Indications, Safety, and Warnings

NIM Vital™ nerve monitoring system

Intended use

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

Indications for use

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

Device description

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

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

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

Contraindications

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

Warnings and precautions

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

Warnings

- **W1** The NIM Vital™ system does not prevent the surgical severing of nerves. If monitoring is compromised, the surgical practitioner must rely on alternate methods, or surgical skills, experience, and anatomical knowledge to prevent damage to nerves.
- **W2** If paralyzing anesthetic agents have been used, the patient must regain muscle activity prior to the use of the NIM Vital™ EMG monitor.
- **W3** Surgical identification of exposed nerves is key to their preservation. Failure to use the Medtronic nerve stimulation probe may contribute to unintended surgical nerve damage or resection.

The user is responsible for ensuring the electrodes are placed or inserted into the target muscles. The electrode check or tap test only indicates that the electrodes are making contact with the patient's tissue and does not indicate that the needle is inserted into the correct muscle.

- **W4** To avoid the risk of fire or explosion, do not use the Medtronic NIM Vital™ system in the presence of flammable anesthetics and/or oxygen-rich environment.
- **W5** After each procedure, properly clean and disinfect all reusable system components.

- **W6** To avoid alternate site patient burns or lesions when patient interface is connected to the NIM Vital™ console through the patient interface cord:
  - Do not activate the electrosurgical instruments (ESU) while stimulator is in contact with tissue.
  - Do not leave dissection instruments, stimulating electrodes, or probes in the surgical field.
  - Do not store dissection instruments, stimulating electrodes, or probes in an electrosurgical instrument holder.
  - Do not allow a second surgeon (for example, fat harvesting) to use electrosurgical instruments while the stimulator is in use.
  - Do not activate the electrosurgical instrument for prolonged periods while ESU is not in contact with tissue.
  - Do not activate the electrosurgical instrument near the recording or stimulating electrodes.
  - Do not allow patient interfaces or recording/stimulating electrode sites to be flooded with saline.
  - Do not allow excessive stray AC or DC leakage currents from the patient connected to equipment. Avoid creating an unintended grounding path through applied electrodes. The practitioner is responsible for proper use, periodic safety certification of patient-connected equipment, and AC power grounding in accordance with the appropriate IEC 60601-1 and/or IEC 60601-1-1 medical safety standard.
- **W7** Disconnect power to the console before cleaning the unit to avoid electrical macro shock.
- **W8** Achieve electrical grounding reliability with proper connections. Connect the console to hospital-grade receptacles only.
- **W9** Do not use any parts:
  - Other than Medtronic components as damage or substandard performance could result
  - That are damaged components or accessories

- **W10** This medical device complies with IEC/EN60601-1-2 safety standards for electromagnetic compatibility, requirements, and tests. 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 the operating time for anesthetized patients.
- **W11** It is important that the NIM Vital operator be familiar with this manual, its precautions, procedures, and safety issues.
- **W12** To avoid electrical shock, do not attach unapproved components or accessories to the Medtronic NIM Vital™ system.
- **W13** All service must be performed by Medtronic qualified personnel only, unless otherwise noted.
- **W14** Do not directly contact active, implanted devices with the stimulator as it may disrupt the implanted device's operation. Consult a medical specialist before use.
- **W15** Electrocardiogram monitoring artifacts may be caused by Medtronic NIM™ stimulus current delivery or EMG electrode impedance monitoring.
- **W16** Use of unapproved stimulators, stimulus probes, stimulus dissection instruments or electrodes may result in compromised Medtronic NIM™ operation, such as, but not limited to decreased accuracy.
- **W17** Repair and/or modification to the Medtronic NIM™ system or any accessory by anyone other than qualified service personnel may significantly compromise the unit's ability to monitor nerve activity and/or void the equipment warranty.
- **W18** To avoid the risk of infection, the user must maintain good sterility practices.

- **W19** False-negative responses, failure to identify the nerve, a condition where the probe is on the nerve but you do not get an EMG tone may result from:
  - Shorted EMG electrode or cabling (conductive parts of applied needle electrodes or cables contacting each other)
  - Patient interface fuse blown and not detected (32 mA, 250 V. Xomed part number 8253075).
  - Patient interface defective
  - Inadequate stimulus current
  - Inadequate current for stimulation of nerve through hardware, such as stimulus dissection instruments, may vary based on the physical size, shape characteristics, design of the hardware, and proximity to the nerve.
  - Simultaneous stimulation of the nerve and the surrounding tissue, resulting in current shunting (inadequate delivery of stimulus current to target nerve tissue)
  - Flatline on the EMG channel caused by a shorted internal amplifier (characterized by baseline activity of < 3 µV peak-to-peak)
  - EMG electrodes are not positioned properly in the target muscles.
- **W20** Stimulator current may cause involuntary patient movement resulting in patient injury.
- **W21** If the incrementing probe handle malfunctions, it could result in increased current delivery to the patient. Immediately disconnect the control plug from the patient interface box and use the console to adjust the stimulus current.
- **W22** Be careful not to damage vascular or neural structures when preparing the nerve for the installation of the continuous monitoring electrodes.
- **W23** Electrode integrity should be checked after electrode insertion and before electrode removal to give additional assurance that electrode continuity was maintained throughout the entire procedure. If the system indicates improper electrode impedance, consult the “Troubleshooting” topic for impedance value troubleshooting.
- **W24** Remove the continuous monitoring electrode from the patient prior to using the external defibrillator to prevent thermal injury to the patient at the continuous monitoring electrode site.
- **W25** Operation in close proximity to high-frequency (shortwave or microwave) equipment may produce instability in the electrical stimulator output.

- **W26** Safe stimulus levels are dependent on various conditions including but not limited to type of excitable tissue, charge per pulse, and charge per unit area. Waveform morphology, repetition rate, and stimulator effective surface area must be considered. Special operator (neurophysiologist) attention is required for stimulus levels that exceed default settings or conditions. Levels higher than 2 mA RMS/cm2 (3 mA) for slim Prass probe and Prass bipolar probe may result in tissue damage.
- **W27** Do not perform magnetic resonance imaging (MRI) on a patient with electrodes, probes, and EMG tubes in the field. The effect of MRI is unknown on these devices.
- **W28** Loud extraneous monitoring noise may be caused by the activation of the electrosurgical unit. A muting detector, if necessary, must be properly attached to the active electrosurgical lead.
- **W29** The user is responsible for at minimum annual functional and safety checks.
- **W30** Avoid trans-thoracic stimulation; when possible, maintain anode and cathode stimulating sites in close proximity.
- **W31** Do not use if the sterile package has been opened or is damaged.

Precautions

- **P1** Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this Guide.
- **P2** Portable and mobile RF including cell phones and communications equipment can affect medical electrical equipment.
- **P3** Use of accessories and cables other than those specified and sold by Medtronic may result in increased emissions and decreased immunity of this unit.
- **P4** The NIM Vital™ system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the NIM Vital™ system should be observed to verify normal operation in the configuration in which it will be used.
- **P5** Avoid accidental contact between “patient applied parts” and other conductive parts including those connected to protective earth.
- **P6** NIM Vital™ is only compatible with the metal muting probe (Ref - 8220325). Earlier model muting probes are not compatible.

- **P7** The muting detector is susceptible to damage from dropping. Visually inspect inner jaw surfaces for cracking, chipping, or damage prior to use. Insufficient muting may result.
- **P8** The patient interface is susceptible to damage from dropping. Visually inspect for damage prior to use. Inability to monitor may result.
- **P9** The ethernet connection of the NIM Vital™ console, if activated, is intended to be connected to the hospital network. Do not connect it to other equipment.
- **P10** At the end of their life cycle, all NIM Vital™ system electronic components must be sent to a WEEE recycling center or disposed of according to local regulations.
- **P11** The NIM Vital™ console contains a Li-Ion battery pack that the user installs/replaces. Failure to follow the instructions for proper installation/replacement of the Li-Ion battery pack may result in a hazard.
- **P12** The patient interface contains a Li-Ion battery pack that must be replaced by trained service personnel only. The replacement of Li-Ion batteries by inadequately trained personnel could result in a hazard.
- **P13** The multiple socket outlet (MSO) inside the locked drawer of the NIM Vital™ cart is only intended to power the NIM Vital™ console and NIM Vital™ power isolator for printer. Connecting both NIM Vital™ console and NIM Vital™ power isolator for the printer into the MSO effectively leads to create a medical electrical system. The system has been tested and met the applicable portions of the IEC 60601-1 standard.
    - Do not plug any device into the MSO other than the NIM Vital™ console and NIM Vital™ power isolator for the printer.
    - Do not overload the MSO by using it for multiple systems. The MSO shall be only used for supplying power to one NIM Vital™ console and one NIM Vital™ power isolator for the printer.
    - The printer shall be always powered through the NIM Vital™ power isolator for the printer. Do not plug the power cord of the NIM Vital™ cart into an extension cord or an additional MSO.
- **P14** The battery inside the NIM Vital™ console can only power the system for a short period of time. NIM Vital™ system shall be always connected to mains power for extended use and loss of power source would result in a risk of loss of monitoring.

- **P15** To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- **P16** A baseline EMG response should be obtained with a stimulating probe once the nerve(s) of interest are identified. Nerve integrity should be checked with a stimulating probe and then compared to the baseline throughout the procedure.