Medtronic

EXTERNAL NEUROSTIMULATOR

4NR003

User manual

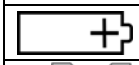
! USA Rx only

! USA **CAUTION:** Investigational device. Limited by Federal (or United States) law to investigational use.

CAUTION: This device is intended exclusively for clinical investigations.

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

	Consult instructions for use
SN	Serial number
PIN No.	Pin number
! USA	For USA audiences only
EC REP	Authorized representative in the European community
	Manufacturer
	Warning
	Type BF applied part (EN 60601-1)
	Universal Serial Bus (USB) 2.0 port
	Battery
A B C D	Omnetics (A29100-065) connector interface ports

! USA FCC Information

The following is communications regulation information on the Model 4NR003 External Neurostimulator.

FCC ID: LF54NR003

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

European Union Compliance
Conformité Européenne
(European Conformity)

Medtronic declares that this product is in conformity with the essential requirements of Directive 93/42/EEC on Medical Devices.

For additional information, contact the appropriate Medtronic representative listed on the inside back cover of this manual.

This product operates at 2.4 GHz with an RF output power of less than 10mW e.i.r.p.

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NOTE:

Algorithm Developers: Refer to instructions shipped separately with the Odin Research System Interface Software for specifications in programmatically interfacing with the neurostimulator.

Managing Physician and Team: Consult the Odin Configuration Tool Instructions for Use, shipped separately with the Odin Research System Interface Software, and the research study protocol for which this neurostimulator is being used, for details on configuring and running an experiment using the neurostimulator.

Description

The Medtronic Model 4NR003 External Neurostimulator (ENS) is designed to provide concurrent sensing and stimulation of the brain as part of an investigational research study in an acute clinical setting. It is intended for use only under the supervision of trained medical personnel.

Package contents

- ENS
- Product literature

Accessories

- None

Device specifications

The Medtronic Model 4NR003 External Neurostimulator (ENS) (Figure 1 and Figure 2) is a programmable device that can be configured to collect neurological signals and provide stimulation using human use surface and depth leads that have been approved per the research study protocol. The ENS is capable of interfacing with up to 256 electrode contacts. The ENS can sense time-domain signals of at least 0.7 µVrms for frequencies between 12-400Hz and at least 4.3671*x^(-0.736) µVrms for frequencies between 0.5-12Hz (where “x” is frequency in Hz). Up to four stimulation patterns can be configured[a] for concurrent delivery[b], each with independently controlled parameters and targeted to a specific collection of anode-cathode electrode pairs. Each stimulation pattern can be configured to start at a future point in time and can run indefinitely until a request is made to terminate the stimulation.

[a] Interlocks and out-of-regulation detection will prevent the use of some parameter combinations.
[b] When the system receives a request to deliver multiple stimulation patterns simultaneously, the stimulation pulse may be dithered in order to ensure that delivered stimulation amplitudes are within designed tolerance limits. Delivering multiple stimulation pulses simultaneously to multiple channels may result in stimulation amplitudes that are different from those requested.

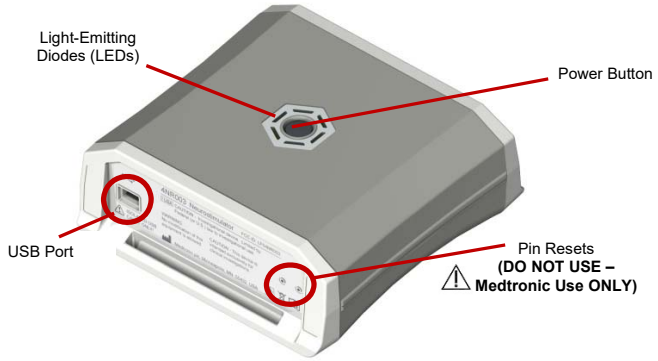

Figure 1. *Model 4NR003 ENS (rear bezel with USB connection interface shown).*

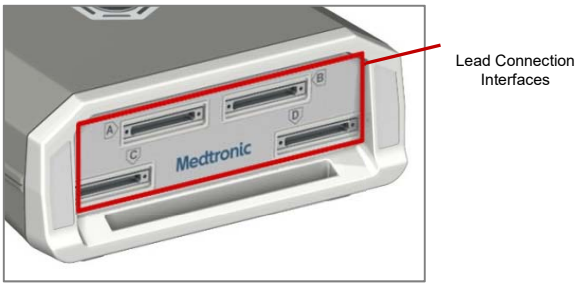

Figure 2. *Model 4NR003 ENS (front bezel with lead connection interfaces shown).*

Table 1. Physical characteristics of the Model 4NR003 ENS[a]

Description	Value
Length	5.01 in (127.25 mm)
Width	4.94 in (125.48 mm)
Thickness	2.11 in (53.59 mm)
Weight (without batteries)	509.0 g (18.0 oz)
Universal Serial Bus port	USB Mini-B
Lead Interface Connector jack	Omnetics A29100-065 (x 4)[b]
Wireless Communication Interface	2.4 GHz WiFi[bc]

[a] All measurements are approximate.
[b] The connector interfaces support connection to lead adapters designed for clinical leads commonly used in Epilepsy Monitoring Units.
[c] Connection interface is limited to a single point-to-point connection with an authenticated device, and communications are encrypted.

Table 2. Electrical specifications for the Model 4NR003 ENS

Description	Value
Nominal Operating Voltage	4.5V DC
Maximum Voltage	5V DC
Nominal Operating Current	250 mA
Maximum Current	1.5 A (continuously fused)
Nominal Operating Power	1.125 W

Table 3. ENS electrical and operating characteristics

Description	Value
Power Source	AA Lithium batteries (quantity 3)
Battery Life	20 hours minimum[a]
Operating Type	Continuous
Degree of protection against electrical shock	Type BF
Ingress protection	IPX0 – normal equipment
Case material	(1) Polycarbonate/ABS blend plastic resin (2) Cycoloy C2950 – Polycarbonate/acrylonitrile butadiene styrene (PC/ABS) (3) Santoprene 211-45 thermoplastic vulcanizate
Automatic shut off	Configurable inactivity timer that upon expiration powers down the device
Automatic stimulation termination[b]	• USB cable disconnected • Loss of WiFi connection to controlling computer
Battery level	Surface LEDs (Figure 1) indicate battery level: • Green – Normal • Orange – Less than 20% battery life remaining • Red – Batteries depleted, replacement needed
Connection Status	Surface LEDs (Figure 1) indicate connection status: • Flashing Color[c] – Disconnected/Connecting • Solid Color – Connected
Stimulation Status	Surface LEDs (Figure 1) indicate stimulation state: • Blue – Stimulation being delivered • Other Color – No stimulation

[a] Battery life is based on continuous stimulation driven over a WiFi connection by computational algorithms running on a controlling computer to eight pairs of electrodes with a 1000 Ω load impedance with the following energy characteristics: Amp = 4mA, PW = 300 µs, Rate = 400 Hz, while sensing on four differential channels at 1000 Hz.

[b] The ENS will terminate the administration of stimulation upon the detection of a dropped connection with the controlling computer (defined as 1000ms of lost communications).

[c] Displayed color is specific to the battery level of the ENS at the given time. For example, when connecting to an ENS that has sufficient battery power, the LEDs will flash in green.

Comment [BZ1]: I had thought this would need to change but I don't think so now that I read this – are you comfortable?

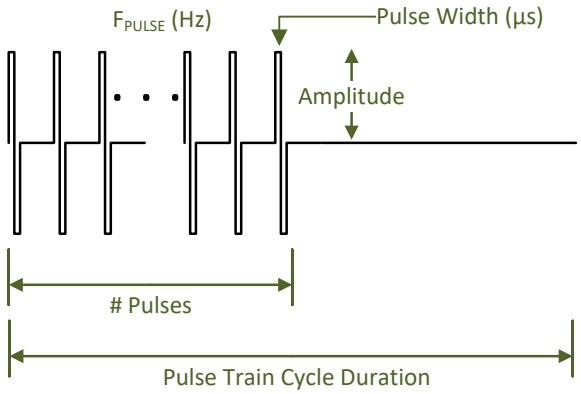

Figure 3. *Illustration of configurable characteristics of a stimulation pattern's pulse train*

Table 4. Operating parameters for a stimulation pattern's pulse train for the Model 4NR003 ENS

Operating Parameter	Operating Range and Resolution[a]
Amplitude[b]	4-256µA, with 4µA resolution 0.25-8.00mA, with 50µA resolution
Pulse Width	~~1~~30-122~~7~~0µs, with 10µs resolution
Pulse Frequency (F_{PULSE})	153mHz-1,000,000mHz~~0.15-5000Hz,~~ with 1mHz~~100µs~~ resolution
Number of Pulses	1-511 pulses, with 1 pulse resolution
Pulse Train Cycle Duration	Maximum of 10 seconds, programmable to 1mHz resolution~~50-1000ms, with 50ms resolution~~

[a] Interlocks and excessive impedance between electrodes will prevent the use or delivery of some parameter combinations.
[b] Step increments/decrements of amplitude are monotonic, and amplitudes delivered at a tolerance of +/- ~~1~~2~~0~~.0%.

Table 5. Other operating stimulation parameters for the Model 4NR003 ENS

Operating Parameter	Range[a]
Global Amplitude Limit (per stimulation channel)	4uA – Maximum[b]

[a] Interlocks and excessive impedance between electrodes will prevent the use or delivery of some parameter combinations.
[b] Maximum will be set to the Shannon McCreery safe charge density limit (k=1.5) using the surface area of the stimulation channel.

Table 6. Operating sense acquisition parameters for the Model 4NR003 ENS

Programmable Parameter	Range and Defaults
Low Pass Filter 1	50Hz, 100Hz, 450~~800~~Hz (Default: ~~800Hz~~450Hz)
Low Pass Filter 2	100Hz, 350Hz, 1700Hz (Default: 1700Hz)
High Pass Filter	~~0.05Hz, 0.5Hz, or 2.5Hz (Default: 0.5Hz)~~0.85Hz
Sampling Rate	250Hz, 500Hz, 1000Hz (Default: 1000Hz)
Samples per Packet	1[a], 2, ~~or~~ 4, 8[b] (Default: 2)

[a] Only permitted when operating over a USB connection
[b] Only supported when 128 channels or less are defined

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Interactions with other medical equipment

In the clinical environment for which the ENS is intended for use, there are other equipment, including medical equipment, whose functional performance can be affected by the presence and use of this device.

- The ENS will produce a stimulation pulse on specified electrodes. This signal will disrupt neurological recordings for the duration of the stimulation period. Once stimulation ceases, neurological recordings return to baseline behavior.
- Connections of the ENS to the controlling computer, including USB 2.0 and WiFi, will produce emissions that could have an adverse effect on the performance of other nearby equipment.

	**Caution:** The device is not certified for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the device near flammable atmospheres are unknown.
	**Caution:** Do not use the device in the proximity of equipment that generates electromagnetic interference (EMI). Sources of EMI may result in (a) operational changes to the neurostimulator, causing it to turn on or off, or to reset to power-on-reset (POR) settings, and (b) a momentary increase in stimulation or intermittent stimulation, effects that may be observable by the patient.
	**Caution:** This device should not be used in proximity to magnetic resonance imaging (MRI) equipment. The consequences of exposing the device to MRI equipment are unknown.

Description of leads tested for compatibility

The Model 4NR003 ENS has been tested and is compatible with the following leads and extensions:

- **Ad-Tech Medical**
  - **SD08R-SP10X-000:** 8-contact depth; 10mm spacing (lead)
  - **L-SRL-8DIN:** 8-contact, Cambrio extension cable
  - **IG64C-SP10X-0TB:** 64-contact, single-tail LTM grid (lead)
  - **L-SRL-64BDIN:** 64-contact, Cambrio extension cable

Electromagnetic compatibility declaration

Tables 7, 8, 9, and 10 apply to the Model 4NR003 ENS.

Table 7. Guidance and manufacturer's declaration – electromagnetic emissions

The Model 4NR003 ENS is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4NR003 ENS should ensure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment – guidance**
Radio-frequency (RF) emissions CISPR 11(EN 50511)	Group 1	The model 4NR003 ENS 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 CISPR 11 (EN 50511)	Class A	The Model 4NR003 ENS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions EN 61000-3-2	Not applicable for a battery-powered device	The Model 4NR003 ENS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions EN61000-3-3	Not applicable for a battery-powered device	

Table 8. Guidance and manufacturer's declaration – electromagnetic immunity

The Model 4NR003 ENS is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4NR003 ENS should ensure that it is used in such an environment.

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD): EN 61000-4-2	±6kV contact ±8kV air	±2kV, ±4kV, ±6kV contact ±2kV, ±4kV, ±8kV 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: EN 61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines ±1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge: EN 61000-4-5	±1kV line(s) to line(s) ±2kV line(s) to earth	±1kV differential mode ±2kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Voltage dips, short interruptions and voltage variations on power supply input lines: EN 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50/60 Hz) magnetic field EN 61000-4-8	30 A/m	30 A/m	Mains power quality should be that of a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Table 9. Guidance and manufacturer's declaration – electromagnetic immunity

The Model 4NR003 ENS is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 4NR003 ENS should ensure that it is used in such an environment.

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Model 4NR003 ENS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1,2\ P$
Conducted RF EN 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d = 1,2\ P$ 80 MHz to 800 MHz $d = 2,3\ P$ 800 MHz to 2,5 GHz 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b]
Radiated RF EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

Immunity Test	EN 60601 test level	Compliance level	Electromagnetic environment – guidance
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. [a] 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 Model 4NR003 **ENS** is used exceeds the applicable RF compliance level above, the Model 4NR003 ENS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 4~~P~~NR003 ENS. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 10. Recommended separation distances between portable and mobile RF communications equipment and the Model 4NR003 ENS

The Model 4NR003 ENS is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model 4NR003 ENS can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model 4NR003 ENS as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to transmitter Power Output (meters)**			
	150 kHz to 80 MHz outside ISM bands	**150 kHz to 80 MHz in ISM bands**	**80 MHz to 800 MHz**	**800 MHz to 2,5 GHz**
W	*d = 3.5 P*	*d = 1.2 P*	*d = 1.2 P*	*D = 2.3 P*
0,01	0,35	1,2	0,12	0,23
0,1	1,1	3,8	0,38	0,73
1	3,5	12	1,2	2,3
10	11	38	3,8	7,3
100	35	120	12	23

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 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3 The recommended separation distances between portable and mobile radio-frequency (RF) communications equipment are not applicable to the equipment provided by Medtronic that have been identified as a programming component used in conjunction with the Model 4~~R~~NR003 ENS.

Means of operator and patient protection

The ENS is designed with means of protection to ensure the safety of both the patient and operator during use (per EN 60601-1), including when it is connected to a controlling computer via USB 2.0 or WiFi.

The ENS is internally powered portable medical electrical (ME) equipment when it is not USB-connected to a controlling computer. The USB connection from the controlling computer powers the device's USB port, so the device is considered Class I medical electrical equipment in this configuration.

Table 11. Means of operator and patient protections provided by Model 4NR003 ENS

ME Equipment Classification	Operator Protection(s)	Patient Protection(s)
Internally Powered	Not applicable – no connection to supply mains	(1) Reverse battery protection on battery terminals (2) AC-coupling of output signals to patient, preventing DC current to patient
Class I	ENS specified for use only with USB cables up to 3 meters in length that support electrical isolation from voltages up to 240 V (e.g. IFTOOLS ISOUSB-Cable-M).	(1) ESD protection (TVS diodes) on the USB circuitry provides protection up to15 kV (contact) and 30kV (air). (2) AC-coupling of output signals to patient, preventing DC current

Instructions for use

The ENS is used to collect neurological signals and deliver stimulation energy upon request in support of clinical research in an acute, clinical environment.

	**Caution:** Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.
	**Caution:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
	**Caution:** Use of transducers or cables, other than those specified in this document, is not recommended as use of these components may result in increased emissions or decreased immunity of the ENS.
	**Caution:** To avoid the risk of electric shock, ensure that any equipment connected directly to the ENS is only connected to supply mains with protective earth.
	**Caution:** Secure the device at all times so as to prevent blunt impacts to the device (e.g. from accidental drops). Blunt impact trauma to the device may result in device malfunction, including unexpected stimulation performance.
	**Caution:** Do not touch the pins on the ENS's lead connection interfaces, especially while also in contact with the patient. Static charges can discharge to the patient, resulting in potential harm.

	**Caution:** Do not touch the pins on the ENS's lead connection interfaces or put the pins in contact with metal objects. In addition, use care when transporting the ENS in static-prone areas (e.g. carpeted floors). If the ENS is connected to implanted patient leads, static charge discharged to the pins may pass through the leads and cause damage to patient tissue.
	**Caution:** Use the ENS only with equipment that is delivered with the device or is otherwise specified as compatible.
	**Caution:** Consult with assigned IT support personnel prior to configuring a communication session using WiFi. Wireless performance will vary based on the environment. It is recommended that the ENS be setup for WiFi communications on a channel identified by IT support personnel as having the most available bandwidth and as being least likely to interfere with other ENS or medical devices being used in the area.

Note: Before placing the ENS into operation, ensure the ENS has had time to adjust to the current temperature and environment.

Using the ENS during a research study

Ensure the ENS is powered on and then connect to it from the controlling computer. Follow the instructions on setting up communications with the controlling computer that are contained in the applicable research study protocol.

Inserting batteries into the ENS

See section "Replacing the ENS batteries~~Replacing the ENS batteries~~" for instructions.

Connecting the USB connector cable to the ENS

When used during a research study, the ENS is connected to a controlling computer equipped with the Odin Interface Software either via a USB connection or WiFi connection. The USB connector cable can be connected to the ENS to enable a USB connection to the controlling computer. Follow the instructions on setting up communications with the controlling computer that are contained in the applicable research study protocol.

	**Caution:** Use only USB cables up to 3 meters in length that support electrical isolation from voltages up to 240 V (e.g. IFTOOLS ISOUSB-Cable-M). Use of unsupported cables can cause damage to electronic components of the device and may cause an electrical shock to the patient if connected.
	**Caution:** USB is designed as a secondary communication mechanism to WiFi and should only be used when WiFi performance is inadequate for the needs of the experiment.
	**Caution:** Disconnect the controlling computer from wall power while USB-connected to the ENS. Failure to disconnect may cause a transfer of energy to the patient in the event of a power surge to the wall outlet.

- Matching the keyed slots of the USB Mini-B connector plug and the USB Mini-B connector jack, push the plug end of the connector cable fully into the USB Mini-B connector jack on the ENS. Failure to fully seat the USB connector plug may result in intermittent connectivity

Note: Attempting to connect the USB connector cable while the ENS is currently connected to the controlling computer via WiFi will result in the automatic re-establishment of the connection using USB. If sensing was enabled at the time of this action, neurological sense data will no longer be collected until the reconnection sequence is complete.

... [1]

Connecting the lead interface adapter cables to the ENS

	**Caution:** Do not pull on the cable. Pulling on the cable may break a wire or dislodge the lead. A broken wire or dislodged lead may result in loss of stimulation and may require surgery to replace the lead.
	**Caution:** Do not use the ENS with unsupported clinical EEG equipment. The ENS is capable of operating with EEG monitoring hardware that supports an input voltage of up to 17 V without damage or clipping, a minimum input impedance of 50 kΩ, and isolation from voltages up to 240 V.
	**Caution:** Use only the Blackrock Microsystems Adapter PN9770 ~~#A0263 revision 2.00~~ with the ENS. Other lead interface adapter cables have not been tested with this device, and use of these cables may result in unexpected device performance.

- Matching the keyed slots of the connector plug and the Omnetics connector jack, slowly guide the plug end of the adapter cable fully into the jack, using a side-to-side motion. The adapter plug has bi-lobe keys that ensure the plug is oriented correctly, so undue force to fully seat the plug is not necessary. After plugging in the adapter plug, perform a visual inspection to ensure the plug is fully seated (i.e. no gaps on the metal shrouds between the mating connectors).

Notes:

- If the Omnetics connector jack will not easily receive the adapter plug, perform a visual magnified examination of the plug and connector jack to ensure there are no bent pins and that pin alignment is consistent in each row.
- The ENS contains four Omnetics connector jacks labeled A-D. To avoid confusion when configuring sense and stimulation on electrodes during an experiment, make particular note of the interfacing electrodes that are connected to each Omnetics connector jack.

Configuring the ENS for sensing and stimulation

⚠	**Caution:** Evaluate the safety of stimulation to intended lead contacts prior to commencing with the research study. This can be accomplished by incrementing stimulation energy to each intended channel to observe patient side effects until side effects are observed or the intended stimulation amplitude target is reached.
⚠	**Caution:** Avoid excessive stimulation. There is a potential risk of brain tissue damage from high amplitude and wide pulse width parameter settings.

The ODIN Configuration Tool Instructions for Use, shipped separately with the Odin Research System Interface Software, provides instructions for developing a sense and stimulation channel configuration file that can be used to configure the device for sensing and stimulation during a research study. Consult this documentation and the associated research study protocol for details on configuring and running an experiment using the ENS.

To power on the ENS:

- Press and hold the power button on the upper surface of the ENS (Figure 1) until LEDs surrounding the button begin to rotate in white color (i.e. about two seconds) to indicate the device is initializing.

Notes:

- For sensing applications using a common reference, connect all “Ref” lines from each Omnetics connection jack (A-D) (Figure 4) that is in use and connect the combined signal to the reference input on the jackbox. All Omnetics connection jacks used must have the Ref lines connected for sensing to function as designed.

- Identify the Emergency Stop “Esc” key location on the controlling computer prior to starting an experiment. In the event that stimulation needs to be terminated during the experiment, this “Esc” key~~, referenced in the associated research study protocol,~~ will terminate stimulation delivery when pressed.

- Once connected to a controlling computer over USB, the ENS will refuse connection requests using WiFi. To enable the ENS to connect using WiFi once a USB session has been established, power-cycle the ENS. Take note of stored configurations, as power-cycling the ENS will reset its configuration.

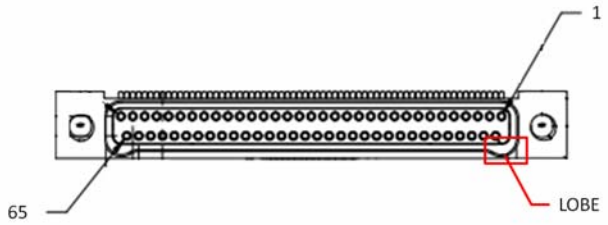

Figure 4. *Omnetics A29100-065 connector jack as viewed with the ENS top side up. Pin 65 (labeled) is the Ref line.*

Terminating stimulation delivery

The delivery of stimulation, including stimulation programmed for delivery in the future, can be terminated upon request. One method is by pressing the Emergency Stop key. The Emergency Stop key is located on the controlling computer as the "Esc" key. Take note of this key's~~e Emergency Stop key~~ location~~, referenced in the associated research study protocol,~~ prior to starting an experiment.

To terminate the administration of stimulation:

- Press the Emergency Stop key on the controlling computer. ~~Consult the research study protocol for detailed instructions.~~

OR

- Press the power button on the upper surface of the ENS (Figure 1).

⚠	**Caution:** Take note of stored configuration settings before turning off power to the ENS. Interruption of power to the ENS will cause stored configurations, including those for sensing and stimulation, to reset.

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Disconnecting lead interface adapter cables from the ENS

⚠	**Caution:** Take note of stored configuration settings before turning off power to the ENS. Interruption of power to the ENS will cause stored configurations, including those for sensing and stimulation, to reset.

1. Press the power button on the upper surface of the ENS to turn it off (Figure 1).
2. Disconnect each lead interface adapter cable from the ENS, one at a time. Slowly remove the connector plug using a side-to-side pulling motion until it is released from the jack.

... [2]

Replacing the ENS batteries

Replace the ENS batteries before each use and when the batteries are low or depleted. The battery status is displayed by LEDs (Figure 1) that surround the power button on the ENS's top surface.

Cautions:

- If batteries are replaced during a research study, stored sense and stimulation configuration may not reflect recent configurations.
- Replace batteries using the correct polarity. Reversing polarity when installing new batteries may result in unexpected device function and/or performance.
- Do not mix chemistries or brands when replacing batteries. **Only use Energizer Ultimate Lithium AA batteries when replacing the ENS batteries.** Other battery types, such as Alkaline or rechargeable, or batteries from other manufacturers, are not supported and may cause damage to the electronic components of the device.
- Take note of stored configuration settings before turning off power to the ENS. Interruption of power to the ENS will cause stored configurations, including those for sensing and stimulation, to reset.

1. End the experiment and disconnect the ENS from the controlling computer, if applicable. Consult the applicable research study protocol for instructions on ending the experiment appropriately.
2. Turn off the ENS by pressing the power button, if applicable.
3. Press into each of the battery compartment tabs to release the battery compartment cover (Figure 5). Pull the cover to remove.
4. Insert three new Energizer Ultimate Lithium AA batteries. Correct battery polarity is indicated inside the battery compartment.
5. Replace the battery compartment cover.

Notes:

- Dispose of depleted batteries according to local requirements.

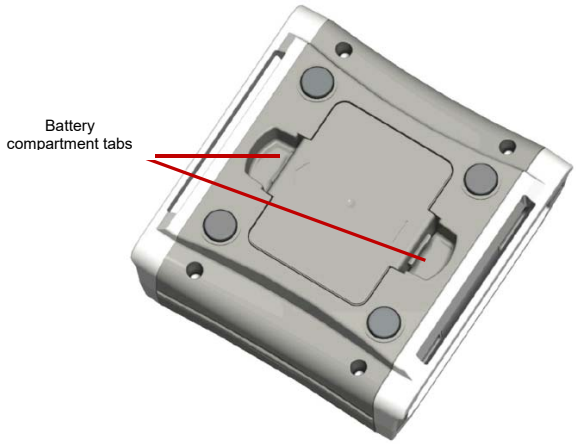

Figure 5. *Model 4NR003 ENS (underside surface shown).*

Troubleshooting

Intermittent WiFi connections

The nature of the environment may produce interference that results in intermittent or no WiFi connection from the ENS to the controlling computer. The following suggestions are recommended to remedy intermittent WiFi connections:

- Reduce or eliminate interfering sources, if possible. For example, phones or other personal items may be removed from the room, or supply mains to the controlling computer may be disconnected.
- Check the WiFi connection on the controlling computer. See the applicable research study protocol for detailed instructions.
- Move the ENS to a different area of the room where fewer interfering sources are present.
- Reconnect the ENS using a USB connection. Consult the research study protocol for instructions on configuring this connection.

Device care and storage

- Check the battery status of the ENS before each research study.
- Replace low or depleted batteries.
- Handle the device and system components with care. Do not drop, strike or step on the device or system components.
- Do not dismantle or tamper with the device.
- Store the ENS at room temperature. Avoid extreme hot or cold temperatures and direct sunlight.
- Upon completion of the research study (or if device is no longer operating as expected), contact the clinical study site coordinator to return the device. Do not dispose of devices.

Cleaning the ENS

Cautions:

- Avoid application of any chemicals to the batteries underneath the battery compartment door. The application of moisture to the batteries may cause damage to electronic components.
- The device and system components are not waterproof. Do not allow moisture to get inside the device or system components.
- Before cleaning the device, be aware that the cleaning procedures identified in this document do not protect against contamination by blood-borne pathogens or other potentially infectious materials.

1. Use a damp cloth with a 1:10 dilution of sodium hypochlorite or a 70% isopropyl alcohol wipe to clean the exterior of the ENS.
2. Wipe the ENS with a clean cloth dampened with clean water.
3. Dry with a clean cloth.

Notes:

- To wipe the recess areas around the battery compartment door, it may be necessary to remove the battery compartment door.
- The battery contacts may be cleaned periodically with a cotton swab dampened with a solution containing up to 70% isopropyl alcohol. Do not use a pencil eraser or sandpaper.

Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the ENS are not required.

The ENS contains no serviceable components. If the ENS is nonfunctional or otherwise requires repair or replacement, contact the clinical study site coordinator for instructions to return the unit.

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Dale is this still true or is the user going to be required to re-enable sensing?

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