

Technical specifications

Physical dimensions - console

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

Weight:

Physical dimensions - patient interface

Size: 6.5 cm W x 7.5 cm H x 21.5 cm D
Weight: .55 Kg

Physical dimensions - cart (NIM4CC01)

Size: 53 cm W x 101 cm H x 61 cm DP
Weight: 45 kg
Capacities: Drawer Max. Load - 4.5 kg
Shelf Max. Load - 9.0 kg
Cart Total Max. Load - 79.5 kg

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

Operating Temperature range: 10 to 33° C (Operating)
Humidity: 30-70% RH non-condensing
Atmospheric Pressure range: 700 hPa to 1060 hPa

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

Shock and Vibration: Verified to Standard ISTA 2A
Ambient Temperature range: -20°C to + 50° C
Relative Humidity range: 10 % to 100 %, including condensation
Atmospheric Pressure range: 500 hPa to 1060 hPa

Amplifier

Channels - 1 to 4: Individually and simultaneously selectable
Input Sensitivities: 5 – 10,000 μ V peak-to-peak AC Coupled \pm 5% at 10 mV to \pm 30% at 100 mV peak-to-peak AC Coupled
Sensitivity Selection: Automatically zeroed
Bandpass: 15 Hz - 1.85 kHz (\pm 3 db @ 500 Hz) EMG Display
Input Noise: 200 Hz - 1.0 kHz (-6, +3 db @ 500 Hz) Audio EMG Speaker
Input Impedance: 3-14 μ V p-p, < 5 μ V RMS @ DC - 2 KHz, inputs shorted
DC offset Rejection: > 10 Meg Ohm
Common Mode Rejection: \pm 0.90 V DC Rejection
Channel Enable/Disable Controls: >80 dB @ 60 Hz, balanced inputs, >66 dB @ 60 Hz, 1 K Ohm imbalance
Event Threshold Control and Display: Dedicated function touch pads for independent channel enable/disable.
Patient Isolation Wired: Adjustable Graduated Touch Screen with Voltage threshold displayed.
1,000 Vrms 60Hz < 100 μ A

Impedance measurement

Control: Automatic CHECK ELECTRODE feature.
Measuring Signal: 6 μ A or 24 μ A peak-to-peak, 7.8 Hz Square wave
Measurement Range: Electrodes:
0K to 2K Ohm \pm 500 Ohm
>2K-175K Ohm \pm 20%
Ground and Stim Returns < 25K.

Artifact detection and rejection

Stimulus Artifact: Synchronized and adjustable muting and warning.
Bipolar Electrocautery Rejection: Continuous Monitoring During Bipolar Cautery < 40 watts
Monopolar Electrocautery (ESU) Interference: Automatic detection and muting in wired or wirefree modes.
Muting Detector Input ESU Sensitivity: Monopolar ESU Cut / Coag
Contact 5 - 100 Watts
Air-Discharge 10-100 Watts
Muting Console Input Sensitivity: Muting (0.6 - 2.0 Volts Vrms)
Non-Muting (<0.3 Volts Vrms)
Muting Detector Input ESU Immunity: ESU < 100 Watts Cut / Coag or
(<3.0 Vrms 100-800 KHz Sq. Wave)
Electrode Lead Off: Automatic detection with Channel Off Muting and Warning message.

Display / touch screen

Type: High contrast, digital, graphic color, visible in complete darkness.
Resolution: Display Full HD - 1920H x 1080W pixels
Dedicated Function Event Touch Screen Controls: Touch Panel - Capacitive Multi and Glove touch capable 4095H x 4095W
Vertical Display: 20, 50, 100, 200, 500, 1,000, 2,000 5K, 10K, 20K, 50K, and 100K μ V display modes.
Event Capture: Enable/disable capture mode indicator on touch screen.
Time Scale: 25 ms, 50 ms, 100 ms or 20 s display modes.

Patient Interface

Color Coded Channel Patient Connections: "Touchproof safety connection protected pin 1.5 mm per specification: DIN 42 802"
Internal Fuse: Electronic limiting protection circuit and standard fuses. See Stimulator 1 and 2
"Internal Fuse".

Stimulator 1 and 2

Stimulus Type Constant: Constant Current

Stimulus Range:	Stim 1 and Stim 2 0-3 mA, a minimum of ± 12 V compliance (tested into a 4K load)
Load Impedance Range: as long as the load impedance X stimulation current is less than or equal to the compliance voltage.	Stim 1 3.1-50mA a minimum of ± 100 V compliance (tested into a 2K load)
Stimulus Control:	< 4K Ohms (0 - 3 mA): Compliance 12 V < 2K Ohms (3.1 - 50 mA): Compliance 100 V
Stimulus Output Accuracy: Stimulus Adjustment:	Digitally controlled, range – dependent adjustment increments of 0.01, 0.05, 0.1, .5 and 1.0 mA $\pm .01$ mA (or $\pm 10\%$ of reading at 1 K load) over Stimulus Range. Dedicated Side Control knobs and Graduated Touch Screen Control with display of command current and delivered current.
Stimulus Measurement Accuracy: Internal Fuse:	$\pm .02$ mA (or $\pm 10\%$ of reading at 1 K 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.

Stimulus 1 and 2 characteristics

Waveform:	Monophasic, Bi-phasic, Alternating Polarity, or Pulse Train of square pulses
Duration (Width):	Software selectable, 50, 100, 150, 200, 250, or 1000 μ s, (Accuracy: 50uS \pm 15uS, 100uS - 1000uS \pm 10% of setting)
Interpulse Interval:	50uS, 100uS, 500uS, 1-5mSec
Interphase Delay:	50, 100, 500, uS (Accuracy of 0uS < 25uS, 50uS – 100uS \pm 15uS, 500uS \pm 25uS)
Train Count:	1, 2, 3, 4, and 5
Rise Time to 30 mA:	Less than 10 μ s
Rate STIM 1 and 2:	Software selectable 1, 4, 7, 10, or 20 Hz ($\pm 10\%$ of setting)
Rate STIM 2 Nervassure selected:	Nervassure repetition rates 1, 2, 4, 10, 30, 60, and 120 pulses per minute
Stimulus Probe:	Monopolar (standard) or bipolar
Stimulus Trigger Input:	TTL compatible remote input. Not active. For future expansion.

Audio output

Volume Adjustment:	Dedicated Side Control knob and Graduated Touch Screen Control with graphic of Volume.
Transducers:	1 x 7.62 x 7.62 cm speaker 4 x 2.5 x 2.5 cm speakers Piezoelectric Sounder 58 \pm 4 dBC SPL at (1 ft) < \pm 4 dBC SPL at (1 ft) > + 20 dBC SPL at (1 ft) > + 88 dBA SPL at (1 ft) > 43 dBA SPL at (1 ft) Continuously processed EMG. Volume Power Up Pre-set Default and a Low Volume Limiter.
Baseline Audio Sound Level: Change in Baseline with added Channels: Change in Baseline due to EMG and Tones: Max Audio Sound Level: Min Audio Volume (Tone and Alarm) sounds: EMG & Event Tone Signals: Volume Preset and Limiter: "Current Delivered" Tone Signals:	Selectable options include continuous and brief warble tone, voice and voice setting. Signal occurs when 80% of set current is delivered over range when greater than (0.05) mA. Constant Power-up / Decaying Power-down Tone Selectable ON/OFF 3.5mm Mini Audio Female Headphone Jack Line level
Power-Down / Power-up Tone :	Constant Power-up / Decaying Power-down Tone
Touch Screen Key Click:	Selectable ON/OFF
Connection:	3.5mm Mini Audio Female Headphone Jack
Headphone Output:	Line level

I/O - Video Output/USB Drive Output/Networking

Data output

Connection:	3 x USB-A (3.0) , 2 x USB-C (3.0)
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Networking

Ethernet:	Not active. For future expansion.
Connection:	RJ45

Video Output 1

Interface:	HD 1920 x 1080 resolution
Connection:	19 pin HDMI

Video Output 2

Interface:	HD 1920 x 1080 resolution
Connection:	20 pin Display Port

Wireless Remote Monitor

Interface:	HD 1920 x 1080 resolution
Connection:	Display Port or HDMI

Electrical - Mains

Input Voltage/Power:	100 - 240VAC, 250VA
Console:	100 - 240VAC, 600VA
Cart:	50 - 60 Hz
Frequency:	62 W Nominal; <78 W Peak (Total 72 W [62 W Console, 10 W Wireless HDMI])
Power consumption:	

Nerve Integrity Monitor

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

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

Internal Fuse:
Potential Equalization Connection:

Patient Connections:
Patient Connection Capacitance:

Electrical - Batteries

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

Classification

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

Battery Safety

IEC 62123-2012:

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

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

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

4000 V Peak-to-Peak 60Hz dielectric withstand from Line Connections to Signal Ground
5 x 20mm, 5Amp, 250V, Quick-acting, Low breaking capacity, POAG Equipotential Earthing Connection for supplemental grounding or convenient electrical safety test connection point
All patient probes and electrodes are Type BF applied parts
100 pF +/- 30% @ 1kHz (All patient probes and electrodes combined to Safety GND)

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

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

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

AND

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

NIM Vital Compatible Accessories

Audio Accessories Verified Compatible

Wireless Video Output

Wireless HDMI:
Interface:
Connection:

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

Printers Verified Compatible

Printer 1:

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

Printer 2:

Printer 3:

USB Drive Data Output

USB Compact Flash Memory:

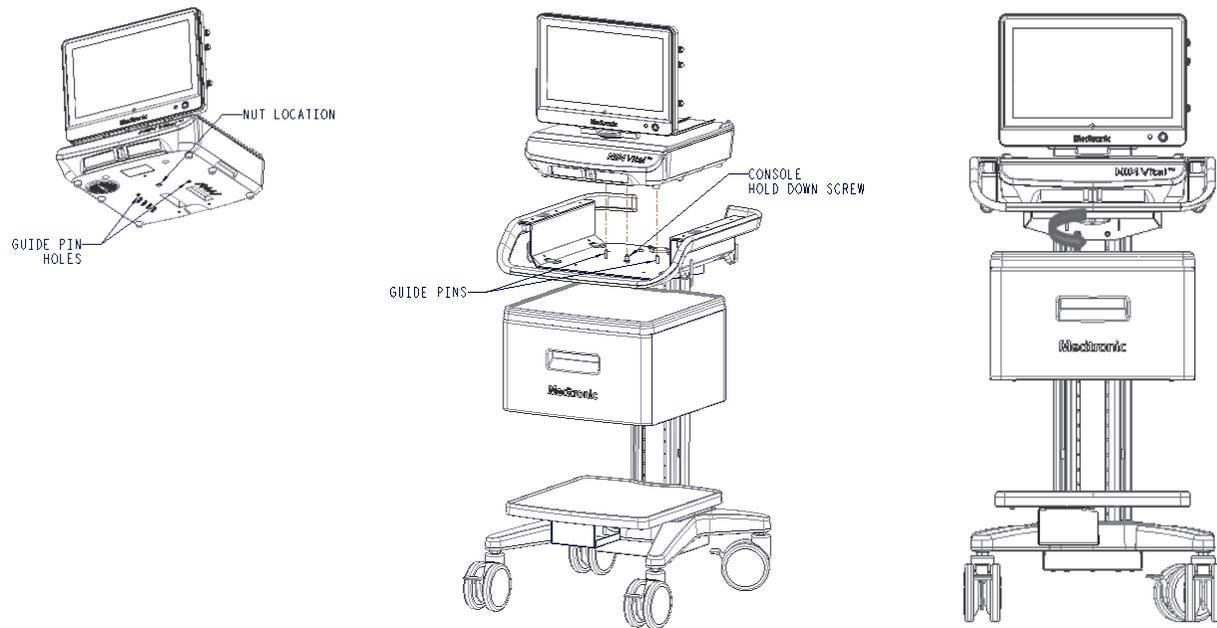
SanDisk Brand, Cruzer Mini SanDisk Brand, Cruzer Micro, Apricorn Aegis Secure Key ASK-256-26GB

The NIM Vital™ equipment cart

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

NIM Vital™ lockdown

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



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

NIM Vital™ cart repair

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

Channel default settings

NIM Vital (4 Channel Patient Interface)															
Procedure Name	Acoustic Neuroma 4 ch (1, 2, 3, 4)	Acoustic Neuroma 4 ch with Nervassure	Acoustic Neuroma 4 ch (4, 1, 2, 3)	Acoustic Neuroma 2 ch with Nervassure	Cochlear Implant	Mastoid	Parotid 4 ch (1, 2, 3, 4)	Parotid 4 ch with Nervassure (4, 1, 2, 3)	Parotid 2 ch with Nervassure	Thyroid	Thyroid with Nervassure	Neck Dissection	Lower Extremity 4 ch	Knee (Peronea I) 2 ch	Ankle (Tibial Nerve) 2 ch
Category Name	Head/Neck														
Ch 1 Name Electrode Type	Peripheral														
Ch 1 Name Electrode Type	Frontalis Subdermal	Orbicularis Oculi Subdermal	Orbicularis Oculi Subdermal	Orbicularis Oculi Subdermal	Frontalis Subdermal	Orbicularis Oculi Subdermal	Orbicularis Oculi Subdermal	Orbicularis Oculi Subdermal	Vocalis 1 Endotracheal Tube	Peroneus Longus Prass Paired	Abductor Digiti Prass Paired				
Ch 2 Name Electrode Type	Orbicularis Oculi Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oculi Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Vocalis 2 Endotracheal Tube	Tibialis Ant. Prass Paired	Abductor or Hallucis Prass Paired				
Ch 3 Name Electrode Type	Orbicularis Oris Subdermal	Mentalis Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Orbicularis Oris Subdermal	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Abductor Digiti Prass Paired	Abductor Digiti Prass Paired	Available to surgeon no default names or Electrode Type
Ch 4 Name Electrode Type	Mentalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Frontalis Subdermal	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Available to surgeon no default names or Electrode Type	Abductor Digiti Prass Paired	Abductor Digiti Prass Paired	Available to surgeon no default names or Electrode Type
Electrode Placement Image	Yes														

Legal information

Contact information

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

Open source software disclosure

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

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

Guidance and manufacturer's declaration – electromagnetic emission and immunity

Environment of intended use: professional healthcare facility environment.

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

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

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

The NIM Vital is intended for use in the electromagnetic environment specified below. The customer or the user of the NIM Vital should assure that it is used in such an environment.

Immunity test	IEC/EN60601-1-2 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM Bands	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz in ISM bands	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the NIM Vital, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
Radiated RF IEC 61000-4-3	3 V / m 80 MHz to 2.7 GHz 9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz Pulse modulation	3 V / m 80 MHz to 2.7 GHz 9 – 28 V/m Spot frequencies 385MHz to 5.785 GHz Pulse modulation	<p>Portable and mobile RF communications equipment should be used no closer to any part of the NIM Vital, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = (6/E)\sqrt{P}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, E is the immunity test levels in volt per meter (V/m), and d is the recommended separation distance in meters (m).</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances between portable and mobile RF communications equipment and the NIM Vital

The NIM Vital is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NIM Vital can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NIM Vital as recommended below, according to the maximum output power of the communications equipment.

Rated maximum power of transmitter P(W)	Separation distance according to frequency of transmitter meters						
	380MHz-390MHz $d = 0.22\sqrt{P}$	430MHz-470MHz $d = 0.22\sqrt{P}$	704MHz-787MHz $d = 0.67\sqrt{P}$	800MHz-960MHz $d = 0.22\sqrt{P}$	1.7GHz-1.99GHz $d = 0.22\sqrt{P}$	2.4GHz-2.57GHz $d = 0.22\sqrt{P}$	5.1GHz-5.8GHz $d = 0.67\sqrt{P}$
0.01	0.03	0.03	0.07	0.03	0.03	0.03	0.07
0.1	0.07	0.07	0.21	0.07	0.07	0.07	0.21
1	0.22	0.22	0.67	0.22	0.22	0.22	0.67
10	0.7	0.7	2.12	0.7	0.7	0.7	2.12
100	2.2	2.2	6.7	2.2	2.2	2.2	6.7

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Limited warranty

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

Transmissible Spongiform Encephalopathies (TSE)

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

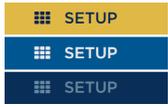
Glossary

APS	Nerve Monitoring Software application featuring trending / alerts during automatic periodic stimulation while performing continuous Intraoperative Nerve monitoring.
APS Electrode	Nerve stimulation electrode for Automatic Periodic Stimulation (CIONM).
CIONM	Continuous Intraoperative Nerve Monitoring.
CRM	Console Radio Module.
DSP	Digital signal processor.
EIC	External Interface Controller.
Event sequence	A series of events separated from each other by less than one second.
GUI	Graphical user interface.
IONM	Intraoperative Nerve Monitoring.
Medtronic Nerve Monitoring Systems	Medtronic IONM Systems, For Example: NIM Vital and NIM 3.0
Nervassure	Nerve Monitoring Software application featuring trending / alerts of automatic periodic stimulation.
NIM	Nerve Integrity Monitor, NIM Vital.
NIM Vital	Medtronic IONM System.
PI	Patient interface.
PMB	Power Management Board.
Stimulus artifact	A monitoring term for an artifact created by stimulus voltage delivered to the patient, which is picked up as feedback either internally or externally to the monitoring equipment. It is normally small and does not impact monitoring but can, under certain conditions, be displayed and sounded on the monitor.
Stimulus artifact on-screen	On the monitoring screen, the stimulus artifact appears as an event (above or below threshold) which starts directly after the stimulus on the left side of the screen and proceeds for a duration into the EMG waveform detection area. The level of the artifact is directly proportional to the stimulus delivery and cannot be EMG because nerve signals need time propagate.
Stimulus artifact sound	The audio representation of a stimulus artifact. It is a high frequency sound similar to a cymbal (ti--tchi). This sound should not be confused with an EMG sound which sounds like a drum beat.
Stimulus rejection period	Adjustable delay reading EMG after stimulation. In previous versions of the NIM, this was referred to as Stimulus Artifact or Artifact Delay.
False negative	The condition where the probe is on nerve, but you do not get an EMG tone.
Tap test	Tapping the electrode location may cause artifactual response on the NIM Vital. This test is not a reliable technique to indicate correct electrode placement/connection.

Buttons and indicators

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

Globally visible



Multi-state for tabs: (Selected, available but not selected, disabled).



Menu: Global settings.



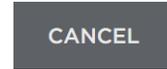
Confirm button.



SETUP tab.



Accept button.



Cancel button.



MONITORING tab.



Dismiss button.



REPORTS tab.



Warning icon.



Continue current case button.



Click to enter patient data.



Wireless connection details.



Start new case button.



Channel buttons.



Battery health.



Signal health.



Wireless peripheral connection (indicator and button).



Wired peripheral connection (indicator and button).



Determining electrode check result.



Pass state for Electrode check.



Electrode check failed.



Show details button.



Acknowledge button.



Edit Case Information Configuration.



Hide details button.



Date entry button.



Indeterminate/ determining state for electrode check.



Help button.



Save to Profile button.

SETUP



Configure channels.



Add new user profile button.



Modify user profile button.



Default categories button.



Go back.



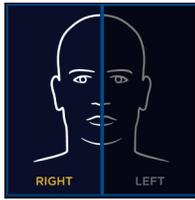
Continue.



Delete user profile.

MONITORING

Nerve Integrity Monitor

	Baseline button.		Electrode check button.		Snapshot button.
	Freeze button.		Settings button.		Decrease button.
	Increase button.		Activate button.		Slow APS Button.
	Fast APS button.		Contextual help button.		Operating side buttons (right currently selected, left currently unselected).
	Restart/start new baseline button.		Next step button (baseline).		Quick tag buttons (green is selected showing it has been taken). The operating side is shown in a Thyroid procedure and Recall button toggles waveform recall for V1 and R1 snapshots.
	Category item. Clicking will open more settings.		Category title. Clicking will open relevant settings.		Yellow mute when trending.
	Toggle slider off/on.		Slider with plus/minus buttons for fine tuning.		Red mute when trending.
	Toggle-enabled drop-down menu.		Drop-down menu.		Measure button.
	Toggle-enabled sliders.		Adjust view.		Save profile.
	Trend button.		Restart new baseline button.		Next step in baseline.
	Channel mute icon.				