Medtronic

Access Review™ Model 7438 Therapy Controller

User Manual
Rx Only
**Key Contact Information**

Doctor___________________________ Telephone _____________________
Nurse____________________________ Hotline _______________________
Clinic ___________________________ Hospital_____________________


To turn Activa Therapy on:
1. Position the therapy controller over your neurostimulator.
   a) Press the Therapy On key. Listen for the confirmation beep.
   b) Check that the green Therapy On light is lit. This light stays on for 8 seconds after you release the key.

To turn Activa Therapy off:
2. To turn Activa Therapy on:
   a) Press the Therapy On key. Listen for the confirmation beep.
   b) Check that the green Therapy On light is lit. This light stays on for 8 seconds after you release the key.

3. To turn Activa Therapy off:
   a) Press the Therapy Off key. Listen for the confirmation beep.
   b) Check that the yellow Therapy Off light is lit. This light stays on for 8 seconds after you release the key.
To check whether your Activa Therapy is on or off:

1. Position the therapy controller over your neurostimulator.

2. a) Press the Therapy Status key. Listen for the confirmation beep.
   b) Check whether the green Therapy On light or yellow Therapy Off light is lit.

To check the neurostimulator battery:

1. Position the therapy controller over your neurostimulator.

2. a) Press the Neurostimulator Battery Status key. Listen for the confirmation beep.
   b) Check the green Neurostimulator Battery light.

<table>
<thead>
<tr>
<th>Neurostimulator Battery light</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>lit</td>
<td>The neurostimulator battery is OK.</td>
</tr>
<tr>
<td>blinking</td>
<td>The neurostimulator battery is low. Make an appointment with your doctor.</td>
</tr>
<tr>
<td>not lit</td>
<td>Move to another room, reposition the therapy controller, and try again. (Interference from electrical equipment may be causing the light to remain off.) If the light still remains off, the neurostimulator may need to be replaced. The neurostimulator should be checked with a physician programmer. Patients should contact their doctor immediately.</td>
</tr>
</tbody>
</table>
Medtronic was founded in 1949 by Earl Bakken, a graduate student in electrical engineering, and his brother-in-law, Palmer J. Hermundslie. Today Medtronic is the world leader in medical technology, pioneering therapies that restore health, extend life, and alleviate pain.

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

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

Welcome to the Medtronic family. We wish you well.
Explanation of symbols on product and packaging.
Refer to the appropriate product to see symbols that apply.

Keypad Symbols
- Activa Therapy On
- Activa Therapy Off
- Therapy Status
- Neurostimulator Battery Status

Status Light Symbols
- Activa Therapy On
- Activa Therapy Off
- Neurostimulator Battery
- Therapy Controller Battery

Beeper Volume Control Switch Symbols
- Volume Off
- Low Volume
- High Volume

Miscellaneous Symbols
- Positioning Symbol
- Conformité Européenne (European Conformity). This symbol means that the device fully complies with European Directive 90/385/EEC.
- For U.S. audiences only.
- Equipment has been tested and accepted for listing under the Canadian Standard Association for distribution in Canada.
Explanation of symbols on product and packaging.
Refer to the appropriate product to see symbols that apply.

Attention, see accompanying documents

Serial number

Storage temperature

Relative humidity

Atmospheric pressure
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- When the Device Should Not be used (Contraindications)
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  - Therapy Status Key
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Activa Therapy

Therapy Will Not Turn On

How to Check Whether Therapy is On or Off

Therapy Controller

All Lights are Off

Only Therapy Controller Battery Light is On

Neurostimulator Battery Light is (or was) Blinking

Therapy Controller Does Not Respond or Beep

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General Warning

The Medtronic® Access Review™ Model 7438 Therapy Controller (the “therapy controller”) is designed to program the adjustable parameters of the Medtronic® Soletra™ Model 7426 or Itrel® II Model 7424 Neurostimulators (or “neurostimulator”) for Activa® Therapy. Do not attempt to use the therapy controller on another device (for example, a cardiac pacemaker). Radio signals from the therapy controller may interfere with the performance of other implantable devices.
The following is federal government communications regulation information about the Access Review Model 7438 Therapy Controller.

**FCC ID: LF57434A**

This device complies with Part 15 Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.
This manual is intended for patients and clinicians. It is organized into the following sections:

- **Quick Programming Guide** is a summary of how to turn on and turn off the Activa Therapy, how to check whether your Activa Therapy (neurostimulator) is on or off, and how to check the condition of the neurostimulator's battery.

- **Description of the Access Review Therapy Controller** describes the different parts of the therapy controller: the keys on the keypad; the front compartment (which covers the battery and Beeper Volume Control switch); and the lights on the back.

- **Using the Therapy Controller** includes instructions for how to place the therapy controller over the neurostimulator, how to check the battery in the neurostimulator, how to turn on and turn off Activa Therapy, and how to check whether Activa Therapy (neurostimulator) is on or off.
About This Manual

- *Caring for the Therapy Controller* describes how to complete and affix the identification label; how to check, remove, and install the therapy controller battery; and how to clean and take care of the therapy controller.

- *Troubleshooting* describes situations that may arise and how to resolve them.

- *Glossary* describes terms used in this manual.

- *Specifications* contains technical information about the therapy controller, such as its size, height, width, and weight.

- *Other Important Information* contains a notice about how the therapy controller is to be used, and warranty information.
Purpose of the Device

Medtronic Activa Therapy includes Activa Parkinson's Control Therapy and Activa Tremor Control Therapy.

Parkinson's Control Therapy

Activa Parkinson's Control Therapy delivers electrical stimulation to areas in your brain to help treat advanced Parkinson's disease. Electrical stimulation can be delivered to both sides of your brain to help relieve symptoms on both sides of your body. You may be a candidate for this therapy if your symptoms respond to levodopa, but levodopa and/or other medications have become less effective or ineffective.
Tremor Control Therapy

Activa Tremor Control Therapy delivers electrical stimulation to an area in your brain to help treat Essential Tremor or tremor associated with Parkinson’s disease. It is used to treat tremor in one arm of your body. The system is used in patients who are diagnosed with Essential Tremor or Parkinsonian tremor not adequately controlled by medications and where the tremor is disabling.

When the Device Should Not be Used (Contraindications)

An Activa Brain Stimulation System should not be used for:

- Patients who will be exposed to diathermy (deep heat treatment). 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, can cause tissue damage and can result 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 may require additional surgery to remove or replace parts of your implanted device. Injury or damage can occur during diathermy treatment whether your neurostimulation system is turned “on” or “off.”

- Patients who will be exposed to Magnetic Resonance Imaging (MRI) using a full body radio-frequency (RF) coil or a head transmit coil that extends over the chest area.
- Patients for whom test stimulation is unsuccessful.
- Patients who are unable to properly operate the neurostimulator.
Warning
Do not use a mercury or zinc-air battery inside the therapy controller. The therapy controller is designed to indicate its battery status with an alkaline battery installed; other battery types may not give an accurate indication of the therapy controller’s battery status.

Precautions
Access Review Model 7438 Therapy Controller—Do not immerse the therapy controller in liquid. Do not clean it with bleach, nail polish remover, or similar substances.

Other devices that use electrical signals from your body—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.

Note: See your neurostimulator patient manual for complete information on warnings, precautions, risks and benefits.
How Does the Therapy Controller Work?

The therapy controller sends signals to your neurostimulator. These signals tell the neurostimulator to turn on the therapy and turn off the therapy.

The neurostimulator also sends signals to the therapy controller that you can hear (beeps) or see (lights on the back of the therapy controller). The beeping means that the neurostimulator has received an instruction (Table 1, page 16). The lights describe the status of the batteries (Table 2, page 25; Table 4, page 37) and whether or not the therapy is turned on (Table 3, page 30). Several lights will also turn on for 8 seconds to indicate that the neurostimulator has received an instruction. Use the lights on the back of the therapy controller to confirm that a change is taking place.
To send signals to your neurostimulator, the internal antenna of the therapy controller must be placed over the internal antenna of the neurostimulator (Figure 1). This is achieved by holding the therapy controller flat against your skin or clothing so that the keypad is directly over your neurostimulator. A positioning symbol on the back of the therapy controller is used to provide proper alignment.

Figure 1. The therapy controller properly placed over the neurostimulator.
Description of the Access Review Therapy Controller

This section describes the parts of the therapy controller (Figure 2).

Figure 2. The Access Review Therapy Controller.
Description of the Access Review Therapy Controller

Keypad

The keypad has 4 keys: Activa Therapy On and Off keys, Therapy Status key, and Neurostimulator Battery Status key (Figure 3).

**Note:** Pressing any key turns on the therapy controller. If another key is not pressed within 8 seconds, the controller will turn off.

![Figure 3: The keypad.](image-url)
**Description of the Access Review Therapy Controller**

**Therapy On and Off Keys**
The Therapy On and Therapy Off keys turn on and turn off the Activa Therapy.

**Therapy Status Key**
The Therapy Status key is used to determine whether your Activa Therapy (neurostimulator) is turned on or off.

*Note:* Pressing the Therapy Status key checks whether your therapy is on or off; it *does not turn your therapy on or off.*

**Neurostimulator Battery Status Key**
The Neurostimulator Battery Status key is used to determine the condition of your neurostimulator’s battery.
Description of the Access Review Therapy Controller

Front Cover

The battery and the Beeper Volume Control switch are located beneath the front cover.

Removing the Front Cover

1. Hold the therapy controller with one hand.
2. Lift the cover release tab on the end of the therapy controller and lift off the cover (Figure 4).

Figure 4. Remove the front cover.
Replacing the Front Cover

1. Place the center hook on the edge of the cover into the center slot in the therapy controller as shown below.

2. Lower the cover.

3. Press down the end of the cover to lock it in place (Figure 5).

Figure 5. Replace the front cover.
Description of the Access Review Therapy Controller

Figure 6. Battery and Beeper Volume Control switch.
Description of the Access Review Therapy Controller

Under The Front Cover
The therapy controller battery and the Beeper Volume Control switch are located under the front cover (Figure 6, page 14).

Therapy Controller Battery
A 9-volt battery is the power source for the therapy controller. You may use either an alkaline or carbon-zinc battery. However, an alkaline battery lasts longer.

⚠️ Warning
Do not use a mercury or zinc-air battery inside the therapy controller. The therapy controller is designed to indicate its battery status with an alkaline battery installed; other battery types may not give an accurate indication of the therapy controller’s battery status.

Notes:
- When not using the therapy controller for more than 4 weeks, remove the battery. This prevents damage to the device.
- Make sure a fresh 9-volt 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.
**Beeper Volume Control Switch**

When the Beeper Volume Control switch is turned on, the therapy controller beeps each time a signal is received by your neurostimulator (Table 1). When you receive the therapy controller, the volume of the beeper is set to high. You can turn the volume to low by moving the Beeper Volume Control switch (Figure 7). However, turning the beeper off prevents you from hearing when the neurostimulator receives a signal; this is not recommended.

Table 1. Beeper description.

<table>
<thead>
<tr>
<th>If you hear</th>
<th>It means</th>
</tr>
</thead>
<tbody>
<tr>
<td>One beep</td>
<td>You have pressed any therapy controller key, and the signal was received by the neurostimulator.</td>
</tr>
<tr>
<td></td>
<td>or</td>
</tr>
<tr>
<td></td>
<td>A new battery was installed in the therapy controller and the controller performed a self-test. Refer to “Installing the Battery,” page 39.</td>
</tr>
</tbody>
</table>
Description of the Access Review Therapy Controller

Figure 7. Beeper Volume Control switch.

Beeper Volume Control switch (High volume is selected)
Description of the Access Review Therapy Controller

Symbols and Status Lights
The back of the therapy controller displays symbols and status lights (Figure 8).

Symbols
A positioning symbol shows where to align the therapy controller over the neurostimulator (Figure 8).

Status Lights
When lit or blinking, the status lights tell you:

- whether the Activa Therapy (neurostimulator) is on or off (Table 3, page 30),
- the status of the neurostimulator battery (Table 2, page 25), and
- the status of the therapy controller battery (Table 4, page 37).
Description of the Access Review Therapy Controller

Figure 8. Symbols and status lights on the back of the therapy controller.
Using the Therapy Controller

This section is organized as follows:

- Placing the Therapy Controller Over the Neurostimulator
- Checking the Neurostimulator Battery
- Turning On and Turning Off the Activa Therapy
- Checking Whether Activa Therapy is On or Off

Placing the Therapy Controller Over the Neurostimulator

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

1. Locate the neurostimulator implanted under your skin and align the positioning symbol on the back of the therapy controller over the neurostimulator (Figure 9, page 22).
Notes:
- The internal antenna of the therapy controller is at the center of the positioning symbol and directly under the keypad.
- Hold the therapy controller flat against your skin or clothing to ensure the devices can send signals to each other.

2. To send and receive signals, hold the therapy controller steady over the neurostimulator for at least 1 second when pressing a key.

Notes:
- Whenever a signal is sent or received by the neurostimulator, several lights on the back of the therapy controller turn on for 8 seconds. If the beeper is on, it will beep.
- If a key is held down for an extended time, additional beeps may occur as the therapy controller and neurostimulator communicate with each other. After releasing the key, the Status lights reflect the last accepted communication and will remain on for 8 seconds.
Using the Therapy Controller

Figure 9. Position the therapy controller over the neurostimulator. The therapy controller can be placed against clothing or skin.
Checking the Neurostimulator Battery

The Neurostimulator Battery light on the back of the therapy controller displays the condition of the neurostimulator battery. The battery should be checked frequently based on guidance from your physician and your neurostimulator settings.

**To check the neurostimulator battery:**

1. Place the therapy controller over the neurostimulator. Align the positioning symbol on the back of the therapy controller over the neurostimulator.

2. Press the Neurostimulator Battery Status key and hold the therapy controller over the neurostimulator for at least 1 second (Figure 10). The therapy controller should beep once to confirm that the signal was received.
Using the Therapy Controller

3. Look at the back of the therapy controller for the indicator light next to this symbol [image of symbol]. Refer to Table 2 to determine the battery's condition.

Notes:
- Move indoors or into the shade if sunlight blocks your view of the therapy controller lights.
- The Therapy On (or Therapy Off) light and the Therapy Controller Battery light will also turn on for 8 seconds.
### Table 2. Neurostimulator Battery Light

<table>
<thead>
<tr>
<th>When the green Neurostimulator Battery light is:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>lit</td>
<td>The neurostimulator battery is OK.</td>
</tr>
<tr>
<td>blinking</td>
<td>The neurostimulator battery is low. Make an appointment with your doctor.</td>
</tr>
<tr>
<td>not lit</td>
<td>Move to another room, reposition the therapy controller, and try again.</td>
</tr>
<tr>
<td></td>
<td>(Interference from electrical equipment may be causing the light to remain off.)</td>
</tr>
<tr>
<td></td>
<td>If the light still remains off, the neurostimulator may need to be replaced.</td>
</tr>
<tr>
<td></td>
<td><strong>The neurostimulator should be checked with a physician programmer. Patients should contact their doctor immediately.</strong></td>
</tr>
</tbody>
</table>

**Note:** The Therapy On (or Therapy Off) light and the Therapy Controller Battery light will also turn on for 8 seconds.
Turning On and Turning Off the Activa Therapy

Patients should turn on and turn off their therapy as advised by their doctor.

To turn on the therapy:

1. Place the therapy controller over the neurostimulator. Align the positioning symbol on the back of the therapy controller over the neurostimulator (Figure 11).

Figure 11. Place the therapy controller over the neurostimulator.
Using the Therapy Controller

2. Press the Therapy On key and hold the therapy controller over the neurostimulator for at least 1 second (Figure 12). The therapy controller should beep once to confirm that a change has occurred.

![Figure 12. Press the Therapy On key.](image)

3. Check that the green Therapy On light on the back of the therapy controller is lit (Table 3, page 30). This light stays on for 8 seconds after you release the key.

**Notes:**
- The therapy will turn on with the settings programmed by your doctor.
- The Therapy Controller Battery light will also turn on for 8 seconds.
Using the Therapy Controller

To turn off the therapy:

1. Place the therapy controller over the neurostimulator. Align the positioning symbol on the back of the therapy controller over the neurostimulator (Figure 13).

Figure 13. Place the therapy controller over the neurostimulator.
2. Press the Therapy Off key and hold the therapy controller over the neurostimulator for at least 1 second (Figure 14). The therapy controller should beep once to confirm that a change has occurred.

Figure 14. Press the Therapy Off key.
3. Check that the yellow Therapy Off light on the back of the therapy controller is lit (Table 3). This light stays lit for 8 seconds after you release the key.

**Notes:**
- Move indoors or into the shade if sunlight blocks your view of the therapy controller lights.
- The Therapy Controller Battery Light will also turn on for 8 seconds.

<table>
<thead>
<tr>
<th>When this happens:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Green Therapy On light is lit,</td>
<td>the therapy is turned on. (This light remains lit for 8 seconds.)</td>
</tr>
<tr>
<td>Yellow Therapy Off light is lit,</td>
<td>the therapy is turned off. (This light remains lit for 8 seconds.)</td>
</tr>
<tr>
<td>Therapy On or Off lights are not lit,</td>
<td>refer to the Troubleshooting section, page 46.</td>
</tr>
</tbody>
</table>
Checking Whether Activa Therapy is On or Off

The therapy controller can help you determine if you are receiving therapy. The Activa Therapy On 🌟 or Activa Therapy Off 🌟 lights on the back of the therapy controller tell you the status (on or off) of your neurostimulator.

To check the therapy on/off status:

1. Place the therapy controller over the neurostimulator. Align the positioning symbol on the back of the therapy controller over the neurostimulator.

2. Press the Therapy Status key 🌟 and hold the therapy controller over the neurostimulator for at least 1 second (Figure 15). The therapy controller should beep once to confirm that the signal was received.

Note: Pressing the Therapy Status key checks whether your therapy is on or off; it does not turn your therapy on or off.
Using the Therapy Controller

3. Look at the back of the therapy controller for the indicator light next to the Activa Therapy On \(\text{On}^{1}\) or Activa Therapy Off \(\text{Off}^{1}\) symbol. The light that is lit indicates whether your therapy (neurostimulator) is on or off.

*Note:* If you want to change the neurostimulator's status (on or off), follow the directions for turning on and turning off the Activa Therapy that were provided earlier.
Caring for the Therapy Controller

Identification Label

The therapy controller comes with an identification label.

1. Write the information (name, phone number, etc.) on the label with permanent ink.
2. Peel off the backing and stick the label to the underside of the front cover (Figure 16).

*Note:* Do not place the identification label over the ridges on the cover.
Caring for the Therapy Controller

Figure 16. Placement of the identification label inside the cover.
Caring for the Therapy Controller

Therapy Controller Battery

A 9-volt battery is the power source for the therapy controller. You may use either an alkaline or carbon-zinc battery. However, an alkaline battery lasts longer.

⚠️ Warning

Do not use a mercury or zinc-air battery inside the therapy controller. The therapy controller is designed to indicate its battery status with an alkaline battery installed; other battery types may not give an accurate indication of the therapy controller's battery status.

Notes:

- When not using the therapy controller for more than 4 weeks, remove the battery. This prevents damage to the device.

- **Make sure a fresh 9-volt 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.
Checking the Therapy Controller Battery

The Therapy Controller Battery light is located on the back of the controller. It tells you the status of the therapy controller battery.

To check the therapy controller battery:

1. Hold the therapy controller away from the neurostimulator.
2. Press any key on the therapy controller keypad. The green Therapy Controller Battery light will respond. Refer to Table 4.

   Note: If the therapy controller is held over your neurostimulator and the Therapy On key or Therapy Off key is pressed, the neurostimulator may be turned on or turned off.
### Caring for the Therapy Controller

Table 4. Therapy Controller Battery light.

<table>
<thead>
<tr>
<th>When the green Therapy Controller battery light is:</th>
<th>It means:</th>
</tr>
</thead>
<tbody>
<tr>
<td>lit</td>
<td>controller battery is OK. (The light remains on for 8 seconds.)</td>
</tr>
<tr>
<td>blinking</td>
<td>controller battery is low. Replace with new 9-volt battery.</td>
</tr>
<tr>
<td>not lit</td>
<td>replace with new 9-volt battery.</td>
</tr>
</tbody>
</table>

**Note:** The Therapy On (or Therapy Off) light will also turn on for 8 seconds if the therapy controller is held over the neurostimulator during the battery check.
Caring for the Therapy Controller

Removing the Battery

1. Remove the front cover.

2. Place one finger on the edge of the battery near the Beeper Volume Control switch.

3. Lift the battery out of the compartment without using excessive force (Figure 17).

Figure 17. Remove the battery.
Installing the Battery

An alkaline battery is recommended for longer battery life.

⚠️ Warning

Do not use a mercury or zinc-air battery inside the therapy controller. The therapy controller is designed to indicate its battery status with an alkaline battery installed; other battery types may not give an accurate indication of the therapy controller’s battery status.

1. Match the positive + and negative – contacts on the battery with the same symbols under the front cover.

2. Press the battery down fully into the battery compartment without using excessive force (Figure 18, page 41).
Caring for the Therapy Controller

Notes:

- Do not press any of the therapy controller’s keys during battery installation.
- The therapy controller performs a self-test when the battery is inserted. A successful check is indicated by a single flash of the Status lights followed by a short beep. If this does not occur, the self-test has failed. Refer to “Troubleshooting, Therapy Controller Battery,” page 53.

3. Replace the cover.
Caring for the Therapy Controller

Figure 18. Insert the battery.
Caring for the Therapy Controller

Wrist Strap and Carrying Case

A wrist strap is packaged with the therapy controller. It can be used to help avoid dropping the controller. Attach the wrist strap to the therapy controller on the loop near the cover release tab (Figure 19, page 44).

A carrying case is also included. Store the therapy controller in the carrying case to protect 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.
Caring for the Therapy Controller

- Clean the outside of the therapy controller with a slightly damp cloth. Mild household cleaners will not damage the case or labels.
- 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.

- Clean the battery contacts periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Replace low or depleted batteries to ensure that the therapy controller works properly. This will also prevent corrosion of the therapy controller.
- When not using the therapy controller for more than 4 weeks, remove the battery. This will prevent corrosion of the therapy controller.
Caring for the Therapy Controller

Figure 19. Location of the wrist strap attachment.
Service

The Access Review Therapy Controller has been designed and tested to provide long, trouble-free service. If repair or service is needed, call Medtronic at 1-800-328-0810 from 8:00 - 5:00 pm CST and ask for Patient Services.

To register the therapy controller for service covered by the warranty, complete and mail the warranty registration card. It is inserted in this manual.

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

Disposal of the Battery and Device

Dispose of depleted batteries and worn out devices according to local regulations. Return devices for disposal to the manufacturer.
Troubleshooting

This section will help you solve problems or identify when to call your doctor.

Problems are organized into these categories:

- Activa Therapy (cannot turn on, how to check if on or off)
- Therapy Controller (no lights, only one light, blinking light, controller not working)
- Therapy Controller Gets Wet or is Dropped
- Therapy Controller Battery

Problems are described in the left column. The blue text in the right column lists possible causes of the problem (Causes); the bold text in the right column describes how to correct the problem (Action). If there is more than one cause/action, do the first action listed. If that doesn't solve the problem, proceed down the list.

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

Problem
The therapy will not turn on. (Only the Therapy Controller Battery light is on).

Cause and Action
The therapy controller is not aligned correctly over the neurostimulator.
Reposition the therapy controller and try again.

The therapy controller was removed from the neurostimulator too soon.
Hold the therapy controller closer to the neurostimulator, align the positioning symbol, and try again. Hold the therapy controller over the neurostimulator for at least 1 second. The green Therapy On light should be lit for 8 seconds after the key is pressed. Try again.

Radio signals from electrical equipment, appliances, computers, or machinery may be affecting the therapy controller.
Move to a different room and try again.
**Problem**
You want to check whether the therapy is on or off without changing the setting.

**Cause and Action**
If you do not know whether your therapy is on or off, press the Therapy Status key. The appropriate light should be lit.

For complete instructions, refer to “Checking Whether Activa Therapy is On or Off,” page 31.

For information on the neurostimulator’s battery condition, refer to “Checking the Neurostimulator Battery,” page 23.
Therapy Controller

Problem
No lights are on after you try to program your neurostimulator. (You should always see the light on the Therapy Controller Battery.)

Cause and Action
Sunlight may be blocking your view of the therapy controller lights. If you are outdoors, move indoors or into the shade.

The battery in the therapy controller is not working. (No battery, depleted battery, battery in backwards.) Replace the battery with a new 9-volt battery.

You waited longer than 8 seconds to check the lights. Try to program again. This time, look at the lights before 8 seconds have elapsed.

The temperature and/or humidity conditions may be outside those specified for the therapy controller. Refer to “Specifications,” page 56.
Troubleshooting

Problem
When you press any key, only the Therapy Controller Battery light is on.

Cause and Action
The therapy controller is not aligned correctly over the neurostimulator.
Reposition the therapy controller and try again.

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

Radio signals from electrical equipment, appliances, computers, or machinery may be affecting the therapy controller.
Move to a different room and try again.

The neurostimulator battery is depleted.
Contact your doctor.
**Problem**

*The Neurostimulator*

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

*The therapy controller does not respond or beep when you press any key.* (Only the Therapy Controller Battery light is on.)

**Cause and Action**

*The neurostimulator battery is low or depleted.*

Contact your doctor.

*The therapy controller is not aligned correctly over the neurostimulator.*

Reposition the controller and try again.

*The therapy controller was removed from the neurostimulator too soon.*

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

Radio signals from electrical equipment (such as appliances, computers, machinery) may be affecting the therapy controller.

Move to a different room and try again.

*The beeper is not on.*

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

Therapy Controller Gets Wet or is Dropped

<table>
<thead>
<tr>
<th>Problem</th>
<th>Cause and Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>You spill fluid on the therapy controller.</td>
<td>Dry it with a towel.</td>
</tr>
<tr>
<td>You drop the therapy controller 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 top cover and battery. Shake the controller to remove as much water as possible.</td>
</tr>
<tr>
<td></td>
<td>4. Dry the battery compartment with a towel.</td>
</tr>
<tr>
<td></td>
<td>5. Allow battery compartment to dry at room temperature for as long as possible (24 hours recommended).</td>
</tr>
<tr>
<td></td>
<td>6. Shake the therapy controller. If you hear water inside, or if it doesn’t work properly, repeat steps 4 and 5.</td>
</tr>
<tr>
<td></td>
<td>7. When the therapy controller is dry, replace the battery.</td>
</tr>
<tr>
<td></td>
<td>8. If the therapy controller does not work properly, contact your doctor.</td>
</tr>
</tbody>
</table>
## Problem Cause and Action

### The therapy controller is dropped.

**Cause and Action**
The therapy controller is designed to withstand short drops.

Try the controller; it should work. If it doesn't work, open the front cover and make sure the battery is connected completely. If the therapy controller still doesn't work, contact your doctor.

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### Therapy Controller Battery

#### Problem
*The Status lights do not flash and the beeper does not beep when a fresh battery is installed.*

#### Cause and Action
*The therapy controller failed the self-test.*

Remove the battery, press any key, turn the beeper to low or high, and reinsert another fresh battery, making sure no keys are pressed during battery installation. The status lights should flash and you should hear one beep. If this does not occur, contact your doctor.
Glossary

**Activa Therapy**—A medical treatment developed by Medtronic in collaboration with medical researchers. The Activa System works by electrically stimulating sites in the brain that control movement.

**Battery**—A power source.

The battery inside a neurostimulator is the power source for the Activa System. When a neurostimulator battery is depleted, the neurostimulator must be replaced.

The battery inside the Access Review Therapy Controller is a 9-volt battery. When this battery is depleted, another 9-volt battery can be used.

**Beeper Volume Control Switch**—A movable switch under the top cover of the Access Review Therapy Controller. It allows the beeper volume to be set to low or high. It also allows the beeping sound to be turned off, but this is not recommended.
**Controller**—See *Therapy Controller*.

**Neurostimulator**—The power source of the Activa System. A neurostimulator emits mild electrical pulses. These pulses travel through the extension and lead to the brain. This stimulation helps control symptoms.

**Physician Programmer**—A small computer used to program the Activa System. A programming head is connected to the computer. When the programming head is placed over the neurostimulator, the doctor can change the therapy.

**Positioning Symbol**—A graphic on the back of the therapy controller that shows where to align the therapy controller over the neurostimulator. The two devices must be properly aligned to send signals to each other.

**Therapy Controller**—A hand-held device that allows the Activa Therapy to be turned on and turned off. This device may also be called a controller.
## Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Power Source:</strong></td>
<td>9-volt alkaline battery</td>
</tr>
<tr>
<td></td>
<td>(type 6LR61 or 6F22E)</td>
</tr>
<tr>
<td><strong>Operating Temperature:</strong></td>
<td>49° F to 110° F</td>
</tr>
<tr>
<td></td>
<td>9° C to 43° C</td>
</tr>
<tr>
<td><strong>Storage Temperature:</strong></td>
<td>-40° F to 149° F</td>
</tr>
<tr>
<td></td>
<td>-40° C to 65° C</td>
</tr>
<tr>
<td><strong>Relative Humidity:</strong></td>
<td>30% to 75%</td>
</tr>
<tr>
<td><strong>Atmospheric Pressure:</strong></td>
<td>20.7 in. Hg to 31.3 in. Hg (700 hPa to 1060 hPa)</td>
</tr>
<tr>
<td><strong>Therapy Controller Size:</strong></td>
<td>Approximately 2.4 x 5.3 x 1.2 inches</td>
</tr>
<tr>
<td></td>
<td>(61 mm x 135 mm x 30 mm)</td>
</tr>
<tr>
<td><strong>Therapy Controller Weight:</strong></td>
<td>Approximately 6 oz (170 g)</td>
</tr>
<tr>
<td><strong>Battery Life:</strong></td>
<td>3 months (average) for an alkaline battery</td>
</tr>
<tr>
<td><strong>Mode of Operation:</strong></td>
<td>Continuous</td>
</tr>
</tbody>
</table>
Special Notice

The Medtronic® Access Review™ Therapy Controller (the “Controller”) Model 7438 is designed to program the adjustable parameters of the Medtronic® Soletra™ Model 7426 or Itrel® II Model 7424 Neurostimulators for Activa® Therapy. The programming functions of the controller are not compatible with any other devices. For information regarding difficulties which may be encountered using the therapy controller, consult the other portions of this manual.
Warranty

MEDTRONIC® NEUROLOGICAL ACCESS REVIEW™ MODEL 7438 THERAPY CONTROLLER LIMITED WARRANTY*

(U.S. Customers Only)

A. This Limited Warranty provides the following assurance to the purchaser of the Medtronic® Access Review™ Model 7438 Therapy Controller, hereafter referred to as “Equipment”:

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

B. To qualify for Limited Warranty set forth in Section A(1), the following conditions must be met:

(1) The Equipment must be returned to Medtronic within thirty (30) days after discovery of the defect. (Medtronic may, at its option, repair the Equipment on site.)

(2) The Equipment must not have been repaired or altered outside of Medtronic’s factory in any way which, in the judgment of Medtronic, affects its stability and reliability. The Equipment must not have been subjected to misuse, abuse or accident.
C. This Limited Warranty is limited to its express terms. In particular:

(1) Except as expressly provided by this Limited Warranty, MEDTRONIC IS NOT RESPONSIBLE FOR ANY DIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES BASED ON ANY DEFECT, FAILURE OR MALFUNCTION OF THE EQUIPMENT, WHETHER THE CLAIM IS BASED ON WARRANTY, CONTRACT, TORT OR OTHERWISE.

(2) This Limited Warranty is made only to the purchaser of the Equipment. AS TO ALL OTHERS, MEDTRONIC MAKES NO WARRANTY, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE WHETHER ARISING FROM STATUTE, COMMON LAW, CUSTOM OR OTHERWISE. NO EXPRESS OR IMPLIED WARRANTY TO THE PATIENT SHALL EXTEND BEYOND THE PERIOD SPECIFIED IN A(1) ABOVE. THIS LIMITED WARRANTY SHALL BE THE EXCLUSIVE REMEDY AVAILABLE TO ANY PERSON.
(3) The exclusions and limitations set out above are not intended to, and should not be construed so as to contravene mandatory provisions of applicable law. If any part or term of this Limited Warranty is held to be illegal, unenforceable or in conflict with applicable law by a court of competent jurisdiction, the validity of the remaining portions of the Limited Warranty shall not be affected, and all rights and obligations shall be construed and enforced as if this Limited Warranty did not contain the particular part or term held to be invalid. This Limited Warranty gives the purchaser specific legal rights. The purchaser may also have other rights which vary from state to state.

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

* This Limited Warranty is provided by Medtronic Inc, 710 Medtronic Parkway, Minneapolis, MN 55432-5604. It applies only in the United States. Areas outside the United States should contact their local Medtronic representative for exact terms of the Limited Warranty.
**Access Review™ Therapy Controller Model 7438**

Warranty Registration Card

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serial Number</td>
<td>N H L</td>
</tr>
<tr>
<td>Purchase Date</td>
<td>(Mo) (Day) (Yr)</td>
</tr>
<tr>
<td>Name:</td>
<td>(Last) (First)</td>
</tr>
<tr>
<td>Address:</td>
<td></td>
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<tr>
<td>City:</td>
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<tr>
<td>State:</td>
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<td>Zip Code:</td>
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<tr>
<td>Phone:</td>
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<tr>
<td>Implant Physician Name</td>
<td></td>
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<td>Hospital Name:</td>
<td></td>
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<td>Address:</td>
<td></td>
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<tr>
<td>City:</td>
<td></td>
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<tr>
<td>State:</td>
<td></td>
</tr>
<tr>
<td>Zip Code:</td>
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*IMPORTANT: Please detach, fill out, and mail this card to register your programmer.
(The serial number is located under the 9-volt battery.)*