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		Writer Suzanne Dawidowicz	Date 19 August 2004
Part No.	Part No. Rev	Comments	
A01560004	A	Release for US/OUS Market Release Submissions	

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- Grade #1, 80 lb. white gloss coated cover stock, minimum brightness level: 89

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- 60 lb. white smooth opaque text stock

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- N/A

2. Colors: To confirm all colors, graphics and text, refer to electronic file

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- 4-color cover and solid gloss varnish

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4. Type of Binding: Clear plastic coil, MWE lay-flat, or perfect bound

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Medtronic

EXTERNAL NEUROSTIMULATOR

37021

Test stimulation patient guide



! USA Rx only



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FCC Information

The following is communications regulation information on the Model 37021 external neurostimulator.

FCC ID: LF537021

This device complies with Part 15 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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Label symbols

Explanation of symbols on products and packaging. Refer to the appropriate product to see symbols that apply.



CE
0123

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.



IEC 60601-1/EN60601-1, Type BF Equipment



Caution, consult accompanying documents



Non-ionizing electromagnetic radiation



For USA audiences only

Label symbols

6

English 37021 2004-08



1 Introduction

Purpose of the device

The Model 37021 external neurostimulator is designed to evaluate the success of Medtronic neurostimulation systems for pain therapy prior to implant. The external neurostimulator provides the same output characteristics as the Medtronic Restore Neurostimulation System for Pain Therapy.



The Medtronic neurostimulation system is intended to provide electrical stimulation to relieve severe, intractable pain. The Medtronic neurostimulation system for pain therapy indications, contraindications, risks and benefits, warnings, precautions, and individualization of treatment information are located in the *Model 37742 Patient Programmer: Pain Therapy User Manual*.

Precautions

When operating an external neurostimulator, use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using a battery-powered device near flammable or explosive atmospheres are unknown.

How to use this guide

For over 30 years, stimulation has helped thousands of patients manage their pain and improve their quality of life. Test stimulation will determine if stimulation is helpful for you. Stimulation will not cure your pain. It may, however, reduce your pain to a tolerable level. As a result, you may be able to resume your daily activities.

This guide includes the following information:

- Chapter 1, “Introduction,” provides an overview and goals of test stimulation.
- Chapter 2, “Using your test stimulation system,” describes how to use your external neurostimulator.
- Chapter 3, “Your daily activities,” gives recommendations regarding your daily activities during test stimulation.

Ask your doctor to explain anything that is unclear.

Test stimulation overview

Your pain is unique to you. Because pain relief can only be evaluated by you, your doctor has prescribed a test stimulation period. Test stimulation is designed to help you and your doctor evaluate the benefits of stimulation for managing your pain.

Some doctors may prescribe three to five days for test stimulation; others may prescribe more days. Your doctor will

determine the number of days that is best for you.

Test stimulation allows you to experience stimulation during your daily activities. Your doctor may ask you to keep a log of how you feel at different times during the day. The log helps your doctor determine if the stimulation is effective for managing your pain.

If you experience adequate pain relief during test stimulation and you are comfortable using the system, your doctor may decide to implant a neurostimulation system.

Test stimulation goals

The goals of a test stimulation are to determine:

- If stimulation covers your body's painful areas
- If you are comfortable with the sensation of stimulation
- If you can use the patient programmer to control your stimulation

Patient guides

In addition to the information contained in this guide, your clinician should have provided you with the following patient materials:

- *Medtronic Model 37742 Patient Programmer: Pain Therapy User Manual.*
This manual provides an overview of how stimulation works, a detailed description of how to use your patient programmer, and troubleshooting steps.
- *Medtronic Model 37742 Patient Programmer: Quick Reference Guide.*
This guide provides basic, step-by-step instructions on how to use your patient programmer.

Review these materials and keep them in a convenient place during test stimulation.

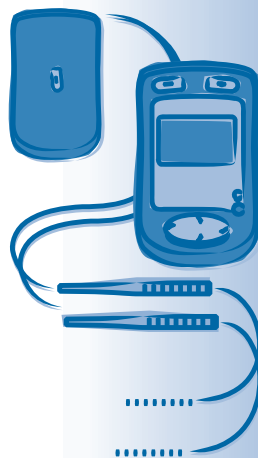


2 Using your test stimulation system

Knowing your system components

For test stimulation, your clinician will provide you with the following components:

- External neurostimulator
 - Two AA alkaline batteries (LR6)^a
- Snap-lid connector cable (cable)
- Patient programmer
 - Two AAA alkaline batteries (LR03)^a
- External neurostimulator holder with belt clip



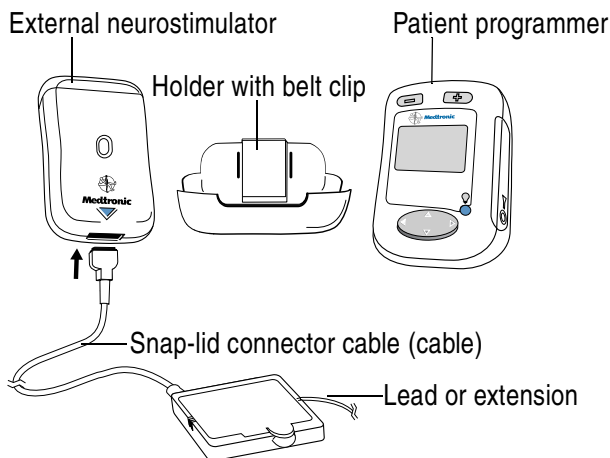


Figure 2.1 Test stimulation system components.

Using your external neurostimulator and accessories

This section provides you with the instructions for:

- Using the external neurostimulator holder
- Checking the external neurostimulator batteries
- Replacing the external neurostimulator batteries
- Using the THERAPY-STOP key
- Reconnecting the cable to the external neurostimulator

Using the external neurostimulator holder

Use the external neurostimulator holder to carry the external neurostimulator on your belt or garment.

1. Slide the external neurostimulator holder over your belt or garment (Figure 2.2).

Note: A belt with device pouches is available as an option. Refer to the instructions provided with the belt for additional information.

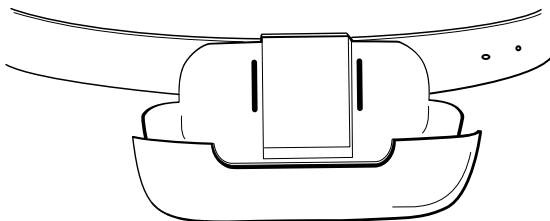


Figure 2.2 Slide the external neurostimulator holder over your belt or garment.

2. With the triangles on the cable plug and the external neurostimulator pointing toward each other (Figure 2.3), gently insert the plug fully into the output jack.

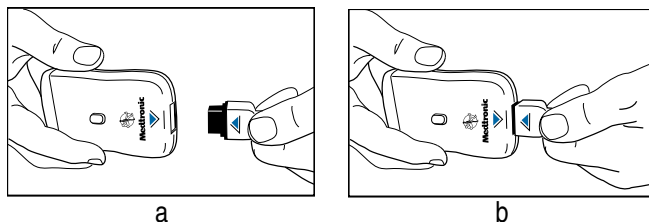


Figure 2.3 Insert the plug into the output jack.

3. Place the external neurostimulator into the holder with the red THERAPY-STOP key facing out (Figure 2.4).

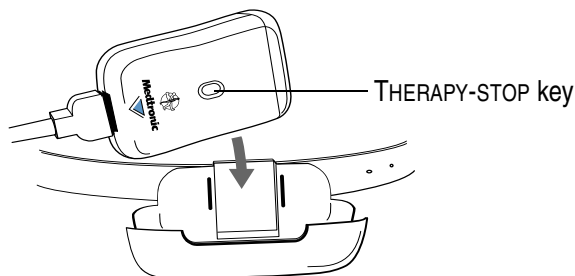


Figure 2.4 Place the external neurostimulator into the holder.

Checking the external neurostimulator batteries

Use your patient programmer to check your external neurostimulator battery level every day. For instructions on checking the external neurostimulator battery level, refer to the manual packaged with the patient programmer.

If the external neurostimulator batteries need immediate replacement, the patient programmer will display an information or warning screen. Information and warning screens are described in the Troubleshooting section of the manual packaged with your patient programmer.

If test stimulation lasts seven days or less, you should not need to replace your batteries. Battery usage depends on your specific therapy settings and length of test stimulation.

Replacing the external neurostimulator batteries

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.

- Before installing batteries, always decrease all amplitudes to the lowest setting, turn OFF the external neurostimulator and then disconnect the cable from the external neurostimulator to prevent possible uncomfortable or unexpected stimulation (jolting or shocking sensation) when stimulation is turned ON.

Using your test stimulation system 2

1. Use your patient programmer to decrease all amplitudes and turn OFF the external neurostimulator.
2. Remove the external neurostimulator from the holder.
3. Gently pull the cable plug from the output jack.

△ **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.

4. Press down lightly on the battery compartment cover (Figure 2.5a).

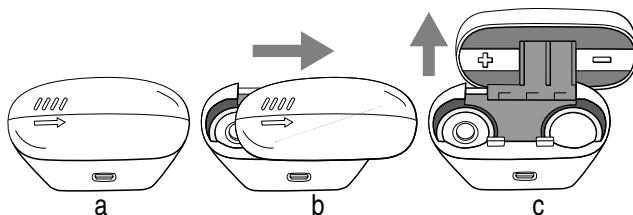


Figure 2.5 Open the battery compartment cover.

5. Push the cover in the direction of the arrow, then swing the cover open (Figure 2.5b, c).
6. Remove the depleted batteries and insert two new AA alkaline batteries into the battery compartment (Figure 2.5c).

Note: Match the battery polarity to the positive (+) and negative (–) markings on the inside of the battery compartment cover (Figure 2.5c).

7. Push down the battery compartment cover until it clicks into position. Then slide the cover back in the opposite direction of the arrow until it closes.
8. Reconnect the cable. (For detailed instructions, see “Reconnecting the cable to the external neurostimulator” on page 23.)
9. Place the external neurostimulator into the holder.

Note: After the batteries are installed and the battery compartment cover is closed, stimulation may not be available for up to 60 seconds.
10. Use the patient programmer to turn ON your external neurostimulator.
11. Dispose of depleted batteries according to local requirements.

Using the THERAPY-STOP key

Typically, you will use the patient programmer to turn stimulation OFF. However, if you need to turn stimulation OFF immediately, press the red THERAPY-STOP key (Figure 2.6). You must use the patient programmer to turn the external neurostimulator ON again.

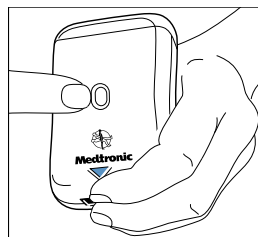



Figure 2.6 Use the THERAPY-STOP key to immediately turn stimulation OFF.

Reconnecting the cable to the external neurostimulator

If the cable plug is disconnected from the external neurostimulator, stimulation will stop.

1. With the triangles on the cable plug and the external neurostimulator pointing toward each other, gently insert the plug fully into the output jack (Figure 2.7).

 **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.

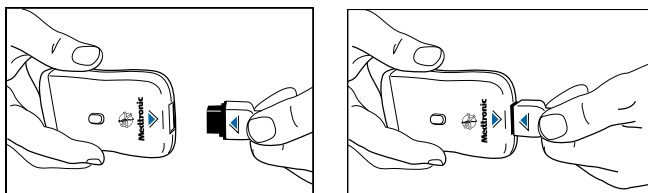


Figure 2.7 Insert the plug into the output jack.

2. Use your patient programmer to turn stimulation ON.

Specifications

Table 2.1 External neurostimulator specifications

Item	Specification
Power source	2 AA alkaline batteries (non-rechargeable, LR6)
Battery life	144 hours minimum (21 days average) for alkaline batteries
Operating temperature	+10°C to +44°C (+50°F to +111°F)
Storage temperature	−40°C to +65°C (−40°F to +149°F)
Relative humidity	30% to 75% (operating) 10% to 95% (storage)
Operating atmospheric pressure	700 hPa to 1060 hPa (20.7 in. Hg to 31.3 in. Hg)
Storage atmospheric pressure	700 hPa to 1060 hPa (20.7 in. Hg to 31.3 in. Hg)
Size	Approximately 8.9 x 5.4 x 2.8 cm (3.5 in. x 2.1 in. x 1.1 in.)

Using your test stimulation system 2

Table 2.1 External neurostimulator specifications
(continued)

Item	Specification
Weight, including batteries	Approximately 100 g (3.5 oz.)
Mode of operation	Continuous
Case material	Polycarbonate/ABS blend plastic resin
External neurostimulator automatically shuts OFF ^a when:	
<ul style="list-style-type: none">• Device detects moisture• Battery door opens• Snap-lid connector cable is not connected• Snap-lid connector opens	

^a Use the patient programmer to turn the external neurostimulator ON when the condition is resolved.

Declaration of Conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5EC 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



3 Your daily activities

What you should know about your activities

To reduce the risk of moving your implanted lead(s) after surgery, always follow your clinician's instructions during test stimulation.

Read and understand this patient guide and the other patient materials about your system.

Keep a record of your stimulation parameter settings, daily activities, and pain relief.



- Do not pull on the cable or lead.
- Keep the device out of the reach of children.
- 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 device is not waterproof. Do not allow moisture to get inside the device.

Physical activities

To reduce the risk of moving your implanted lead(s), always follow your clinician's instructions and these guidelines:

- Limit your physical activities to low or moderate levels.
- Avoid reaching over your head.

- Avoid turning side to side.
- Avoid climbing too many stairs.
- Avoid sitting in a chair for a long period of time.
- Avoid sudden, rapid movements such as twisting, stretching, or bending.

Note: You can move your body in bed without twisting by moving your shoulders and hips at the same time with a 'log-rolling' movement. Ask your clinician to teach this movement to you while you are in the hospital.

- Avoid bending forward, backward, or from side to side.
- Avoid lifting more than 2.3 kilograms (5 pounds).
- Talk to your doctor about when it is appropriate for you to resume sexual activity.

Incision care

- Keep your incision site(s) dry by taking sponge baths instead of showers to help avoid infections.
- Follow your clinician's instructions about cleaning the incision site(s) or changing dressings.
- Follow your clinician's advice about managing your incision pain.
- Call your clinician if you notice any of these signs of an infection:
 - Increased pain in your incision
 - Fever
 - Chills
 - Pus
 - Redness

Sleeping

- Do not sleep on your stomach.
- Sleep on your back or on the side opposite the device.
- Use a firm mattress that supports your legs and back equally.

What changes in sensation to expect during test stimulation

The sensation of stimulation is different from person to person. Most people report a steady, tingling sensation in the area of their pain.

Generally, people experience a constant sensation of stimulation. However you may feel some normal stimulation changes when you suddenly move or change position.

Some movements, such as leaning back, may cause the lead to move closer to your spinal cord. These movements can increase your sensation of stimulation. Other movements may cause the lead to move

further away from your spinal cord. These movements may decrease your sensation of stimulation.

Typically, you will use the patient programmer to turn stimulation OFF. However, if you feel a sudden and unpleasant change in stimulation, press the red THERAPY-STOP key on your external neurostimulator to turn OFF the stimulation immediately.

If you use the red THERAPY-STOP key, you must use the patient programmer to turn your stimulation ON again.

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