ACCESS® THERAPY CONTROLLER 7436
USER MANUAL

Rx only

USA

1998

CE0123

Medtronic Confidential
NeuroPatntR03

Printing instructions:
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**FCC Information**

The following is federal government communications regulation information about the Access Model 7436 Therapy Controller.

**FCC ID: LF57435**

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.
Key contact information
Doctor 
Nurse 
Clinic 
Telephone 
Hospital 

Program record
Indicate side of body affected:
Program 1   Left   Right
Program 2   Left   Right
# Label symbols

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

<table>
<thead>
<tr>
<th>Keypad Symbols</th>
<th>Indicator Light Symbols</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Symbol" /></td>
<td>Neurostimulator on</td>
</tr>
<tr>
<td><img src="image2" alt="Symbol" /></td>
<td>Neurostimulator off</td>
</tr>
<tr>
<td><img src="image3" alt="Symbol" /></td>
<td>Decrease</td>
</tr>
<tr>
<td><img src="image4" alt="Symbol" /></td>
<td>Increase</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stimulation Control Switch Symbols</th>
<th>Beeper Volume Control Switch Symbols</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image5" alt="Symbol" /></td>
<td>Amplitude</td>
</tr>
<tr>
<td><img src="image6" alt="Symbol" /></td>
<td>Rate</td>
</tr>
<tr>
<td><img src="image7" alt="Symbol" /></td>
<td>Pulse width</td>
</tr>
<tr>
<td><img src="image8" alt="Symbol" /></td>
<td>Volume off</td>
</tr>
<tr>
<td><img src="image9" alt="Symbol" /></td>
<td>Low volume</td>
</tr>
<tr>
<td><img src="image10" alt="Symbol" /></td>
<td>High volume</td>
</tr>
</tbody>
</table>

[Label symbols]
Miscellaneous Symbols

Positioning symbol

Consult instructions for use

Manufacturer

Temperature limitation

Magnetic Resonance (MR) Unsafe

Serial number

PIN number

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

Authorized Representative of the European Community

For USA audiences only.
IEC 60601-1/EN 60601-1, Type BF Equipment

Keep dry

Ingress protection rating IP22, per 60601-1-11

Non-ionizing electromagnetic radiation

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

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

Chinese Standard (SJ/T11364-2006)

Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)
CONTENTS

Label symbols  5

Glossary  13

1 Introduction  17
How to use this manual  18
For important safety information  19
Purpose of the therapy controller  20
Purpose of the implanted brain stimulation system  21
Precautions  21
How the therapy controller works  23
Therapy controller components  24
  Keypad  25
  Symbols and indicator lights  26
  Front cover  29
  Identification label  31
  Beeper volume control switch  33
  Stimulation control switch  35
Accessories  35
  Wrist strap  35
  Carrying case  36
Contents

1 Battery 36

2 Using the therapy controller 39
   Placing the therapy controller over the neurostimulator 41
   Turning the neurostimulator on or off 43
   Checking the neurostimulator battery 45
   Adjusting stimulation settings 48
      Program 1 and Program 2 49
      Tips when adjusting stimulation 50
      Adjusting amplitude and pulse width 51
      Adjusting rate 53

3 Troubleshooting 57
   Possible problems and solutions 58
   Therapy controller assistance 67

4 Maintenance 69
   Therapy controller batteries 70
   Checking the therapy controller battery 71
   Replacing the therapy controller battery 72
   Cleaning and care 75
   Service 77
   Battery and therapy controller disposal 77
Contents

11

Neurostimulator disposal 78
Declaration of conformity 79
Specifications 80

Index 83
Glossary

Amplitude – The strength or intensity of an electrical pulse.

Beeper volume control switch – Located under the front cover. It lets you turn the beeper off or set the volume to low or high.

Command signals – Signals sent from the therapy controller to the neurostimulator that can control the function of the neurostimulator.

Electromagnetic interference (EMI) – A field of energy made by equipment found in the home, work, medical, or public environments that is strong enough to interfere with the operation of your therapy controller.

Indicator lights – Located on the back of the therapy controller. They tell you whether the neurostimulator is on or off, the neurostimulator battery status, and the therapy controller battery status.
**Neurostimulator** – The implanted device that contains a battery and electronics to control stimulation.

**Program** – A specific combination of amplitude, pulse width, and rate settings. You may have two programs defined—one for each side of your body.

**Pulse width** – The length or duration of an electrical pulse.

**Rate** – The number of stimulation pulses delivered each second.

**Status signals** – Signals sent from the neurostimulator to the therapy controller. These signals are received by the therapy controller, and the neurostimulator status is “reported” using a beeper and lights.

**Stimulation control switch** – Located under the front cover. You select the stimulation setting to be adjusted with the stimulation control switch.

**Stimulation settings** – The settings that can be adjusted to affect stimulation. These
settings are amplitude, pulse width, and rate.

**Therapy controller** – A portable hand-held device that may be used to turn on and turn off your neurostimulator or adjust stimulation settings.
1 Introduction
How to use this manual

Refer to this manual after you receive an implanted neurostimulator. Ask your clinician to explain anything that is unclear.

- A glossary is provided to describe terms that may be unfamiliar to you.
- Chapter 1, “Introduction,” describes what the therapy controller does and the components of the therapy controller. It also provides general precautions related to using your therapy controller.
- Chapter 2, "Using the therapy controller," includes instructions for how to place the controller over the neurostimulator; how to turn the neurostimulator on or off; how to check the neurostimulator battery; and how to adjust stimulation settings.
- Chapter 3, “Troubleshooting,” describes therapy controller warning and information screens, how to solve possible problems, and who to contact if your device is lost or broken.
• Chapter 4, "Maintenance," describes how to care for your therapy controller and system specifications.

For important safety information

Please see your Patient Therapy guide provided with your therapy controller for important safety information, related warnings and precautions, and additional information about your therapy.
Purpose of the therapy controller

The Access Therapy Controller is a portable, hand-held device intended for use with your implanted Kinetra neurostimulator. The controller is used to:

- turn the neurostimulator on or off,
- check the status of the neurostimulator battery,
- check the status of the therapy controller battery,
- confirm that the neurostimulator has received information from the therapy controller, and
- adjust the implanted neurostimulator settings (this is an advanced function not available to all patients).
Purpose of the implanted brain stimulation system

Refer to the therapy-specific patient manual for the purpose of your implanted brain stimulation system and a description of the components.

Precautions

Other implanted medical devices – If you also have another implanted device (such as a pacemaker or defibrillator), make sure the therapy controller is held only over the neurostimulator. This prevents the radio signals (telemetry) from the therapy controller from interfering with how the other implanted device works.

Therapy controller use – The device 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 device near flammable atmospheres are unknown.
Therapy controller modification – Do not modify this equipment. Modification of this equipment can result in damage to the programmer, causing the programmer to malfunction or become unusable.

Communication interference from EMI – When using your therapy controller 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 therapy controller and neurostimulator. Examples of EMI sources are computer monitors, cellular telephones, and motorized wheelchairs. For more information about EMI, refer to your therapy-specific patient manual.
How the therapy controller works

**Note:** You can turn on your therapy controller by touching any of the function keys. The controller functions whenever a key is pressed as long as a working battery is properly installed. If another key is not pressed within 8 seconds, the controller will turn off.

When you place the therapy controller over your neurostimulator and press a key on the keypad, the therapy controller sends a command signal to the neurostimulator.

When the neurostimulator receives a command signal, the therapy controller gives you two kinds of feedback:

- **Indicator lights** – Found on the back of the controller. They stay lit for 5 – 8 seconds after receiving a signal.
- **Beeps** – If the beeper is turned on, the therapy controller beeps when a change has occurred.
Therapy controller components

The therapy controller components are shown in Figure 1.1.

Figure 1.1 The Access Therapy Controller.
Keypad

The keypad has keys for turning the neurostimulator on or off and for adjusting stimulation settings.

![Keypad diagram]

**Figure 1.2** The keypad.

**Note:** Your clinician will explain if you can adjust stimulation settings. If you don’t have this capability, pressing the *Increase* and *Decrease* keys will not alter your stimulation. You will hear three rapid beeps indicating that the...
stimulation settings on your neurostimulator cannot be adjusted.

**Symbols and indicator lights**

The back of the therapy controller displays symbols and indicator lights.

![Symbols and indicator lights diagram]

*Figure 1.3* Symbols and indicator lights.
Symbols

- **Positioning symbol** – helps you correctly place the therapy controller over your neurostimulator.

- **Antenna symbol** – represents an external antenna connector that is not used with your system.

  **Note:** To help maintain water resistance, keep the rubber plug in the external antenna connector.

Indicator lights

When the neurostimulator receives a command signal, the indicator lights show:

- Neurostimulator on or off status
- Neurostimulator battery status
- Therapy controller battery status

Table 1.1 explains what the indicator lights mean. Refer to Chapter 2 on page 39 for more complete information about how to use the therapy controller and how to analyze the indicator lights.
### Table 1.1 Indicator light descriptions.

<table>
<thead>
<tr>
<th>When:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>🟢 light is lit.</td>
<td>Neurostimulator is on.</td>
</tr>
<tr>
<td>🟢 light is lit.</td>
<td>Neurostimulator is off.</td>
</tr>
<tr>
<td>🟡 – 🟢 is lit.</td>
<td>Neurostimulator battery is OK.</td>
</tr>
<tr>
<td>🟡 – 🟢 is blinking.</td>
<td>Neurostimulator battery is low. <strong>Contact your clinician immediately.</strong></td>
</tr>
<tr>
<td>🟡 – 🟢 is not lit.</td>
<td>Move to another room, check the therapy controller battery, reposition the therapy controller, and try again. (Interference from electrical equipment may be causing the light to remain off.) <strong>If the light remains off, contact your clinician immediately.</strong></td>
</tr>
<tr>
<td>🟢 – 🟡 is lit.</td>
<td>Controller battery is OK.</td>
</tr>
<tr>
<td>🟢 – 🟡 is blinking.</td>
<td>Controller battery is low. <strong>Replace with new 9-volt alkaline battery.</strong></td>
</tr>
<tr>
<td>🟢 – 🟡 is not lit.</td>
<td>Controller battery is depleted. <strong>Replace with new 9-volt alkaline battery.</strong></td>
</tr>
</tbody>
</table>
Front cover

These components are found under the front cover. You need to remove the cover to access them.

• Identification label (see page 31)
• Beeper volume control switch (see page 33)
• Stimulation control switch (see pages 35 and 45)
• Therapy controller battery (see page 70)

To remove the front cover

1. Lift the cover release tab on the end of the therapy controller and lift off the cover.

![Figure 1.4 Remove the front cover.](image-url)
To replace the front cover

1. Insert the front cover tabs into the slots on the therapy controller.
2. Press down on the end of the cover to lock it in place.

Figure 1.5 Replace the front cover.
Identification label

The therapy controller has an identification label that you need to complete and apply to the inside front cover.

1. Remove the front cover (see page 29).
2. Write the information (your name, phone number, etc.) on the label with permanent ink.
3. Peel off the backing and stick the label to the underside of the front cover.
   
   **Note:** Do not place the identification label over the ridges on the cover.
Figure 1.6 Placement of the identification label inside the front cover.

4. Replace the front cover (see page 30).
Beeper volume control switch

The **Beeper volume control** switch is located under the front cover (Figure 1.7). When the switch is set to low or high, the therapy controller beeps each time the neurostimulator receives a command signal.

Turning the beeper off prevents you from hearing the status indications. Turning the beeper off is not recommended.

![Image of beeper volume control switch](image-url)

**Figure 1.7** Beeper volume control switch set to High (with cover removed).
### Table 1.2 Beeper descriptions.

<table>
<thead>
<tr>
<th>If you hear:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>One beep</td>
<td>• You pressed an <strong>On/Off</strong> or <strong>Increase/Decrease</strong> key and the change was successfully received by the neurostimulator.</td>
</tr>
<tr>
<td>Three rapid beeps (no change to settings)</td>
<td>• You tried to adjust the amplitude, pulse width, or rate beyond the lowest or highest settings programmed by your clinician.</td>
</tr>
<tr>
<td></td>
<td>• You tried to increase the amplitude, pulse width, or rate with the neurostimulator turned off.</td>
</tr>
<tr>
<td></td>
<td>• You tried to adjust the amplitude, pulse width, or rate and your neurostimulator is not programmed for that advanced function.</td>
</tr>
<tr>
<td>No beeps</td>
<td>• The <strong>Beeper volume control</strong> switch may be in the <strong>Off</strong> position.</td>
</tr>
<tr>
<td></td>
<td>• See “Troubleshooting” on page 57 for other possible explanations and actions.</td>
</tr>
</tbody>
</table>
Stimulation control switch

The **Stimulation control** switch will not function unless your clinician gives you the ability to adjust stimulation settings. See “Adjusting stimulation settings” on page 48 for more information.

**Note:** If you move the **Stimulator control** switch to a function to which you do not have access, then press an **Increase** or **Decrease** key, the therapy controller will beep rapidly three times, but will not change your stimulation.

Accessories

Wrist strap

A wrist strap is packaged with the therapy controller. Using the wrist strap can help you avoid dropping the controller. Attach the wrist strap to the therapy controller on the loop near the cover release tab.
Carrying case
A carrying case is included with the controller. Store the therapy controller in the carrying case to protect it.

Battery
A 9-volt battery that provides power for your therapy controller is also included. See “Therapy controller batteries” on page 70 for...
more information on checking and replacing the battery.
2 Using the therapy controller
This section includes step-by-step instructions for the following activities:

- Placing the therapy controller over the neurostimulator
- Turning the neurostimulator on or off
- Checking the neurostimulator battery
- Adjusting the amplitude, pulse width, and rate
Placing the therapy controller over the neurostimulator

The therapy controller must be placed directly over the neurostimulator for the devices to send signals to each other.

1. Locate the neurostimulator under your skin.

2. Place the positioning symbol on the back of the therapy controller over the neurostimulator.
Using the therapy controller 2

Figure 2.1 Place the controller over the neurostimulator.

3. Hold the therapy controller steady and flat against your skin or clothing while pressing the desired key.

Note: When the neurostimulator receives a command signal, the therapy controller gives you two kinds of feedback:

– Indicator lights
  Found on the back of the controller.
  They stay lit for 5 – 8 seconds after receiving a signal.
– Beeps
If the beeper sound is turned on, the therapy controller beeps when a change has occurred.

**Turning the neurostimulator on or off**

Patients should turn on and turn off their neurostimulator as advised by their clinician.

**To turn the neurostimulator on**

1. Place the therapy controller over your neurostimulator (see page 41).

2. Press the Neurostimulator on key. Listen for the confirmation beep.

![Figure 2.2 Neurostimulator on key.](image)
3. Check that the green **Neurostimulator on** light is lit on the back of the controller.

**To turn the neurostimulator off**

1. Place the therapy controller over your neurostimulator (see page 41).
2. Press the **Neurostimulator off** key. Listen for the confirmation beep.

![Figure 2.3 Neurostimulator off key.](image)

3. Check that the yellow **Neurostimulator off** light is lit on the back of the controller.

**Notes:**

- The yellow light means that the neurostimulator is turned off. Verify
that you intended the neurostimulator to be in **Off** mode.

- If neither of the lights are lit, refer to “Troubleshooting” on page 57.

### Checking the neurostimulator battery

You can use the therapy controller to check the current status of your neurostimulator battery. Your clinician will tell you how often to check the status.

**Note:** The status of your neurostimulator battery can change quickly, depending on the current drainage of your battery. Do not rely on this light to predict the longevity of your battery. It is important to attend your regular follow-up visits as your clinician can use a clinician programmer to more accurately calculate your neurostimulator battery life.
To check the neurostimulator battery

1. Place the therapy controller over your neurostimulator (see page 41).

2. Complete the appropriate step:
   - If the neurostimulator is on, press the Neurostimulator on key. Listen for the confirmation beep.
   - If the neurostimulator is off, press the Neurostimulator off key. Listen for the confirmation beep.

3. Check the Neurostimulator battery light on the back of the controller.
**Table 2.1 Neurostimulator battery light.**

<table>
<thead>
<tr>
<th>When the light is:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lit</td>
<td>Neurostimulator battery is OK.</td>
</tr>
<tr>
<td>Blinking</td>
<td>Neurostimulator battery is low. <strong>Contact your clinician immediately.</strong></td>
</tr>
<tr>
<td>Not lit</td>
<td>Move to another room, check the therapy controller battery, reposition the therapy controller, and try again. (Interference from electrical equipment may be causing the light to remain off.) <strong>If the light remains off, contact your clinician immediately.</strong></td>
</tr>
</tbody>
</table>
Using the therapy controller 2

Adjusting stimulation settings

Your clinician may program your implanted neurostimulator so the therapy controller can control one or more stimulation settings:

- Amplitude (\(\text{\textbullet}\))—strength or intensity of pulse
- Rate (\(\text{\textbullet}\text{\textbullet}\text{\textbullet}\))—number of pulses per second
- Pulse width (\(\text{\textbullet}\text{\textbullet}\))—length or duration of pulse

If you have this functionality, the Increase \(\text{\textbullet}\text{\textbullet}\text{\textbullet}\text{\textbullet}\text{\textbullet}\text{\textbullet}\) and Decrease \(\text{\textbullet}\text{\textbullet}\text{\textbullet}\text{\textbullet}\) keys allow you to adjust the stimulation settings. For each setting that you can adjust, your clinician sets an upper and lower adjustment limit that you cannot go beyond.

Make sure that both you and your caregiver know how to adjust the stimulation settings and completely understand your clinician's instructions.
**Note:** Not all patients can adjust their stimulation settings. Consult your clinician about your therapy controller’s setting options.

**Program 1 and Program 2**

If your implanted neurostimulator is used to relieve symptoms on both sides of your body, Program 1 delivers stimulation to one side and Program 2 delivers stimulation to the other side.

Your clinician will explain which side of your body is affected by the **Program 1** keys and which side is affected by the **Program 2** keys. Record this information in the front of this manual.
Tips when adjusting stimulation

The following tips will be helpful when using the therapy controller.

- The neurostimulator must be on to increase amplitude, pulse width, and rate but may be either on or off to decrease them.

- Always adjust the neurostimulator to the lowest possible settings that provide symptom relief. The higher the settings, the faster the neurostimulator battery will wear out. When the battery wears out, the neurostimulator must be surgically replaced, so you want to make it last as long as possible.

- To quickly increase or decrease a setting, hold down the Increase or Decrease key.

- If you hear three rapid beeps, that means you have tried to adjust a setting beyond the upper or lower limit set by your clinician.
• If you experience uncomfortable stimulation or unwanted side effects when increasing a setting, use the Decrease key to return to comfortable stimulation. You may also use the Neurostimulator off key to stop stimulation.

**Adjusting amplitude and pulse width**

1. Ensure that the Stimulation control switch is set to the desired function:
   a. Remove the front cover (see page 29).
   b. Move the switch to the desired setting: Amplitude ( ) or Pulse width ( ).
Using the therapy controller 2

2. Turn the neurostimulator on and verify that the green Neurostimulator on light is lit (see page 43).

3. Increase or decrease the amplitude or pulse width for the desired program:
   
a. Determine which program you are changing (Program 1 or 2).

   b. Place the therapy controller over the neurostimulator (see page 41).

**Figure 2.4** Stimulation control switch set to Amplitude.

c. Replace the front cover (see page 30).
c. Press the Increase or the Decrease key under the desired program. The therapy controller beeps once with each successful increase or decrease.

d. Repeat step c for the other program if desired.

**Adjusting rate**

Only adjust the rate on one program. Each time you adjust the rate on either program, the rate changes for both programs.

1. Ensure that the Stimulation control switch is set to Rate:
   a. Remove the front cover (see page 29).
   b. Move the switch to Rate ( ).
c. Replace the front cover (see page 30).

2. Turn the neurostimulator on and verify that the green **Neurostimulation on** light is lit (see page 43).

3. Increase or decrease the rate:
   a. Place the therapy controller over the neurostimulator (see page 41).
   b. Press the **Increase** or the **Decrease** key under either program. The therapy controller beeps once with each successful increase or decrease.
Using the therapy controller 2
3 Troubleshooting
Possible problems and solutions

Table 3.1 will help you solve problems or identify when to call your clinician. Problems are described in the left column. The right column lists possible causes of the problem (plain text) and how to correct the problem (bold blue text).

If there is more than one explanation/action, do the first action listed. If that doesn’t solve the problem, proceed down the list.

Note: If your problem is not solved after several attempts, or if your problem is not described here, contact your clinician. If your clinician thinks there is a problem with your therapy controller, contact Medtronic (refer to “Service” on page 77).
### Table 3.1 Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>No lights turn on when you send a command signal to your neurostimulator.</td>
<td>No battery or depleted battery in the therapy controller.</td>
</tr>
<tr>
<td></td>
<td><strong>Replace the battery; use a new 9-volt alkaline battery.</strong></td>
</tr>
<tr>
<td></td>
<td>Sunlight may be preventing your viewing of the indicator lights.</td>
</tr>
<tr>
<td></td>
<td><strong>If you are outdoors, move indoors or into the shade.</strong></td>
</tr>
<tr>
<td></td>
<td>You waited longer than 8 seconds to check the indicator lights.</td>
</tr>
<tr>
<td></td>
<td><strong>Try again. This time, look at the lights before 8 seconds have elapsed.</strong></td>
</tr>
<tr>
<td></td>
<td>The temperature and/or humidity conditions may be outside those specified for the therapy controller.</td>
</tr>
<tr>
<td></td>
<td><strong>Refer to “Specifications” on page 80.</strong></td>
</tr>
</tbody>
</table>
### Table 3.1 Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The <strong>Therapy controller battery</strong> light turns on, but none of the other lights are on.</td>
<td>The therapy controller is not positioned correctly over the neurostimulator.</td>
</tr>
<tr>
<td></td>
<td><strong>Reposition the controller and try again.</strong></td>
</tr>
<tr>
<td></td>
<td>The therapy controller was removed from the neurostimulator too soon.</td>
</tr>
<tr>
<td></td>
<td><strong>Hold the controller over the neurostimulator for at least 1 second after pressing a key.</strong></td>
</tr>
<tr>
<td></td>
<td>Electromagnetic interference (EMI) from appliances, computers, machinery, large speakers, gasoline engines, etc, may be affecting the controller. (Refer to your therapy-specific patient manual for detailed information on EMI and EMI effects on therapy.)</td>
</tr>
<tr>
<td></td>
<td><strong>Move to a different room and try again.</strong></td>
</tr>
<tr>
<td></td>
<td>The neurostimulator battery is depleted. When the neurostimulator battery is depleted, therapy is no longer available.</td>
</tr>
<tr>
<td></td>
<td><strong>Contact your clinician immediately.</strong></td>
</tr>
</tbody>
</table>
The neurostimulator battery is low or depleted. When the neurostimulator battery is depleted, therapy is no longer available. Contact your clinician immediately.

If the neurostimulator is on, press the Neurostimulator on key. The green Neurostimulator on light should be lit.

If the neurostimulator is off, press the Neurostimulator off key. The yellow Neurostimulator off light should be lit.

For information on the neurostimulator’s battery status, refer to “Checking the neurostimulator battery” on page 45.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The neurostimulator battery is low or depleted.</td>
<td>The neurostimulator battery is low or depleted. When the neurostimulator battery is</td>
</tr>
<tr>
<td></td>
<td>depleted, therapy is no longer available. Contact your clinician immediately.</td>
</tr>
</tbody>
</table>

| You want to check the neurostimulator without   | If the neurostimulator is on, press the Neurostimulator on key. The green Neurostimulator |
| changing the setting.                            | on light should be lit.                                                                  |
|                                                  | If the neurostimulator is off, press the Neurostimulator off key. The yellow Neurostimulator |
|                                                  | off light should be lit.                                                                 |

For information on the neurostimulator’s battery status, refer to “Checking the neurostimulator battery” on page 45.
## Table 3.1 Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The indicator lights do not flash and the beeper does not beep when a new battery is installed.</td>
<td>The therapy controller failed its self-test. <strong>Remove the battery, and insert a new 9-volt alkaline battery. The indicator lights should flash and you should hear one beep. If this does not occur, contact your clinician.</strong></td>
</tr>
</tbody>
</table>
The beeper does not sound. Only the Therapy controller battery light is on.

The beeper is not on.

Set the Beeper volume control switch to Low or High and listen to be sure it is working.

The therapy controller is not positioned correctly over the neurostimulator.

Reposition the controller and try again.

The controller was removed from the neurostimulator too soon.

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

Electromagnetic interference (EMI) from appliances, computers, machinery, large speakers, gasoline engines, etc, may be affecting the controller. (Refer to your therapy-specific patient manual for detailed information on EMI and EMI effects on therapy.)

Move to a different room and try again.

---

**Table 3.1 Troubleshooting (continued)**

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The beeper does not sound. Only the Therapy controller battery light is on.</td>
<td>The beeper is not on. Set the Beeper volume control switch to Low or High and listen to be sure it is working. The therapy controller is not positioned correctly over the neurostimulator. Reposition the controller and try again. The controller was removed from the neurostimulator too soon. Hold the controller over the neurostimulator for at least 1 second. Electromagnetic interference (EMI) from appliances, computers, machinery, large speakers, gasoline engines, etc, may be affecting the controller. (Refer to your therapy-specific patient manual for detailed information on EMI and EMI effects on therapy.) Move to a different room and try again.</td>
</tr>
</tbody>
</table>
Troubleshooting 3

Table 3.1 Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The neurostimulator will not turn on.</td>
<td>The therapy controller is not positioned correctly over the neurostimulator.</td>
</tr>
<tr>
<td></td>
<td><strong>Reposition the controller and try again.</strong></td>
</tr>
<tr>
<td></td>
<td>The therapy controller was removed from the neurostimulator too soon.</td>
</tr>
<tr>
<td></td>
<td><strong>Hold the controller closer to the neurostimulator, line up the positioning symbol and try again. Hold the controller over the neurostimulator for at least 1 second. The therapy controller should beep and the green Neurostimulator on light should be lit for 5 – 8 seconds after the key press. Try again.</strong></td>
</tr>
<tr>
<td></td>
<td>The neurostimulator battery is depleted. When the neurostimulator battery is depleted, therapy is no longer available.</td>
</tr>
<tr>
<td></td>
<td><strong>Contact your clinician immediately.</strong></td>
</tr>
</tbody>
</table>
### Table 3.1 Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Your therapy controller does not respond to key presses.</td>
<td>No battery or depleted battery in the therapy controller.</td>
</tr>
<tr>
<td></td>
<td><em>Replace the battery; use a new 9-volt alkaline battery.</em></td>
</tr>
<tr>
<td>You spilled fluid on the therapy controller.</td>
<td><em>Dry it with a towel.</em></td>
</tr>
</tbody>
</table>
Troubleshooting 3

Table 3.1 Troubleshooting (continued)

<table>
<thead>
<tr>
<th>Problem</th>
<th>Explanation and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>The therapy controller fell into water.</td>
<td>1. Remove the therapy controller from the water.</td>
</tr>
<tr>
<td></td>
<td>2. Wipe it with a towel dampened with clean tap water.</td>
</tr>
<tr>
<td></td>
<td>3. Remove the battery cover and battery.</td>
</tr>
<tr>
<td></td>
<td>4. Dry the battery compartment with a towel.</td>
</tr>
<tr>
<td></td>
<td>5. Allow the battery compartment to dry at room temperature for as long as possible (24 hours recommended).</td>
</tr>
<tr>
<td></td>
<td>6. Replace the battery.</td>
</tr>
<tr>
<td></td>
<td>7. Shake the therapy controller; if you hear water inside, or if it doesn't work properly, contact Medtronic (see “Service” on page 77).</td>
</tr>
<tr>
<td>The controller falls off a cabinet or table.</td>
<td>Try the controller; it should work. If it doesn’t work, contact Medtronic (see “Service” on page 72).</td>
</tr>
</tbody>
</table>
Therapy controller assistance

The therapy controller has been designed and tested to provide trouble-free service. If repair or service is needed, contact your clinician or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

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

• If your therapy controller stops working, first try the steps in “Troubleshooting” on page 59. Contact your clinician if indicated by the troubleshooting information or if you need additional assistance.

• If you lose your therapy controller, contact your clinician to order a new therapy controller.
Note: To register the therapy controller for service covered by the warranty, complete and mail the warranty registration.
4 Maintenance
This chapter describes how to care for and dispose of your therapy controller and accessories.

**Therapy controller batteries**

A 9-volt alkaline battery is the power source for the therapy controller.

*Note: Make sure a fresh 9-volt alkaline battery is always available.* This ensures that you can always turn on or turn off your therapy. Typically, at least 3 months of use can be expected from a new alkaline battery.

Keep your programmer out of the reach of children and pets. Keep the batteries away from children. If children or pets swallow the batteries, contact a doctor at once.

⚠️ **Caution:** The therapy controller is designed to indicate battery status with an alkaline battery installed. Other battery types may not give an accurate indication of the therapy controller’s battery status.
Caution: If you think you will not be using the therapy controller for more than 4 weeks, remove the battery. A battery left in the device may corrode, causing damage to the electronic components.

Checking the therapy controller battery

1. Hold the therapy controller away from your neurostimulator so that you do not send a command signal to the neurostimulator.

2. Press any key on the therapy controller keypad.

3. Check the Therapy controller battery light on the back of the controller.
Table 4.1 Therapy controller battery light.

<table>
<thead>
<tr>
<th>When the light is</th>
<th>It means</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lit</td>
<td>Controller battery is OK.</td>
</tr>
<tr>
<td>Blinking</td>
<td>Controller battery is low. Replace with new 9-volt alkaline battery.</td>
</tr>
<tr>
<td>Not lit</td>
<td>Controller battery is depleted. Replace with new 9-volt alkaline battery.</td>
</tr>
</tbody>
</table>

Replacing the therapy controller battery

To remove the therapy controller battery

1. Remove the front cover (see page 29).
2. Place one finger on the edge of the battery near the keypad (between the control switches).
3. Lift the battery out of the compartment without using excessive force.
Figure 4.1 Remove the battery.

To insert the therapy controller battery

1. Insert the battery and listen for a beep:
   a. Match the positive (+) and negative (–) contacts on the battery with the same symbols on the controller.
   b. Press the battery down into the battery compartment without using excessive force. Do not press any keys on the front of the controller while inserting the battery.
2. Replace the front cover (see page 30).

3. Check the therapy controller battery status (see page 75).

**Notes:**

- When the battery is installed correctly, the therapy controller beeps and all of the indicator lights flash briefly.

- If you did not hear a beep when you inserted the battery, remove the battery and reinsert it.
Cleaning and care

- Handle your therapy controller with care.
- Do not take apart or tamper with the therapy controller; this could affect how it works.
- Protect the therapy controller from sharp blows or physical shocks.
- Replace low or depleted batteries to ensure that the therapy controller works properly.

⚠️ Caution: If you think you will not be using the therapy controller for more than 4 weeks, remove the battery. A battery left in the device may corrode, causing damage to the electronic components.

- Clean the battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Your therapy controller is not waterproof. Do not allow moisture to get inside it.
**Caution:** Do not immerse the therapy controller in liquid. Do not clean it with bleach, nail polish remover, or similar substances. Immersing the therapy controller in liquid or cleaning it with bleach, nail polish remover, or a similar substance can make the therapy controller nonfunctional.

- Clean the outside of the therapy controller with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- Table 4.2 on page 80 shows the optimal environmental conditions for operating your therapy controller. If your therapy controller is not working, check Table 4.2 to see if the cause might be related to environmental conditions.
Service

The Access Therapy Controller has been designed and tested to provide long, trouble-free service. If repair or service is needed, contact Medtronic. Refer to the contact information at the end of this manual.

To register the therapy controller for service covered by the warranty, complete and mail the warranty registration card.

A serial number, printed on a label under the battery, identifies each Access Therapy Controller. If you write or call Medtronic about your therapy controller, refer to the serial number.

Battery and therapy controller disposal

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

**Neurostimulator disposal**

The implanted device should be removed before burial or cremation. In some countries, removal of battery-powered implantable devices is required before burial because of environmental concerns. Also, the device should be removed before cremation. The cremation process causes the battery to explode. Explanted devices should not be resterilized or reimplanted.

We suggest you request that your explanted device be returned to Medtronic for analysis and disposal. Letting us analyze the condition of your device will help us improve future devices. Refer to the back cover for contact information if you or your doctor have any questions.
Declaration of conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment, and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact Medtronic. Refer to the contact information at the end of this manual.
## Specifications

**Table 4.2** Therapy controller specifications.

<table>
<thead>
<tr>
<th>Item</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Power source</td>
<td>9-volt alkaline battery (type 6LR61 or 6F22E)</td>
</tr>
<tr>
<td>Battery life</td>
<td>3 months (average)</td>
</tr>
<tr>
<td>Service Life</td>
<td>Up to 5 years</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>Ingress protection</td>
<td>IP22 rating for solid objects greater than or equal to 12.5 mm, and for vertically dripping water when the device is tilted 15 degrees, per 60601-1-11.</td>
</tr>
<tr>
<td>Controller size</td>
<td>Approximately 13.5 x 6.1 x 3.0 cm (5.3 x 2.4 x 1.2 in)</td>
</tr>
<tr>
<td>Controller weight</td>
<td>Approximately 170 g (6 oz)</td>
</tr>
</tbody>
</table>
a Product remains safe when operated at temperatures from 5 °C (41 °F), to less than or equal to 43 °C (110 °F), in relative humidity from 15% to 93%, non-condensing, and in atmospheric pressures from 700 hPa to 1060 hPa.

b Batteries should be removed from the device for storage or transport.

c Product remains safe when stored or transported in temperatures from -34 °C (-30 °F) without relative humidity control, to less than or equal to 70 °C (158 °F) at a relative humidity of less than or equal to 93%, non-condensing.
Index

amplitude
  adjusting 51
  definition 48
antenna symbol 26, 27
battery
  checking neurostimulator battery 71
  checking therapy controller battery 75
  inserting therapy controller battery 73
  removing therapy controller battery 72
  therapy controller 24, 70
beeper
  interpreting beeps 34
beeper volume control switch 24, 33
front cover 24, 29
  removing 29
  replacing 30
identification label 31
indicator lights 26, 27
  interpreting lights 28
  neurostimulator battery 47, 72
  neurostimulator on and off 43
keypad 24, 25
neurostimulator
  checking battery 71
  turning off 43
  turning on 43
positioning symbol 26, 27
precautions 21
program 1 and 2  
  definition 49  
pulse width  
  adjusting 51  
  definition 48  
rate  
  adjusting 53  
  definition 48  
rubber plug 26, 27  
stimulation control switch 24, 35  
  adjusting 51, 53  
stimulation limits, upper and lower 48, 50  
symbols 26  
therapy controller  
  checking battery 75  
  components 24  
  how it works 22  
  inserting battery 73  
  placing over neurostimulator 41  
  removing battery 72  
  wrist strap 35
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  Fax (09)-766-2511

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  Fax 01-5538-1800

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- Medtronic GmbH
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  Fax (045)-566-8668

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  Fax 210-63-79-399

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  Fax 1-800-88-99

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  Fax 01-890-7220

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- Medtronic Italia SpA
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  Fax 02-241381

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  Fax 67-10-32-10

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  Fax 21-274-5199

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