Medtronic

VERIFY™ EXTERNAL NEUROSTIMULATOR

3531

User manual

! USA Rx only

CE 0123

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Conformité Européenne (European Conformity). This symbol means that the device fully complies with MDD 93/42/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

System meets the applicable Canadian (CAN/CSA-C22.2 No. 60601-1) electrical safety standard requirements.

Do not reuse

Consult instructions for use

Serial number

Manufacturer

Authorized representative in the European community

IEC60601-1/EN60601-1, Type BF equipment

Non-ionizing electromagnetic radiation

Temperature limitation

For USA audiences only

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

Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)

! USA **FCC Information**

The following is communications regulation information on the Model 3531 External Neurostimulator.

FCC ID: LF53531

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.

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Table of contents

Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to the Test stimulation lead implant manual packaged with the test stimulation lead for test stimulation-specific contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

! USA **Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.**

Purpose of the device

The Medtronic Model 3531 Verify External Neurostimulator (ENS) is used to evaluate a Medtronic Sacral Neuromodulation (SNM) System during lead placement or test stimulation.

Description

The Medtronic Model 3531 External Neurostimulator is a disposable, single-use device equipped with Bluetooth wireless technology, and is part of a sacral neuromodulation system.

Package contents

- External neurostimulator
- External neurostimulator boot
- AAAA alkaline batteries (4)
- Product literature
- ! USA Warranty card

Device specifications

The external neurostimulator (Figure 1) is a programmable device that delivers stimulation through one or more leads (delivered through one lead at a time). The stimulation settings are stored in programs. A program is a specific combination of pulse width, rate, and amplitude settings acting on a specific electrode combination.

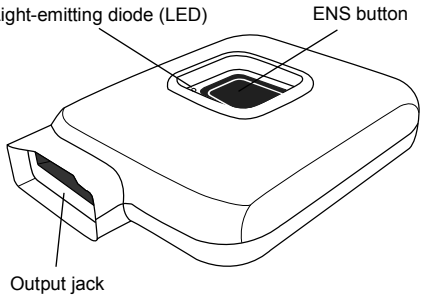

Figure 1. *Model 3531 External Neurostimulator.*

Table 1. Operating values for the Model 3531 External Neurostimulator[a]

Programmable parameter	Operating values and ranges[b]
Number of programs	1 to 3
Electrode configuration	1 to 4 electrodes as anode, cathode, or off
Amplitude	0 to 12.5 mA with 0.1-mA resolution
Amplitude – upper patient limit	Programmed value to 12.5 mA (same resolution as amplitude)
Amplitude – lower patient limit	0 mA to the programmed value (same resolution as amplitude)
Pulse width	60 to 450 µs (10-µs resolution)
Rate	3 to 130 Hz (1-Hz resolution between 3 and 30 Hz; 5-Hz resolution between 30 and 130 Hz)

[a] Selection of parameters and values is limited by the controller with regards to appropriate applications, therapies, and devices.

[b] Out-of-regulation detection may prevent the use of some parameter combinations.

Table 2. Physical characteristics of the Model 3531 External Neurostimulator[a]

Description	Value
Length	51 mm (2.0 in)
Length, including cable connector	58 mm (2.3 in)

Table 2. Physical characteristics of the Model 3531 External Neurostimulator[a] (continued)

Description	Value
Width	43 mm (1.7 in)
Thickness	15 mm (0.6 in)
Weight (with batteries)	53.9 g (1.9 oz)
Output jack	21 pin
Identification code	NLM

[a] All measurements are approximate.

Table 3. Electrical and physical characteristics for the Model 3531 External Neurostimulator

Description	Value
Power source	AAAA alkaline batteries (2)
Battery life	14 days minimum for alkaline batteries[a]
Operating type	Continuous
Degree of protection against electrical shock	Type BF
Degree of protection against fluid ingress	IP24[b]
Case material	Polycarbonate/ABS blend plastic resin
Automatic shut off[c]	Connector cable disconnected

[a] Battery life is based on 24-hour per day stimulation using 1 program: impedance = 1200 Ω, amplitude = 4.2 mA, pulse width = 210 µs, rate = 14 Hz, and multiple communications between the controller and the external neurostimulator.

[b] The ENS device, with cable fully inserted and battery door side protected either by the device being bandaged directly to the skin or by having the device in the boot or belt, meets the IP24 classification for particulate and water exposure resistance. IP classification is IPN1N2, where: N1 is 2 = protection of equipment against a solid foreign objects ≥ 12.5 mm diameter and N2 is 4 = protection of equipment against ingress of water with harmful effects of splashing.

[c] Use the controller to turn the external neurostimulator on once the condition is resolved.

Table 4. Storage, shipping, and operating conditions for the Model 3531 External Neurostimulator

Parameter	Storage	Shipping	Operating
Minimum temperature	Room temperature	-35 °C (-31 °F)	9 °C (49 °F)
Maximum temperature	Room temperature	57 °C (135 °F)	43 °C (110 °F)
Maximum humidity	—	95% (non-condensing)[a]	95% (non-condensing)[b]
Minimum atmospheric pressure	—	—	50 kPa
Maximum atmospheric pressure	—	—	106 kPa

[a] Tested at 30 °C (86 °F). Not tested at the maximum temperature.

[b] Tested at 35 °C (95 °F). Not tested at the maximum temperature.

Declaration of Conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 93/42/EEC on Medical Devices.

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

Instructions for use

The external neurostimulator is used to evaluate lead placement and stimulation settings.

⚠ **Warning:** This device was 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.

⚠ **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 modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.

⚠ **Caution:** Do not use the device in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in device function. Examples of common medical sources of EMI are magnetic resonance imaging (MRI) and lithotripsy. Powerful computer monitors, cell phones, x-ray equipment, and other monitoring equipment may also generate EMI.

Note: Turn off and dispose of the external neurostimulator after defibrillation. For more information on the effects of defibrillation on the neurostimulator, refer to the *Information for Prescribers Booklet*.

Pairing the external neurostimulator to the controller

For instructions on pairing the external neurostimulator to the controller, refer to the appropriate controller programming guide.

Using the external neurostimulator during test stimulation

When programming during test stimulation, keep the controller within 3 meters (10 feet) of the external neurostimulator. The external neurostimulator does not attach to the controller.

Using the ENS button

The **ENS** button is used to place the external neurostimulator into discovery mode to establish communication with a controller. It can also be used when you need to immediately turn off the external neurostimulator. You must use the controller to turn on the external neurostimulator. The **ENS** button is not an on/off control.

➤ Press and hold the **ENS** button for at least three seconds to turn off the external neurostimulator or to place the external neurostimulator into discovery mode.

Understanding the LED on the external neurostimulator

Once batteries are inserted into the external neurostimulator, the external neurostimulator turns on, and the light-emitting diode (LED) shines continuously for a few seconds. When the LED begins to blink, the external neurostimulator has completed initiation, has entered discovery mode, and can be paired to a controller.

Notes:

- The external neurostimulator will remain in discovery mode for 90 seconds, or until it successfully pairs with a controller, at which point the LED will stop blinking and turn off.
- The LED blinks whenever the external neurostimulator is in discovery mode, or when it receives data from a controller.
- Refer to the appropriate programming guide for more information on using the controller.

Replacing the external neurostimulator batteries

For instructions on checking the external neurostimulator batteries using the controller, refer to the appropriate controller programming guide.

△ **Caution:** Do not leave depleted batteries in the external neurostimulator. The batteries may corrode and cause damage to the electronic components.

△ **Caution:** If the device will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, causing damage to the electronic components.

Notes:

- Before inserting batteries, check for signs of battery leakage. If any residue is present, do not use.
- Stimulation settings may not reflect programming changes that were made prior to replacing the batteries.

1. If the external neurostimulator is on, use the programmer to turn the external neurostimulator off.
2. If the connector cable is attached to the external neurostimulator, disconnect the cable.
3. If the external neurostimulator is in the external neurostimulator belt or boot, remove the external neurostimulator from the belt or boot.
4. Press down lightly on the battery compartment cover, slide the cover outward, then remove the cover (Figure 2).

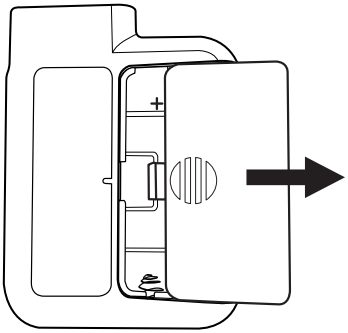

Figure 2. *Removing battery cover.*

5. Remove the depleted batteries, and insert new batteries. Correct battery polarity is indicated inside the battery compartment (Figure 3).

Note: For optimal performance, use the same AAAA alkaline batteries as those supplied by Medtronic.

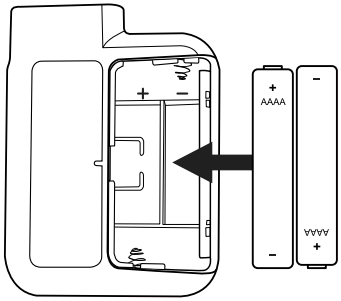

Figure 3. *Inserting new batteries.*

6. Replace the battery compartment cover, then slide the cover inward until it snaps into place (Figure 4).

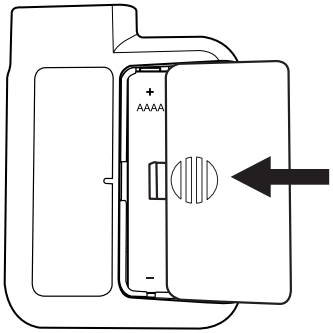

Figure 4. *Replacing battery cover.*

Notes:

- After the batteries are installed and the battery compartment cover is closed, the external neurostimulator may take up to 6 seconds for device initiation. Stimulation is not available until device initiation is complete.
- Dispose of depleted batteries according to local requirements.

7. Use the controller to turn stimulation on. For instructions on using the controller to program the external neurostimulator, refer to the Medtronic Clinician Programming Guide packaged with the controller.

Using the external neurostimulator boot

The external neurostimulator boot is a single-use accessory. The external neurostimulator boot is attached to an adhesive pad, which can be used to adhere the external neurostimulator to the patient's body.

Note: Schedule a visit during the test stimulation phase to replace the initial boot with a new boot.

1. Ensure that no cable is attached to the external neurostimulator. The external neurostimulator can not be inserted into the boot with a cable attached.
2. Insert the external neurostimulator into the boot (Figure 5).

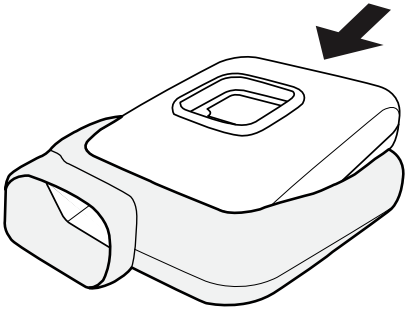

Figure 5. *Inserting external neurostimulator into boot.*

3. Clean the patient's skin, if necessary, at the location where the external neurostimulator boot is to be placed.
4. Peel off the adhesive backing of the adhesive pad and apply the external neurostimulator boot to the patient's skin. Press firmly to ensure complete contact and adhesion.

   Notes:

   - If adhesive is dry or does adhere to the patient's skin, discard the boot and use a different boot.
   - The external neurostimulator belt cannot be used with the external neurostimulator boot.

Using the external neurostimulator belt

The external neurostimulator belt is a single-use device that can be used to hold the external neurostimulator near the patient's body.

1. Insert the external neurostimulator, with cable attached, into the pouch on the external neurostimulator belt and snap the pouch closed (Figure 6).

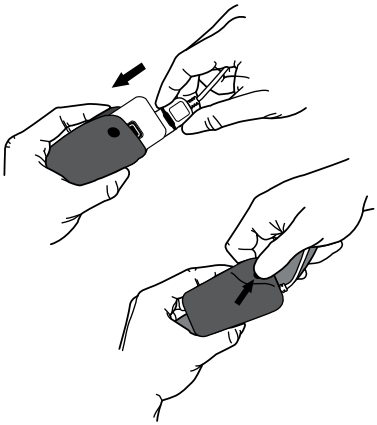

Figure 6. *Inserting external neurostimulator into belt.*

Note: Leave enough slack in the cable to allow the patient to adjust or move the belt as needed without causing additional strain on the connections.

2. Coil and place any excess cable length into the pouch of the external neurostimulator belt.
3. Fasten the external neurostimulator belt around the patient's waist.

   Note: The belt can be adjusted for patient comfort and fit.

Device care and storage

- Keep new batteries available. For optimal performance, use the same AAAA alkaline batteries as those supplied by Medtronic.
- Use the controller to check the external neurostimulator battery level daily. For instruction on using the controller, refer to the Medtronic Clinician Programming Guide packaged with the controller.
- Replace low or depleted batteries.
- Handle the device and system components with care. Do not drop, strike or step on the device.
- Do not dismantle or tamper with the device or system components.
- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- Store the external neurostimulator at room temperature. Avoid extreme hot or cold temperatures and direct sunlight.
- The device and system components are not waterproof. Do not allow moisture to get inside the device or system components. With the patient cable connected, the external neurostimulator is water-resistant, but is not waterproof. Sponge baths are acceptable.
- Dispose of depleted batteries and devices according to local requirements.

Safety and technical checks

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

The external neurostimulator contains no serviceable components. If the external neurostimulator requires repair or is nonfunctional, send it to the appropriate address.

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