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FCC Information

The following is communications regulation information on the Model 3037 Patient Programmer.

FCC ID: LF537741

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.
Contact Information

Doctor

Telephone

Nurse

Hotline

Clinic

Hospital

If you lose your identification card contact:

USA
Medtronic Inc., Patient Registration Services
Mail Stop SLK35
800 53rd Avenue NE
Minneapolis, MN 55421-1200
(1-800-551-5544)

Europe, Africa, Middle East, and Asia-Pacific Countries
Your local Medtronic sales office
(Refer to the Medtronic contacts at the end of this manual.)
# Label symbols

This section explains the symbols on all products and packaging related to the patient programmer.

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>!</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>!</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="symbol" alt="CE" /></td>
<td>Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&amp;TTE Directive 1999/5/EC.</td>
</tr>
<tr>
<td><img src="symbol" alt="USA" /></td>
<td>For USA audiences only</td>
</tr>
<tr>
<td><img src="symbol" alt="C22.2" /></td>
<td>System meets the applicable Canadian (CAN/CSA-C22.2 No. 60601-1) electrical safety standard requirements.</td>
</tr>
<tr>
<td><img src="symbol" alt="Temp" /></td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>SN</td>
<td>Serial number</td>
</tr>
<tr>
<td><img src="symbol" alt="IEC" /></td>
<td>IEC 60601-1/EN60601-1, Type BF Equipment</td>
</tr>
<tr>
<td>Symbol</td>
<td>Description</td>
</tr>
<tr>
<td>--------</td>
<td>-------------</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See <a href="http://recycling.medtronic.com">http://recycling.medtronic.com</a> for instructions on proper disposal of this product.</td>
</tr>
<tr>
<td>![Logo]</td>
<td>Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product).</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Non-ionizing electromagnetic radiation</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Screen light</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Antenna jack</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Authorized representative in the European community</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Manufacturer</td>
</tr>
</tbody>
</table>
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Glossary

Amplitude – The strength or intensity of an electrical pulse.

Bonding – The process of associating a patient programmer with a specific neurostimulator so that the programs defined in the patient programmer are functional and apply only to that neurostimulator.

Clinician – A health care professional such as a doctor or nurse.

Clinician programmer – A device used by a clinician to send instructions to the neurostimulator and the patient programmer.

Contraindication – A condition or circumstance when a person should not have a neurostimulation system.

Cycle Time Off – In a cycling mode, the length of time between stimulation periods, that is, the time of the “resting” period.
**Cycle Time On** – In a cycling mode, the length of time that stimulation is delivered.

**Diathermy** – A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing. For additional information, refer to “Contraindications” on page 20.

**Electrode** – A metal component near the tip of the lead. Electrodes deliver electrical pulses to your sacral nerve.

**Electromagnetic interference (EMI)** – A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly, damage the neurostimulator, or even injure
you. Refer to the *InterStim Therapy Patient Guide*.

**Indication** – The purpose of the neurostimulation system and the medical condition for which it may be implanted.

**Information screen** – A screen displayed on the patient programmer that alerts you to a problem with the programmer, antenna, or neurostimulator.

**Lead** – A thin wire with protective coating that has metal electrodes on one end and a connector on the other.

**Neurostimulation system** – Components that deliver electrical pulses to your sacral nerve.

**Neurostimulator** – The power source of a neurostimulation system. It contains the battery and electronics that control the stimulation you feel.

**Parameter** – One of three stimulation settings that adjust the electrical pulse: amplitude, pulse width, and rate. You will
only be able to adjust amplitude. Your clinician can adjust all parameters.

**Patient programmer** – A hand-held device that allows you to turn your neurostimulator on and off. It is also used to adjust some stimulation settings.

**Precaution** – A statement describing actions that could result in damage to or improper functioning of a device.

**Program** – Stimulation directed to a specific area of the sacral nerve. Each program consists of specific parameters prescribed by your clinician.

**Programming** – Using a clinician or patient programmer to communicate stimulation settings to a neurostimulator.

**Program row** – The bottom row on the Therapy screen. This row includes programs and amplitude values that a patient can change.

**Pulse width** – The length or duration of an electrical pulse. See Parameter.
Rate – The number of electrical pulses delivered each second. See Parameter.

Sacral Nerve – A nerve in the lower back near the tailbone that controls bladder and bowel function.

Settings – See Stimulation settings.

SoftStart/Stop – This optional feature, that may be programmed by your clinician, starts and stops stimulation gradually by slowly increasing it to the programmed amplitude or slowly decreasing it to off.

Status row – The top row on the Therapy screen. Icons represent information about the neurostimulator and the patient programmer.

Stimulation – The delivery of electrical pulses to the sacral nerve.

Stimulation settings – Refers to all the features that define the stimulation you feel. The clinician programs all stimulation settings. You can adjust some stimulation settings.
**Synchronize** – The process of sending and receiving information between the patient programmer and neurostimulator.

**Telemetry** – A radio-frequency signal that allows the neurostimulator and the patient programmer to communicate with each other.

**Therapy** – Treatment of a disease or condition. InterStim Therapy is the delivery of stimulation to your sacral nerve.

**Therapy screen** – The main screen displayed on the patient programmer.

**Warning** – A statement describing an action or situation that could harm you.

**Warning screen** – A screen displayed on the patient programmer that alerts you to a problem with the programmer, antenna, or neurostimulator.
1 Introduction
This manual contains important information about your Medtronic patient programmer. The patient programmer is a hand-held device that allows you to turn your neurostimulator on and off and adjust the stimulation. The neurostimulator is an implanted device that sends mild electrical pulses through an attached lead system to deliver stimulation.

The Medtronic InterStim iCon Model 3037 Patient Programmer is used with the Medtronic Models 3058 and 3023 Neurostimulators.

Please read this entire manual before using your patient programmer. This manual will help you understand and use your InterStim system so you can adjust your therapy as your needs change.
Manual overview
This manual covers the following topics:

- A description of your patient programmer
- How to use your patient programmer
- Troubleshooting suggestions
- How to care for your patient programmer
- A glossary of terms

Ask your clinician to explain anything that is unclear.

Package contents
The patient programmer package contains the following:

- One patient programmer
- Two AAA alkaline batteries
- Carrying case
- Product literature
Contraindications

Implantation of an InterStim system is contraindicated (absolutely not allowed under any circumstances because the risk outweighs any benefits) for:

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

After implantation of any system components, the following contraindication applies:

Diathermy – Inform anyone treating you that you CANNOT have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, and can cause tissue damage, resulting in severe injury or death.
Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and can require additional surgery to remove or replace parts of your implanted system.

Personal injury or device damage can occur during diathermy treatment when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on your body (not just where your neurostimulation system is located).
- diathermy is used to deliver heat or no heat.
- any component of your neurostimulation system (lead, extension, neurostimulator) remains in your body.
Precautions

Communication interference from EMI –
When using your patient programmer to communicate with your neurostimulator, move away from equipment that may generate electromagnetic interference (EMI) or turn off the likely source of EMI. EMI may disrupt communication between the patient programmer and neurostimulator. Examples of EMI sources are computer monitors, cellular telephones, and motorized wheelchairs.
For more information about EMI, refer to the InterStim Therapy Patient Guide.

Patient control devices – Do not place patient control devices (e.g., patient programmer) over another device (e.g., pacemaker, defibrillator, another neurostimulator). The patient control device could accidentally change the operation of another device.

Patient device handling – To avoid damaging the device, do not immerse it in
liquid; do not clean it with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or mishandle it in a way that may damage it.

**Patient device modification** – Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.

**Patient device use** – Equipment is not certified for use in the presence of a flammable or anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

**Note:** For additional warnings, precautions, and adverse events related to InterStim Therapy, refer to the *InterStim Therapy Patient Guide*. If you did not receive this patient guide, contact your clinician.
2 Using your patient programmer
Patient Programmer Description

After surgery, your clinician used a small computer (clinician programmer) to send stimulation instructions to your neurostimulator. These instructions control the stimulation you feel. The instructions are stored in the neurostimulator. If needed, your clinician can use the clinician programmer to change the instructions.

Stimulation is the delivery of mild electrical pulses to your sacral nerve by the neurostimulator. An electrical pulse consists of three parameters: amplitude, pulse width, and rate.

- Amplitude is the strength of the pulse.
- Pulse width is the duration of the pulse.
- Rate is the number of pulses per second.
A set of programmed parameters is called a program. Your clinician may prescribe up to four different programs. This gives you alternate stimulation options if you are not experiencing symptom relief or if stimulation is uncomfortable.

Stimulation instructions are also sent from the clinician programmer to the patient programmer. The patient programmer allows you to:

- Turn your neurostimulator on and off
- Change programs
- Adjust amplitude within the limits set by your clinician.

Your neurostimulator only accepts programming from the clinician programmer or patient programmer; other devices are not able to program your neurostimulator and may injure you or damage your neurostimulator.
How the patient programmer works

The patient programmer communicates with your neurostimulator by sending signals to and receiving signals from the neurostimulator. To send and receive the signals, either the internal antenna of the patient programmer, or the detachable external antenna (Model 37092), must be placed over the neurostimulator (Figure 2.2).
Notes:

- The internal antenna is located inside the back of the patient programmer.
- The patient programmer screen must face outward, away from your body.
- The detachable external antenna can be used if you have difficulty reaching the neurostimulator and plugs into the side of the patient programmer. For more information, see “Optional detachable antenna” on page 55.

![Diagram](image)

**Figure 2.2** Place the patient programmer over the neurostimulator.
Summary of keys

Table 2.1 describes the patient programmer keys and their function.

<table>
<thead>
<tr>
<th>Key</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="on.png" alt="On" /></td>
<td><strong>Turns the neurostimulator on or off.</strong></td>
</tr>
</tbody>
</table>
| ![Off](off.png) | - The patient programmer must be held over the neurostimulator while pressing the **Neurostimulator on** or **off** key.  
- Pressing either of these keys also automatically synchronizes the neurostimulator and patient programmer and displays the **Therapy** screen. |
| ![Sync](sync.png) | **Synchronizes the neurostimulator and patient programmer.** |
| | **Activates the selected program.**  
The patient programmer must be held over the neurostimulator while pressing the **Sync** key. |
### Table 2.1 Summary of keys (continued)

<table>
<thead>
<tr>
<th>Key</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decrease</td>
<td><strong>Decreases</strong> or <strong>increases</strong> amplitude.</td>
</tr>
<tr>
<td></td>
<td>- The patient programmer must be held over the neurostimulator while pressing the <strong>Increase</strong> or <strong>Decrease</strong> key.</td>
</tr>
<tr>
<td>Increase</td>
<td>- Pressing and holding the <strong>Increase</strong> or <strong>Decrease</strong> key changes the amplitude approximately every half-second.</td>
</tr>
<tr>
<td></td>
<td>- Amplitude change occurs immediately without pressing the <strong>Sync</strong> key.</td>
</tr>
<tr>
<td>Navigator</td>
<td><strong>Moves the selection box on the Therapy screen up/down/left/right.</strong></td>
</tr>
<tr>
<td></td>
<td>The left and right <strong>Options</strong> arrows at the left and right end of the selection box on the <strong>Therapy</strong> screen indicate that the row continues.</td>
</tr>
<tr>
<td>Power/Backlight</td>
<td><strong>Turns the patient programmer power on and off.</strong></td>
</tr>
<tr>
<td></td>
<td>Pressing and holding this key also turns the backlight on and off. The backlight provides light to the display.</td>
</tr>
</tbody>
</table>
Always carry your patient programmer

Because your patient programmer is the only way to turn your neurostimulator on or off or adjust the stimulation, you should always carry it with you.

In particular, always bring your patient programmer with you to InterStim Therapy appointments. For your programmer to be fully functional, your clinician needs to “bond” it electronically to the neurostimulator with the clinician programmer.

In addition, always bring your patient programmer to appointments with other healthcare providers. During certain procedures, you may need to turn your neurostimulator off. You should also bring your InterStim Therapy Patient Guide. It contains important information about the InterStim system that your healthcare providers should be aware of.
Using the patient programmer

Synchronizing and displaying the Therapy screen

Synchronizing sends information between your neurostimulator and patient programmer. All communication with the neurostimulator begins with synchronization.

• To synchronize your neurostimulator and the patient programmer, hold the programmer over your neurostimulator with the screen facing outward and press the **Neurostimulator on** key, the **Neurostimulator off** key, or the **Sync** key as shown in Figure 2.3.

**Notes:**

– Using the **Neurostimulator on** key to synchronize, also turns on the neurostimulator.
- Using the **Neurostimulator off** key to synchronize, also turns off the neurostimulator.

- Using the **Sync** key only synchronizes the programmer and does not turn the neurostimulator on or off.

**Figure 2.3** Synchronizing your neurostimulator and patient programmer.

After synchronizing, the **Therapy** screen appears (Figure 2.4).
Figure 2.4 Therapy screen.

Icons on the Therapy screen indicate your neurostimulator settings and the patient programmer battery level (Table 2.2).

Table 2.2 Therapy screen icons

<table>
<thead>
<tr>
<th>Row</th>
<th>Icons</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Status</td>
<td>⚡️</td>
<td>Neurostimulator is on</td>
</tr>
<tr>
<td></td>
<td>🕔</td>
<td>Neurostimulator is off</td>
</tr>
<tr>
<td></td>
<td>⚡️</td>
<td>Neurostimulator battery level is low</td>
</tr>
<tr>
<td></td>
<td>📦</td>
<td>Patient programmer battery level</td>
</tr>
</tbody>
</table>
To receive the most effective therapy, some days you may need to adjust your stimulation several times; other days you may not need to adjust it at all. Your clinician will provide complete guidelines about when you may want to adjust your stimulation. Table 2.3 provides general guidelines for adjusting your stimulation.

Table 2.2 Therapy screen icons (continued)

<table>
<thead>
<tr>
<th>Row</th>
<th>Icons</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Program</td>
<td>✓</td>
<td>Active</td>
</tr>
<tr>
<td>1, 2, 3, 4</td>
<td>Program name</td>
<td></td>
</tr>
<tr>
<td>Amplitude</td>
<td>. . .</td>
<td>Amplitude</td>
</tr>
</tbody>
</table>

**Guidelines for adjusting your stimulation**
Table 2.3  Stimulation adjustment guidelines

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stimulation is too strong</td>
<td>Decrease amplitude</td>
</tr>
<tr>
<td>Stimulation is not strong enough</td>
<td>Increase amplitude</td>
</tr>
<tr>
<td>Stimulation does not relieve your symptoms</td>
<td>Adjust amplitude or change to a different program</td>
</tr>
<tr>
<td>The pulses (tapping sensations) feel too slow</td>
<td>Change to a different program</td>
</tr>
<tr>
<td>The pulses (tapping sensations) feel too fast</td>
<td>Change to a different program</td>
</tr>
<tr>
<td>You have unexpected changes in stimulation</td>
<td>1. Turn off the neurostimulator.</td>
</tr>
<tr>
<td></td>
<td>2. Decrease amplitude, turn on the neurostimulator, and slowly increase amplitude to the desired level.</td>
</tr>
<tr>
<td></td>
<td>or Change to a different program and turn on the neurostimulator.</td>
</tr>
</tbody>
</table>
### Table 2.3 Stimulation adjustment guidelines (continued)

<table>
<thead>
<tr>
<th>Situation</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>You have tried changing programs and adjusting stimulation but are unable to find an effective setting.</td>
<td>Contact your clinician.</td>
</tr>
<tr>
<td>You will be passing through a theft detector or security device</td>
<td>Before engaging in any of these activities, consult the InterStim Therapy Patient Guide for details.</td>
</tr>
<tr>
<td>You will be using potentially dangerous equipment</td>
<td>△ WARNING Failure to follow the recommendations in the InterStim Therapy Patient Guide may injure you or damage your InterStim system.</td>
</tr>
<tr>
<td>You will be having a medical or dental procedure</td>
<td></td>
</tr>
</tbody>
</table>

### Turning your neurostimulator on or off

**Note:** You may want to turn the neurostimulator off when you don’t require stimulation and if your doctor has instructed you to do so. Turning the neurostimulator off
when you don’t need it saves neurostimulator battery life.

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the **Neurostimulator on** or **off** key (Figure 2.5). The Therapy screen appears.

2. Verify that the appropriate on or off icon is displayed on the Therapy screen (Figure 2.5).

![Figure 2.5 Turning your neurostimulator on or off.](image)

**Figure 2.5** Turning your neurostimulator on or off.

**Notes:**

- When you turn your neurostimulator on or off, the patient programmer and neurostimulator are synchronized.
– If your clinician programmed SoftStart/Stop, the amplitude will gradually increase from zero to the selected setting when you turn your neurostimulator on or gradually decrease from the selected setting to zero when you turn your neurostimulator off.

**Adjusting stimulation settings**

The following instructions describe how to use the Navigator key, change programs, and increase or decrease amplitude.

**Notes:**

- When a stimulation setting is changed, you will see the change on the Therapy screen.
- If audio is on, the tones are described below. (Refer to changing the audio format on page 50.)
  – One tone means the stimulation setting was successfully changed.
- Three rapid tones mean the stimulation setting change did not occur.
- Up to ten short tones means the patient programmer is unsuccessfully trying to establish communication with the neurostimulator.

**Using the Navigator key**

The **Navigator** key arrows move the selection box on the **Therapy** screen (Figure 2.6).

**Figure 2.6** Navigator key.
• To move the selection box between the Status and Program rows, press the up ▲ and down ▼ arrows on the Navigator key. Changing programs and adjusting amplitude can only be done when the selection box is in the Program row. Changing preferences and accessing patient programmer information screens can only be done when the selection box is in the Status row.

• To move the selection box across a row that continues, press the left ◀ and right ► arrows on the Navigator key. If the selection box is in the Program row, this allows you to scroll through the four available programs. If the selection box is in the Status row, this allows you to scroll through the audio, contrast, and number format preferences as well as the patient program information screens.

• When moving the selection box with the Navigator key, you do not need to hold your patient programmer over your
neurostimulator. However, you must hold your patient programmer over your neurostimulator when pressing all other keys except the **Power** key.

A row continues when the left and right **Options** arrows appear to the left and right of the selection box (Figure 2.7).

![Figure 2.7 The Options arrows and selection box.](image)

**Changing a program**

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the **Sync** key. The **Therapy** screen appears.

   **Note:** Changing a program may take up to 5 seconds.
2. Press the left or right arrows on the **Navigator** key to move the selection box to the desired program (Figure 2.8).

   **Note:** A blank box indicates that a program is not active. It will become active when you press the **Sync** key (refer to Step 3 on page 44).

   ![Figure 2.8 Change to a different program.](image)

3. Hold the programmer over your neurostimulator with the screen facing outward and press the **Sync** key to send the change to your neurostimulator (Figure 2.9).

4. Verify that the new program is active on the **Therapy** screen (Figure 2.9).
Using your patient programmer 2

**Figure 2.9** Active program.

**Increasing or decreasing amplitude**

**Notes:**

- To increase amplitude, the neurostimulator must be on.
- To decrease amplitude, the neurostimulator may be on or off.
- You can only change amplitude in a program that is active.
- You can only increase or decrease amplitude within the limits programmed by your clinician.
1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the **Neurostimulator on** key, **Neurostimulator off** key, or **Sync** key. The **Therapy** screen appears.

2. Hold the patient programmer over your neurostimulator with the screen facing outward and press the **Increase** key or **Decrease** key as needed (Figure 2.10). The increase or decrease occurs without pressing the **Sync** key and is saved in the neurostimulator. However, you may not feel the change immediately.

**Figure 2.10** Decrease and Increase keys.
Notes:

- Pressing and holding the **Increase** or **Decrease** key, changes the value approximately every half-second.

- If one of the information screens in Table 2.4 appears, you tried to increase or decrease the value beyond the limits programmed by your clinician.

<table>
<thead>
<tr>
<th>Lower limit</th>
<th>You tried to decrease amplitude below the lowest value allowed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Lower limit icon]</td>
<td>Press any arrow on the Navigator key to clear the screen.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Upper limit</th>
<th>You tried to increase amplitude above the highest value allowed.</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Upper limit icon]</td>
<td>Press any arrow on the Navigator key to clear the screen.</td>
</tr>
</tbody>
</table>

**Table 2.4 Parameter limit screens**
Patient programmer batteries

Always keep two new AAA alkaline batteries immediately available for replacement. New batteries provide about two months use, depending upon how often the programmer is used.

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

Checking patient programmer batteries

The patient programmer battery level is displayed on the **Therapy** screen (Figure 2.11).

- To check the programmer battery level, hold the patient programmer over your neurostimulator with the screen facing outward and press the **Sync** key. The **Therapy** screen appears displaying the programmer battery level (Figure 2.11).
Using your patient programmer

Figure 2.11 Patient programmer battery level.

If the patient programmer batteries need replacement, one of the screens in Table 2.5 appears.

Table 2.5 Patient programmer battery replacement screens

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="Battery level" /></td>
<td>The patient programmer batteries are low. You can finish programming. <strong>Press any arrow on the Navigator key to clear the screen; then continue programming. Replace the patient programmer batteries before the batteries become depleted.</strong></td>
</tr>
<tr>
<td><img src="image" alt="Battery level" /></td>
<td>The patient programmer batteries are depleted. Programming is not possible. <strong>Replace the patient programmer batteries now.</strong></td>
</tr>
</tbody>
</table>
Changing preferences: audio, contrast, and number format

Audio, contrast and number format preferences are accessed from the Status row of the Therapy screen. Table 2.6 lists the preference icons and the options available. To change preferences, follow the instructions below.

<table>
<thead>
<tr>
<th>Icons</th>
<th>Preference</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>🎧</td>
<td>Audio</td>
<td>On or off</td>
</tr>
<tr>
<td>🌃</td>
<td>Contrast</td>
<td>Lighten or darken</td>
</tr>
<tr>
<td>🕵️</td>
<td>Number format</td>
<td>Decimal or comma</td>
</tr>
</tbody>
</table>

1. Hold the patient programmer over your neurostimulator with the screen facing outward and press the Sync key. The Therapy screen appears.

2. Press the up arrow on the Navigator key to move the selection box to the Status row (Figure 2.12).
3. Press the left or right arrow on the Navigator key to move the selection box to the preference which you would like to change (Figure 2.13).

4. Press the down arrow to move the selection box to the Change row (Figure 2.14).
Figure 2.14 Move to Change row.

5. Follow the steps in Table 2.7 to change the selected preference.

Table 2.7 Changing preferences

<table>
<thead>
<tr>
<th>Preference</th>
<th>Steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Audio</strong></td>
<td>1. Press the left or right arrow on the Navigator key to move the selection box to audio on or off. 2. Go to step 3 on page 53.</td>
</tr>
<tr>
<td><strong>Contrast</strong></td>
<td>1. Press the left or right arrow on the Navigator key to make the contrast lighter or darker. 2. Go to step 3 on page 53.</td>
</tr>
<tr>
<td><strong>Number format</strong></td>
<td>1. Press the left or right arrow on the Navigator key to change from the comma to the decimal point format. 2. Go to step 3 on page 53.</td>
</tr>
</tbody>
</table>
3. When the change is displayed on the screen, move the selection box to the Status (top) row and scroll back to the Therapy screen. Scrolling to the Therapy screen saves the preference change in the patient programmer.

4. Press the left ⬅ or right ➤ arrow on the Navigator key to move to another preference or return to the Therapy screen.

**Accessories**

A carrying case and identification label are included with the programmer. Two AAA alkaline batteries that provide the power for your patient programmer are also included.

**Using the carrying case and labeling the patient programmer**

The carrying case has a pouch to hold the patient programmer and the quick reference guide (Figure 2.15).
The case also has a loop on the back that attaches to a belt.

**Figure 2.15** Insert the patient programmer into the case.

An identification label is provided with your patient programmer. Write your name and phone number on the label using permanent ink and place it on the back of your patient programmer in case the programmer is lost (Figure 2.16).

**Figure 2.16** Place the adhesive label on the back of the patient programmer.
Optional detachable antenna

The detachable external antenna (Model 37092) can be used if you have difficulty reaching the neurostimulator with your patient programmer. It is also useful for viewing the patient programmer screen while you are adjusting stimulation.

Connecting the antenna

1. Place the antenna over your neurostimulator (Figure 2.17).

Figure 2.17 Place the antenna over your neurostimulator.
2. Pull the fabric of your clothing through the large opening in the antenna. Then, wedge the fabric in the narrow slit to secure the antenna in place (Figure 2.18).

![Figure 2.18](image)

**Figure 2.18** Pull the fabric through the slit (a) and wedge in place (b).

3. Push the antenna plug firmly into the antenna jack ( genital ) on the side of the patient programmer (Figure 2.19).
Using the antenna

After the antenna is connected, follow the previous instructions for using the patient programmer.

When you have finished using the patient programmer, grasp the antenna plug and pull it out of the patient programmer.

**Note:** Do not pull directly on the antenna cable to disconnect the cable from the patient programmer because this may damage the antenna cable.
3 Caring for your patient programmer
This section describes how to care for and dispose of your patient programmer and accessories.

**Cleaning and care**

Follow these guidelines to ensure that the patient programmer and accessories function properly.

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

- Keep the device out of the reach of children.
- Use the device only as explained to you by your clinician or as discussed in this manual.
• Follow all warnings and precautions in this chapter and the *InterStim Therapy Patient Guide* provided by your clinician.

• Handle the device with care. Do not drop, strike, or step on the device.

• Do not dismantle or tamper with the device. Do not attempt to service it yourself.

• Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.

• The device is not waterproof. Do not allow moisture to get inside the device.

• Keep two fresh AAA batteries available.

• Replace low or depleted batteries.
Replacing patient programmer batteries

1. Open the battery compartment cover (Figure 3.1).

![Figure 3.1 Opening the battery cover.](image)

2. Remove the depleted batteries. (For disposal information, see “Battery and patient programmer disposal” on page 64.)

3. Insert the new batteries as shown on the battery compartment label.

4. Close the battery compartment cover.
Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the patient programmer are not required. If the patient programmer requires repair or is nonfunctional, refer to the contact information below. The patient programmer contains no user-serviceable parts.

USA and Asia-Pacific countries
Medtronic Neuromodulation
Repair Lab RCC 135
Dock B
7000 Central Ave. N.E.
Minneapolis, MN 55432-3576
Tel. 1-800-328-0810

Europe, Africa, and Middle East countries
Medtronic EOC
Earl Bakkenstraat 10
Industry Park Trilandis
Heerlen, 6244PJ
The Netherlands
Tel. 31-45-566-8000
Fax. 31-45-566-8668
Battery and patient programmer disposal

Dispose of depleted batteries and worn out devices according to local requirements. If you no longer need your patient programmer and would like to donate it, contact your clinician.

Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of AIMD Directive 90/385/EEC and R&TTE Directive 1999/5/EC.

For additional information, contact Medtronic at the telephone numbers and addresses provided on the back cover.
# Specifications

Table 3.1  Patient programmer specifications

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power source</td>
<td>2 AAA alkaline batteries (non-rechargeable, LR03)</td>
</tr>
<tr>
<td>Operating temperature</td>
<td>9 °C to 43 °C (49 °F to 110 °F)</td>
</tr>
<tr>
<td>Temperature limitation</td>
<td>-34 °C to 57 °C (-30 °F to 135 °F)</td>
</tr>
<tr>
<td>Size</td>
<td>Approximately 9.4 x 5.6 x 2.8 cm (3.7 x 2.2 x 1.1 inches)</td>
</tr>
<tr>
<td>Weight, including batteries</td>
<td>Approximately 111 g (3.9 oz.)</td>
</tr>
<tr>
<td>Battery life</td>
<td>2 months (average) for alkaline batteries</td>
</tr>
</tbody>
</table>
4 Troubleshooting
This chapter will help you solve problems with your patient programmer. It also provides information on when to call your clinician or Medtronic.

Note: If you cannot solve a problem or if your problem is not described here, contact your clinician.

**Patient programmer screens**

The programmer displays warning (⚠️), communication (🚫), and information (_OPCODE) screens to alert you to a problem with your system or guide you during programmer use. If the audio is on, a series of tones alerts you to some messages.

**Warning screens**

Warning screens indicate a problem with the patient programmer, antenna, or
neurostimulator. Table 4.1 describes warning screens and provides instructions (see blue text) on how to resolve the problem and clear the screen.

Table 4.1 Warning screens

<table>
<thead>
<tr>
<th>Screen</th>
<th>Cause and action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synchronize programmer and neurostimulator</strong></td>
<td>The programmer and the neurostimulator are not synchronized.</td>
</tr>
<tr>
<td>![Warning symbol]</td>
<td><strong>Synchronize the programmer and neurostimulator.</strong></td>
</tr>
<tr>
<td><strong>Replace programmer batteries</strong></td>
<td>The programmer batteries are depleted. Programming is not possible.</td>
</tr>
<tr>
<td>![Warning symbol]</td>
<td><strong>Replace the programmer batteries now.</strong></td>
</tr>
</tbody>
</table>
### Table 4.1 Warning screens (continued)

<table>
<thead>
<tr>
<th>Screen</th>
<th>Cause and action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Call Medtronic</td>
<td>The system is not working correctly, but it may be possible to correct the problem remotely. You probably are receiving stimulation.</td>
</tr>
<tr>
<td></td>
<td><strong>Write down the code shown on the lower right corner of the screen. Call Medtronic.</strong></td>
</tr>
<tr>
<td>Call clinician</td>
<td><strong>EOS:</strong> Your neurostimulator battery is depleted. You cannot adjust the stimulation. You can only turn the neurostimulator off.</td>
</tr>
<tr>
<td></td>
<td><strong>Other code:</strong> The system is not working correctly. Stimulation might have stopped.</td>
</tr>
<tr>
<td></td>
<td><strong>Write down the code shown on the lower right corner of the screen. Call your clinician.</strong></td>
</tr>
</tbody>
</table>
Communication screen

A communication screen shows you that a process is in progress. Table 4.2 describes the communication screen for your neurostimulation system.

The communication screen automatically clears when the neurostimulation system finishes the process.

Table 4.2 Communication screen

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description and action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Communication</td>
<td>The programmer is communicating or attempting to communicate with the neurostimulator. No action required.</td>
</tr>
</tbody>
</table>

Information screens

The information screens show the programming status and the battery level for your programmer and neurostimulator. Table 4.3 describes information screens and instructions on how to proceed (see blue text).
Note: Press any arrow on the Navigator key to clear an information screen.

Table 4.3 Information screens

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description and action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poor communication</td>
<td>The programmer attempted to communicate with the neurostimulator, but communication was unsuccessful.</td>
</tr>
<tr>
<td></td>
<td>Reposition the programmer over the neurostimulator with the screen facing outward and try communication again.</td>
</tr>
<tr>
<td></td>
<td>If using the detachable antenna, check that the antenna is connected properly, reposition the antenna, and try communication again.</td>
</tr>
<tr>
<td>Press Neurostimulator on key</td>
<td>You tried increasing amplitude with the neurostimulator off.</td>
</tr>
<tr>
<td></td>
<td>Turn your neurostimulator on and try increasing amplitude again.</td>
</tr>
<tr>
<td>Screen</td>
<td>Description and action</td>
</tr>
<tr>
<td>--------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Upper limit</td>
<td>You tried increasing amplitude above the highest value allowed.</td>
</tr>
<tr>
<td><img src="upper_limit_icon.png" alt="Upper limit icon" /></td>
<td></td>
</tr>
<tr>
<td>Lower limit</td>
<td>You tried decreasing amplitude below the lowest value allowed.</td>
</tr>
<tr>
<td><img src="lower_limit_icon.png" alt="Lower limit icon" /></td>
<td></td>
</tr>
<tr>
<td>Programmer batteries are low</td>
<td>The patient programmer batteries are low. You can finish programming.</td>
</tr>
<tr>
<td><img src="batteries_are_low_icon.png" alt="Programmer batteries are low icon" /></td>
<td>Replace the programmer batteries before the batteries become depleted.</td>
</tr>
<tr>
<td>Neurostimulator battery is low</td>
<td>The neurostimulator battery is low. Stimulation will not be available soon.</td>
</tr>
<tr>
<td><img src="battery_low_icon.png" alt="Neurostimulator battery is low icon" /></td>
<td>Call your clinician.</td>
</tr>
</tbody>
</table>
### Table 4.3 Information screens (continued)

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description and action</th>
</tr>
</thead>
</table>
| **Sync up**| You tried increasing or decreasing amplitude for an inactive program.  
             | **Synchronize the programmer and neurostimulator.**                                   |
| ![Sync up](image) |                                                                                       |
| **New program** | The patient programmer has detected a new program in the neurostimulator and added it to the program list.  
                      | The number shown indicates the number of the new program. This may replace an existing program.  
                      | **No action is required.**                                                            |
| ![New program](image) |                                                                                       |
Table 4.3 Information screens (continued)

<table>
<thead>
<tr>
<th>Screen</th>
<th>Description and action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient programmer information for Medtronic or your Clinician</td>
<td></td>
</tr>
</tbody>
</table>

The screens below provide information to your clinician or Medtronic during troubleshooting and are accessed from the Status row on the Therapy screen.

If you accidentally encounter these screens ignore them and use the Navigator key to return to the Program row on the Therapy screen.

![Diagram](image-url)
Possible problems and solutions

Table 4.4 will help you solve problems or identify when to call your clinician or Medtronic. Problems are described in the left column (bold black text). The right column lists possible causes of the problem (plain text) and how to correct the problem (bold blue text).

Note: If a problem is not solved after several attempts, or if a problem is not described here, contact your clinician.
## Troubleshooting problems

<table>
<thead>
<tr>
<th>Problems</th>
<th>Causes and actions</th>
</tr>
</thead>
</table>
| **Uncomfortable stimulation:** You are too uncomfortable with the current stimulation. | The selected program or stimulation settings are not suitable for your current activity or posture.  
1. Turn the neurostimulator off.  
2. Change one or more of the following:  
   • Reduce the amplitude in the active program.  
   • Change the program.  
3. Turn the neurostimulator on. |

| **Delayed stimulation changes:** You do not feel stimulation right away after turning on the neurostimulator or you feel stimulation after turning off the neurostimulator. | Your clinician programmed SoftStart/Stop so that stimulation starts and stops gradually:  
Allow about 30 seconds for your neurostimulator to turn on and off.  
You may feel a residual effect after the neurostimulator is turned off. |
### Table 4.4 Troubleshooting problems (continued)

<table>
<thead>
<tr>
<th>Problems</th>
<th>Causes and actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intermittent stimulation:</strong> You feel stimulation only some of the time.</td>
<td>Your clinician may have programmed your neurostimulator to turn on and off at regular intervals. <strong>However, if you are not receiving adequate symptom relief, contact your clinician.</strong></td>
</tr>
</tbody>
</table>
| **No stimulation:** You do not feel stimulation but you think stimulation should be on. | Stimulation is off. **Use your patient programmer to turn your neurostimulator on.**  
The amplitude in the active program is set too low to feel. **Use your patient programmer to increase the amplitude.** |
### Table 4.4 Troubleshooting problems (continued)

<table>
<thead>
<tr>
<th>Problems</th>
<th>Causes and actions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient programmer is unresponsive:</strong> The display screen is blank when you press a key.</td>
<td>You are pressing two or more patient programmer keys at the same time.</td>
</tr>
<tr>
<td></td>
<td><em>Make sure you are pressing only one key at a time.</em></td>
</tr>
<tr>
<td></td>
<td>The programmer batteries are depleted.</td>
</tr>
<tr>
<td></td>
<td><em>Replace the programmer batteries.</em></td>
</tr>
<tr>
<td></td>
<td>The programmer batteries are in backwards.</td>
</tr>
<tr>
<td></td>
<td><em>Check the battery polarity (+ and - symbols) and reinstall the patient programmer batteries.</em></td>
</tr>
<tr>
<td><strong>Dropped programmer:</strong> Your patient programmer falls off a cabinet or table.</td>
<td>The patient programmer is designed to withstand a short drop to a hard surface and still operate normally, even if the case is chipped or nicked.</td>
</tr>
<tr>
<td></td>
<td><em>Try the patient programmer; it should work. If not, call Medtronic.</em></td>
</tr>
<tr>
<td>Problems</td>
<td>Causes and actions</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Fluid on the programmer:</td>
<td>The patient programmer is not waterproof, and water can damage the device.</td>
</tr>
<tr>
<td>Fluid was spilled onto the</td>
<td><strong>Immediately remove the programmer from the water, then clean the programmer with a</strong></td>
</tr>
<tr>
<td>programmer or the programmer was</td>
<td><strong>towel dampened with clean tap water. Dry with a towel.</strong></td>
</tr>
<tr>
<td>dropped into water.</td>
<td><strong>Remove the batteries, then allow the battery compartment to air dry at room</strong></td>
</tr>
<tr>
<td></td>
<td><strong>temperature for 24 hours.</strong></td>
</tr>
<tr>
<td></td>
<td><strong>If the programmer does not work, call Medtronic and return for service.</strong></td>
</tr>
<tr>
<td>Cannot use program.</td>
<td>No program is selected.</td>
</tr>
<tr>
<td></td>
<td><strong>Choose a new program. (See Page 43).</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Press the Sync key.</strong></td>
</tr>
</tbody>
</table>
User assistance

The patient programmer has been designed and tested to provide trouble-free service. If repair or service is needed, refer to the Medtronic contact information on page 63.

The serial number is located in the battery compartment. This number identifies each patient programmer. If you contact Medtronic about your patient programmer, refer to the serial number.

If your programmer stops working – First try the steps in Table 4.4. Otherwise, contact your clinician or Medtronic.

If you lose your programmer – Contact your clinician to order a new programmer.

[USA] To register the programmer for service covered by the Limited Warranty, complete and mail the warranty registration packaged with your patient programmer.

Note: Medtronic’s Limited Warranty does not cover loss or theft of your programmer or damage caused by misuse. For additional
information, refer to the *Limited Warranty* packaged with your patient programmer.