



**Medtronic**

**CONTROLLER**  
Patient Programming Manual for Test  
Stimulation

3537



!USA Rx only



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The following is communications regulation information on the Model 3537 Controller.

**FCC ID: LF597745**

This device complies with Part 15 of the FCC 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 device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

## Label symbols

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



Consult instructions for use



Manufacturer



Temperature limitation



Serial number



Conformité Européenne (European Conformity). This symbol means that the device fully complies with MDD 93/42/EEC (NB 0123) and R&TTE Directive 1999/5/EC.



Authorized representative in the European community



For USA audiences only



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



Non-ionizing electromagnetic radiation



System meets the applicable (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.)

Label symbols

4 English 3537 2013-3

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## Glossary

**Amplitude** - The strength or intensity of an electrical pulse.

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

**Clinician** - A healthcare professional such as a doctor or nurse.

**Controller** - A hand-held device that allows you to turn your neurostimulator on and off and check your neurostimulator battery. It is also used to adjust some of the stimulation settings.

**External neurostimulator (ENS)** - See Neurostimulator.

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

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

**Precaution** - See Caution.

**Program** - A specific combination of stimulation settings assigned to deliver therapy to a specific site.

**Settings** - See Stimulation settings.

**Stimulation** - The delivery of electrical pulses to a specific site.

**Stimulation settings** - Refers to all the features assembled to define the stimulation you feel. The clinician programs all stimulation. You can adjust some stimulation settings within clinician-defined limits.

**Test stimulation** - A postoperative multiday trial period of a patient's reaction to stimulation using an external neurostimulator and implanted leads.

**Therapy** - Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to a specific site.





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## 1 Introduction

## How to use this manual

Use this manual during test stimulation. Ask your clinician to explain anything that is unclear.

- A glossary is provided at the beginning of this manual to describe terms that may be unfamiliar to you.
- Chapter 1 "Introduction" describes how to use this manual, a list of patient guides, and information on your patient identification card.
- Chapter 2 "Using your controller" describes the controller and how to perform specific tasks, including turning your stimulation on and off, adjusting your stimulation, changing stimulation sides (if applicable), changing programs (if applicable), and checking and replacing batteries. This chapter also describes how to use the controller carrying case, how to label your controller, and an overall description of the **Home** screen.

- Chapter 3 "Troubleshooting" describes controller warning and information screens, how to solve possible problems, and who to contact if your device is lost or broken.
- Chapter 4 "Maintenance and assistance" describes how to care for your controller, including how to change the batteries, as well as device specifications and user assistance.

**Please read this entire manual before using your controller.** This manual will help you understand and use your InterStim system so you can adjust your stimulation as your needs change.

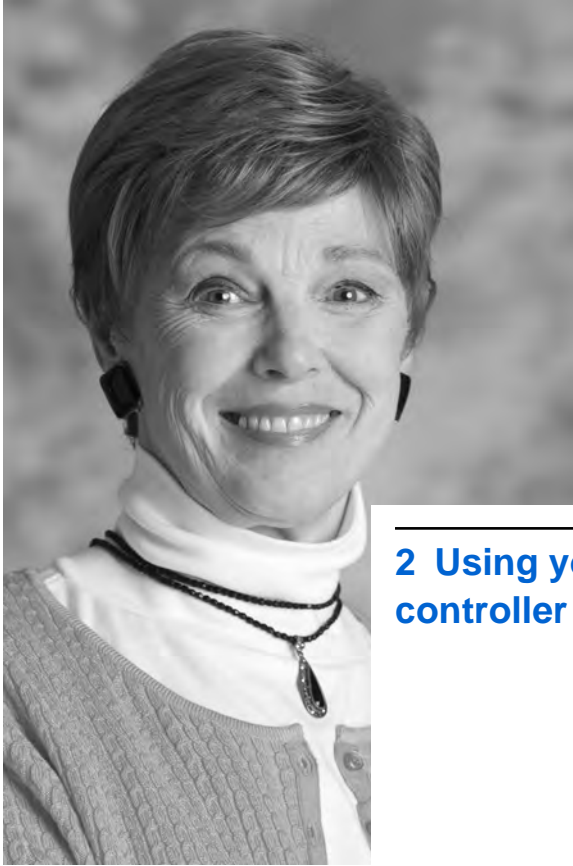
## Patient guides

In addition to this manual, you should receive the following documents during test stimulation:

- *Model 3537 Patient Test Stimulation Quick Reference Card*
- *InterStim Patient Therapy Guide*

**Note:** For additional warnings, precautions, and adverse events related to InterStim Therapy, refer to the *InterStim Patient Therapy Guide* provided by your clinician.

If you did not receive these documents, contact your clinician or Medtronic Patient Services. Refer to the Medtronic contacts at the end of this manual.



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## 2 Using your controller

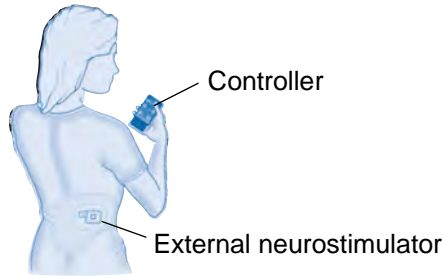
## How your controller works

The controller is used to control and monitor your external neurostimulator. You will use your controller to perform the following tasks:

- Turn your stimulation on or off.
- Check the external neurostimulator and controller battery status.
- Change stimulation settings.

The controller communicates wirelessly with your external neurostimulator by sending signals to and receiving signals from the external neurostimulator. Your clinician has already set up the controller according to your specific test stimulation needs.

**Note:** Make sure to keep your controller with you at all times in the event that you need to adjust or turn your stimulation off.

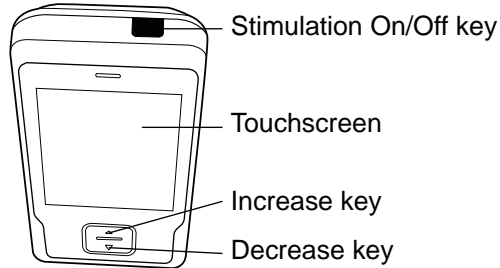


**Figure 2.1** A patient using her controller.

## Controller screen and keys

Your controller has a touchscreen, a display screen that reacts to your touch, that allows you to press buttons that are displayed on the screen. In addition to these on-screen buttons, your controller also has a number of keys (Figure 2.2).


**Note:** There is a cable port on the bottom of the controller. This port is not for patient use.



**Figure 2.2** Controller keys.


See Table 2.1 for a list of these keys and their functions.

**Table 2.1** Controller keys

Key	Function
 <b>Stimulation On/Off</b>	<ul style="list-style-type: none"><li>• Turns stimulation on or off.</li></ul>



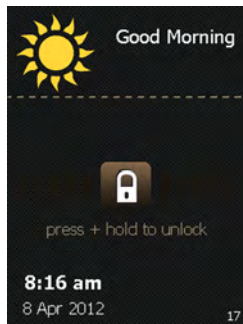
**Table 2.1 Controller keys (continued)**

Key	Function
 <b>Increase/ Decrease</b>	<ul style="list-style-type: none"><li>• Increases or decreases stimulation when you are on the <b>Home</b> screen.</li><li>• Press and release the <b>Increase/Decrease</b> key to slowly increase or decrease the stimulation value (by 0.1). Press and hold to quickly increase or decrease the stimulation value (by 0.5).</li></ul>

## Unlocking and locking your controller

### Unlocking your controller

When the **Increase/Decrease** key is pressed, the **Unlock** screen appears (Figure 2.3).

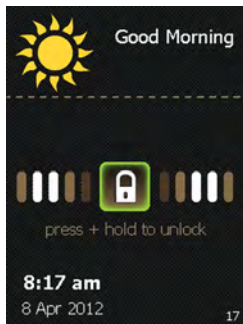


**Figure 2.3** The Unlock screen.

### Notes:

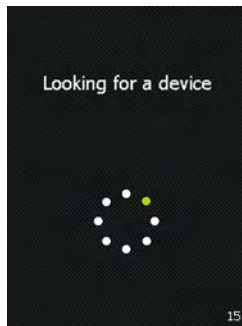
- If the controller does not display the **Unlock** screen, the controller may not have been properly initiated. Call your clinician if the **Unlock** screen does not appear.
  - When the controller is locked, pressing the **Stimulation On/Off** key will provide the option to bypass the **Unlock** screen and to turn stimulation on or off.
1. Press and hold the **Lock** button on the **Unlock** screen.

As the **Lock** button is held, bars appear on the screen and move toward the **Lock** button (Figure 2.4).



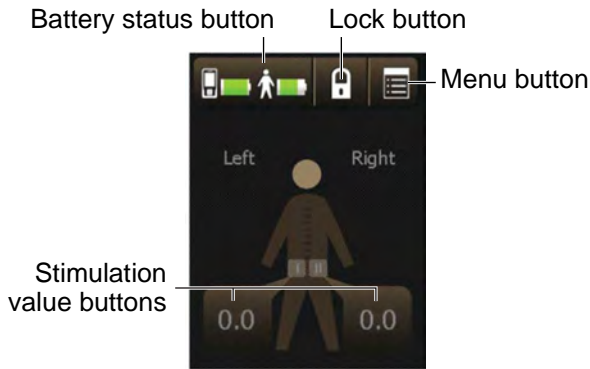
**Figure 2.4** Unlocking the controller.

2. Stop pressing the screen when the screen changes to a circle of dots (Figure 2.5). The controller is searching for your external neurostimulator.



**Figure 2.5** The controller searching for your external neurostimulator.

After unlocking the controller, the first screen you see is the **Home** screen (Figure 2.6).



**Figure 2.6** The Home screen.

If the **Home** screen does not appear, see "Possible problems and solutions" on page 64.

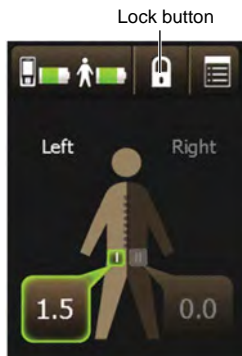
## Locking your controller

Your controller can be locked, so if buttons or keys are accidentally pressed, there will not be an unexpected change in your stimulation.

**Note:** The controller screen will dim after 15 seconds of inactivity, and will automatically lock itself after 2 minutes of inactivity. You can

also press the **Lock** button to lock the controller immediately.

1. From the **Home** screen, press the **Lock** button to lock the controller (Figure 2.7).



**Figure 2.7** Pressing the **Lock** button.

## Turning your stimulation on or off

You can turn stimulation on or off at any time. Follow these steps to turn your stimulation on or off.

## Turning your stimulation on

1. To turn stimulation on, press the **Stimulation On/Off** key, which is located on the top of your controller.

**Note:** Pressing the **Stimulation value** button on the **Home** screen also allows you to turn stimulation on.

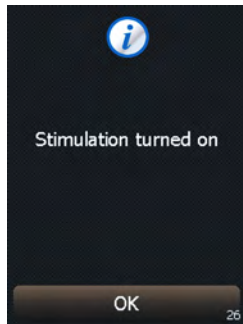
2. Press the **On** button to turn stimulation on (Figure 2.8).

**Note:** If you do not wish to turn stimulation on or off, but want to access the **Home** screen, press the **Go To Unlock** button and unlock your controller.



**Figure 2.8** Turning stimulation on.

3. A confirmation screen will appear (Figure 2.9). Press the **OK** button to continue to the **Home** screen.

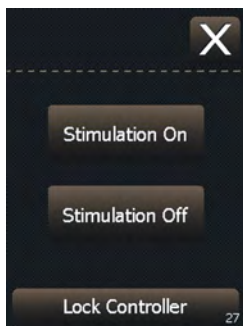


**Figure 2.9** Stimulation turned on.



## Turning your stimulation off

1. To turn stimulation off, press the **Stimulation On/Off** key, which is located on the top of your controller.
2. Press the **Off** button to turn stimulation off (Figure 2.10).

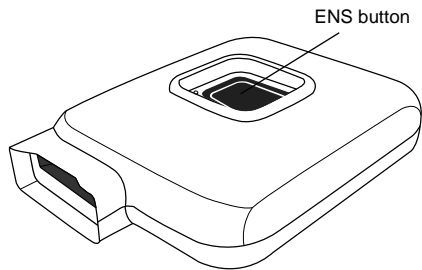


**Figure 2.10** Turning stimulation off.

3. If you do not wish to turn stimulation off, but instead wish to access the **Home** screen, press the **Go To Unlock** button and unlock your controller.

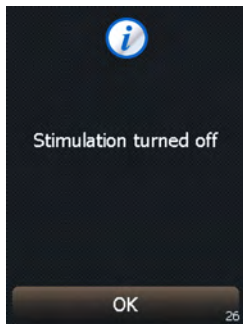
**Note:** If your controller was already on, you will instead have the option to lock the controller.

**Note:** If stimulation is uncomfortable and you need to turn off your stimulation immediately, but your controller is unavailable or not responding, press and hold the **ENS** button on the external neurostimulator for 3 seconds (Figure 2.11).



**Figure 2.11** The ENS button on the external neurostimulator.

4. A confirmation screen will appear (Figure 2.12). Press the **OK** button to continue to the **Home** screen.




**Figure 2.12** Stimulation turned off.

## Adjusting stimulation

### Notes:

- Stimulation needs to be turned on before adjusting your stimulation. If stimulation is not on, see "Turning your stimulation on or off" on page 22.
- Every time you turn your stimulation on, the stimulation value starts at zero.

1. From the **Home** screen, press the **Increase** or **Decrease** key to adjust your stimulation as advised by your clinician.
  - Press and release the **Increase/Decrease** key to slowly increase or decrease stimulation (by 0.1).
  - Press and hold to quickly increase or decrease stimulation (by 0.5).

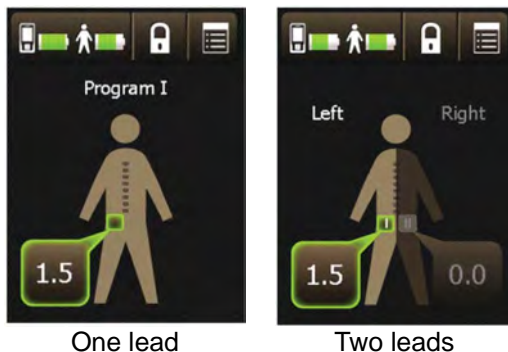
**Note:** When you press and hold the **Increase** key, stimulation will continue to quickly increase until you release the button.
2. When finished adjusting stimulation, press the **Lock** button () to lock the controller.

## Switching stimulation sides (if your clinician placed two leads)

### Notes:

- Instructions on when to switch stimulation sides are provided by your clinician.

- If your clinician placed only one lead, switching stimulation sides will not be available. Figure 2.13 shows what your **Home** screen looks like if you have one lead, and what your **Home** screen looks like if you have two leads.

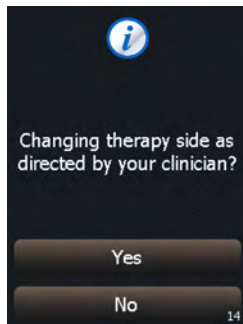


**Figure 2.13** Home screens for one lead and for two leads.

Follow these steps to switch stimulation sides:

1. Press the **Stimulation value** button on the inactive side of the **Home** screen. A screen

will appear asking you to confirm that you wish to change stimulation sides (Figure 2.14).



**Figure 2.14** Confirming switch of stimulation sides.

2. Press the **Yes** button to confirm switching stimulation sides.


**Note:** Pressing the **No** button cancels the change and continues stimulation on the same side.

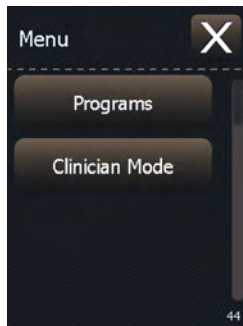
3. Your stimulation will switch sides, and the amplitude will be set to zero. Use the **Increase/Decrease** key to adjust

stimulation (see "Adjusting stimulation" on page 27).

## Changing programs (if applicable)

### Notes:

- Instructions on when to change programs, and which program to select, are provided by your clinician.
  - Depending on how your clinician set up your system, you may not be able to change programs.
1. Press the **Menu** button () in the top right corner of the **Home** screen. A screen appears with two buttons: **Programs** and **Clinician Mode** (Figure 2.15).



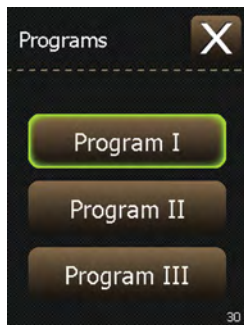
**Figure 2.15** The Patient menu.

**Note:** If your screen does not look like Figure 2.15 but instead asks you to enter a code, then your clinician has set up your system so that changing programs is not available. Press the **Exit** button to go back to the Menu, and then press the **Exit** button again to go back to the **Home** screen.

2. Press the **Programs** button. A screen appears with three buttons: **Program I**, **Program II**, and **Program III** (Figure 2.16). The button outlined in green represents the program that is currently active.



**Note:** If only one program is available, your clinician set up your system so that changing programs is not possible. Press the **Exit** button to return to the Menu. Press the **Exit** button again to return to the **Home** screen.



**Figure 2.16** Selecting a program.

**Note:** Your system may have been set up so that one or more programs is not available. Available program buttons become highlighted in green when they are pressed.

3. Select an available program as instructed by your clinician.

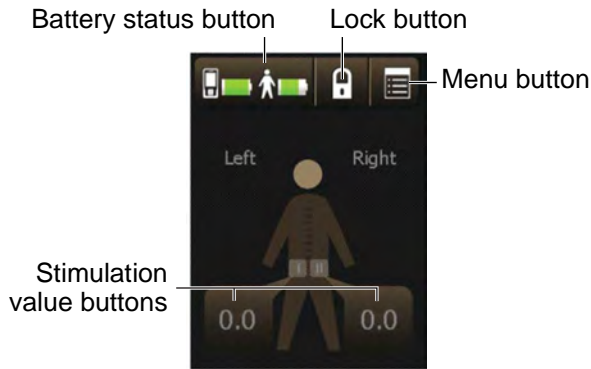
**Note:** After switching programs, amplitude automatically decreases to zero.

4. Press the **Exit** button (ⓧ) to return to the Menu.
5. Press the **Exit** button (ⓧ) to return to the **Home** screen.
6. Adjust stimulation as advised by your clinician. See "Adjusting stimulation" on page 27.

## Home screen

The **Home** screen is the first screen to appear after unlocking your controller. The **Home** screen provides an overview of your stimulation settings (Figure 2.17).

**Note:** Your **Home** screen may look slightly different than the one shown.



**Figure 2.17** The **Home** screen.

Information on the **Home** screen is split into two sides: the **Left** side and the **Right** side.

**Note:** It is normal for some patients to be able to adjust only the left side or only the right side. This means you have only one lead placed for test stimulation instead of two leads.

The buttons at the top of the **Home** screen allow you to perform the following tasks:


- Check the battery status of the controller.

- Check the battery status of the external neurostimulator.
- Lock the controller.
- Access the **Programs** screen.


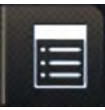
**Note:** Whether you can access the **Programs** screen depends on how your clinician set up your test stimulation system. Discuss this with your clinician.

Refer to Table 2.2 for more information on these buttons.

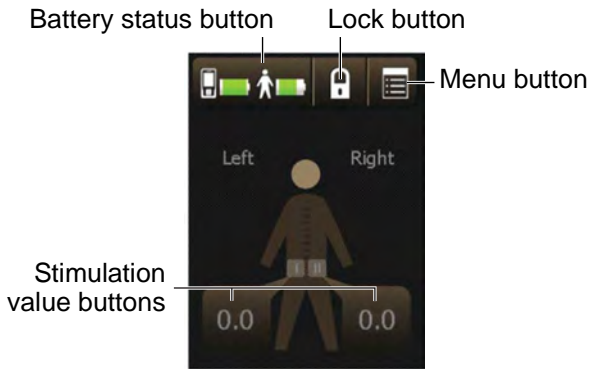
**Table 2.2 Home screen buttons**

Icons	Description
	<b>Battery status</b> button The left icon on this button displays the controller battery status. The right icon on this button displays the external neurostimulator battery status.  Press this button to check the battery status in detail. For more information on checking batteries, see "Checking and replacing batteries" on page 38.

**Table 2.2 Home screen buttons (continued)**

Icons	Description
	<b>Lock</b> button Press this button to lock the controller.
	<b>Menu</b> button Press this button to access the Patient menu (if applicable).

The body figure at the center of the **Home** screen indicates which side is receiving stimulation (if two leads were placed). The number shown in the **Stimulation value** button is the amplitude of that stimulation (Figure 2.18).



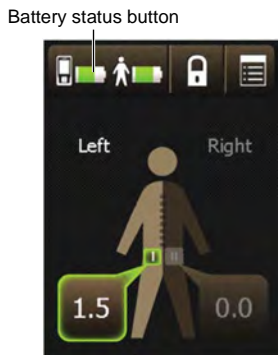
**Figure 2.18** The Home screen.

## Checking and replacing batteries

### Checking the batteries (external neurostimulator and controller)

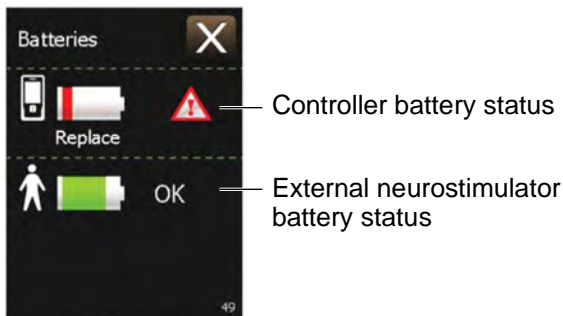
Check the status of the batteries in your external neurostimulator and your controller every day. You can check the status of the batteries at any time.

**Note:** The battery levels of the controller and the external neurostimulator are shown on the **Battery status** button on the **Home** screen (Figure 2.19). For further detail about battery levels, follow the steps below.



**Figure 2.19** Viewing the battery status on the Home screen.

1. From the **Home** screen, press the **Battery status** button. Two battery figures appear (Figure 2.20).



**Figure 2.20** Example of a Battery status screen.


2. Press the **Exit** button (  ) at the top right corner of the touchscreen to exit.

Table 2.3 lists several examples of external neurostimulator battery levels and whether action is needed.

**Table 2.3 Battery level definitions for the external neurostimulator**



External neurostimulator battery icon is green. Battery level is full. No action is needed.



**Table 2.3 Battery level definitions for the external neurostimulator (continued)**



External neurostimulator battery icon is green. Battery level is half full. No action is needed.



External neurostimulator battery icon is orange. Stimulation is still being provided, but the external neurostimulator batteries need to be replaced soon. Call your clinician.



External neurostimulator battery icon is red. Stimulation may no longer be available. The external neurostimulator batteries need to be replaced. Call your clinician.

Table 2.4 lists several examples of controller battery levels and whether action is needed.

**Table 2.4 Battery level definitions for the controller**



Controller battery icon is green. Battery level is full. No action is needed.



Controller battery icon is green. Battery level is half full. No action is needed.

## Table 2.4 Battery level definitions for the controller (continued)



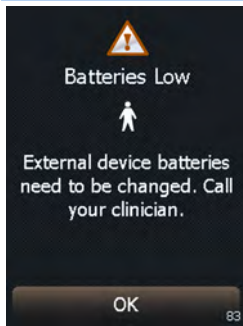
Controller battery icon is orange. The controller batteries are low. Replace the controller batteries. See "Replacing the batteries (controller only)" on page 45.



Controller battery icon is red. The controller batteries are nearly depleted and programming will not be possible soon. Replace the controller batteries. See "Replacing the batteries (controller only)" on page 45.

Table 2.5 lists the warning and alert screens associated with the batteries for the external neurostimulator and the controller.

**Table 2.5 Battery message screens for the controller and the external neurostimulator**



The external neurostimulator batteries are low and stimulation will not be available soon.

**Call your clinician. Press the OK button to exit this screen.**

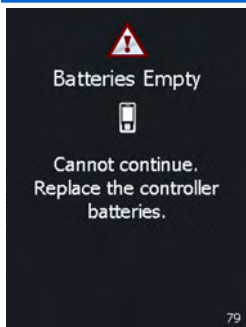


Cause: The external neurostimulator batteries are depleted and stimulation is not available.

**Action: The external neurostimulator batteries need to be replaced. Call your clinician.**

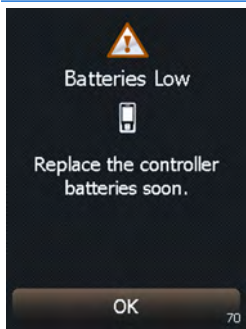
**Press the OK button to exit this screen.**

**Table 2.5 Battery message screens for the controller and the external neurostimulator (continued)**



The controller batteries are depleted. Programming is not possible.

**Replace the controller batteries now. Refer to "Replacing the batteries (controller only)" on page 45.**



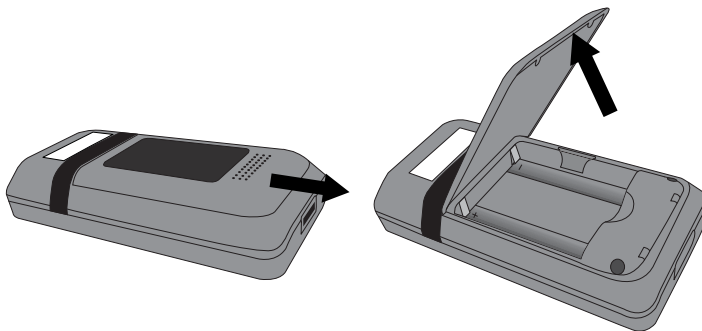
The controller batteries are low. Programming will not be possible soon.

**Replace the controller batteries now. Refer to "Replacing the batteries (controller only)" on page 45. Press the OK button to exit this screen.**

## Replacing the batteries (controller only)

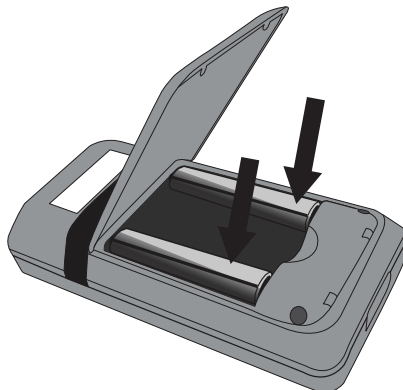
**Note:** This section is for replacing the controller batteries. Do not attempt to replace the external neurostimulator batteries unless directed by your clinician.

1. Open the battery compartment cover (Figure 2.21).



**Figure 2.21** Opening the battery cover.

2. Remove the depleted batteries.
3. Insert two new AA alkaline batteries as shown on the battery compartment label (Figure 2.22).



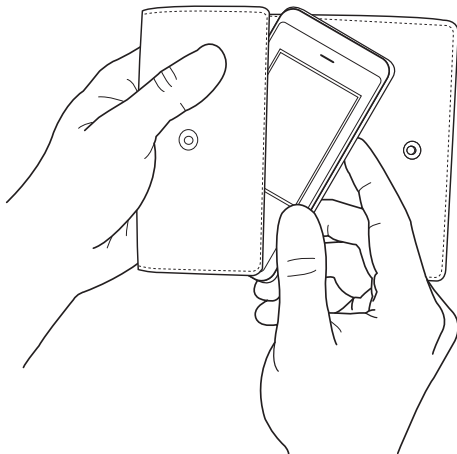
**Figure 2.22** Inserting new batteries.

4. Close the battery compartment cover.
5. Dispose of old batteries according to local regulations.

## Using the carrying case

The carrying case has a pouch to hold the controller (Figure 2.23).

The carrying case also has a clip on the back that can be attached to a belt.



**Figure 2.23** Insert the controller into the carrying case.

## Always carry your controller

Because your controller is the only way to adjust or turn your stimulation on, you should always carry your controller with you. The controller is also the recommended way to turn your stimulation off.

In particular, always bring your controller with you to follow-up appointments.

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





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## 3 Troubleshooting

This chapter will help you solve problems with your controller.

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

## Controller screens

The controller displays three different types of screens: warning screens, alert screens, and notification screens. These screens provide you with information about your system, alert you to a problem with your system, or guide you during controller use.

- Warning screens display a red triangle at the top with an exclamation point (.
- Alert screens display an orange triangle at the top with an exclamation point (.
- Notification screens display a blue circle at the top with the letter 'i' (.

## Warning screens

Warning screens indicate a problem with the controller or the external neurostimulator.

Table 3.1 describes the possible warning screens and provides instructions ([see blue text](#)) on how to resolve the problem and clear the screen.

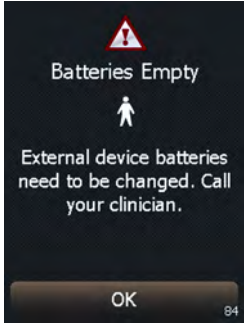
**Table 3.1 Warning screens**

Screen	Cause and action
<b>System Problem</b> Cannot continue. Please call your clinician.	<p>Explanation: The system is not working correctly. Stimulation may have stopped.</p> <p><b>Solution: Write down the message on the screen and the screen number in the bottom right corner, then follow these steps:</b></p> <ol style="list-style-type: none"><li>1. Remove and reinsert the controller batteries, then retry the action that caused the error screen to appear. For instructions on removing and inserting the controller batteries, refer to "Replacing the batteries (controller only)" on page 45.</li><li>2. If this does not solve the problem, call your clinician.</li></ol>

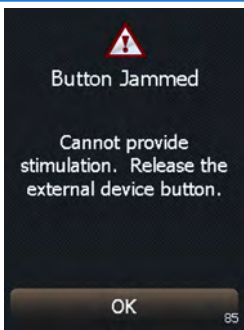
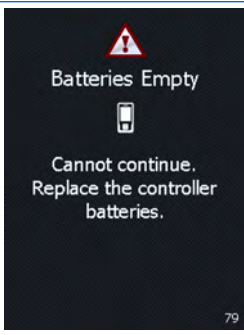
**Table 3.1 Warning screens (continued)**

Screen	Cause and action
<p><b>Software Problem</b> Cannot continue. Please call your clinician.</p>	<p>Explanation: The software is not working correctly. Stimulation may have stopped.</p> <p><b>Solution: Write down the message on the screen and the screen number in the bottom right corner, then follow these steps:</b></p> <ol style="list-style-type: none"><li data-bbox="517 606 894 928">1. Remove and reinsert the controller batteries, then retry the action that caused the error screen to appear. For instructions on removing and inserting the controller batteries, refer to "Replacing the batteries (controller only)" on page 45.</li><li data-bbox="517 949 894 1039">2. If this does not solve the problem, call your clinician.</li></ol>

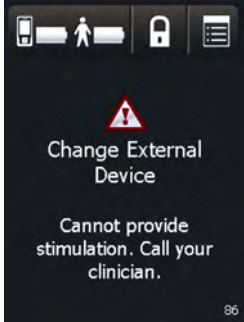
**Table 3.1 Warning screens (continued)**

Screen	Cause and action
	<p>Cause: The external neurostimulator batteries are depleted and stimulation is not available.</p> <p><b>Action: The external neurostimulator batteries need to be replaced. Write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p> <p><b>Press the OK button to clear the screen.</b></p>

**Table 3.1 Warning screens (continued)**

Screen	Cause and action
 <p>The screenshot shows a dark background with a red warning triangle icon at the top. Below the icon, the text reads: "Button Jammed", "Cannot provide stimulation. Release the external device button.", and "OK" at the bottom. A small number "85" is in the bottom right corner.</p>	<p>Cause: The <b>ENS</b> button on the external neurostimulator is stuck in the pressed position.</p> <p><b>Action: Press and release the ENS button, then press the OK button to clear the screen.</b></p> <p><b>If this does not solve the problem, write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p>
 <p>The screenshot shows a dark background with a red warning triangle icon at the top. Below the icon, the text reads: "Batteries Empty", a battery icon, "Cannot continue. Replace the controller batteries.", and "79" in the bottom right corner.</p>	<p>Explanation: The controller batteries are depleted. Programming is not available.</p> <p><b>Replace the controller batteries now. Refer to "Replacing the batteries (controller only)" on page 45.</b></p>

**Table 3.1 Warning screens (continued)**

Screen	Cause and action
	<p>Cause: The external neurostimulator has reached the end of service. This external neurostimulator will no longer provide stimulation.</p> <p><b>Action: Write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p>

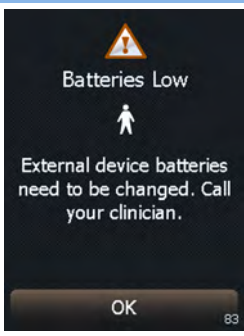
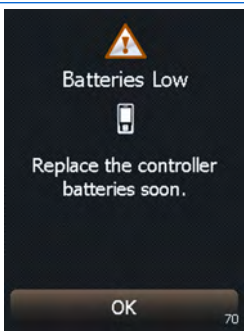
## Alert screens

Alert screens indicate a pairing or other connection problem between the controller and the external neurostimulator.


Table 3.2 describes the possible alert screens and provides instructions ([see blue text](#)) on how to resolve the problem and clear the screen.



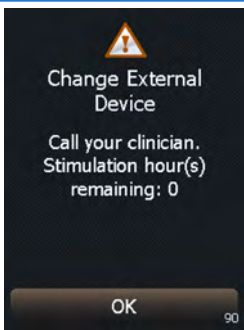
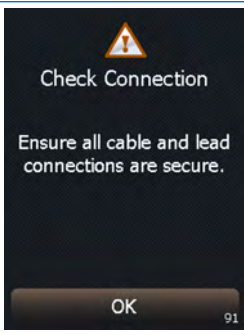
**Table 3.2 Alert screens**

Screen	Cause and action
 <p>The screenshot shows a dark background with a yellow warning triangle icon at the top. Below it, the text reads "Batteries Low" and "External device batteries need to be changed. Call your clinician." At the bottom, there is an "OK" button and the number "83" in the bottom right corner.</p>	<p>The external neurostimulator batteries are low and stimulation will not be available soon.</p> <p><b>Action: Write down the message on the screen and the screen number in the bottom right corner, and call your clinician. Press the OK button to exit this screen.</b></p>
 <p>The screenshot shows a dark background with a yellow warning triangle icon at the top. Below it, the text reads "Batteries Low" and "Replace the controller batteries soon." At the bottom, there is an "OK" button and the number "70" in the bottom right corner.</p>	<p>The controller batteries are low. Programming will not be possible soon.</p> <p><b>Replace the controller batteries now. Refer to "Replacing the batteries (controller only)" on page 45. Press the OK button to exit this screen.</b></p>

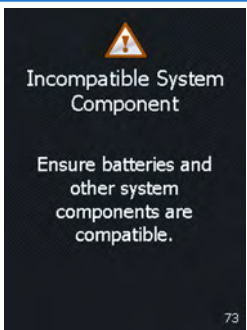
**Table 3.2 Alert screens (continued)**

Screen	Cause and action
	<p>Cause: The controller cannot find the paired external neurostimulator. The external neurostimulator may be out of range or the external neurostimulator batteries may be depleted.</p> <p><b>Action: Move the controller closer to the external neurostimulator and make sure your hand is not covering the top of the controller, then press the Try Again button.</b></p> <p>If this does not solve the problem, the external neurostimulator batteries may need to be replaced. Write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</p> <p>Press the Cancel button to clear the screen.</p>

**Table 3.2 Alert screens (continued)**

Screen	Cause and action
 <p data-bbox="245 337 487 668">An alert screen with a black background. At the top center is a yellow warning triangle icon with a black exclamation mark. Below the icon, the text reads: "Change External Device", "Call your clinician.", "Stimulation hour(s) remaining: 0". At the bottom center is a grey button with the text "OK". In the bottom right corner of the screen, the number "90" is visible.</p>	<p data-bbox="487 337 889 753">Cause: The external neurostimulator has less than 24 hours of service remaining. This external neurostimulator will be unable to provide stimulation soon.</p> <p data-bbox="487 337 889 753"><b>Write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p> <p data-bbox="487 337 889 753"><b>Press the OK button to clear the screen.</b></p>
 <p data-bbox="245 753 487 1089">An alert screen with a black background. At the top center is a yellow warning triangle icon with a black exclamation mark. Below the icon, the text reads: "Check Connection", "Ensure all cable and lead connections are secure.". At the bottom center is a grey button with the text "OK". In the bottom right corner of the screen, the number "91" is visible.</p>	<p data-bbox="487 753 889 1089">Explanation: The external neurostimulator has detected that either a cable or a lead is not connected.</p> <p data-bbox="487 753 889 1089"><b>Solution: Ensure all cable and lead connections are secure. Press the OK button to clear the screen.</b></p>

**Table 3.2 Alert screens (continued)**


Screen	Cause and action
	<p>Cause: The system has detected that one or more components in the system is not intended for use with your system.</p> <p><b>If you replaced the controller batteries with new batteries that were not given to you by your clinician, remove the new batteries and use correct batteries as instructed by your clinician.</b></p> <p><b>If the issue persists, the controller batteries may need to be replaced. For instructions on replacing the controller batteries, see "Replacing the batteries (controller only)".</b></p> <p><b>If this does not solve the problem, write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p> <p><b>Press the OK button to clear the screen.</b></p>

## Notification screens

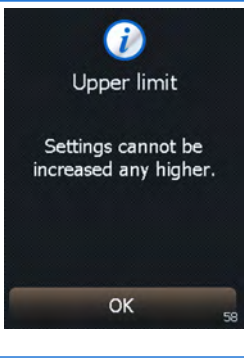
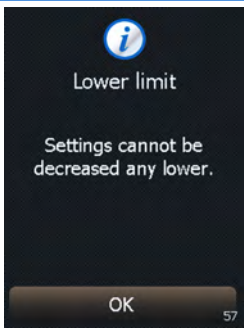
The information screens provide information about therapy settings, error conditions, and battery levels.

Table 3.3 describes the possible information screens and provides instructions on how to proceed ([see blue text](#)) when these messages appear.

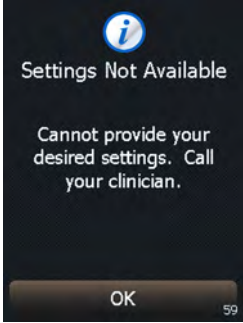
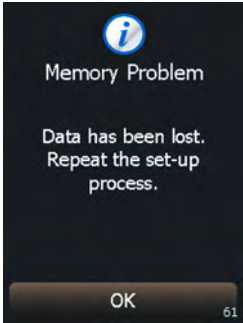
**Table 3.3 Notification screens**

Screen	Description and action
	<p>Cause: You tried to adjust your stimulation when stimulation was off.</p> <p><b>Action: Press the Turn On button on the controller screen to turn stimulation on, then try adjusting stimulation again.</b></p> <p><b>To keep stimulation off and not change settings, press the Cancel button to clear the screen.</b></p>

**Table 3.3 Notification screens (continued)**

Screen	Description and action
	<p>Cause: You tried increasing your stimulation above the highest value allowed. You can not increase your stimulation any higher.</p> <p><b>Action: Press the OK button to clear the screen and return to the highest allowed setting.</b></p> <p><b>If not receiving symptom relief, call your clinician.</b></p>
	<p>Cause: You tried decreasing your stimulation below the lowest value allowed. You can not decrease your stimulation below zero.</p> <p><b>Press the OK button to clear the screen and return to the lowest allowed setting.</b></p> <p><b>If feeling discomfort, call your clinician.</b></p>

**Table 3.3 Notification screens (continued)**

Screen	Description and action
	<p>Cause: Your combined settings can not currently be delivered by the external neurostimulator.</p> <p><b>Action: Press the OK button to clear the screen.</b></p> <p><b>If not receiving symptom relief, call your clinician.</b></p>
	<p>Cause: Controller settings are not available.</p> <p><b>Action: Write down the message on the screen and the screen number in the bottom right corner, and call your clinician.</b></p> <p><b>Press the OK button to clear the screen.</b></p>

## Possible problems and solutions

Table 3.4 will help you solve problems or identify when to call your clinician. 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.



**Table 3.4 Troubleshooting problems**

<b>Problems</b>	<b>Causes and actions</b>
<b>Uncomfortable or Intolerable stimulation</b> You are experiencing side effects from the stimulation.	<ol style="list-style-type: none"><li>1. <b>Use your controller to turn stimulation down or off. See "Adjusting stimulation" on page 27 for instructions on adjusting stimulation. See "Turning your stimulation on or off" on page 22 for instructions on turning stimulation off.</b></li><li>2. <b>If your controller is unavailable or not responding, press and hold the ENS button on the external neurostimulator for 3 seconds.</b></li><li>3. <b>If not receiving symptom relief, call your clinician.</b></li></ol>
<b>Stimulation area changes</b> You notice an unexpected change in where you feel stimulation.	<b>Call your clinician.</b>

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**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>Stimulation is too strong</b>	<ol style="list-style-type: none"><li>1. <b>Turn stimulation down or off.</b>  See "Adjusting stimulation" on page 27.</li><li>2. <b>If this does not work, call your clinician.</b></li></ol>
<b>Not receiving symptom relief</b> You think that your stimulation may be turned off, or that your stimulation might not be strong enough.	<ol style="list-style-type: none"><li>1. <b>Check that your stimulation is on, then increase stimulation as needed.</b></li><li>2. <b>If this does not solve the problem, call your clinician.</b></li></ol>

**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>Controller is unresponsive.</b> The display screen is blank when you press a key.	<ol style="list-style-type: none"><li><b>1. Make sure to press only one button. The controller does not respond when two or more buttons are pressed at the same time.</b></li><li><b>2. If this does not work, check that the batteries are inserted correctly as shown in the battery compartment.</b></li><li><b>3. If batteries are inserted correctly, the batteries are depleted. Replace the controller batteries. For instructions on replacing controller batteries, see "Checking and replacing batteries" on page 38.</b></li></ol>

**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>Controller automatically resets.</b> Controller screen blinks and returns to the Unlock screen.	<ol style="list-style-type: none"><li><b>1. Unlock the controller. The controller screen may return to the screen you were on when the controller reset.</b></li><li><b>2. If the controller continues to reset and you are unable to program your stimulation, call your clinician.</b></li></ol>
<b>Uncomfortable tapping sensation</b> You feel a tapping sensation that is too slow or too fast.	<ol style="list-style-type: none"><li><b>1. Turn stimulation down or off.</b></li><li><b>2. If this does not solve the problem, call your clinician.</b></li></ol>

**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>You will be passing through a theft detector or security device.</b>	<b>Before engaging in any of these activities, consult the <i>InterStim Patient Therapy Guide</i> for details.</b>
<b>You will be using potentially dangerous equipment.</b>	<b>WARNING: Failure to follow the recommendations in the <i>InterStim Patient Therapy Guide</i> may injure you or damage your InterStim system.</b>
<b>You will be having a medical or dental procedure.</b>	
<b>External defibrillation</b> You received external defibrillation.	<b>Turn your stimulation off and call your clinician.</b>
<b>Controller settings</b> Controller settings (eg, brightness) are making it difficult to adjust your stimulation.	<b>Call your clinician.</b>

**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>Dropped controller</b> Your controller fell or was dropped.	The controller is designed to withstand a short drop to a hard surface and still operate normally, even if the case is chipped or nicked.  <b>Turn your stimulation off and call your clinician.</b>

**Table 3.4 Troubleshooting problems  
(continued)**

<b>Problems</b>	<b>Causes and actions</b>
<b>Fluid on the controller</b> Fluid was spilled onto the controller or the controller was dropped into water.	The controller is not waterproof, and water can damage the device. <b>Immediately remove the controller from the water, then dry with a soft towel.</b> <b>Remove the batteries, then allow the battery compartment to air dry at room temperature for 24 hours.</b> <b>Clean any spills from the controller with a damp towel.</b> <b>If the controller does not work, or if you need to adjust stimulation while the controller is drying, call your clinician.</b>

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**72** English 3537 2013-3





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## **4 Maintenance and assistance**

## Cleaning and care

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

- Keep the device out of the reach of children and pets.
- Use the device only as explained to you by your clinician or as discussed in this manual.
- Handle the device with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the device.
- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners will not damage the device or labels.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Keep fresh batteries available.
- Replace low or depleted batteries.

## Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the controller are not required. The controller contains no user-serviceable parts. 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.

## Battery and controller disposal

Dispose of depleted batteries and worn out devices according to local requirements. Return your controller to your clinician.

## 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 93/42/EEC on Medical Devices.

For additional information, contact Medtronic. Refer to the list of Medtronic contacts at the end of this manual.

## Specifications

**Table 4.1 Controller specifications**

Item	Specification
Power source	2 AA alkaline batteries (non-rechargeable, LR03)
Operating temperature	+9 °C to +43 °C (+49 °F to +110 °F)
Temperature limitation	-30 °C to +57 °C (-22 °F to +135 °F)
Size	Approximately 12.0 cm x 6.0 cm x 2.4 cm (4.7 in x 2.4 in x 0.9 in)
Weight, including batteries	Approximately 150 g (5.3 oz.)
Battery life	2 months (average) for alkaline batteries
Mode of operation	Continuous

## Assistance for the controller

The 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.

**[USA]** For assistance in the US, call Medtronic Patient Services at: 1-800-510-6735. Patient Services hours are Monday through Friday, 8 am to 5 pm Central Time.

- If your controller stops working, first try the steps in Chapter 3 "Troubleshooting" on page 49.

Contact your clinician if indicated by the troubleshooting information or if you need additional assistance.

- If you lose your controller, contact your clinician to order a new controller.

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Version: 01-18-2012

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Contacts for specific countries are listed  
inside this cover.



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