



Medtronic

Itrel[®] EZ[™] Model 7434A Patient Programmer

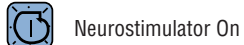


User Manual
Rx Only

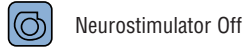
Explanation of Symbols on Products and Packaging

Refer to the appropriate product to see symbols that apply.

Keypad Symbols



Neurostimulator On



Neurostimulator Off

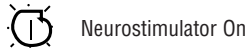


Decrease

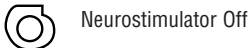


Increase

Status Light Symbols



Neurostimulator On



Neurostimulator Off

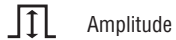


Neurostimulator Battery



Programmer Battery

Stimulation Control Switch Symbols



Amplitude

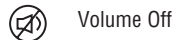


Rate

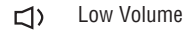


Pulse Width

Beeper Volume Control Switch Symbols



Volume Off



Low Volume



High Volume

Miscellaneous Symbols



Positioning Symbol



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



Antenna Connector



Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 90/385/EEC.



For U.S. audiences only.



Equipment has been tested and accepted for listing under the Canadian Standard Association, for distribution in Canada.



Storage Temperature



Atmospheric Pressure



Relative Humidity



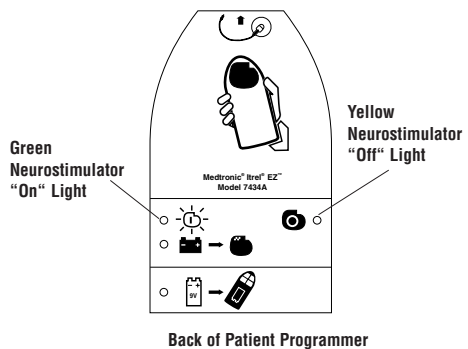
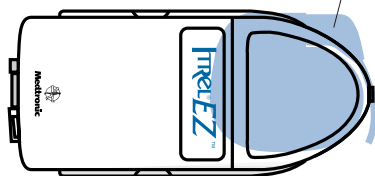
Attention, see accompanying documents

Itrel® EZ™ Patient Programmer

Quick Programming Guide

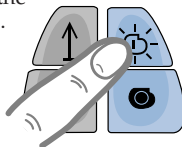
To turn the neurostimulator on or off:

- 1 Place the programmer over your neurostimulator. Location of Neurostimulator



- 2 To turn the neurostimulator on:

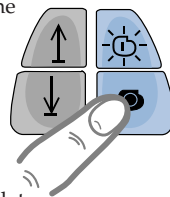
a) Press the Neurostimulator **On** key. Listen for the confirmation beep.



b) Check that the green Neurostimulator **On** light is lit. This light stays on for 8 seconds after you release the key.

- 3 To turn the neurostimulator off:




a) Press the Neurostimulator **Off** key. Listen for the confirmation beep.

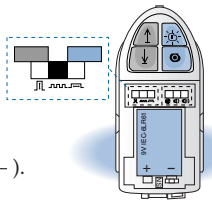


b) Check that the yellow Neurostimulator **Off** light is lit. This light stays on for 8 seconds after you release the key.

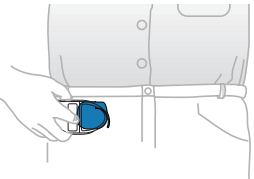
To adjust amplitude, rate, or pulse width:

1 Remove the battery compartment cover.

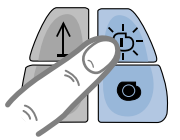
2 Select the stimulation setting: amplitude (), rate (), or pulse width ().





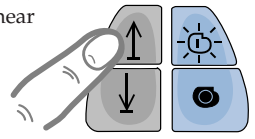
3 Place the programmer over your neurostimulator.



4 Press the neurostimulator **On** key. Listen for the confirmation beep.



5 Press the Increase () or the Decrease () key to make a change. You should hear one beep for each change.



6 Repeat steps 2-5 for other stimulation settings. Replace the battery cover.

If the patient programmer beeps:

SOUND	ACTION
One beep	You have pressed the On/Off or Increase/Decrease key and the change was received by the neurostimulator.
Three rapid beeps	Indicates one of the following: <ul style="list-style-type: none"> You tried to adjust the lowest neurostimulator beyond their highest settings. You tried to increase stimulation with the neurostimulator turned off.



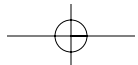
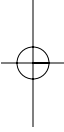
A COMPANY DEDICATED TO PATIENTS

Medtronic was founded in 1949 by Earl Bakken, a graduate student in electrical engineering, and his brother-in-law, Palmer J. Hermundslie. Today Medtronic is the world leader in medical technology, pioneering therapies that restore health, extend life, and alleviate pain.

From its modest beginnings in a 600-square-foot Minneapolis garage, we have transformed Medtronic into a worldwide company that serves customers in more than 120 countries. Each year, millions of patients are treated with Medtronic products and therapies. We invest almost \$500 million each year in research and development, working closely with the world's leading physicians and scientists to enhance our current products and therapies, and to develop new ones. Although we are a large company, individual patients and their needs are still the driving force behind what we do and how we do it.

Our goal is to improve the quality of your life. This booklet, which provides information about your stimulation system, is one small way we try to help.

Welcome to the Medtronic family. We wish you well.



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 **General Warning**

The Medtronic® Itrel® EZ™ Model 7434A Patient Programmer (the “Programmer”) is designed to program the adjustable parameters of the Medtronic® Itrel® 3 Implantable Neurostimulator (the “neurostimulator”). Do not attempt to use the programmer on another device (for example, a cardiac pacemaker). Radio signals from the patient programmer may interfere with the performance of other implantable devices.

FCC INFORMATION

The following is communications regulation information on the Itrel® EZ™ Model 7434A Patient Programmer.

FCC ID: LF57434A

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.

ABOUT THIS BOOKLET

For over 30 years, **stimulation** has helped thousands of patients manage their pain. This has also improved their quality of life. Your **stimulation system** may be used with other pain treatments like physical therapy or medicine. 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 booklet provides you with the following:

- Indications, contraindications, warnings, precautions, risks of surgery, possible side effects, changes in therapy, and possible device complications
- What to expect as you recover from surgery
- Definition of pain and stimulation
- Description of your implanted system and how it works to manage your pain
- Description of your patient programmer, and how to use it and care for it
- Steps to take to help you solve problems or identify when you should call your doctor
- How to live with your stimulation system
- Answers to common questions
- Important terms that appear as **bold** in text; these terms are listed in the Glossary at the end of this booklet.

Ask your doctor to explain anything that is unclear.

INTRODUCTION

Indications

The Medtronic® Itrel® 3 System is indicated as an aid in the management of chronic, intractable pain of the trunk or limbs.

Patients should be carefully selected to assure that their pain is of physiologic origin. Also, patients must be appropriate candidates for surgery.

Caution

All other uses remain investigational.

Contraindications

Implantation of an Itrel 3 System is contraindicated for:

- Patients for whom trial stimulation is unsuccessful.
- Patients who are unable to properly operate the system.

Warnings

Case Damage—If the neurostimulator case is pierced, severe burns could result.

Equipment Operation—Do not use potentially dangerous equipment (cars, power tools, etc.) when your neurostimulator is on. What may feel like a sudden increase in stimulation (“jolt” or “shock”) could cause you to lose control of the equipment you are using. Turn the neurostimulator off and set the amplitude to the lowest setting.

Postural Changes—As your spine moves, you may sense an increase or decrease in the stimulation. It may seem as though the neurostimulator is turning on or off. When you bend over or move suddenly, you may even feel an uncomfortable “jolt” or “shock.”

Pregnancy—Safety for use during pregnancy or delivery has not been established.

Theft Detectors and Screening Devices—Use care when approaching theft detectors and security arches (such as those found in airports, libraries, and some department stores) as these devices can cause momentary, uncomfortable, or painful stimulation. Similarly, avoid airport security wands.

When approaching these devices do the following:

1. Show your patient identification card to security staff. Ask that you be allowed to bypass the security device, request a hand search, or ask that the security device be turned off.
2. If passing through the security device is unavoidable, turn the neurostimulator off.
3. Reduce the amplitude to the lowest setting.
4. Approach the security device slowly. If any stimulation is felt, back out of the security device immediately without changing body position. If no stimulation is felt, move quickly through to the other side.

Precautions

Patient Management—To ensure the most benefit from your system, regular appointments with your doctor are recommended.

Medical Procedures—Some medical procedures can damage the neurostimulation system or can cause changes to the system which may produce discomfort, pain, or injury. Consult your doctor about risks and benefits of procedures such as:

- Electrosurgery (surgery performed using electrical methods)
- Diathermy (heat treatment)
- Lithotripsy (the crushing of a blockage within the urinary tract using electrical methods)
- Radiation therapy (that is, cancer treatment)
- Magnetic resonance imaging (MRI)—not recommended
- Defibrillation (electric shock to the heart)

Electromagnetic Interference (EMI)—Strong electrical fields, such as those produced by radio towers or some industrial equipment, can affect the function of your neurostimulator. This can cause uncomfortable stimulation (a “jolt” or “shock”). This problem is called electromagnetic interference, or EMI.

High/Low Pressure Effects—The effects of high/low pressure (that is, scuba diving, unpressurized airplanes) on patients with an implanted neurostimulation system are unknown.

Home Appliances—Be sure that appliances and equipment are properly installed and in good working condition before using them.

Occupational Environments—Strong interference could cause your neurostimulator to deliver inappropriate or additional stimulation to your spinal cord. Turning the neurostimulator off may reduce the effect of interference. Devices or equipment to avoid are theft detectors, airport/security screening devices, electric arc welding equipment, electric substations and power generators, CB or ham radio antennas, electric induction heaters used in industry to bend plastic, TV/radio transmitting towers, or electric steel furnaces.

Risks of Surgery

Implanting the Irel 3 System has the same risks as any other neurostimulation implant procedure. These risks include:

- Spinal fluid leak, headache
- Fluid collection (seroma) or bruising (hematoma) at the neurostimulator site
- Bleeding near the spinal cord (epidural hemorrhage or hematoma) or paralysis
- Infection

Possible Side Effects

Side effects of spinal cord stimulation are usually mild and go away when stimulation is turned off. Possible side effects include:

- Chest wall stimulation
- Uncomfortable stimulation
- Jolting or shocking sensation
- Pain at the surgery sites

Changes in Therapy

There may be changes in the level of your pain control over time. In most cases, your doctor can correct these changes without surgery. However, it is possible that surgery may be required.

Possible Device Complications

- There may be pain, redness, or swelling at the neurostimulator site more than 6 weeks after surgery.
- The lead may move; surgery may be needed to reposition the lead.
- The system may wear through your skin; this can cause an infection or scarring.
- Pain control may decrease or stop due to device problems. One example is the lead or extension wires could break.

Note: Do not twist or turn the system through your skin; this can disconnect or damage the system.

- Your body may have an allergic response to implanted materials.

RECOVERING FROM SURGERY

Healing

It takes several weeks to heal from surgery. You will feel some discomfort from the incision(s). You will also have some pain at the **neurostimulator** site for 2 to 6 weeks. This pain is normal.

Physical Therapy and Medications

Your physician may also prescribe physical therapy, medication, or both to help manage your pain. Always follow your doctor's instructions for the therapy(ies) prescribed.

Activities

During your recovery (about 6 weeks), follow your doctor's advice. Avoid activities where you must bend, stretch, or twist your body; this can move your **lead** and alter your stimulation.

To prevent lead movement, **AVOID** the following activities during your recovery:

- Lying on your stomach
- Reaching over your head
- Turning from side to side
- Bending forward, backward, or from side to side
- Lifting more than 5 pounds

As you begin to feel better, you should be able to return to activities such as:

- Bathing or showering
- Sexual activity
- Working at home or at your business
- Hobbies or other activities such as walking, gardening, cycling, or swimming
- Traveling

Discuss any type of strenuous activity with your doctor first, to avoid any possible damage to your system. Remember that returning to your daily activities should make you feel better, not worse.

Note: As you adjust to life with better pain control, you may want to try activities that you could not perform before your surgery. Discuss this with your doctor first.

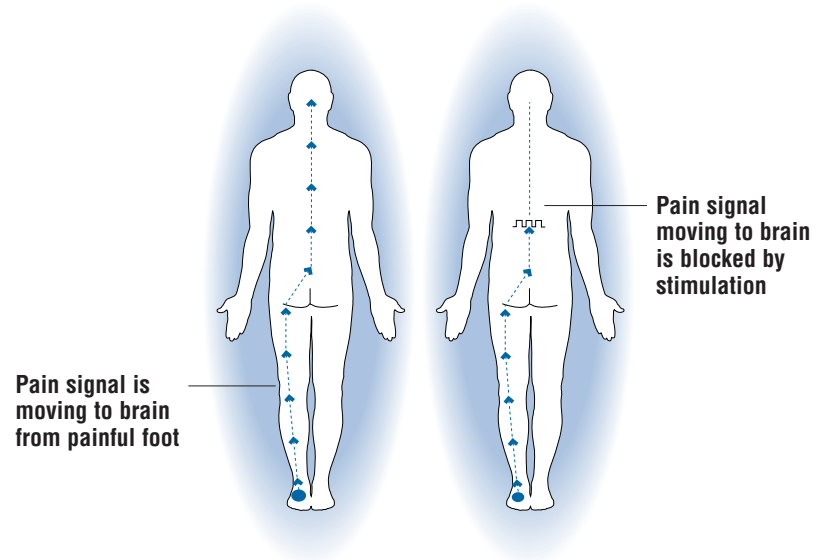
WHAT IS PAIN?

Nerve signals from all over your body travel to your **spinal cord**, and then to your brain. Your brain translates nerve signals into feelings such as pressure, itching, tingling, or pain. It is your brain that feels pain, not the area of your body where the signal started.

WHAT IS STIMULATION AND HOW DOES IT MANAGE PAIN?

Stimulation delivers tiny electrical pulses to the spinal cord. This blocks the pain signal as it travels to the brain. If the signal does not reach the brain, the pain is not “felt.”

Note: Stimulation will not cure your pain nor will it block sharp pain caused by a recent injury.



Stimulation blocks pain signals as they move to the brain.

WHAT DOES YOUR STIMULATION SYSTEM LOOK LIKE?

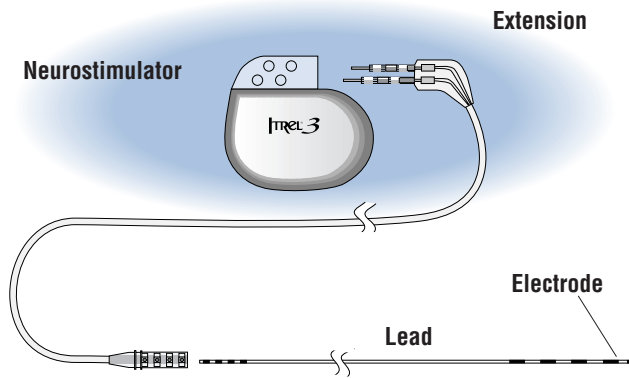
A typical stimulation system has three implanted parts: one **neurostimulator**, one **lead**, and one **extension**.

Neurostimulator: The neurostimulator is the power source of your system. It contains a special battery and electronics to control the stimulation you feel.

Note: In time, the battery inside your neurostimulator will wear out. When this occurs, your neurostimulator will need to be surgically replaced.

Lead: The lead (pronounced “leed”) is a thin wire covered with a protective coating. The lead has small metal **electrodes** near the tip. The lead is surgically placed with the metal electrodes near your spinal cord. The electrodes transmit tiny electrical pulses to the area where your pain signals will be blocked.

Extension: The extension is a thin wire placed under the skin. It also is covered with a protective coating. The extension connects to the neurostimulator at one end and to the lead at the other end.



The parts of your stimulation system.

HOW DOES YOUR STIMULATION SYSTEM WORK?

After your surgery, your doctor used a **physician programmer** (a small computer) to send stimulation instructions to your neurostimulator. These instructions control the stimulation you feel.

The instructions are stored in your neurostimulator. If needed, your doctor can use the programmer to change the instructions.

You have been given a **patient programmer** to use with your system. It allows you to turn your neurostimulator on and off. It also allows you to fine tune your stimulation. Your doctor or nurse will explain how to use the patient programmer. Refer to “Using the Patient Programmer,” on page 41.

An optional **control magnet** can also be used to turn your neurostimulator on and off. This magnet can also be used to start a dosage of stimulation if programmed by your doctor. You cannot use the control magnet to adjust amplitude.

If necessary, your doctor can disable the circuit that allows on/off control with the magnet.

A special code inside your neurostimulator allows only programming from the physician or patient programmer; other devices, such as the control magnet, are not able to program your neurostimulator.

**Itrel® EZ™ Patient
Programmer**



**Control
Magnet**



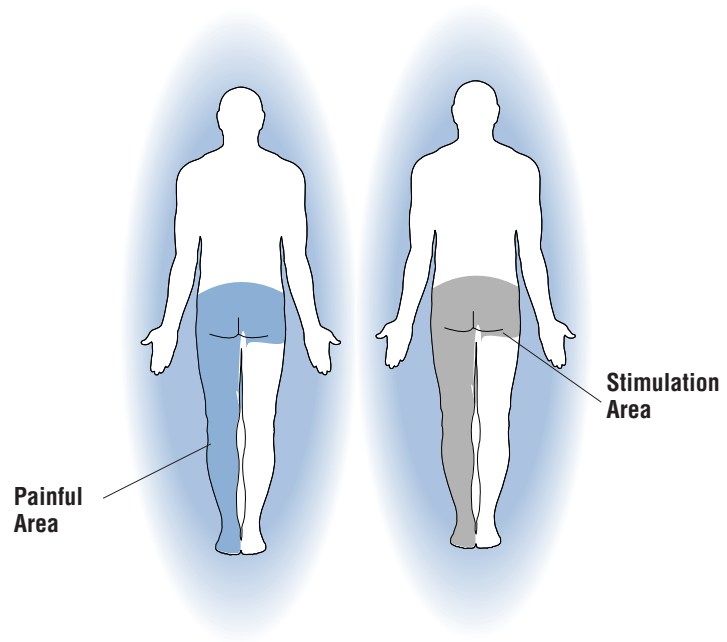
Neurostimulator controlling devices.

HOW DOES STIMULATION FEEL?

Your neurostimulator sends tiny electrical pulses through the extension to the lead. The electrical pulses move through the lead and electrodes to the area where your pain signals will be blocked.

To most patients, these pulses feel like tingling in the pain area. Sensations vary from patient to patient.

When your neurostimulator is turned on, the tingling slowly increases until it levels off. When your neurostimulator is turned off, the tingling slowly decreases until it stops.



Stimulation feels like tingling in the area of pain.

As your spine moves, you may sense an increase or decrease in the stimulation. It may seem as though the neurostimulator is turning on or off. When you bend over or move suddenly, you may even feel an uncomfortable “jolt” or “shock.”

Do not be alarmed if these sudden changes in stimulation occur. The instructions inside your neurostimulator have not changed. Your movement has probably caused your spinal cord to move closer to or farther from the lead electrodes. For a moment, the stimulation may feel more or less intense than it should.

Sudden changes in stimulation like these are most common during the recovery period. They usually decrease as you heal and the lead becomes more secure in your spinal column.

HOW IS YOUR ITREL® 3 SYSTEM IMPLANTED?

Implantation of your Itrel® 3 System has four basic steps and usually is done in one or two operations. The four steps are as follows:

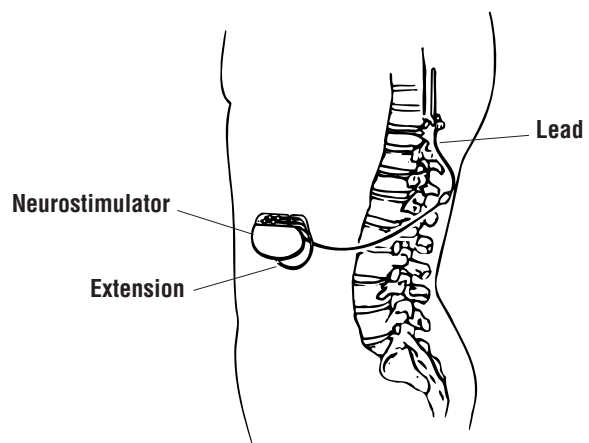
- Lead placement
- Screening
- Neurostimulator internalization
- Neurostimulator programming

During the lead placement, you may be under a local anesthetic. The doctor will ask you to help determine when the lead is in the correct place. You will know the lead is correctly placed when you feel a tingling sensation in the area of your pain. This is the sensation you will feel instead of pain when your Itrel® 3 System is blocking pain.

An external “screener” device provides the energy for the trial stimulation during the lead placement. If your doctor chooses to internalize the system in one operation., the neurostimulator is implanted after a successful lead placement.

If the procedure is done in two operations, you will have a trial screening period of several days. Your doctor will use the “screener” to determine the most comfortable and effective **stimulation settings** for you.

The neurostimulator is internalized while you are under local or general anesthesia. This will occur after the screening period or, as previously explained, immediately after the lead placement. The doctor makes an incision in the skin, usually in the abdomen.



The neurostimulator is usually placed in the abdomen.

The neurostimulator is placed under the skin. The lead is then connected to the neurostimulator via the extension (wire). Your doctor will try to place the neurostimulator in an area that is most comfortable and cosmetically acceptable.

After the internalization, your doctor will use the physician programmer to program the neurostimulator to the therapy settings that are appropriate to your needs. Your doctor may also choose to program a **SoftStart™/Stop** stimulation. The SoftStart is a feature that gradually increases the amplitude from zero (0) to the programmed amplitude when your neurostimulator is turned on. When you turn off the neurostimulator, SoftStop gradually decreases the amplitude to zero (0) before turning off.



WHAT DOES THE PATIENT PROGRAMMER DO?

Use the patient programmer only with your implanted neurostimulator. DO NOT use the programmer on other devices (such as a cardiac pacemaker).

Warning

Signals (telemetry) from the patient programmer may disrupt the function of other implanted devices.

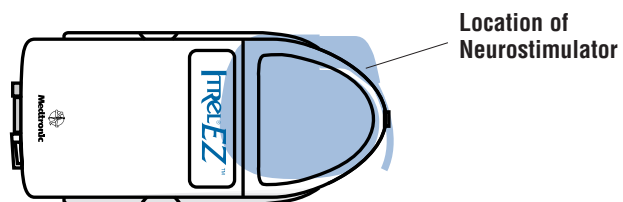
Your programmer is easy to use. You can use it to:

- Turn the neurostimulator on or off.
- Adjust the stimulation of your neurostimulator.
- Check the status of the neurostimulator battery and the programmer battery.
- Confirm that the neurostimulator has received instructions from the programmer.

HOW DOES THE PATIENT PROGRAMMER WORK?

The patient programmer sends signals to your neurostimulator. These signals tell the neurostimulator to turn on or off or to change stimulation.

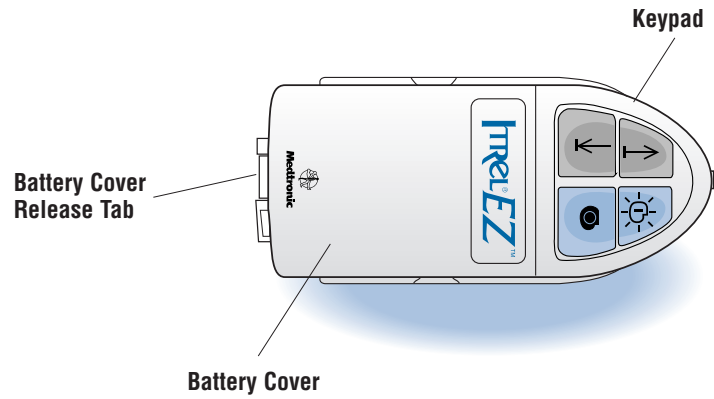
The neurostimulator also sends signals to the patient programmer. Signals from the neurostimulator confirm changes you have made. Signals also tell you the status of the neurostimulator battery.



The programmer placed over the neurostimulator.





PATIENT PROGRAMMER FEATURES

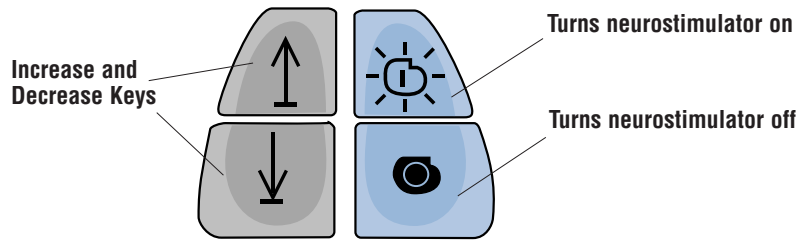
This section describes the features of the patient programmer.



The patient programmer.

Keypad

The keypad has 4 keys: Neurostimulator On  and Off  keys, and Increase  and Decrease  keys.





The keypad.

On and Off Keys

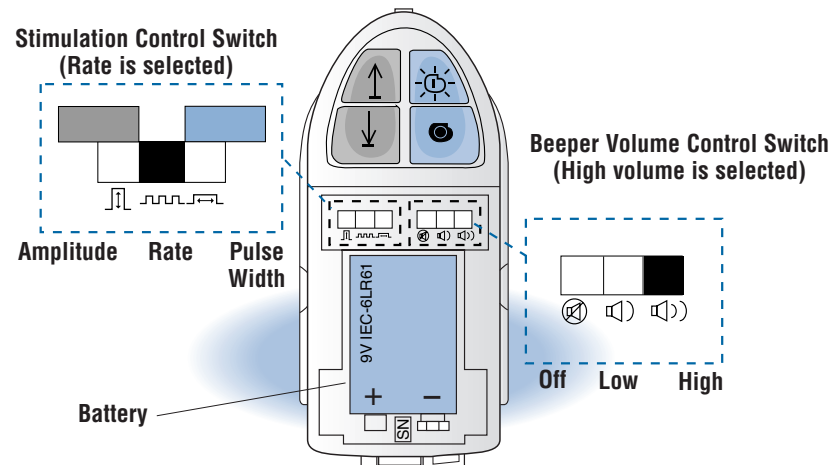
Press the On  and Off  keys to turn the neurostimulator on and off.

Increase and Decrease Keys

A **Stimulation Control switch**, under the battery cover, is used to select the **amplitude, rate, or pulse width**. (See page 79 for information on removing the battery cover.) Press the Increase  and/or Decrease  key to adjust the amplitude, rate, or pulse width within ranges set by your doctor.

Control Switches

The control switches and battery are located under the battery cover. For instructions on removing the battery cover, refer to page 79.

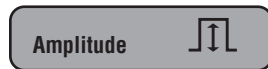


Control switches and battery.

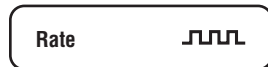
Stimulation Control Switch

Depending on the instructions your doctor has programmed into your neurostimulator, you can adjust some or all of these settings with the Stimulation Control switch: amplitude, rate, and pulse width. Colors and symbols identify each setting (see below).

Changing these settings will help you find the highest level of comfort and pain relief.



The amount or "volume" (strength or intensity) of stimulation required to mask your pain. This is the setting most often adjusted by patients.



The number of pulses per second; rate feels like "tapping."



The length or duration of the electrical pulse. A longer pulse covers a larger area.

Note: The Increase ↑ and Decrease ↓ keys on your keypad adjust the selected stimulation control.

Beeper Volume Control Switch




The programmer beeps each time a change is received by your neurostimulator. Turn the beeper Off  or set the volume to Low  or High  with the **Beeper Volume Control switch**. (See Table 1.)

Table 1. Beeper description.

If you hear	It means
One beep	You have pressed the On/Off or Increase/Decrease key and the change was successfully received by your neurostimulator.
Three rapid beeps	<p>You tried to adjust the amplitude, pulse width, or rate beyond the highest and lowest settings.</p> <p>You tried to increase amplitude, rate, or pulse width with the neurostimulator turned off.</p> <p>You pressed On while your neurostimulator was in "dose lockout." Some patients' doctors set a lockout period during which no stimulation is delivered. You cannot adjust stimulation during the lockout.</p>

Symbols and Status Lights

The back of your programmer displays symbols and **status lights**. These will help you during a programming session.

Symbols

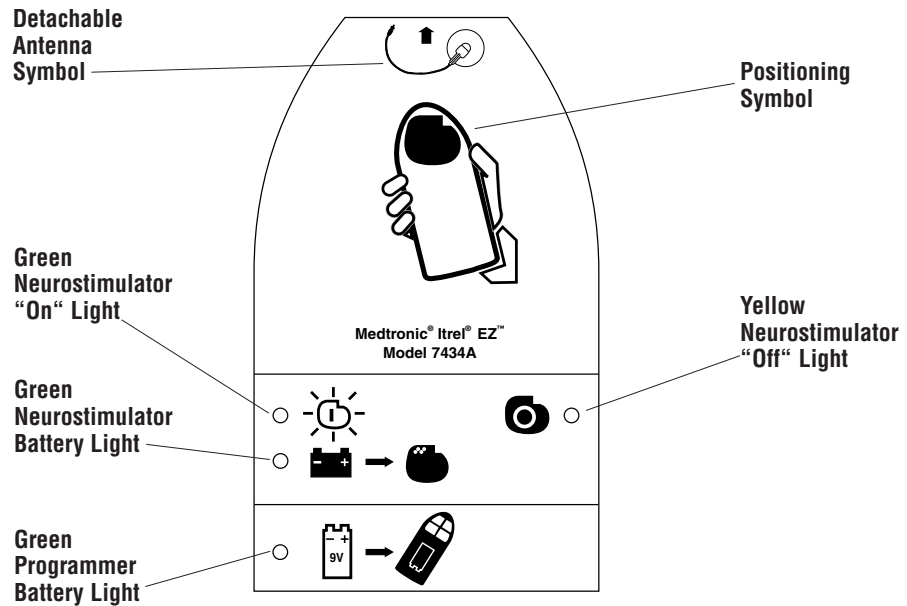
A positioning symbol helps you align your programmer over the neurostimulator.

An antenna symbol directs you to the detachable antenna connector. An optional, detachable antenna can be plugged in here.

Status Lights

When lit or blinking, the status lights tell you the following:

- Whether the neurostimulator is on or off
- The neurostimulator battery status
- The programmer battery status



Symbols and status lights on the back of the patient programmer.



USING THE PATIENT PROGRAMMER

This section is organized as follows:

- Placing the Programmer over the Neurostimulator
- Checking the Neurostimulator Battery
- Turning the Neurostimulator On and Off
- Adjusting Your Stimulation

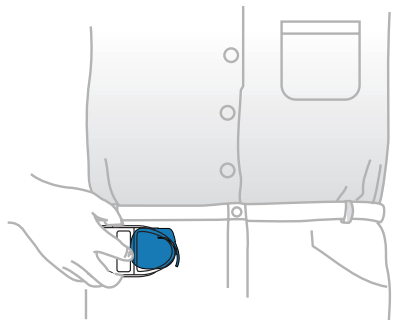
Placing the Programmer over the Neurostimulator

Locate the neurostimulator implanted under your skin and hold the programmer over it. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator. To send and receive signals, hold the programmer steady over the neurostimulator for at least 1 second while you press any key. When you align the programmer correctly over the neurostimulator, two or more lights will shine.

If the beeper is on, it will beep.

The lights and beeper tell you that you have lined up the programmer and neurostimulator and they are sending signals to each other. If only the programmer battery light is lit and the beeper does not beep, move the programmer an inch or two and try again.

Note: A detachable antenna is also available. This is helpful for patients who cannot reach their neurostimulator. Refer to “Accessories” on page 65 for more information.



Position the programmer over the neurostimulator.

(Place against clothing or skin.)



Checking the Neurostimulator Battery

The Neurostimulator Battery light on the back of the programmer tells you the status of your neurostimulator battery.

See page 112 for information on what to do when your battery runs down.

To check the neurostimulator battery:

1. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
2. If your neurostimulator is off, press the Off key. If your neurostimulator is on, press the On key. Hold the programmer over the neurostimulator for at least 1 second.
3. Confirm that the green Neurostimulator Battery light on the back of the programmer is lit. Refer to Table 2 for more information about the Neurostimulator Battery light.



  **Note:** Move indoors or into the shade if sunlight dims the programmer lights.

Table 2. Neurostimulator Battery    lights.

When this happens	It Means
Green Neurostimulator Battery light is on for 8 seconds after pressing any key.	Neurostimulator battery is OK.
Green Neurostimulator Battery light is blinking for 8 seconds after pressing any key.	The neurostimulator battery is low. Call your doctor's office.
Green Neurostimulator Battery light is off after pressing any key.	Reposition programmer and try again. Interference from electrical equipment can cause lights to remain off. Move to another room and try again. If the light remains off, the neurostimulator battery may need to be replaced. The neurostimulator should be reviewed with a physician programmer. Contact your doctor immediately.

Turning the Neurostimulator On and Off

Turn your neurostimulator on when:

- You require pain relief, or
- You want to adjust the amplitude, rate, or pulse width.

Turn your neurostimulator off when:

- The amplitude is set at the lowest setting and you do not need stimulation.
- You are using equipment that could be harmful to you or others if you should receive a sudden shock (for example, driving a car).
- You are having a medical or dental procedure. See "Precautions," page 6.
- You are passing through a theft detector or a security device such as those used in department stores and airports.


Notes:

- Turning the neurostimulator off extends the battery life of your neurostimulator. When the battery wears out, the neurostimulator must be surgically replaced. You will want to make it last as long as possible.
- Decreasing the amplitude to the lowest setting will not turn off the neurostimulator.

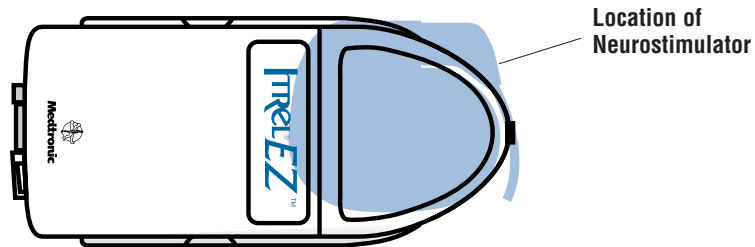
Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting:

- After turning your neurostimulator off.
- Before adjusting the rate or pulse width of your neurostimulator. After rate or pulse width are set, slowly increase the amplitude to your comfort level.

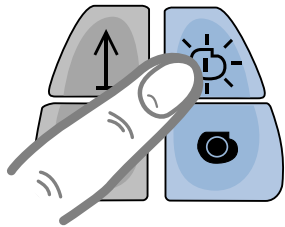
 **To turn the neurostimulator on:**

1. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.



Place the programmer over the neurostimulator.

2. Press the Neurostimulator On key and hold the programmer over the neurostimulator for 1 second. If the beeper is on, you should hear one beep to confirm that a change has occurred.



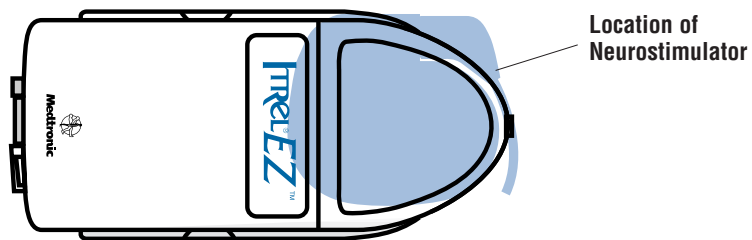
Press the Neurostimulator On key.

3. Check that the green Neurostimulator On light on the back of the programmer is lit; this indicates that the neurostimulator was successfully turned on (see Table 3). This light stays on for 8 seconds after you release the key.

Note: The neurostimulator will turn on with the settings last programmed.

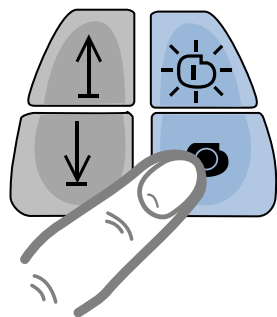
 **To turn the neurostimulator off:**

1. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.



Place the programmer over the neurostimulator.

2. Press the Neurostimulator Off key and hold the programmer over the neurostimulator for 1 second. If the beeper is on, you should hear one beep to confirm that a change has occurred.



Press the Neurostimulator Off key.

3. Check that the yellow Neurostimulator Off light on the back of the programmer is lit; this indicates that the neurostimulator was successfully turned off (see Table 3). This light stays on for 8 seconds after you release the key.

Note: Move indoors or into the shade if sunlight dims the programmer lights.

4. Decrease the amplitude to the lowest setting (refer to pages 56 - 57 for instructions).

⚠ Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting after turning your neurostimulator off.

Table 3. Neurostimulator On  and Off  lights.

When	It Means
The green Neurostimulator On light is lit for 8 seconds after pressing any key.	Neurostimulator is on.
The yellow Neurostimulator Off light is lit for 8 seconds after pressing any key.	Neurostimulator is off.
Neither Neurostimulator On nor Off light is lit after pressing any key.	The programmer does not know if the neurostimulator is on or off because it failed to communicate with the neurostimulator. Refer to “Troubleshooting,” page 96.

Adjusting Your Stimulation

Table 4 provides some general guidelines for when you should adjust your stimulation. Your doctor will provide more complete guidelines.

Table 4. When to adjust your stimulation.

Adjust the Amplitude	Press This Key
Before you adjust rate or pulse width	↓
After you turn the neurostimulator off	↓
When the tingling is not strong enough	↑
When the tingling is too strong	↓
Adjust the Pulse Width	Press This Key
If the tingling does not cover your pain area	↑
If the tingling seems to cover too much area	↓
Adjust the Rate	Press This Key
If the tapping is uncomfortable	↑

Programming Tips

The following tips are helpful when using the patient programmer.

Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting:

- After turning your neurostimulator off.
 - Before adjusting the rate or pulse width of your neurostimulator. After rate or pulse width are set, slowly increase the amplitude to your comfort level.
-
- **Always set your neurostimulator to the lowest settings that provide pain relief. The higher the settings, the faster your neurostimulator battery will wear out. When the battery wears out, the neurostimulator must be surgically replaced. You will want to make it last as long as possible.**
 - Select amplitude, rate, or pulse width using the Stimulation Control switch. The Increase ↑ and Decrease ↓ keys will adjust the stimulation setting that you select.

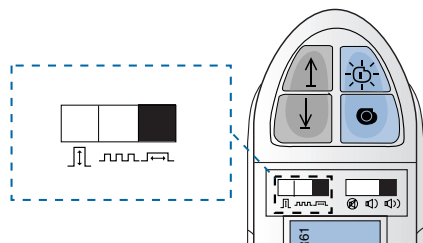
- The neurostimulator must be on to increase amplitude, rate, and pulse width. However, the neurostimulator may be either on or off to decrease the amplitude, rate, or pulse width.
- Use the lights on the back of the programmer to confirm that a change is taking place. The Neurostimulator On or Off lights, the Programmer Battery light, and the Neurostimulator Battery light should be lit after sending a change to the neurostimulator. This confirms that the neurostimulator is turned on or off, and that the neurostimulator and the programmer batteries are OK. These lights stay on for 8 seconds after you release the key.

- If the beeper is on, the programmer will beep once for each change that is programmed into your neurostimulator. Your programmer will beep three times if you try to increase a stimulation setting when the neurostimulator is off. It will also beep three times if you have reached the lowest or highest value for the selected setting (amplitude, rate, or pulse width). The programmer will beep three times if you press On while the system is in “dose lockout.”
- You can increase or decrease settings more quickly by pressing and holding down the desired key. Every second, the programmer will send a change to the neurostimulator.

Decreasing the Amplitude to the Lowest Setting

Always decrease the amplitude to the lowest setting before adjusting pulse width and rate or after turning your neurostimulator off.

1. Remove the battery cover. (Refer to “Removing the Battery Cover,” page 79.)
2. Move the Beeper Volume Control switch to Low ⏏ or High ⏏ .
3. Move the Stimulation Control switch to amplitude ⏏ .



Move the Stimulation Control switch to amplitude.

4. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
5. Press and hold the Decrease ↓ key until the programmer beeps rapidly three times. This reduces the amplitude to the lowest setting.

Note: The neurostimulator may be on or off when decreasing amplitude.

6. Replace the battery cover. (Refer to “Replacing the Battery Cover,” page 80.)

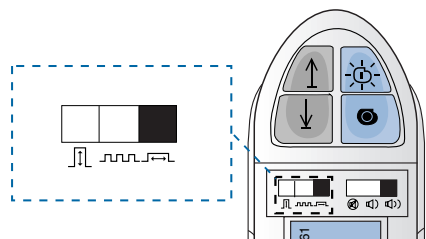
Adjusting the Pulse Width

1. Remove the battery cover. (Refer to “Removing the Battery Cover,” page 79.)
2. Decrease the amplitude to the lowest setting as described on page 56.


⚠ Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting before adjusting the pulse width or rate of your neurostimulator. After rate or pulse width is set, slowly increase the amplitude to your comfort level.

3. Move the Stimulation Control switch to pulse width .



Move the Stimulation Control switch to pulse width.

4. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
5. Press Neurostimulator On  to turn on the neurostimulator.
6. Press the Increase ↑ or Decrease ↓ key to make a change.
7. Move the Stimulation Control switch to amplitude \square .
8. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
9. Press the Increase ↑ key to assess the change. Repeat steps 2 through 9 until the change is acceptable.
10. Replace the battery cover. (Refer to "Replacing the Battery Cover," page 80.)

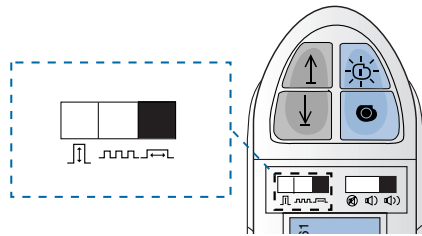
Adjusting the Rate

1. Remove the battery cover. (Refer to “Removing the Battery Cover,” page 79.)
2. Decrease the amplitude to the lowest setting as described on pages 56 - 57.






Caution

To avoid unpleasant stimulation, always decrease the amplitude to the lowest setting before adjusting the pulse width or rate of your neurostimulator. After rate or pulse width is set, slowly increase the amplitude to your comfort level.

3. Move the Stimulation Control switch to rate .

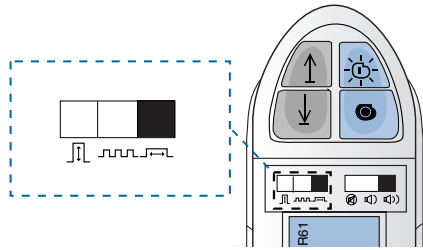


Move the Stimulation Control switch to rate.


4. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
5. Press Neurostimulator On  to turn on the neurostimulator.
6. Press the Increase  or Decrease  key to make a change.
7. Move the Stimulation Control switch to amplitude .
8. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
9. Press the Increase  key to assess the change. Repeat steps 2 through 9 until the change is acceptable.
10. Replace the battery cover. (Refer to "Replacing the Battery Cover," page 80.)

Adjusting the Amplitude

1. Remove the battery cover. (Refer to “Removing the Battery Cover,” page 79.)
2. Move the Stimulation Control switch to amplitude $\square\Pi$.



Move the Stimulation Control switch to amplitude $\square\Pi$.

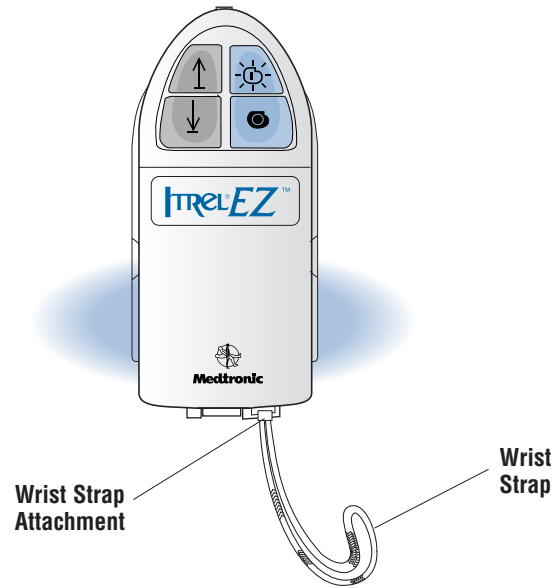
3. Place the programmer over your neurostimulator. Hold the programmer flat against your skin or clothing so that the keypad is directly over your neurostimulator.
4. Press Neurostimulator On  to turn on the neurostimulator.
5. Press the Increase ↑ or Decrease ↓ key to make a change.
6. Replace the battery cover. (Refer to “Replacing the Battery Cover,” page 80.)



ACCESSORIES

Wrist Strap and Carrying Case

A wrist strap is packaged with the patient programmer and can be used to help you avoid dropping it. The wrist strap is attached near the battery cover release tab. A carrying case is also enclosed with the programmer. Store the patient programmer in the carrying case to protect it.



Location of the wrist strap attachment.

Detachable Antenna

A detachable antenna is available for patients who cannot reach their neurostimulator. The patient programmer can be used to program the neurostimulator as previously described. When connected, the detachable antenna turns off the programmer's internal antenna.

Caution

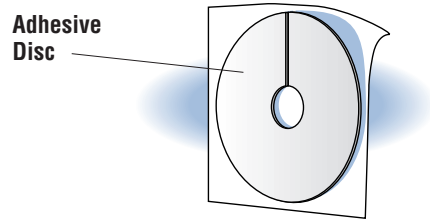
Do not attach the antenna over your neurostimulator incision using the adhesive discs until the incision heals.

Note: When the detachable antenna is not used, keep the rubber plug in the antenna connector of the patient programmer. The rubber plug helps keep water out of the programmer.

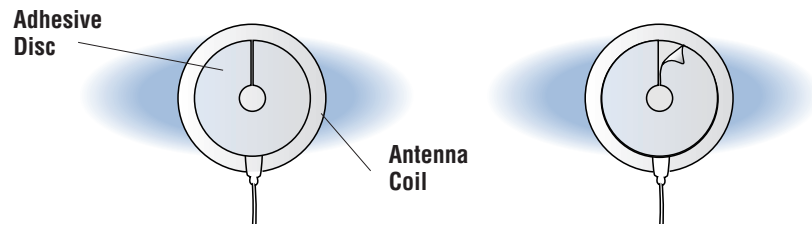
To keep the antenna in place, use the adhesive discs supplied with the antenna. The adhesive discs are hypoallergenic. This helps reduce the chance of irritation. If irritation occurs, consult your doctor.

Replace the adhesive discs every day. Before replacing an old disc with a fresh one, clean your skin using an antibacterial soap and dry thoroughly.

Attaching the Antenna over the Neurostimulator

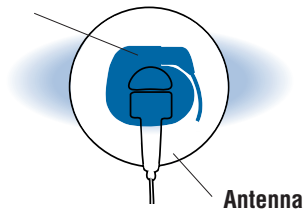


1. Remove adhesive disc from square sheet.

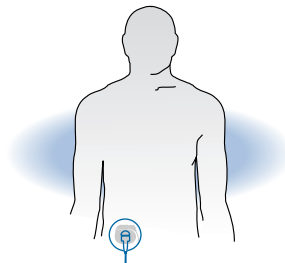


2. Attach disc to antenna coil. Remove protective covering.

Neurostimulator



Antenna



3. Position antenna over neurostimulator as shown.

4. Press antenna firmly in place.

Note: The antenna must be properly lined up over the neurostimulator for programming to occur. The programmer's internal antenna is disabled when the antenna is properly connected.

Connecting the Antenna to the Patient Programmer

1. Pull out the rubber plug on the patient programmer to reveal the antenna connector.

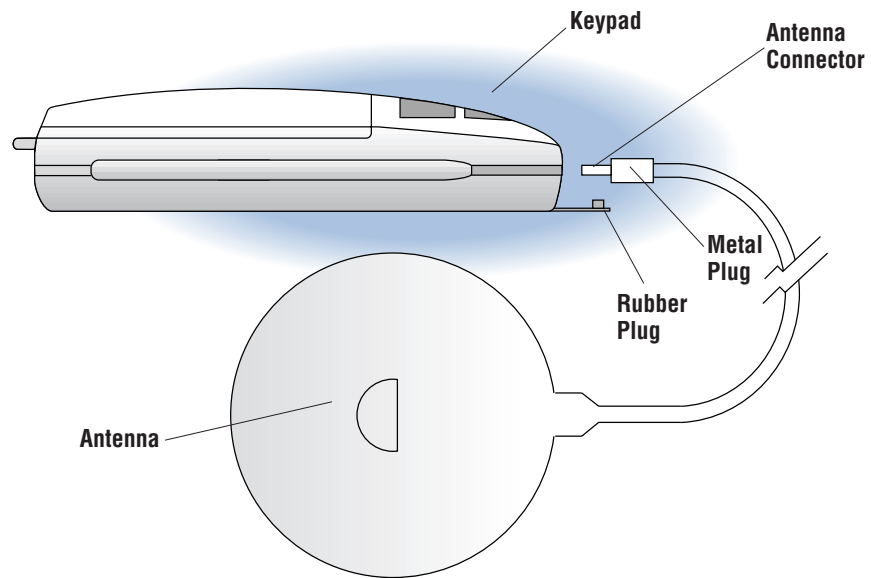
Note: The antenna connector is located on the end of the programmer near the keypad.

2. Insert the antenna's metal plug into the antenna connector and push the metal plug until it fits securely into place.

Disconnecting the Antenna

1. Grasp the plug and pull it straight out. Do not pull on the cable because this may break the wires.
2. Insert the rubber plug into the antenna connector.

Note: Keep the rubber plug in the antenna connector when not in use; this helps keep water out of the programmer.



The detachable antenna and patient programmer.

Caring for the Antenna

If you use the detachable antenna, you should wash it daily with mild soap and water.

Note: Do not allow the metal plug end of the cord to get wet.

1. Disconnect the antenna from the programmer before cleaning.
2. Wash the antenna with mild soap and water.
3. Rinse the antenna. Make sure no soap remains on it.
4. Dry the antenna with a clean towel immediately after washing.

Note: When not in use, store the antenna in a plastic bag to protect it from dust.

Caring for Your Skin

Skin may become irritated from the pressure of the antenna or from an allergic reaction to the adhesive used to hold the antenna in place. Therefore, it is very important to keep the skin in this area clean and dry. Inspect the area every day to see that the skin remains healthy.

Caution

If you notice swelling or redness in the area where you place the antenna, contact your doctor before using the antenna again.

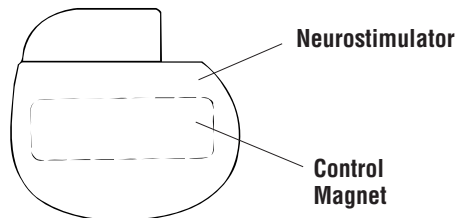
Clean the skin over the neurostimulator with an antibacterial soap and change the antenna adhesive discs daily.

If the discs irritate your skin, you may want to wear a soft, snug-fitting undergarment to protect your skin and then tape the antenna to the outside of the undergarment.

Using Your Control Magnet (Optional)

By briefly applying and then removing the optional **control magnet** over your neurostimulator, you can turn it on or off. This feature can be disabled by your doctor, however. If it is disabled, the magnet will not turn the neurostimulator on or off.

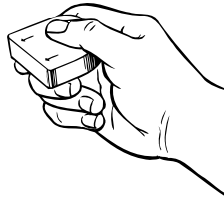
Your implant site and the final placement of your neurostimulator can vary from the examples shown in the following instructions. Have your doctor show you how to locate or position the magnet on your neurostimulator so that it is centered as shown in the following figure.



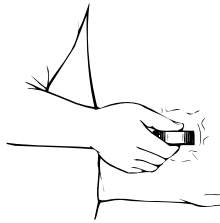
Magnet properly centered over neurostimulator.

To turn the neurostimulator on or off, follow these steps:

Step 1. Grasp the magnet with the flat end away from you.



Step 2. Press the flat end of the magnet directly over and along the length of the neurostimulator.



Step 3. Hold the magnet steady for 1 to 2 seconds.

Step 4. Remove the magnet.

If the magnet fails to turn the neurostimulator on or off, repeat steps 3 and 4, holding the magnet against the neurostimulator in a different position. Try a "1 o'clock" or "4 o'clock" position.

1 o'clock position



4 o'clock position



If your doctor has programmed the neurostimulator with the **SoftStart™/Stop** feature, the magnet will automatically start the increase or decrease. If the neurostimulator has been programmed with a dosage of stimulation, the magnet will start the dose.

Note: Allow a few seconds for the SoftStart circuit to raise the amplitude to the point where you can feel it.

If your doctor has programmed the neurostimulator with the cycling feature and you use your magnet (or patient programmer) to turn off the neurostimulator, your therapy will then stop. When you reapply the magnet to turn on the neurostimulator again, your therapy always starts at the beginning of the On cycle.

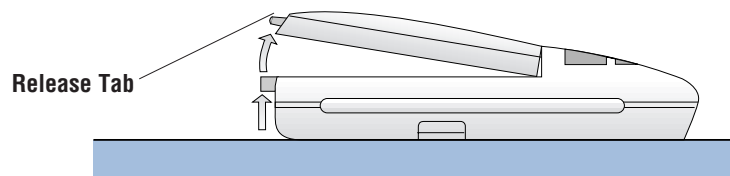
CARING FOR YOUR PATIENT PROGRAMMER

Battery Cover

When the battery cover is removed, you can replace the battery or access the Stimulation Control switch.

Removing the Battery Cover

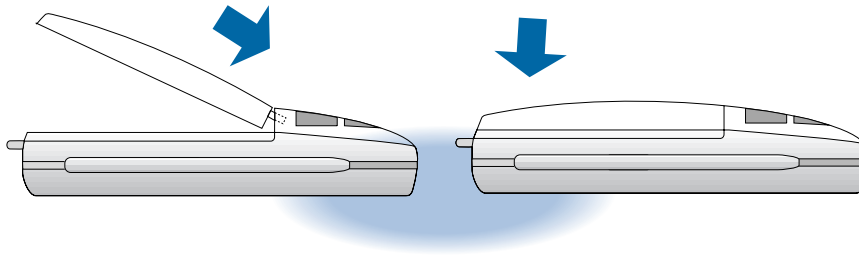
1. Hold the programmer with one hand.
2. Lift the battery cover release tab on the end of the programmer. Lift off the cover.



Remove the battery cover.

Replacing the Battery Cover

1. Place the center hook on the edge of the cover into the center slot in the programmer.
2. Lower the battery cover.
3. Press down the end of the cover to lock it in place.



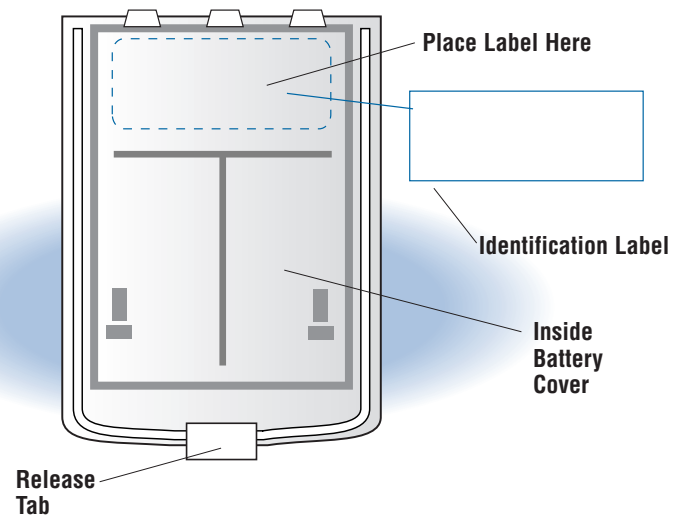
Replace the battery cover.

Identification Label

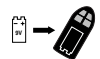
Your patient programmer comes with an identification label.

1. Fill in the label (name, phone number, etc.) with permanent ink.
2. Peel off the backing and stick the label to the inside of the battery cover.

Note: Do not place the label over the ridges on the battery cover.



Placement of the identification label in the battery cover.



Checking the Programmer Battery

A 9-volt battery provides the power for the patient programmer. Use an alkaline battery for best performance and economy.

Notes:

- When not using the programmer for more than 4 weeks, remove the battery to prevent possible damage to the device due to battery leakage.
- **Make sure that you always have a fresh 9-volt battery so that you can turn your neurostimulator on and off or adjust the stimulation settings when necessary.**
- Do not use a rechargeable or zinc-air battery. The programmer is designed to indicate its battery status with an alkaline battery installed; other battery types may not give accurate indications of the programmer's battery status.

The Programmer Battery light is located on the back of the programmer. It tells you the status of your programmer battery.

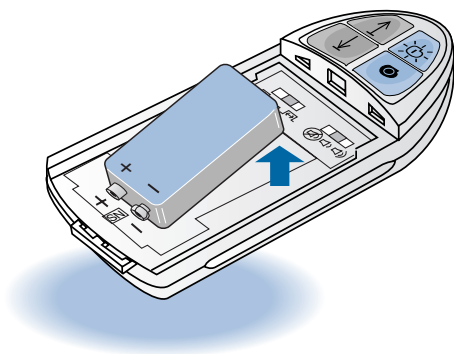
To check the programmer battery: Press any key on the patient programmer keypad. The green Programmer Battery light will respond. Refer to Table 5 for more information about the Programmer Battery light.

Table 5. Programmer Battery  **light.**

When	It Means
Green Programmer Battery light is on for 8 seconds after pressing any key.	Programmer battery is OK.
Green Programmer Battery light is blinking after pressing any key.	Programmer battery is low. Replace with new 9-volt battery.
Green Programmer Battery light is off after pressing any key.	Replace with new 9-volt battery.

Removing the Battery

1. Remove the battery cover. (Refer to “Removing the Battery Cover,” page 79.)
2. Place one finger on the edge of the battery between the Control switches.
3. Lift the battery out of the compartment without using excessive force.



Remove the battery.

Installing the Battery

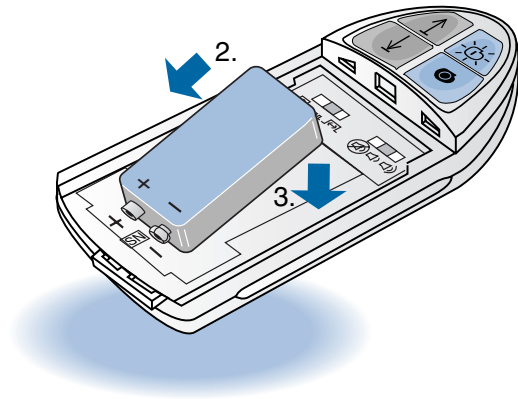
An alkaline battery is recommended for longer battery life.

1. Remove the battery cover (refer to page 79) and the old battery (refer to page 85), if necessary.
2. Check the battery label for positive [+] and negative [-] contacts. Match them with the [+] and [-] symbols in the battery compartment.
3. Press the battery down fully into the battery compartment without using excessive force.

Notes:

- Do not press any of the programmer's keys during battery insertion.
- The programmer performs a self-test when the battery is inserted. A successful check is indicated by a single flash of the status lights followed by a short beep. If this does not occur, the self-test has failed. Refer to "Troubleshooting," page 96.

4. Replace the battery cover. (Refer to "Replacing the Battery Cover," page 80.)



Install the battery.

Cleaning and Care

- Your patient programmer is a precision device; handle it with care.
- Do not take apart or tamper with the programmer; this could affect how it works.
- Protect the programmer from sharp blows or physical shocks.
- Clean the outside of the programmer with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- Your patient programmer is not waterproof. Do not allow moisture to get inside the device.
- If you drop your patient programmer in water, refer to “Troubleshooting,” page 101.

Caution

Do not immerse the programmer in liquid. Do not clean it with bleach, nail polish remover, or other similar substances.

- Clean the battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Replace low or depleted batteries to ensure proper operation.
- When not using the programmer for more than 4 weeks, remove the battery to prevent possible corrosion of the patient programmer due to battery leakage.

Service

The Itrel® EZ™ Patient Programmer has been designed and tested to provide long, trouble-free service. If repair or service is needed, call Medtronic at 1-800-328-0810.

To register the programmer for service covered by the warranty, complete and mail the warranty registration card. It is inserted in this manual. The serial number is located on a label within the battery compartment. It identifies each Itrel® EZ™ Patient Programmer. If you write or call Medtronic about your patient programmer, refer to the serial number.

Battery and Device Disposal

Dispose of depleted programmer batteries and worn-out devices according to local regulations.



TROUBLESHOOTING

This section will help you solve problems or identify when to call your doctor. Problems are described in the left column. The blue text in the right column lists possible causes of the problem (Causes); the bold text in the right column describes how to correct the problem (Action).

Note: If your problem is not solved after several attempts, or if your problem is not described here, contact your doctor.

Problem

You're too uncomfortable with your current stimulation to think about how to change it.

Causes and Action

1. Turn the neurostimulator off.
2. Reduce the amplitude, rate, and pulse width.
3. Turn the neurostimulator on.
4. Reset the rate and pulse width; reset amplitude last.

Problem

Causes and Action

No lights turn on after you try to program your neurostimulator.

No battery or depleted battery.
Replace the battery; use a new 9-volt battery.

Sunlight may be making the programmer lights too dim.

If you are outdoors, move indoors or into the shade.

Your programmer does not respond to key presses.

No battery or depleted battery.
Replace the battery; use a new 9-volt battery.

The Programmer Battery light turns on, but none of the neurostimulator lights are on.

Programmer or detachable antenna is not aligned correctly over neurostimulator.
Move the programmer or antenna and try again.

Problem

Causes and Action

The Neurostimulator Battery light is blinking, or it has been blinking and is now off.

The neurostimulator battery is low or depleted.
Contact your doctor.

The programmer does not work with the detachable antenna connected.

Antenna not connected correctly.
Disconnect the antenna, plug it in, and try again.

The antenna is not aligned over the neurostimulator.
Refer to the instructions on page 69.

The antenna is broken.
Try programming without the detachable antenna.
Replace detachable antenna with a new one.

Problem

You want to check your neurostimulator without changing the setting.

All the lights on your programmer are on, and it does not respond when you press a key.

Causes and Action

If the neurostimulator is off, push the Off key. The yellow Neurostimulator Off light should be lit. If the neurostimulator is on, push the On key. The green Neurostimulator On light should be lit. Refer to “Checking the Neurostimulator Battery” on page 43 for more information.

One of the programmer’s keys may have been pressed during battery installation.
Remove the battery for at least 3 seconds and then replace it, making sure no keys are pressed during battery installation.

Problem

The neurostimulator lights are off when you press any key.

Causes and Action

The programmer or detachable antenna is not aligned correctly over the neurostimulator.
Move the programmer or antenna and try again.

The programmer was removed from the neurostimulator too soon.
Hold the programmer over the neurostimulator for at least 1 second after pressing a key.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.
Move to a different room and try again.
Remove the detachable antenna and try again.

The status lights do not flash and the beeper does not beep when a fresh battery is installed.

The programmer failed the self-test and/or one of the programmer's keys was pressed during battery installation.
Remove battery, press any key, turn the beeper to low or high, and insert a second fresh battery, making sure no keys are pressed during battery installation. The status lights should flash, and you should hear one beep. If this does not occur, contact your doctor.

Problem

The beeper does not sound. Only the Programmer Battery light is on.

Causes and Action

The beeper is not on.

Set the Beeper Volume Control switch to low or high volume and listen to be sure it is working.

The programmer or detachable antenna is not aligned correctly over the neurostimulator.

Move the programmer or antenna and try again.

The programmer was removed from the neurostimulator too soon.

Hold the programmer over the neurostimulator for at least 1 second.

Radio signals from appliances, computers, machinery, etc. are affecting your programmer.

Move to a different room and try again.

Remove the detachable antenna and try again.

Problem

You feel a programming change after pressing a key, but the beeper didn't beep and the Neurostimulator On or Off lights did not light.

Causes and Action

The programmer was too far away from the neurostimulator. The neurostimulator might have received the signal to change but did not tell the programmer what it did.

Hold the programmer closer to your neurostimulator and try again.

An electrical appliance blocked your neurostimulator radio signal from telling the lights and beeper to turn on.

- 1. Move to another room. Press any key to check the lights.**
- 2. Move the programmer and try again.**

The programmer was moved away too soon after pressing the keys.

Hold the programmer over the neurostimulator for at least 1 second after pressing a key.

Problem

You do not feel stimulation right away after turning your neurostimulator on, or you feel stimulation after you turn the neurostimulator off.

Causes and Action

Your doctor programmed a feature called SoftStart/Stop so that your stimulation will start and stop gradually.

Allow about 8 seconds for your neurostimulator to turn on and off.

The programmer or detachable antenna is not aligned correctly over your neurostimulator.

Move the programmer or antenna and try again.

Your amplitude is set at its lowest setting.

Slowly increase the amplitude until you feel stimulation.

Problem

Your neurostimulator will not turn on.

Causes and Action

The programmer or detachable antenna is not aligned correctly over the neurostimulator.
Move the programmer or antenna and try again.

The programmer was removed from the neurostimulator too soon.
Hold the programmer closer to your neurostimulator and try again. Hold the programmer over the neurostimulator for at least 1 second. The green Neurostimulator On light should be lit for 8 seconds after the key is pressed. Try again.

Your amplitude is set at the lowest setting, and you don't feel the stimulation.
Slowly increase the amplitude until you feel stimulation.

Problem

Causes and Action

You spill fluid on your programmer. Dry it with a towel.

Your programmer falls into water.

1. Remove the programmer from water.
2. Briefly rinse the patient programmer with clean tap water. Wipe it with a towel dampened with clean tap water.
3. Remove the battery cover and battery. Shake the programmer to remove as much water as possible.
4. Dry the battery compartment with a towel.
5. Allow the battery compartment to dry at room temperature for as long as possible (24 hours recommended).
6. Shake the programmer; if you see or hear water inside, repeat steps 4 and 5.
7. When the programmer is dry, replace the battery and cover.
8. If the programmer does not work properly, return it to Medtronic for service.

Your programmer falls off a cabinet or table. Try the programmer; it should work. If it does not work, return it to Medtronic for service.

LIVING WITH YOUR STIMULATION SYSTEM



Patient Identification Card

When you leave the hospital, your doctor will give you a temporary identification card. This card supplies basic information about your neurostimulator and identifies your doctor in the event of an accident. Your identification card might allow you to bypass security arches or wands such as those used in airports.

After Medtronic receives your device registration information from your hospital, you will receive a permanent identification card. Carry this card with you at all times. If you move, change doctors, or lose your card, contact Medtronic Patient Services for a new card.

Patient Services

Medtronic Neurological
710 Medtronic Parkway, NE
Minneapolis, MN 55432-5604
Toll-free: (800) 510-6735

 **Medtronic** 

Medical Device Temporary Identification

The bearer of this card has an implanted medical device prescribed by his or her doctor.

Patient's Name _____

Address _____

City _____ State or Country _____

Phone () _____

In case of an emergency, please notify:

Physician _____

Phone () _____

Model Number _____

Serial Number _____

Implant Date _____

Medtronic Neurological, Minneapolis MN 55432-5604
Telephone: (763) 514-5000 Toll-Free: (800) 510-6735

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When to Call Your Doctor

Your doctor will schedule follow-up visits. Your doctor will check your neurostimulator and make sure you are receiving the most appropriate treatment. However, you should contact your doctor if any of the following events occur:

- You have pain, redness, or swelling at the incision site later than 6 weeks after surgery.
- Your neurostimulator is not working properly.
- You are not getting enough pain relief.
- You feel discomfort or pain during stimulation. Turn the neurostimulator off first, then call your doctor.
- You feel no stimulation, “tingling,” when the neurostimulator is on.
- You cannot turn the neurostimulator on or off.
- You are unable to adjust stimulation with your patient programmer.

- Stimulation changes or stops and your pain returns.
- The area of stimulation has changed dramatically (for example, moving from your right leg to your left leg).
- The Neurostimulator Battery light on your patient programmer is blinking.
- The Neurostimulator Battery light on your patient programmer was blinking but is now off, regardless of which key you press.

Do's and Don'ts

By following the guidelines listed below, you can ensure that your patient programmer will function properly.

Do:

- Keep your patient programmer out of the reach of children.
- Use your patient programmer only as explained to you by your doctor or as discussed in this manual.
- Handle your patient programmer with care. It is a sensitive device that can be damaged by rough handling.
- Remove a worn-out battery from your patient programmer and replace it with a new one. Worn-out batteries may damage electronic circuits due to battery leakage.
- Keep a fresh 9-volt battery available so that you can turn your neurostimulator on and off or adjust the stimulation settings when needed.

- Turn your neurostimulator off when not in use. The neurostimulator battery is not replaceable. When it wears out, the neurostimulator must be surgically replaced, so you will want to make it last as long as possible. Battery life is dependent on the settings required to control your pain symptoms and on how many hours per day you use your device.
- Go to all follow-up appointments. Reschedule if an appointment is missed.
- Carry your patient identification card with you at all times.

Don't:**⚠ Warning**

Do not use potentially dangerous equipment (cars, power tools, etc.) when your neurostimulator is on. What may feel like a sudden increase in stimulation ("jolt" or "shock") could cause you to lose control of the equipment you are using. Turn the neurostimulator off and set the amplitude to the lowest setting before using this type of equipment.

- Don't do any strenuous activity, such as heavy lifting, extreme twisting or bending, or running, without first talking to your doctor.

Environmental Problems

Strong electrical fields, such as those produced by radio towers or some industrial equipment, can affect the function of your neurostimulator. This can cause uncomfortable stimulation (a “jolt” or “shock”). This problem is called **electromagnetic interference**, or EMI.

Warning

Electrical interference or a strong magnetic field (electromagnetic or from a permanent magnet) could switch your neurostimulator on or off unless your doctor has disabled the circuit that allows on/off control with the magnet. If this happens, use your programmer to switch the neurostimulator back on or off. Electrical interference should not change the stimulation settings that are programmed into your neurostimulator.

Most household appliances and office equipment do not produce interference strong enough to affect your neurostimulator.

You can normally operate the following household items and office equipment:

Microwave ovens

Televisions, AM/FM radios, VCRs, etc.

Tabletop appliances such as toasters, blenders, electric can openers, and food processors

Hand-held items such as hair dryers, electric shavers, and remote controls

Appliances such as washers, dryers, garage door openers, electric stoves, and vacuum cleaners

Electric blankets and heating pads

Personal computers, electric typewriters, copiers, and fax machines

Note: Be sure that appliances and equipment are properly installed and in good working condition before using them.

Strong interference could cause your neurostimulator to deliver inappropriate or additional stimulation to your spinal cord. Turning the neurostimulator off may reduce the effect of interference.

Devices or equipment to AVOID:

Theft detectors

Airport/security screening devices

Electric arc welding equipment

Electric substations and power generators

CB or ham radio antennas

Electric induction heaters used in industry to bend plastic

TV/radio transmitting towers

Electric steel furnaces

If you suspect that an electric or magnetic device is interfering with your neurostimulator, move away from the device or, if possible, turn the device off. Then use the patient programmer to turn your neurostimulator on or off.

 **Warning**

Use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores) as these devices can cause inappropriate or additional stimulation if you pass through them. Similarly, avoid airport security wands.

When approaching security arches or gates, do the following:

1. Show your patient identification card to security staff. Ask that you be allowed to bypass the security device, request a hand search, or ask that the security device be turned off.
2. If passing through the security device is unavoidable, turn the neurostimulator off.
3. Reduce the amplitude to the lowest setting.

4. Approach the security device slowly. If any stimulation is felt, back out of the security device immediately without changing body position. If no stimulation is felt, move quickly through to the other side.

Battery Information

Your neurostimulator operates on a sealed battery and, like all batteries, it will not run indefinitely. To replace the battery, your physician must replace the entire neurostimulator. This requires a surgical procedure.

See page 43 for information on how to check the status of your neurostimulator battery.

As the battery runs down, the stimulation may feel less intense, more intense, or different. These changes are normal and are no cause for alarm. When you feel this change in stimulation, make an appointment with your doctor to have your neurostimulator battery checked.

 **Caution**

If you have very low stimulation thresholds when your battery nears total depletion, you may feel more intense stimulation. Adjust your neurostimulator amplitude to a desired level or turn it off.

If the Neurostimulator Battery light on your patient programmer flashes, your neurostimulator may need replacement. Make an appointment with your doctor to have your neurostimulator battery checked.

As the neurostimulator battery wears down, you may have to increase the stimulation amplitude slightly to receive adequate pain relief.

Battery and Device Disposal

Remove the neurostimulator before burial or cremation. In some countries removal of battery-operated implantable devices is mandatory because of environmental concerns; please check your

local regulations. Also, the cremation process causes the battery to explode. Dispose of depleted batteries and worn-out devices according to local regulations.

Medical and Dental Procedures

With proper precautions, most medical procedures are unlikely to interfere with your neurostimulator. Always tell any medical staff that you have an implanted stimulation system. Turn the neurostimulator off and decrease your amplitude to its lowest setting before all medical and dental procedures.

Some common medical and dental procedures that should not affect your neurostimulator include:

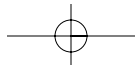
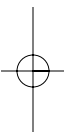
- Diagnostic x-rays such as dental x-rays—Exception: some x-rays that require tight enclosure of the area where your neurostimulator is implanted (such as mammography) may require adjustment to lessen pressure on your system.

- Dental drills and ultrasonic probes used to clean teeth—
Exception: These should not be placed directly over your implant site.
- Therapeutic ultrasound and electrolysis—Exception: These should not be used directly over your implant site.

 **Caution**

Some medical procedures can damage the neurostimulation system or can cause changes to the system that may produce discomfort, pain, or injury. Consult your doctor about risks and benefits of procedures such as:

- Electrosurgery (surgery performed by electrical methods)
- Diathermy (heat treatment)
- Lithotripsy (the crushing of a blockage within the urinary tract using electrical methods)
- Radiation therapy (that is, cancer treatment)
- Magnetic resonance imaging (MRI)—not recommended
- Defibrillation (electric shock to the heart)





COMMONLY ASKED QUESTIONS

What does stimulation feel like?

The electrical pulses delivered by your neurostimulator usually feel like tingling in the area of your pain.

Can I turn my neurostimulator on or off?

Yes. You can use your patient programmer or the control magnet to turn your neurostimulator on and off.

Will I be able to adjust the stimulation?

Yes. You can use your patient programmer to fine tune the amplitude, pulse width, and rate. However, this depends on the instructions and limits your doctor has stored in your neurostimulator.

What should I do if I have trouble turning my neurostimulator on?

Be sure to wait at least 8 seconds to feel stimulation after turning your neurostimulator on. If you do not feel any stimulation after 8 seconds, try again to turn the neurostimulator on while holding the patient programmer flat against your skin or clothing so that the keypad is directly over the neurostimulator. If you still cannot turn your neurostimulator on, contact your doctor.

How long will the battery in my neurostimulator last?

The battery life of the neurostimulator depends on the number of hours you use it each day and how strong the stimulation must be to control your pain. Your doctor can give you an estimate after your neurostimulator settings have been determined.

Can the battery be recharged?

No.

How is the neurostimulator battery replaced?

The entire neurostimulator must be surgically replaced because the neurostimulator's battery is sealed within the device. This replacement procedure usually does not include replacement of the lead or extension.

How large is the neurostimulator?

The neurostimulator is oval and approximately 2.4 inches long, 2.2 inches wide, and 0.4 inches thick.

Will the neurostimulator show through my clothes?

Depending on your body build, the neurostimulator may appear as a small bulge under the skin. However, your doctor will try to place the neurostimulator in an area that is most comfortable and cosmetically acceptable.

Will my system limit my activities?

Generally, no—you should be able to resume your normal daily activities. However, be sure to consult your doctor before undertaking any particularly strenuous activities such as heavy lifting or extreme twisting or bending.

What happens if my neurostimulator stops working?

Stimulation will stop and your pain may return. If this happens, contact your doctor.

Does the neurostimulator make any noise?

No.

What should I do if the stimulation changes or becomes painful?

Use your patient programmer or the control magnet to turn your neurostimulator off and contact your doctor.

What does it mean if I can feel stimulation only sometimes?

Your doctor may have programmed your neurostimulator to turn on and off at regular intervals. However, if you do not receive adequate pain relief, contact your doctor.

Is it normal for the stimulation to increase or decrease when I change position?

Generally, stimulation should feel constant. However, abrupt movements or changes in posture can make the stimulation feel more or less intense due to the position of the electrode(s) relative to your spinal cord.

Will a microwave oven interfere with the neurostimulator?

No.

How often should my doctor check the neurostimulator?

Your neurostimulator should be checked once every 6 months. However, your doctor may want to see you more or less often, depending on your condition.

What happens at a follow-up visit?

Your doctor will assess any changes in your medical condition, check your neurostimulator's battery level, monitor any drugs you are taking, and answer any questions you may have. As your condition changes, your physician may also reprogram your neurostimulator.

How often will I have to replace the battery in my patient programmer?

Battery life depends on how often the programmer is used. Typically, a patient can expect at least 3 months of use from a new alkaline battery. Always keep a fresh battery available.

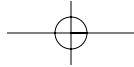
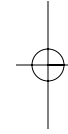
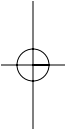
PATIENT PROGRAMMER SPECIFICATIONS

Power Source:	9-volt alkaline battery (type 6LR61 or 6F22E)
Operating Temperature:	49° F to 110° F 9° C to 43° C
Storage Temperature:	-40° F to 149° F -40° C to 65° C
Relative Humidity:	30% to 75%
Atmospheric Pressure:	20.7 in. Hg to 31.3 in. Hg (700 hPa to 1060 hPa)
Programmer Size:	Approximately 2.4 x 5.3 x 1.2 inches (135 mm x 61 mm x 30 mm)
Programmer Weight: (including battery)	Approximately 6 oz (170 g)
Battery Life:	3 months (average) for an alkaline battery
Mode of Operation:	Continuous

SPECIAL NOTICE

Medtronic® Neurostimulator kits consist of a neurostimulator and tools to connect the neurostimulator to implantable extensions. Neurostimulators are used with extensions, which are implanted in the extremely hostile environment of the human body. Neurostimulators may fail to function for a variety of causes including, but not limited to, medical complications, body rejection phenomena, or component failure. In addition, neurostimulators and tools may be easily damaged by improper handling or use. For tools, Medtronic disclaims all warranties, both express and implied, including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. Medtronic shall not be liable to any person or entity for any medical expenses or any direct incidental or consequential damages caused by any defect, failure, or malfunction of any tool, whether a claim for such damage is based upon warranty, contract, tort, or otherwise. No person has any authority to bind

Medtronic to any representation or warranty with respect to tools.



**MEDTRONIC® NEUROLOGICAL
IMPLANTABLE NEUROSTIMULATOR
LIMITED WARRANTY
(U.S. Customers Only)**

A. This Limited Warranty provides the following assurance to the patient who receives a Medtronic® Itrel® 3 Model 7425 Neurostimulator, hereafter referred to as Neurostimulator:

- (1) Should the Neurostimulator fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the date of implantation of the Neurostimulator, Medtronic will at its option: (a) issue a credit to the purchaser of the replacement Neurostimulator equal to the Purchase Price, as defined in ` requested as its replacement, or (b) provide a functionally comparable replacement Neurostimulator at no charge.

(2) Battery cell depletion will occur with time and is not considered to be a defect in materials or workmanship. The batteries have a specified capacity which may deplete at different rates depending on Neurostimulator settings and requirements for neurostimulation functions. Therefore, no representation is made that the Neurostimulator will last the entire term of this Limited Warranty.

(3) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original or current functionally comparable, or replacement Neurostimulator.

B. To qualify for the Limited Warranty, these conditions must be met:

(1) The Neurostimulator must be implanted prior to its "USE BY" date in conjunction with Medtronic leads or leads of equal quality and comparable electrical characteristics.

(2) All device registration materials must be completed and returned to Medtronic within thirty (30) days of implantation of the Neurostimulator.

(3) Replaced Neurostimulators must be returned to Medtronic within thirty (30) days of explantation and shall be the property of Medtronic.

C. This Limited Warranty is limited to its express terms. In particular:

- (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE, OR MALFUNCTION OF THE NEUROSTIMULATOR TO FUNCTION WITHIN NORMAL TOLERANCES, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.
- (2) This Limited Warranty is made only to the patient in whom the Neurostimulator was originally implanted. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM,

OR OTHERWISE. NO SUCH EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

- (3) 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. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions 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. This Limited Warranty gives the patient specific legal rights. The patient may also have other rights which vary from state to state.

(4) No person has any authority to bind Medtronic to any representation, condition, or warranty except this Limited Warranty.

(5) This Limited Warranty is not applicable to leads, extensions, or accessories used with this Neurostimulator.

* This Limited Warranty is provided by Medtronic Neurological, 800 53rd Avenue NE, Minneapolis, MN 55421-1200. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

**MEDTRONIC® NEUROLOGICAL
ITREL® EZ™ MODEL 7434A PATIENT PROGRAMMER
LIMITED WARRANTY
(U.S. Customers Only)**

A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic® Itrel® EZ™ Model 7434A Patient Programmer, hereafter referred to as "Equipment":

- (1) Should the Equipment fail to function within normal tolerances due to a defect in materials or workmanship within a period of one (1) year, commencing with the delivery of the Equipment to the purchaser, Medtronic will at its option: (a) repair or replace any part or parts of the Equipment; (b) issue a credit to the purchaser equal to the Purchase Price, as defined in Subsection A(2), against the purchase of the replacement Equipment or (c) provide a functionally comparable replacement Equipment at no charge.

- (2) As used herein, Purchase Price shall mean the lesser of the net invoiced price of the original, or current functionally comparable, or replacement Equipment.
- B. To qualify for Limited Warranty set forth in Section A(1), the following conditions must be met:
 - (1) The Equipment must be returned to Medtronic within thirty (30) days after discovery of the defect (Medtronic may, at its option, repair the Equipment on site).
 - (2) The Equipment must not have been repaired or altered outside of Medtronic's factory in any way which, in the judgment of Medtronic, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse, or accident.
- C. This Limited Warranty is limited to its express terms. In particular:
 - (1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED

ON ANY DEFECT, FAILURE, OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE.

- (2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM, OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.

(3) 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. If any part or term of this Limited Warranty is held to be illegal, unenforceable, or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions 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. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

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* This Limited Warranty is provided by Medtronic Neurological, 800 53rd Avenue NE, Minneapolis, MN 55421-1200. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.

GLOSSARY

Amplitude—The amount or “volume” (strength or intensity) of stimulation required to mask your pain. This setting is adjusted most often by patients.

Beeper Volume Control Switch—The switch located under the battery cover. It lets you turn the beeper Off or set the volume to Low or High.

Control Magnet—An optional magnet that allows you to turn your neurostimulation system on and off.

Electrode—The small metal conductor near the tip of the lead that is placed near your spinal cord. Electrodes deliver tiny pulses of electricity to the area where your pain signals will be blocked.

Electromagnetic Interference (EMI)—Interference caused by the energy field generated by electrical or magnetic devices such as

airport security systems or television transmitting towers.

Extension—The thin wire that connects the neurostimulator to the lead.

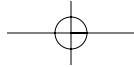
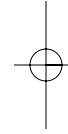
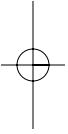
Lead—The wire with small metal electrodes near the tip that is implanted near the nerves to be stimulated.

Neurostimulator—The power source of your system. It contains a special battery and electronics to control the stimulation you feel.

Patient Programmer—The hand-held device that allows you to turn your neurostimulator on and off and finely adjust some of the stimulation settings programmed by your doctor.

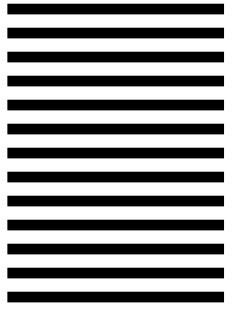
Physician Programmer—The small computer your doctor uses to send stimulation instructions to your neurostimulator.

Pulse Width—The length or duration of an electrical pulse.





NO POSTAGE
NECESSARY
IF MAILED
IN THE
UNITED STATES

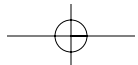
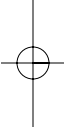


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