or Electrode Type |                                                         |                  | Vocalis 1 Endotracheal Tube | Available to surgeon no default names or Electrode Type |                                                         | Available to surgeon no default names or Electrode Type |                     | Hypoglossal Subdermal         |                 | Available to surgeon no default names or Electrode Type |                      |                                                         |                                |
| Ch 6 Name Electrode Type       |                                                         |                                                         |                  | Vocalis 2 Endotracheal Tube |                                                         |                                                         |                                                         |                     |                               |                 |                                                         |                      |                                                         | Glossopharyngeal Subdermal     |
| Ch 7 Name Electrode Type       | Available to surgeon no default names or Electrode Type |                                                         |                  |                             |                                                         |                                                         |                                                         |                     |                               |                 |                                                         |                      |                                                         |                                |
| Ch 8 Electrode Placement Image | Yes                                                     |                                                         |                  |                             |                                                         |                                                         |                                                         |                     |                               |                 |                                                         |                      |                                                         |                                |

Display Default Settings

| NIM-Response® 3.0 and NIM-Neuro® 3.0 |                       |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
|--------------------------------------|-----------------------|-----------------------|------------------|---------|---------|-------------------|---------|-----------------|--------|----------------------|----------------------|---------------------------|
| Procedure Name                       | Acoustic Neuroma 4 ch | Acoustic Neuroma 2 ch | Cochlear Implant | Mastoid | Thyroid | Thyroid with APS™ | Parotid | Neck Dissection | Glomus | Lower Extremity 4 Ch | Knee (Peroneal) 2 Ch | Ankle (Tibial Nerve) 2 Ch |
| Event Threshold                      | 100 µV                |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
| Event Capture                        | Largest               |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
| Stimulus Rejection Period            | 3.1 mS                |                       |                  |         | 1.2 mS  |                   | 3.1 mS  |                 |        | 5.0 mS               |                      |                           |
| Time Scale                           | 50 mS                 |                       |                  |         | 25 mS   |                   | 50 mS   |                 |        |                      |                      |                           |
| Vertical Scale                       | 500 uV                |                       |                  |         | 1000 µV |                   | 500 µV  |                 |        | 2000 uV              |                      |                           |
| Detect Artifacts                     | Yes                   |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
| Monitoring Audio                     | EMG + Event Tones     |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
| Stimulus Delivery Tone               | Brief                 |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |

STIM 1 & 2 Default Settings

| NIM-Response® 3.0 and NIM-Neuro® 3.0 |                       |                       |                  |         |         |                   |         |                 |        |                      |                      |                           |
|--------------------------------------|-----------------------|-----------------------|------------------|---------|---------|-------------------|---------|-----------------|--------|----------------------|----------------------|---------------------------|
| Procedure Name                       | Acoustic Neuroma 4 Ch | Acoustic Neuroma 2 Ch | Cochlear Implant | Mastoid | Thyroid | Thyroid with APS™ | 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 APS™   | 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                |                       |                  |         |         |                   |         |                 |        | 12.0 mA              |                      |                           |
| STIM 2 Rate                          | 4/sec                 |                       |                  |         |         | 10/min            | 4/sec   |                 |        |                      |                      |                           |

Microscope Default Settings

| NIM-Neuro® 3.0              |                            |                       |                  |         |         |                   |         |                 |                          |                      |                     |                           |
|-----------------------------|----------------------------|-----------------------|------------------|---------|---------|-------------------|---------|-----------------|--------------------------|----------------------|---------------------|---------------------------|
| Procedure Name              | Acoustic Neuroma 4 Ch      | Acoustic Neuroma 2 Ch | Cochlear Implant | Mastoid | Thyroid | Thyroid with APS™ | Parotid | Neck Dissection | Glomus                   | Lower Extremity 4 CH | Knee (Peroneal) 2CH | Ankle (Tibial Nerve) 2 CH |
| Microscope Overlay Enabled  | Yes                        |                       |                  |         | No      |                   |         | No              | Yes                      | No                   |                     |                           |
| Microscope Overlay Position | Bottom Left                |                       |                  |         | N/A     |                   |         | N/A             | Bottom Left              | N/A                  |                     |                           |
| Microscope Overlay Format   | Highest Chan - no waveform |                       |                  |         | N/A     |                   |         | N/A             | Highest Chan no waveform | N/A                  |                     |                           |
| Microscope Overlay Timeout  | 7 sec                      |                       |                  |         | N/A     |                   |         | N/A             | 7 sec                    | N/A                  |                     |                           |

# Guidance and manufacturer's declaration – electromagnetic immunity

## Part I

| Guidance and manufacturer's declaration – electromagnetic immunity – Part I                                                                                                                                                                 |                                                                                                                                                                                                                       |                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The NIM-Response® 3.0 and NIM-Neuro® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Response® 3.0 and NIM-Neuro® 3.0 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)<br>IEC 61000-4-2                                                                                                                                                                                              | ±6 kV contact<br>±8 kV air                                                                                                                                                                                            | ±6 kV contact<br>±8 kV air                                                                                                                                                                                            | Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.                                                                                                                                                                                           |
| Electrical fast transient/burst<br>IEC 61000-4-4                                                                                                                                                                                            | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                                                                          | ±2 kV for power supply lines<br>±1 kV for input/output lines                                                                                                                                                          | Mains power quality should be that of a typical commercial or hospital environment.                                                                                                                                                                                                                                                       |
| Surge<br>IEC 61000-4-5                                                                                                                                                                                                                      | ±1 kV differential mode<br>±2 kV common mode                                                                                                                                                                          | ±1 kV differential mode<br>±2 kV common mode                                                                                                                                                                          | 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<br>IEC 61000-4-11                                                                                                                                      | <5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 0.5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$ )<br>for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$ )<br>for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 5 sec | <5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 0.5 cycle<br>40 % $U_T$<br>(60 % dip in $U_T$ )<br>for 5 cycles<br>70 % $U_T$<br>(30 % dip in $U_T$ )<br>for 25 cycles<br><5 % $U_T$<br>(>95 % dip in $U_T$ )<br>for 5 sec | Mains power quality should be that of a typical commercial or hospital environment. If the user of the NIM-Response® 3.0 and NIM-Neuro® 3.0 requires continuous operation during power mains interruptions, it is recommended that the NIM-Response® 3.0 and NIM-Neuro® 3.0 be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8                                                                                                                                                                                  | 3 A/m                                                                                                                                                                                                                 | 3 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 emissions                                                                                                                                                                         |            |                                                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The NIM-Response® 3.0 and NIM-Neuro® 3.0 is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM-Response® 3.0 and NIM-Neuro® 3.0 should assure that it is used in such an environment. |            |                                                                                                                                                                                                                                   |
| Emissions test                                                                                                                                                                                                                              | Compliance | Electromagnetic environment - guidance                                                                                                                                                                                            |
| RF emissions<br>CISPR 11                                                                                                                                                                                                                    | Group 1    | The NIM-Response® 3.0 and NIM-Neuro® 3.0 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 emissions<br>CISPR 11                                                                                                                                                                                                                    | Class A    | The NIM-Response® 3.0 and NIM-Neuro® 3.0 is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purpose. |
| Harmonic emissions<br>IEC 61000-3-2                                                                                                                                                                                                         | Class A    |                                                                                                                                                                                                                                   |
| Voltage fluctuations<br>IEC 61000-3-3                                                                                                                                                                                                       | Complies   |                                                                                                                                                                                                                                   |

| Recommended separation distances between portable and mobile RF communications equipment and the NIM-Response® 3.0 and NIM-Neuro® 3.0                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                                                     |                                        |                                         |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|----------------------------------------|-----------------------------------------|
| The NIM-Response® 3.0 and NIM-Neuro® 3.0 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIM-Response® 3.0 and NIM-Neuro® 3.0 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIM-Response® 3.0 and NIM-Neuro® 3.0 as recommended below, according to the maximum output power of the communications equipment.                                                                                     |                                                                     |                                        |                                         |
| Rated maximum power of transmitter<br>W                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Separation distance according to frequency of transmitter<br>meters |                                        |                                         |
|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 150 kHz to 80 MHz<br>$d = 1.2\sqrt{P}$                              | 80 MHz to 800 MHz<br>$d = 1.2\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.3\sqrt{P}$ |
| 0.01                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.12                                                                | 0.12                                   | 0.23                                    |
| 0.10                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 0.38                                                                | 0.38                                   | 0.73                                    |
| 1.00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 1.20                                                                | 1.20                                   | 2.30                                    |
| 10.00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 3.80                                                                | 3.80                                   | 7.30                                    |
| 100.00                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 12.00                                                               | 12.00                                  | 23.0                                    |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance $d$ in meters (m) can be estimated 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.<br>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. |                                                                     |                                        |                                         |

## Part II

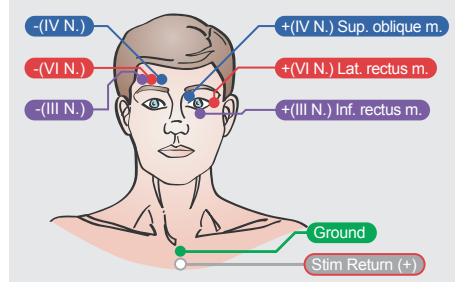
| The NIM-Response® 3.0 and NIM-Neuro® 3.0 is intended for use in the electromagnetic environment specified below.<br>The customer or the user of the NIM-Response® 3.0 and NIM-Neuro® 3.0 should assure that it is used in such an environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                          |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Immunity test                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | IEC/EN60601-1-2 test level                                               | Compliance level             | Electromagnetic environment - guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <p>Conducted RF<br/>IEC 61000-4-6</p> <p>Radiated RF<br/>IEC 61000-4-3</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>3 Vrms<br/>150 kHz to 80 MHz</p> <p>3 V / m<br/>80 MHz to 2.5 GHz</p> | <p>3 Vrms</p> <p>3 V / m</p> | <p>Portable and mobile RF communications equipment should be used no closer to any part of the NIM-Response® 3.0 and NIM-Neuro® 3.0, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p><b>Recommended separation distance</b></p> <p><math>d = 1.2 \sqrt{P}</math></p> <p><math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz</p> <p><math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz</p> <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,<sup>a</sup> should be less than the compliance level in each frequency range.<sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol:</p>  |
| <p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                                                          |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><sup>a</sup> Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the NIM-Response® 3.0 and NIM-Neuro® 3.0 is used exceeds the applicable RF compliance level above, the NIM-Response® 3.0 and NIM-Neuro® 3.0 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NIM-Response® 3.0 and NIM-Neuro® 3.0.</p> |                                                                          |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| <p><sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                          |                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |

## Electrode Placement

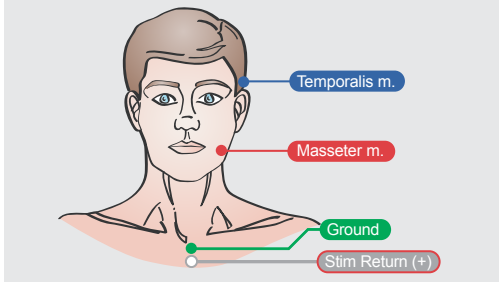
The surgeon will insert electrodes into the appropriate muscle location innervated by the monitored nerve. Additionally, you need a ground electrode (green) and a stim return (white) to complete the electrode setup. NIM 3.0 systems include nerve and electrode placement guides that are color-coded to help reduce confusion.

This page of electrode placement guides contains some, but not all, possible electrode placements. Refer to the  button on the NIM screen for an additional list of electrode placement guides.

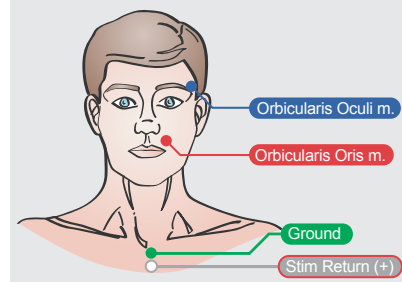
### Extraocular Cranial Nerve III, IV, VI



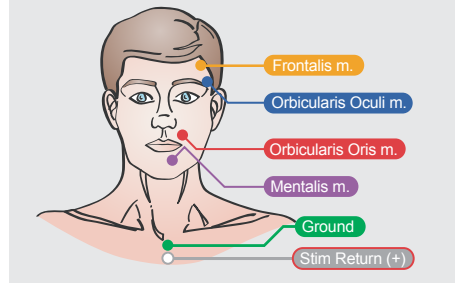
### Trigeminal Cranial Nerve V



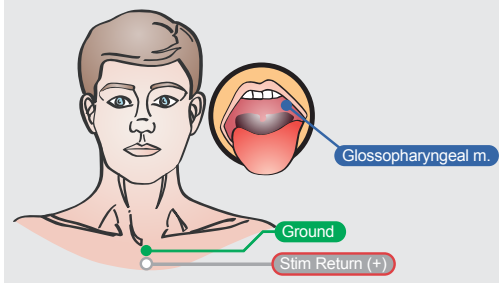
### Facial Cranial Nerve VII - 2 Ch.



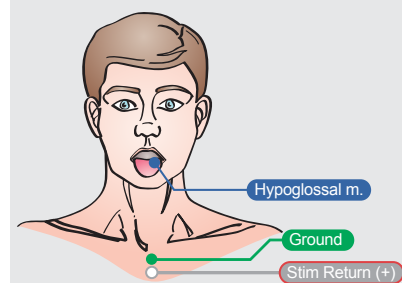
### Facial Cranial Nerve VII - 4 Ch.



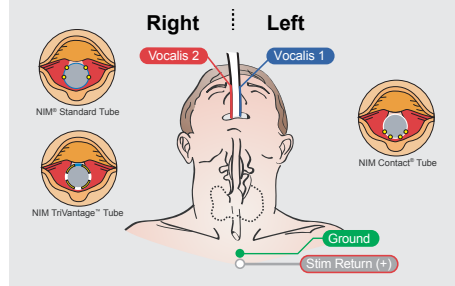
### Glossopharyngeal Cranial Nerve IX



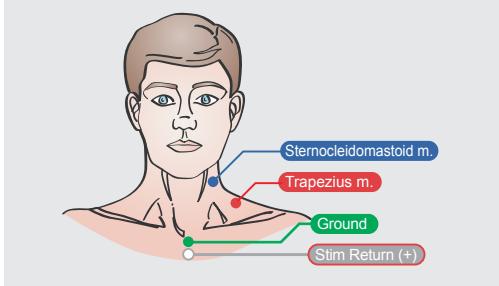
### Hypoglossal Cranial Nerve XII



### Vagus Cranial Nerve X



### Spinal Accessory Cranial Nerve XI



## Limited Warranty

- A. This Limited Warranty provides the following assurance for the customer who purchases a Medtronic NIM-Neuro® 3.0 and NIM-Response® 3.0 System. This Limited Warranty is extended only to the buyer purchasing the NIM-Neuro® 3.0 and NIM-Response® 3.0 System directly from Medtronic or from its affiliate or its authorized distributor or representative. The NIM-Neuro® 3.0 and NIM-Response® 3.0 System may include the Mainframe (including Power Cable), Patient Interface Box, Simulator, and Muting Detector (hereafter referred to as System Components), Surgeon Mini Screen and Cable, Keyboard, Printer System, Cart, Storage Case, Cable to Microscope, and Video/Audio Recording Adapter Kit (hereinafter referred to as "Attachments"), APS™ Electrode Handswitch (hereinafter referred to as Semi-reusable Components) and single use electrodes and probes (hereinafter referred to as Single Use Components) and jointly 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 either repair or replace the 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 either repair or replace the Attachment or any portion thereof.
  - (3) Should a Semi-reusable Component fail to function to Medtronic's published specifications during the term of this Limited Warranty (30 days from the date of sale of a new Semi-reusable Component), Medtronic will replace the Semi-reusable Component or any portion thereof.
  - (4) 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.
  - (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 NIM® 3.0 System, 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): RETURN POLICY

Medtronic Xomed will not authorize or accept the return of Medtronic Xomed products that directly contact patients or is contaminated with a patient's body fluids who is suspected or confirmed with a Transmissible Spongiform Encephalopathies / Creutzfeldt-Jakob Disease (TSE/CJD) diagnosis. Furthermore, Medtronic Xomed recommends that all Medtronic Xomed products used on a patient confirmed with a TSE diagnosis be incinerated. Contact your Sales Representative for replacement of product incinerated under this policy or for temporary equipment while original equipment is quarantined. Contact Medtronic Xomed Quality Services Department, regarding TSE contamination, for additional information. **Probes used on a patient suspected of a TSE/CJD diagnosis must be incinerated.**

If TSE/CJD is excluded as a diagnosis, the quarantined reusable equipment may be returned for use after appropriate cleaning, decontamination and sterilization.

The following are recommended guidelines and may vary according to specific policy and procedures among hospitals. Hospital personnel should contact their infection control personnel for current procedures and policy for reusable equipment processing when suspect of contamination with Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathies (TSE).

Reusable equipment that have been used on patients with suspected Creutzfeldt-Jakob Disease (CJD) or other Transmissible Spongiform Encephalopathies (TSE) should be quarantined and not reused until diagnosis is confirmed or excluded. Reusable equipment should be quarantined after having been cleaned, decontaminated, sterilized and packed in a rigid sealed container until final diagnosis.

**EN** Symbols **FR** Symboles **IT** Simboli **DE** Symbole **ES** Símbolos **NL** Symbolen **DA** Symboler **FI** Symbolit **SV** Symboler **PT** Símbolos **EL** Σύμβολα **PL** Symbol **CS** Symboly **HU** Jelölések **TR** Semboller **NO** Symboler **RU** Символы **SR** Simboli **HR** Simboli



**EN** Device Complies with Medical Device Directive 93-42-EEC **FR** Appareil conforme à la directive 93-42-CEE applicable aux appareil médicaux **IT** Dispositivo conforme alla direttiva sui dispositivi medici MDD 93-42-CEE **DE** Das Gerät entspricht der Medizinprodukte-Richtlinie 93/42/EWG **ES** Este dispositivo cumple la directiva sobre productos sanitarios 93/42/CEE **NL** Dit apparaat voldoet aan Richtlijn 93/42/EEG betreffende medische hulpmiddelen **DA** Anordningen lever op til kravene i Rådets direktiv 93/42/EØF om medicinsk udstyr **FI** Laite on lääkintälaitteita koskevan direktiivin 93-42-ETY mukainen **SV** Denna produkt följer EU-direktiv 93-42-EEC för medicinsk utrustning **PT** O dispositivo cumpre a Directiva 93-42-CEE relativa a dispositivos médicos **EL** Η συσκευή συμμορφώνεται με την Ευρωπαϊκή Οδηγία 93/42/ΕΟΚ περί ιατρικών συσκευών **PL** To urządzenie spełnia wymogi określone w dyrektywie 93-42-EWG **CS** Přístroj vyhovuje směrnici o zdravotnických prostředcích 93-42-EHS **HU** Az eszköz megfelel az orvosi műszerekre vonatkozó 93-42-EGK irányelvnek **TR** Cihaz, 93-42-AET Tibbi Cihaz Direktifi ile uyumludur **NO** Dette produktet er i overensstemmelse med direktiv 93/42/EØF om medisinsk utstyr. **RU** Это устройство соответствует требованиям Директивы об устройствах медицинского назначения 93-42-EEC **SR** Uredaj je uskladen sa Direktivom o medicinskim uređajima 93-42-EEC **HR** Uredaj je sukladan Direktivi za medicinske uređaje 93-42-EEC.

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