Medtronic

EXTERNAL NEUROSTIMULATOR

37022

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.

The use of this device might be subject to individual country licensing regimes in Europe.

System meets the applicable Canadian [C22.2-601.1-M90 (R2001)] electrical safety standard requirements.

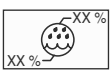
Caution: consult accompanying documents

Serial number

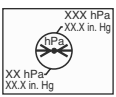
IEC60601-1/EN60601-1, Type BF equipment

Non-ionizing electromagnetic radiation

Storage temperature



Relative humidity



Atmospheric pressure

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.)

Medtronic® is a registered trademark of Medtronic, Inc.

! USA **FCC Information**

The following is communications regulation information on the Model 37021 External Neurostimulator.

FCC ID: LF537021

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.

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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 System Eligibility, Battery Longevity, Specifications reference manual packaged with the software application card for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

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

Purpose of the device

The Medtronic Model 37022 External Neurostimulator is used to evaluate a Medtronic Neurostimulation System during lead placement or test stimulation. The external neurostimulator and the implantable neurostimulator produce comparable symptom suppression when set to the same parameter settings.

Device description

The Medtronic Model 37022 External Neurostimulator is part of a neurostimulation system.

Package contents

- External neurostimulator
- External neurostimulator holder
- 2 AA alkaline batteries
- Product literature
- Warranty card (USA only)

Device specifications

The external neurostimulator (Figure 1) is a programmable device that delivers stimulation through one or more leads. 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. Up to four programs can be combined into a group. When using more than one program, the pulses are delivered sequentially—first a pulse from one program, then a pulse from the next program.

Pulse width, amplitude, and electrode polarity for each program within a group can have different values. Rate, rate limits, SoftStart/Stop value, and cycling for each program within a group have the same values.

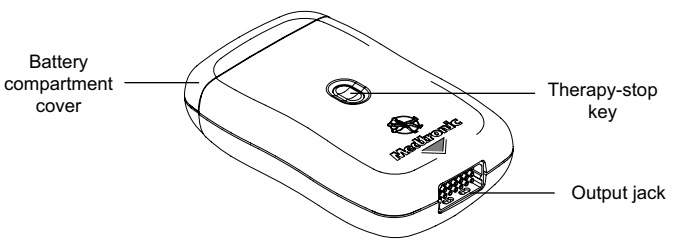

Figure 1. *Model 37022 external neurostimulator.*

Table 1. Operating values for the Model 37022 external neurostimulator[a]

Programmable parameter	Operating range and resolution[b]
Number of defined groups	1 to 8[c]
Number of programs per group	1 to 4[c]
Electrode configuration	2 to 16 electrodes as anode, cathode, or OFF
Amplitude	0 to 10.5 V with 0.05-V or 0.1-V resolution 0 to 25.5 mA with 0.1-mA resolution
Amplitude – upper patient limit	Programmed value to 10.5 V (same resolution as amplitude) Programmed value to 25.5 mA (same resolution as amplitude)
Amplitude – lower patient limit	0 V to the programmed value (same resolution as amplitude) 0 mA to the programmed value (same resolution as amplitude)
Pulse width	60 to 1000 µs (10-µs resolution)
Pulse width – upper patient limit	Programmed value to 1000 µs (10-µs resolution)
Pulse width – lower patient limit	60 µs to the programmed value (10 µs resolution)
Rate	2 to 1000 Hz[d]
Rate – upper patient limit	Programmed value to 1000 Hz (same resolution as rate)
Rate – lower patient limit	2 to the programmed value
SoftStart/Stop	OFF, ON: 1, 2, 4, or 8 second ramp duration
Cycling	OFF, ON: 0.1 s to 24 hrs
Scheduled therapy	OFF, ON: 1 to 8 events per 24-h period

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

[b] Interlocks and out-of-regulation detection will prevent the use of some parameter combinations.

[c] No more than 16 programs may be defined within the 8 groups.

[d] Rate and rate upper limit for the ENS is limited to 500 Hz when two programs are active in a group, 330 Hz when three programs are active in a group and to 250 Hz when four programs are active in a group.

Table 2. Physical characteristics of the Model 37022 external neurostimulator[a]

Description	Value
Length	89 mm (3.5 in)
Width	54 mm (2.1 in)
Thickness	28 mm (1.1 in)

Table 2. Physical characteristics of the Model 37022 external neurostimulator[a]

Description	Value
Weight (with batteries)	100 g (3.5 oz)
Output jack	21 pin
Identification code	NJS

[a] All measurements are approximate.

Table 3. External neurostimulator electrical and operating characteristics

Description	Value
Power source	2 AA alkaline batteries
Battery life	144 hours minimum (21 days average) for alkaline batteries[a]
Operating type	Continuous
Degree of protection against electrical shock	Type BF
Case material	Polycarbonate/ABS blend plastic resin
Automatic shut off[b]	▪ Moisture detected ▪ Battery door open ▪ Connector cable disconnected ▪ Connector open (snap-lid)

[a] Battery life is based on 24-hour per day stimulation using 1 group containing 3 active programs. For all programs: impedance = 500 Ω, Amp = 4.0 V, PW = 330 µs, Rate = 70 Hz, Cycling = off.

[b] Use the clinician programmer or patient programmer to turn the external neurostimulator ON once the condition is resolved.

Table 4. External neurostimulator storage and operating conditions

Parameter	Storage	Operating
Minimum temperature	-40°C (-40°F)	10°C (50°F)
Maximum temperature	65°C (149°F)	44°C (111°F)
Maximum humidity	95% (non-condensing)	75% (non-condensing)
Minimum atmospheric pressure	70 kPa	70 kPa
Maximum atmospheric pressure	106 kPa	106 kPa

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.

△ **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.

Replacing the external neurostimulator batteries

Replace the external neurostimulator batteries before each test stimulation and when the batteries are low or depleted. The battery level is shown on the clinician programmer screen.

△ **Cautions:**

- When replacing batteries during test stimulation, insert the new batteries within 15 minutes of removing the old batteries. If the batteries are not replaced within 15 minutes, the neurostimulator may reset. When a neurostimulator resets, stimulation history is no longer available, and the stimulation settings may not reflect recent programming changes.
- Do not leave depleted batteries in the external neurostimulator. The batteries may corrode and cause damage to the electronic components.
- 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.

1. If the external neurostimulator is ON, use the clinician programmer or patient programmer to turn the neurostimulator OFF.
2. If the connector cable is attached to the external neurostimulator, disconnect the cable.
3. If the neurostimulator is in the external neurostimulator holder, remove the neurostimulator from the holder.
4. Press down lightly on the battery compartment cover, push the cover in the direction of the arrow, then swing the cover open.
5. Insert 2 new AA alkaline batteries. Correct battery polarity is indicated on the battery compartment cover.
6. Replace the battery compartment cover, then slide the cover in the opposite direction of the arrow until it snaps into place.
7. Reconnect the cable. For detailed instructions, see page 10.

Notes:

- After the batteries are installed and the battery compartment cover is closed, the neurostimulator may take up to 60 seconds for device initiation. Stimulation is not available until device initiation is complete.
- Dispose of depleted batteries and worn out devices according to local requirements.

Attaching the external neurostimulator and connector cable to the clinician programmer

The external neurostimulator is usually attached to the clinician programmer during lead placement.

1. Locate the programming head on the back of the clinician programmer.
2. Place the external neurostimulator so it fits into the slot on the programming head.
3. Turn the neurostimulator so the output jack is positioned as displayed in Figure 2.

   Note: Facing the output jack away from the clinician programmer properly aligns the two devices for communication and prevents the cable from resting on the programmer.

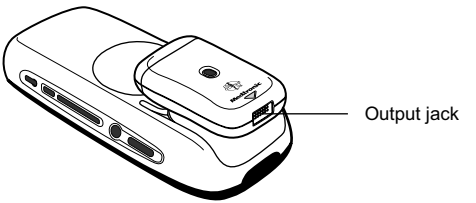

Figure 2. *External neurostimulator attached to the clinician programmer.*

Using the external neurostimulator during test stimulation

When programming during test stimulation, hold the clinician programmer programming head over the external neurostimulator. The neurostimulator does not need to be attached to the programmer.

Connecting the connector cable to the external neurostimulator

△ **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.

➤ Matching the keyed slots of the cable plug and the output jack, push the plug end of the connector cable fully into the output jack on the external neurostimulator.

Using the THERAPY-STOP key

The red THERAPY-STOP key can be used when you need to immediately turn OFF the external neurostimulator. You must use either the patient or clinician programmer to turn the external neurostimulator ON again. The THERAPY-STOP key is not an ON/OFF control.

➤ Press the red THERAPY-STOP key.

Disconnecting the connector cable from the external neurostimulator

1. Using the clinician programmer or patient programmer, turn the external neurostimulator OFF.

2. Disconnect the connector cable from the external neurostimulator.

Device care and storage

- Keep new batteries available.
- Use the patient programmer daily to check the external neurostimulator batteries.
- Replace low or depleted batteries.
- Handle the device with care. Do not drop, strike or step on the device.
- Do not dismantle or tamper with the device.
- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- The battery contacts may be cleaned periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Store the external neurostimulator at room temperature. Avoid extreme hot or cold temperatures and direct sunlight.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Dispose of depleted batteries and worn out 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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