



**Medtronic**

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**CONTROLLER**  
for InterStim® Therapy

**3537**

Clinician Programming Guide

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 Rx only



Filename Date Time  
UC2001xxxx EN  
4.625 x 6 inches (117 mm x 152 mm)

**Medtronic Confidential**  
**PTMClinPrgmManual.xml - PTMClinPrgmTemplate.fm**  
**Template version: 08-08-2011**

## Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Consult instructions for use



Manufacturer



Temperature limitation

SN

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.

EC REP

Authorized representative in the European community

! USA

For USA audiences only



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



Non-ionizing electromagnetic radiation



System meets the applicable Canadian (CAN/CSAC22.2 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.)

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**USA** **FCC Information**

The following is communications regulation information on the Model 3537 Personal Therapy Manager.

**FCC ID: LF53537**

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 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.

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**Refer to the indications sheet for indications and related information.**

**Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.**

**Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations, and specific neurostimulator specifications.**

**USA Refer to the clinical summary booklet for information on the clinical study results of the neurostimulation system and individualization of treatment.**


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## Description

The Medtronic Model 3537 Controller is a hand-held device intended for use with the Medtronic Model 3531 External Neurostimulator. The clinician uses the controller to program settings for the patient. The patient uses the controller to perform the following tasks as directed by the clinician:

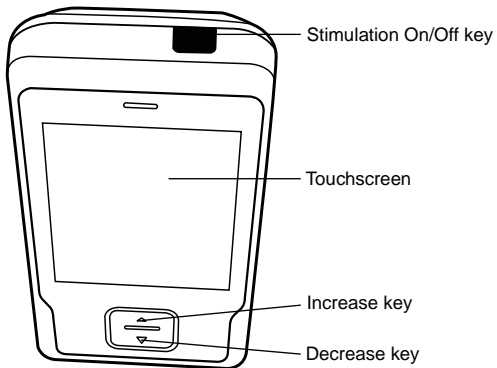
- Adjust amplitude
- Switch between active sides (if two leads were placed)
- Switch programs (if applicable)

## Package contents

- Model 3537 Controller
- Carrying case
- Batteries (AA)
- Product literature
-  Warranty card

## About this manual

This manual contains the information the physician needs to set up, use, and troubleshoot the controller (Figure 1).



**Figure 1.** Features of the Model 3537 Controller.

All information and instructions that are available to the patient are included in the *Model 3537 Controller Patient Test Stimulation Programming Guide* and the *InterStim Patient Therapy Guide*.

## Instructions for use

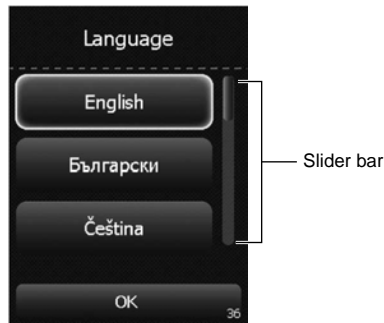
- △ **Caution:** The device is not certified for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the device near flammable atmospheres are unknown.
- △ **Caution:** Do not modify this equipment. Modification of this equipment can result in damage to the device, causing the device to malfunction or become unusable.
- △ **Caution:** Do not use the device in the proximity of equipment that generates electromagnetic interference (EMI). EMI may cause a disruption in device function. Examples of common medical sources of EMI are magnetic resonance imaging (MRI) and lithotripsy. Powerful computer monitors, cell phones, x-ray equipment, and other monitoring equipment may also generate EMI.

## Setting up the controller

After inserting batteries into the controller, a splash screen will appear, followed by a series of steps to set up the controller.

**Note:** After completing these setup instructions, you can change the settings at any time using the Menu.

1. Using the touchscreen, select the desired language from the options available, then press the **OK** button to continue (Figure 2).



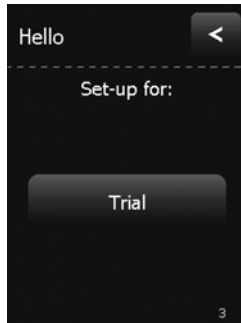
**Figure 2.** Setting the language.

**Note:** Use the slider bar or the **Increase** and **Decrease** keys to scroll up or down to see more languages.

2. Using the touchscreen, press the **Trial** button (Figure 3).

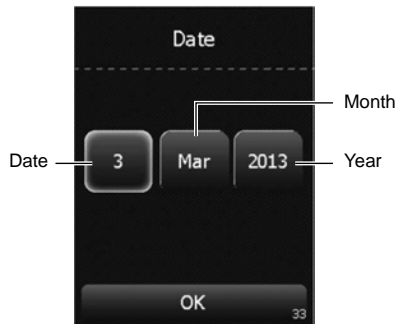
8 English 3537 2012-09





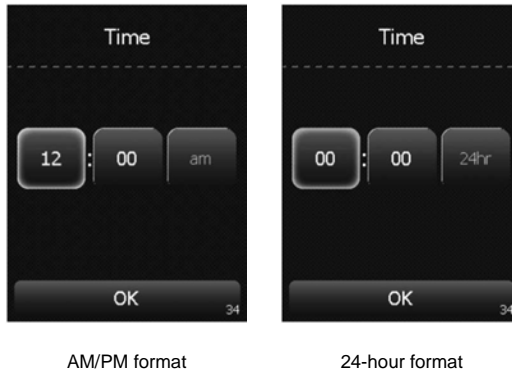
*Figure 3. Pressing the Trial button.*

3. To change the date, the month, or the year, press the touchscreen button with the incorrect value, then use the **Increase** and **Decrease** keys to change the value. Once the date, month, and year are set correctly, press the **OK** button to continue (Figure 4).



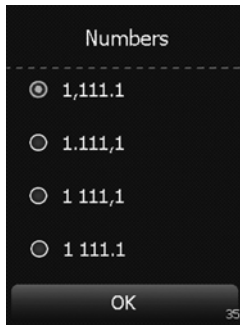
*Figure 4. Setting the date.*

4. To change the hour, the minute, or the time format, press the touchscreen button with the incorrect value, then use the **Increase** and **Decrease** keys to change the value. Once the hour, minute, and time format are set correctly, press the **OK** button to continue (Figure 5).



**Figure 5.** Setting the time.

- Using the touchscreen, press the radio button next to the desired number format for the controller, then press the **OK** button to continue (Figure 6).



**Figure 6.** Selecting the number format.

## Pairing the controller to the external neurostimulator

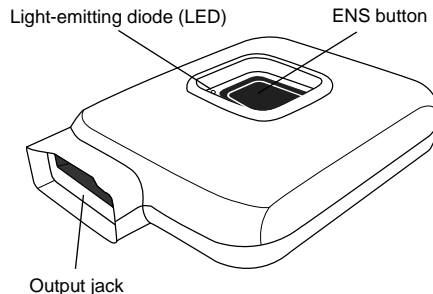
To ensure correct pairing between the controller and the external neurostimulator, consider the following recommendations:

- Ensure that the controller that you provide to the patient is paired with the patient's external neurostimulator.
- Ask the patient to bring his or her controller to all follow-up appointments. Use this same controller during any clinician programming. This will help to avoid pairing the external neurostimulator with multiple controllers.
- If the external neurostimulator is paired with a new controller, the connection to the previous controller will need to be re-established before the previous controller can be used with the external neurostimulator again.

## Pairing a new controller to an external neurostimulator

**Note:** Ensure you have the external neurostimulator serial number available. You will need to confirm this information during the pairing procedure. The serial number is located on the back of the external neurostimulator.

1. Press and hold the **ENS** button for one second to place the external neurostimulator into discovery mode (Figure 7). The light on the external neurostimulator will repeatedly blink for 90 seconds, or until the external neurostimulator has paired with a controller.

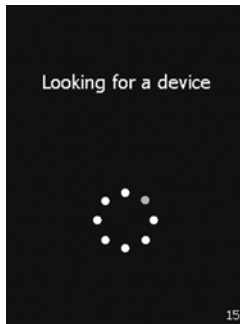


**Figure 7.** Turn on the external neurostimulator.

2. Press the **Continue** button on the controller touchscreen (Figure 8). The controller will look for the external neurostimulator (Figure 9).



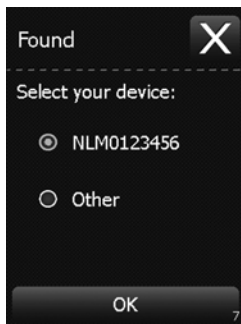
**Figure 8.** Pressing the Continue button.



**Figure 9.** Controller looking for the external neurostimulator.

- Using the touchscreen, select the radio button next to the correct external neurostimulator, then press the **OK** button to continue (Figure 10).

**Note:** The number displayed on the controller screen should match the serial number printed on the back of the external neurostimulator.



**Figure 10.** Selecting the device to pair with the controller.

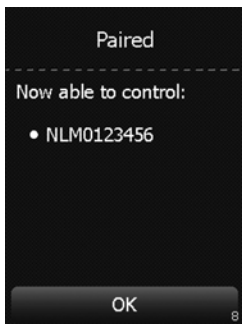
**Notes:**

- If the controller fails to pair with the external neurostimulator, repeat step 1, then press the **Try Again** button to try this step again (Figure 11).
- Pressing the **Exit** button (X) will abort the pairing process.



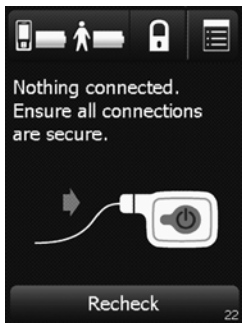
**Figure 11.** Pressing the Try Again button.

4. When the pairing is successful, a confirmation screen will appear (Figure 12). Press the **OK** button to continue.



*Figure 12. Confirming that the devices are paired.*

**Note:** If there is a connection problem, a screen will appear (Figure 13). Check all connections between the lead and the external neurostimulator, and press the **Recheck** button.

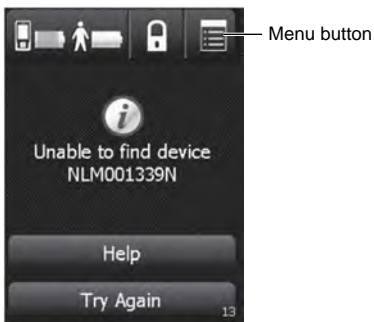


*Figure 13. Screen prompt to check connections.*

### **Pairing a previously used controller to an external neurostimulator**

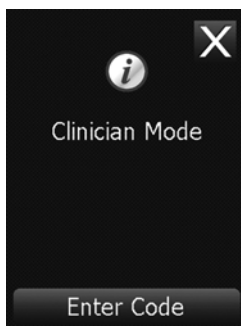
When turned on, the previously used controller will automatically attempt to connect to the external neurostimulator with which it was previously paired.

1. When the controller fails to pair with the previously used external neurostimulator, a screen appears (Figure 14). Press the **Menu** button in the top right corner of the touchscreen.



**Figure 14.** Pressing the Menu button.

2. Press the **Enter Code** button (Figure 15).



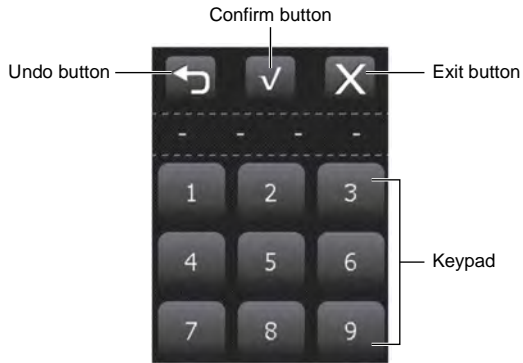
**Figure 15.** Pressing the Enter Code button.

3. Enter the four-digit code by pressing the number buttons on the touchscreen keypad, then press the **Confirm** button to confirm and continue to the Menu (Figure 16).

**Notes:**

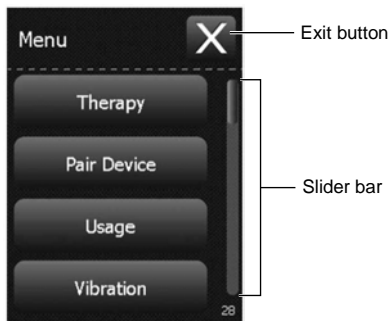
- The code is 1155.
- If you make an error while entering the code, press the **Undo** button to delete the entire code, then re-enter the correct code.

- To cancel code entry, press the **Exit** button (X) to exit and return to the previous screen.



**Figure 16.** Entering the Menu code.

4. From the Menu, select the **Pair Device** button (Figure 17).



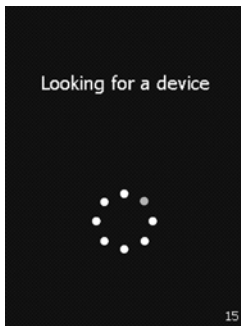
**Figure 17.** Selecting the Pair Device button.



5. Press and hold the **ENS** button on the external neurostimulator for one second to place the external neurostimulator into discovery mode. The light on the external neurostimulator will repeatedly blink for 90 seconds, or until it has paired with a controller.
6. Press the **Continue** button on the controller touchscreen (Figure 18). The controller will look for the external neurostimulator (Figure 19).



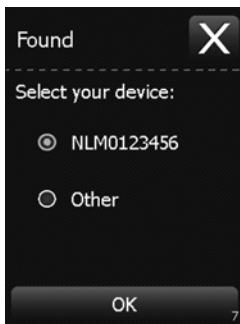
*Figure 18. Pressing the Continue button on the touchscreen.*



*Figure 19. Controller looking for the external neurostimulator.*

7. Using the touchscreen, select the radio button next to the correct external neurostimulator, then press the **OK** button to continue (Figure 10).

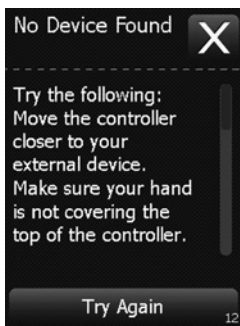
**Note:** The number displayed on the controller screen should match the serial number printed on the back of the external neurostimulator.



*Figure 20. Selecting the correct device from the list.*

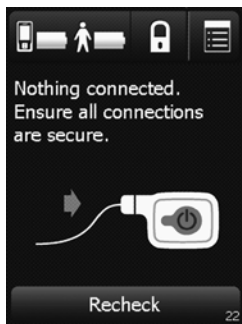
**Notes:**

- If the controller fails to pair with the external neurostimulator, repeat step 5 and press the **Try Again** button to continue (Figure 21).
- Pressing the **Exit** button (X) will abort the pairing process.



*Figure 21. No Device Found screen.*

**Note:** If there is a connection problem, a screen will appear (Figure 13). Check all connections between the lead and the external neurostimulator, and press the **Recheck** button.

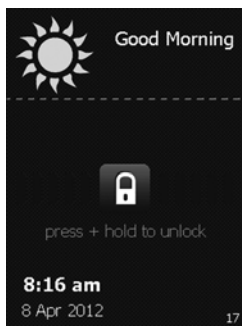


*Figure 22. Screen prompt to check connections.*

## Unlocking and locking the controller

### Unlocking the controller

To unlock the controller, press the **Increase/Decrease** key.

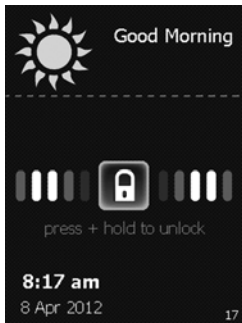


*Figure 23. The Unlock screen.*

**Note:** 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.

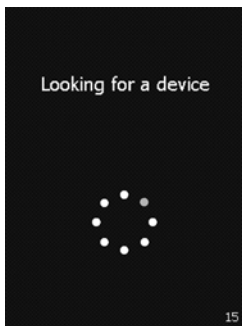
1. Press and hold the **Lock** button on the **Unlock** screen.

As the **Lock** button is held, bars appear on the screen and move toward the **Lock** button (Figure 24).



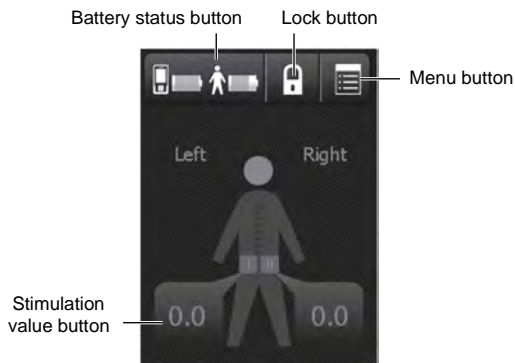
**Figure 24.** Bars appearing on the Unlock screen.

2. Stop pressing the screen when the screen changes to a circle of dots (Figure 25). The controller is looking for the external neurostimulator.



**Figure 25.** The controller looking for the external neurostimulator.

The next screen that appears is the **Home** screen (Figure 26).



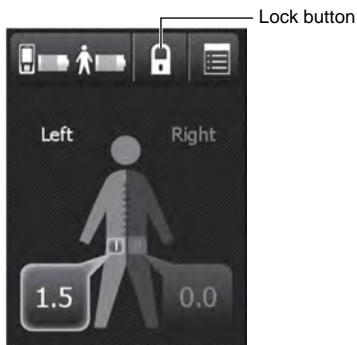
**Figure 26.** *The Home screen.*

If the **Home** screen does not appear, see "Troubleshooting" on page 59.

### **Locking the controller**

The controller can be locked so that when buttons or keys are accidentally pressed there will not be an unexpected change in stimulation.

**Note:** The controller screen will dim after 15 seconds of inactivity, and will automatically lock itself after 2 minutes of inactivity. Pressing the **Lock** button will lock the controller immediately. From the **Home** screen, press the **Lock** button to lock the controller (Figure 27).



*Figure 27. Pressing the Lock button.*

### Turning stimulation on or off

**Note:** You can turn stimulation on or off at any time.

#### Turning stimulation on

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

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

2. A screen appears with the option to turn stimulation on. Press the **Stimulation On** button to turn stimulation on (Figure 28).

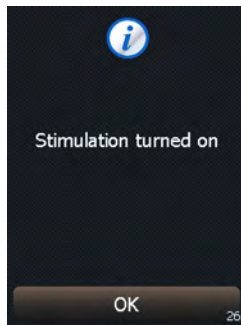
**Notes:**

- To make no change to stimulation and access the **Home** screen, press the **Go To Unlock** button and unlock the controller.
- To keep stimulation off and continue to the **Home** screen, press the **Stimulation Off** button.
- Press the **Exit** button to lock the controller again.



*Figure 28. Turning stimulation on.*

3. A confirmation screen will appear (Figure 29). Press the **OK** button to continue to the **Home** screen.



*Figure 29. Stimulation turned on.*

### Turning stimulation off

1. To turn stimulation off, press the **Stimulation On/Off** key on the top of the controller.
2. A screen appears with the option to turn stimulation off. Press the **Stimulation Off** button to turn stimulation off (Figure 30).

**Notes:**

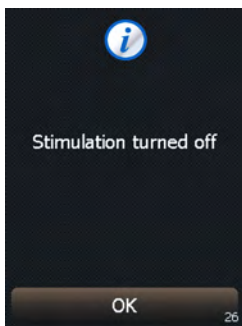
- To make no change to stimulation and lock the controller, press the **Lock Controller** button.
- To keep stimulation on and go to the **Home** screen, press the **Stimulation On** button.
- To make no change to stimulation, press the **Exit** button.



*Figure 30. Turning stimulation off.*

**Note:** If the patient is experiencing discomfort and stimulation must be turned off immediately, press and hold the **ENS** button on the external neurostimulator for 3 seconds.

3. A confirmation screen will appear (Figure 31). Press the **OK** button to continue to the **Home** screen.



*Figure 31. Stimulation turned off.*



## Adjusting stimulation parameters using the Model 3575 Test Stimulation Cable

### Notes:

- Before programming, ensure all connections are secure between the external neurostimulator and the lead(s) or needle.
- For instructions on intraoperative test stimulation, refer to the appropriate lead manual.

### Increasing and decreasing amplitude on the Home screen

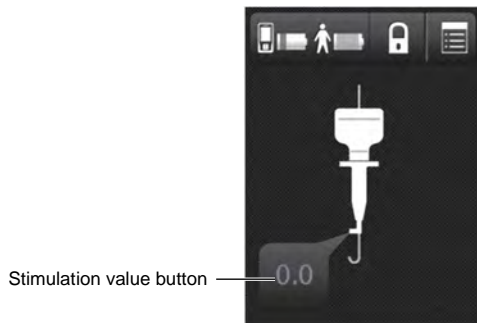
When using the test stimulation cable, the external neurostimulator uses the following default settings:

- The test stimulation cable is the cathode (-).
- The ground pad is the anode (+).
- Amplitude is set to 0 milliamps.
- Pulse width is set to 210 microseconds.
- Rate is set to 14 Hertz.

**Note:** The cathode and anode configuration does not change. To change amplitude, pulse width, and rate, refer to "Adjusting advanced parameters" on page 27.

1. Press the **Stimulation value** button on the **Home** screen (Figure 32). If stimulation is off, a new screen will appear.

**Note:** If stimulation is already on, the **Stimulation value** button will be outlined in green. If this happens, proceed to step 3.



**Figure 32.** Pressing the Stimulation value button.

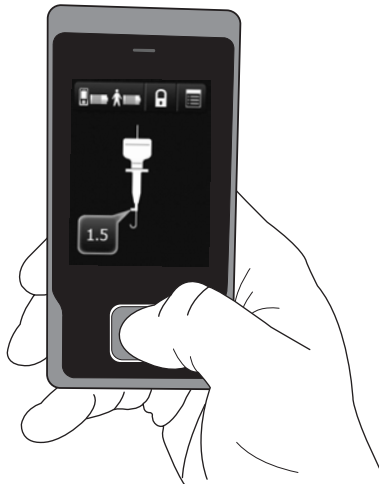
2. Press the **Turn On** button to turn stimulation on and continue (Figure 33).

**Note:** To cancel and go back to the **Home** screen, press the **OK** button.



*Figure 33. Pressing the Turn On button.*

3. Use the **Increase** and **Decrease** keys to adjust amplitude (Figure 34).



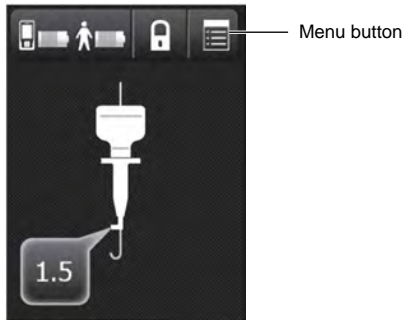
*Figure 34. Adjusting amplitude.*

**Note:** Press and release the **Increase** or **Decrease** key once to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.

4. To adjust pulse width and rate, refer to "Adjusting advanced parameters".

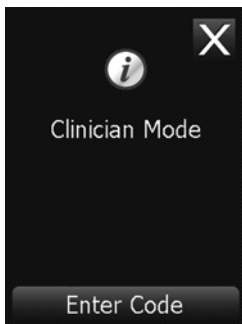
### Adjusting advanced parameters

1. From the **Home** screen, press the **Menu** button in the top right corner of the touchscreen (Figure 35).



**Figure 35.** Pressing the Menu button.

2. Press the **Enter Code** button (Figure 36).

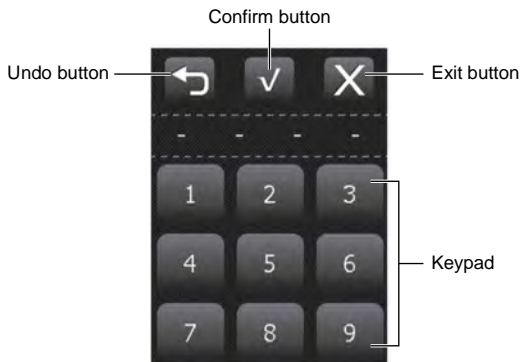


**Figure 36.** Pressing the Enter Code button.

3. Enter the four-digit code by pressing the number buttons on the touchscreen keypad, then press the **Confirm** button to enter the code and continue (Figure 37).

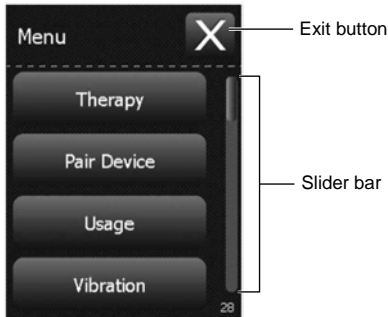
**Notes:**

- The code is 1155.
- If you make an error while entering the code, press the **Undo** button to delete the entire code, then re-enter the correct code.
- To cancel code entry, press the **Exit** button (X) to exit and return to the previous screen.



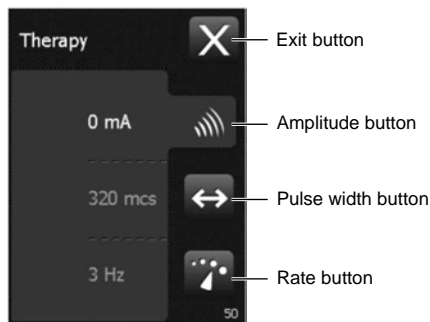
**Figure 37.** Entering the Menu code.

4. Select the **Therapy** button from the Menu (Figure 38).



**Figure 38.** Selecting the Therapy button.

5. Adjust the amplitude, pulse width, and rate (Figure 39).



**Figure 39.** Adjusting amplitude, pulse width, and rate.

- a. To change the amplitude, press the **Amplitude** button, then use the **Increase** and **Decrease** keys to adjust the amplitude parameter.

**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.

- b. To change the pulse width, press the **Pulse width** button, then use the **Increase** and **Decrease** keys to adjust the pulse width parameter.

**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 10 microseconds. Press and hold to quickly adjust the parameter.

- c. To change the rate, press the **Rate** button, then use the **Increase** and **Decrease** keys to adjust the rate parameter.

**Note:** Press the **Increase** or **Decrease** key to change the parameter value by 1 Hertz (from 3 to 30 Hertz) or by 5 Hertz (from 30 to 130 Hertz). Press and hold to quickly adjust the parameter.

6. Press the **Exit** button (X) at the top right corner of the screen to exit.

If using one or more Model 3057 test stimulation lead(s), refer to "Adjusting stimulation parameters for the Model 3057 Test Stimulation Lead(s)" on page 30. If using the Model 3093 or Model 3889 Tined Lead, refer to "Adjusting stimulation parameters for the Model 3093 or Model 3889 Tined Lead" on page 37.

## **Adjusting stimulation parameters for the Model 3057 Test Stimulation Lead(s)**

### **Notes:**

- Before programming, ensure all connections are secure between the external neurostimulator and the lead(s).
- For instructions on intraoperative test stimulation, refer to the appropriate lead manual.

## **Increasing and decreasing amplitude on the Home screen**

When using the test stimulation lead, the external neurostimulator uses the following default settings:

- The test stimulation lead is the cathode (-).
- If the Model 3676 Cable is used, the ground pad is the anode (+). If the Model 3579 Cable is used, the second test stimulation lead is the anode.
- Amplitude is set to 0 milliamps.
- Pulse width is set to 210 microseconds.
- Rate is set to 14 Hertz.

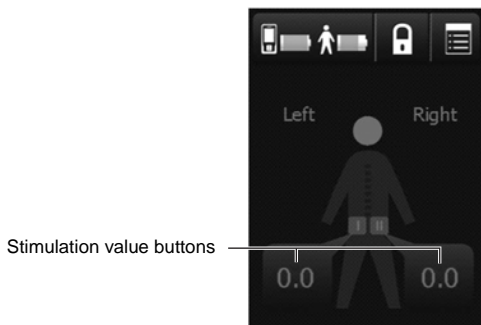
**Note:** The cathode and anode configuration does not change. To change amplitude, pulse width, and rate, refer to "Adjusting advanced parameters" on page 33.

1. Press the **Stimulation value** button on the **Home** screen (Figure 40). If stimulation is off, a new screen will appear.

### **Notes:**

- If two leads were placed, select a side to stimulate by pressing the **Stimulation value** button on that side.

- The image below shows the **Home** screen when two test stimulation leads are placed. If only one test stimulation lead was placed, only one **Stimulation value** button will be available.
- If stimulation is already on, the **Stimulation value** button will be outlined in green. If this happens, proceed to step 4.



**Figure 40.** Pressing the Stimulation value button on the Home screen.

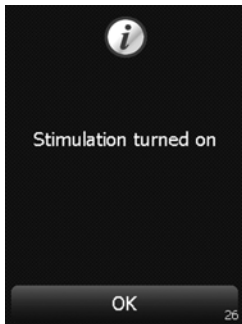
2. Press the **Turn On** button to turn stimulation on and continue (Figure 41).

**Note:** To cancel and go back to the **Home** screen, press the **OK** button.



**Figure 41.** Pressing the Turn On button.

3. A confirmation screen will appear (Figure 42). Press the **OK** button to continue to the **Home** screen.



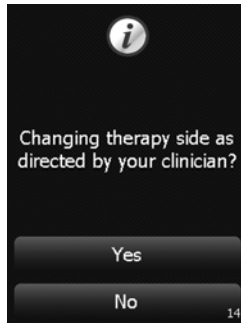
*Figure 42. Stimulation turned on.*

4. Use the **Increase** and **Decrease** keys to adjust amplitude.  
**Note:** Press and release the **Increase** or **Decrease** key once to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.
5. To adjust pulse width and rate, refer to "Adjusting advanced parameters".

#### **Changing the active lead (if two leads were placed)**

1. Press the **Stimulation value** button on the side of the **Home** screen that corresponds to the inactive lead.
2. Press the **Yes** button to continue (Figure 43).





*Figure 43. Confirming change of therapy side.*

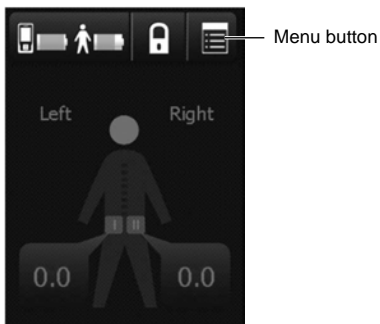
3. Press the **Yes** button to confirm changing sides.

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

4. The active lead will change, and stimulation will be set to zero. Use the **Increase/Decrease** key to adjust stimulation (see "Increasing and decreasing amplitude on the Home screen" on page 30).

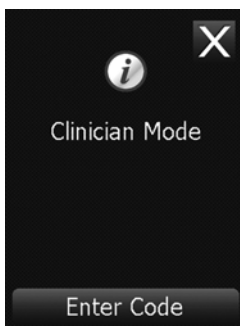
#### **Adjusting advanced parameters**

1. From the **Home** screen, press the **Menu** button in the top right corner of the touchscreen (Figure 44).



**Figure 44.** Pressing Menu button.

2. Press the **Enter Code** button (Figure 36).



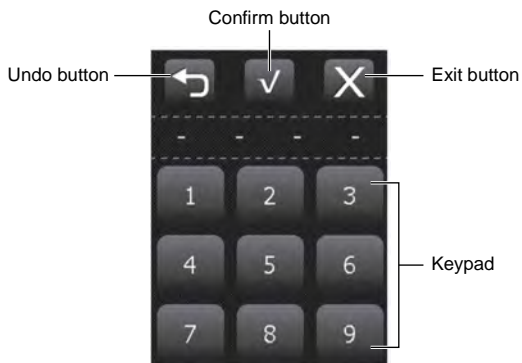
**Figure 45.** Pressing the Enter Code button.

3. Enter the four-digit code by pressing the number buttons on the touchscreen keypad, then press the **Confirm** button to enter the code and continue (Figure 46).

**Notes:**

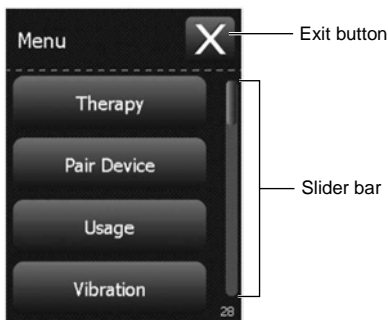
- The code is 1155.
- If you make an error while entering the code, press the **Undo** button to delete the entire code, then re-enter the correct code.

- To cancel code entry, press the **Exit** button (X) to exit and return to the previous screen.



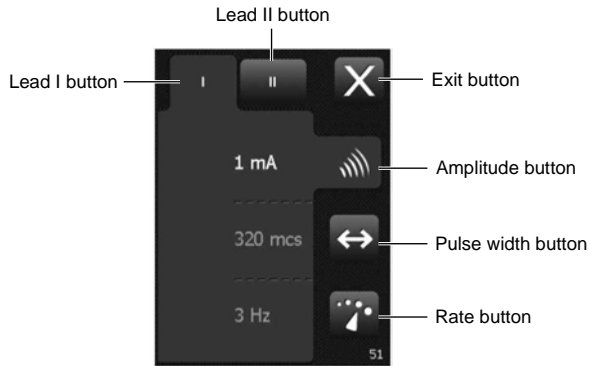
**Figure 46.** Entering the Menu code.

4. Select the **Therapy** button from the Menu (Figure 47).



**Figure 47.** Selecting the Therapy button.

5. Adjust the amplitude, pulse width, and rate (Figure 48).



**Figure 48.** Adjusting amplitude, pulse width, and rate.

- a. To change the amplitude, press the **Amplitude** button, then use the **Increase** and **Decrease** keys to adjust the amplitude parameter.  
**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.
  - b. To change the pulse width, press the **Pulse width** button, then use the **Increase** and **Decrease** keys to adjust the pulse width parameter.  
**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 10 microseconds. Press and hold to quickly adjust the parameter.
  - c. To change the rate, press the **Rate** button, then use the **Increase** and **Decrease** keys to adjust the rate parameter.  
**Note:** Press the **Increase** or **Decrease** key to change the parameter value by 1 Hertz (3 to 30 Hertz) or by 5 Hertz (30 to 130 Hertz). Press and hold to quickly adjust the parameter.
6. If using two leads, ensure stimulation parameters are reviewed and adjusted for both leads.
    - a. Press the **Lead I** or **Lead II** button at the top of the screen to alternate between lead I (left side) and lead II (right side).
    - b. Repeat step 5 to review and adjust stimulation parameters as desired.
  7. Press the **Exit** button (X) at the top right corner of the touchscreen to exit.
  8. When programming is finished, press the **Lock** button to lock the controller before giving the controller to the patient ("Locking the controller" on page 21).

## Adjusting stimulation parameters for the Model 3093 or Model 3889 Tined Lead

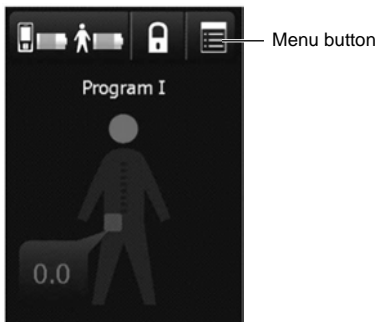
### Notes:

- Before programming, ensure all connections are secure between the external neurostimulator and the lead.
- For instructions on intraoperative test stimulation, refer to the appropriate lead manual.

### Adjusting advanced parameters

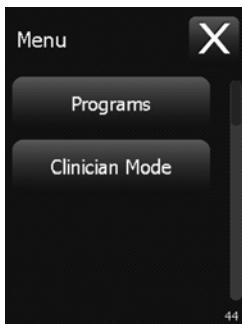
When using a Model 3093 or Model 3889 Tined Lead for test stimulation, advanced settings must be programmed before adjusting amplitude with the **Home** screen.

1. From the **Home** screen, press the **Menu** button in the top right corner of the touchscreen (Figure 49).



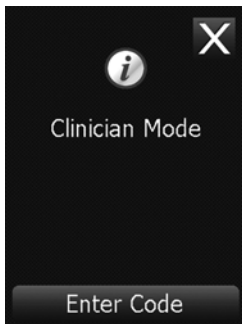
**Figure 49.** Pressing the Menu button.

2. Press the **Clinician Mode** button (Figure 50).



*Figure 50. Pressing the Clinician Mode button.*

3. Press the **Enter Code** button (Figure 51).

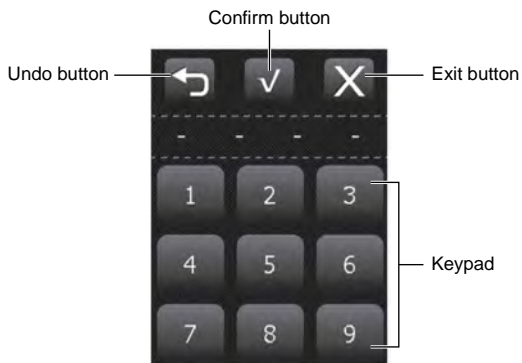


*Figure 51. Pressing the Enter Code button.*

4. Enter the four-digit code by pressing the number buttons on the touchscreen keypad, then press the **Confirm** button to enter the code and continue (Figure 52).

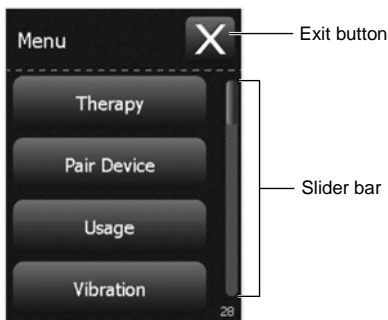
**Notes:**

- The code is 1155.
- If you make an error while entering the code, press the **Undo** button to delete the entire code, then re-enter the correct code.
- To cancel code entry, press the **Exit** button (X) to exit and return to the previous screen.



**Figure 52.** Entering the Menu code.

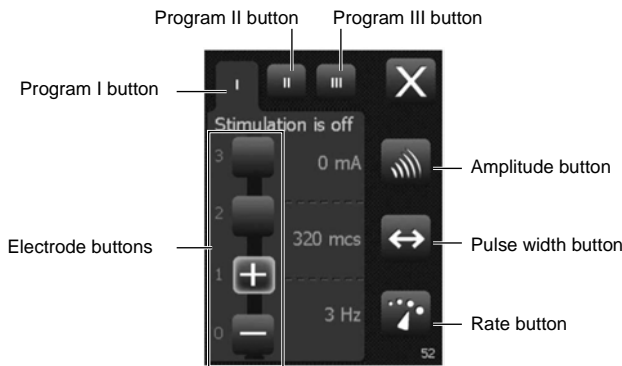
5. Select the **Therapy** button from the Menu (Figure 53).



**Figure 53.** Selecting the Therapy button.

6. Set up electrode configurations as desired (Figure 54).
  - a. Press each individual electrode on the touchscreen to alternate between blank (no polarity), plus (positive), or minus (negative).

- b. To apply stimulation, there must be at least one positive electrode and one negative electrode. One can exit the screen if all electrodes are blank, but stimulation will not be turned on.
  - c. Adjusting the electrode configuration automatically sets the amplitude to zero. Adjust the amplitude parameter again to the desired value.
7. Adjust the amplitude, pulse width, and rate (Figure 54).



**Figure 54.** Adjusting electrode configuration, amplitude, pulse width, and rate.

- a. To change the amplitude, press the **Amplitude** button, then use the **Increase** and **Decrease** keys to adjust the amplitude parameter.  
**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.
  - b. To change the pulse width, press the **Pulse width** button, then use the **Increase** and **Decrease** keys to adjust the pulse width parameter.  
**Note:** Press and release the **Increase** or **Decrease** key to change the parameter value by 10 microseconds. Press and hold to quickly adjust the parameter.
  - c. To change the rate, press the **Rate** button, then use the **Increase** and **Decrease** keys to adjust the rate parameter.  
**Note:** Press the **Increase** or **Decrease** key to change the parameter value by 1 Hertz (3 to 30 Hertz) or by 5 Hertz (30 to 130 Hertz). Press and hold to quickly adjust the parameter.
8. If using multiple programs, ensure that stimulation parameters and electrode configurations are reviewed and adjusted for all programs.
- a. Press the **Program I**, **Program II**, or **Program III** button at the top of the screen to alternate between programs.



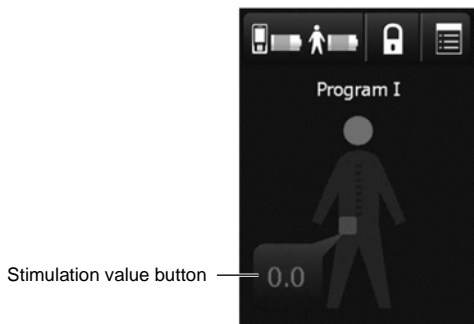
- b. Repeat step 6 through step 7 to review and adjust electrode configurations as desired.
9. When programming is finished, press the **Exit** button (⌫) at the top right corner of the screen to exit to the Menu.

### Increasing and decreasing amplitude on the Home screen

When using a Model 3093 or Model 3889 Tined Lead for test stimulation, advanced settings must be programmed before adjusting amplitude with the **Home** screen.

1. Press the **Stimulation value** button on the **Home** screen (Figure 55). If stimulation is off, a new screen will appear.

**Note:** If stimulation is already on, the **Stimulation value** button will be outlined in green. If this happens, proceed to step 3.



**Figure 55.** Pressing the Stimulation value button on the Home screen.

2. Press the **Turn On** button to turn stimulation on and continue (Figure 56).

**Note:** To cancel and go back to the **Home** screen, press the **OK** button.



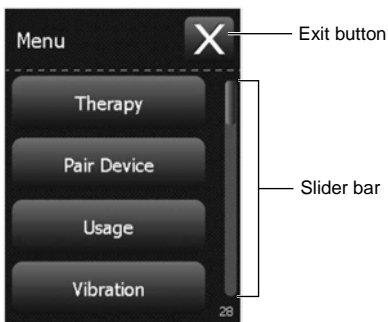
*Figure 56. Pressing the Turn On button.*

3. Use the **Increase** and **Decrease** keys to adjust amplitude.  
**Note:** Press and release the **Increase** or **Decrease** key once to change the parameter value by 0.1 milliamps. Press and hold to change the parameter value in 0.5-milliamp increments.
4. To adjust pulse width, rate, and electrode configuration, refer to "Adjusting advanced parameters".
5. When programming is finished, press the **Lock** button to lock the controller before giving the controller to the patient ("Locking the controller" on page 21).

## Usage Log

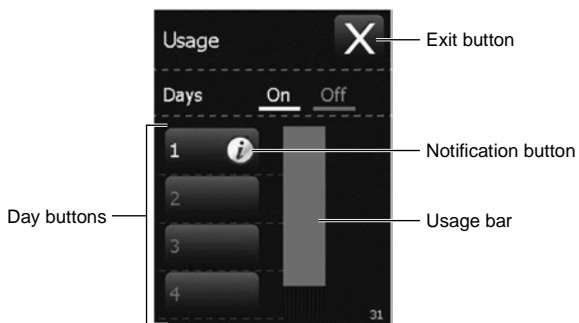
The Usage Log contains data on the patient test stimulation period, shown as a bar graph. The graph displays an approximate timeline of stimulation turned on or off. The graph is shaded in sections representing time when stimulation was on, and blank in sections representing time when stimulation was off. The Usage Log also displays information related to the following:

- When the active side was changed.
  - When the active program was changed (if applicable).
  - When stimulation was on or off.
1. From the Menu, press the **Usage** button (Figure 57).



**Figure 57.** Pressing the Usage button.

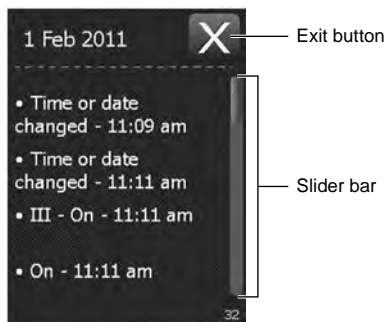
2. The **Usage** bar shows when stimulation was on or off. When stimulation was on, the **Usage** bar is lighter. When stimulation was off, the **Usage** bar is darker.



**Figure 58.** The Usage Log screen.

**Note:** Scroll down using the touchscreen slider bar to see more days.

3. A blue **Notification** icon (🔔) will appear next to days during which an event occurred. Press the **Day** button that contains the **Notification** icon for details on events related to the patient changing lead sides, changing programs, and turning stimulation on or off (Figure 59).



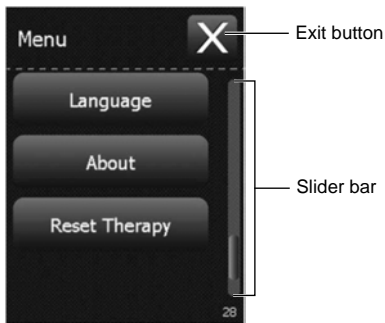
*Figure 59. Example of a Usage log notification.*

**Note:** It is possible for the amplitude is set to zero while stimulation is on.

## Reset Therapy

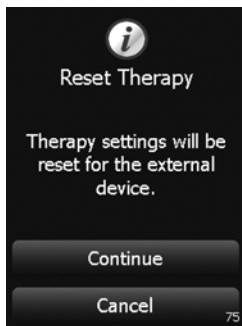
The Reset Therapy function allows you to set all stimulation settings to their default values for any and all programs.

1. From the Menu, press the **Reset Therapy** button (Figure 60).



**Figure 60.** Pressing the Reset Therapy button.

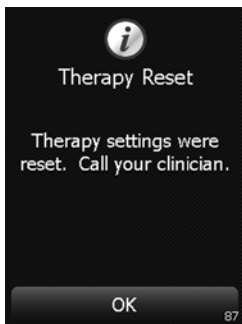
2. Press the **Continue** button to confirm resetting all stimulation settings (Figure 61).  
**Note:** To cancel the therapy reset, press the **Cancel** button.



**Figure 61.** Confirming therapy reset.

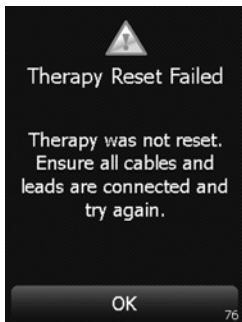
The controller will check the lead and cable connections prior to resetting stimulation settings.

3. If the reset was successful, a confirmation screen will appear (Figure 62). Press the **OK** button to continue to the **Home** screen.



*Figure 62. Therapy Reset successful screen.*

**Note:** If the reset was not successful, a warning screen appears (Figure 63). If this screen appears, check all lead and cable connections, press the **OK** button, and repeat steps 1 through 3 to try again.



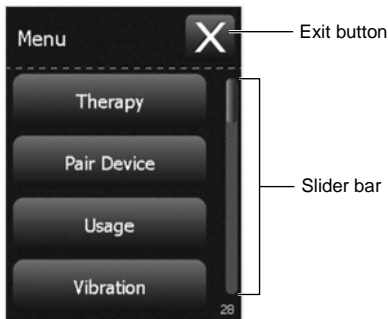
*Figure 63. Therapy Reset Failed warning screen.*

## Changing preferences

**Note:** In the Menu, use the touchscreen slider bar to view all options (Figure 64).

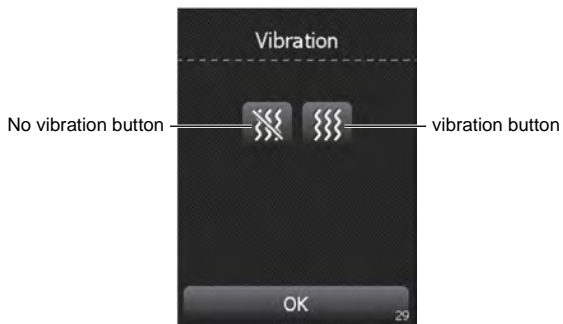
## Changing the vibration settings

1. Select the **Vibration** button from the Menu (Figure 64).



**Figure 64.** *Selecting the Vibration button.*

2. To change vibration settings using the touchscreen, press either the **No vibration** button or the **Vibration** button (Figure 65).



**Figure 65.** *Changing the vibration settings on the controller.*

3. Press the **OK** button to exit.

## Changing the brightness of the controller display

1. Select the **Brightness** button from the Menu (Figure 66).



*Figure 66. Selecting the Brightness button.*

2. Using the touchscreen, press the radio button below the desired brightness level (Figure 67).



*Figure 67. Changing the brightness of the controller screen.*

3. Press the **OK** button to exit.



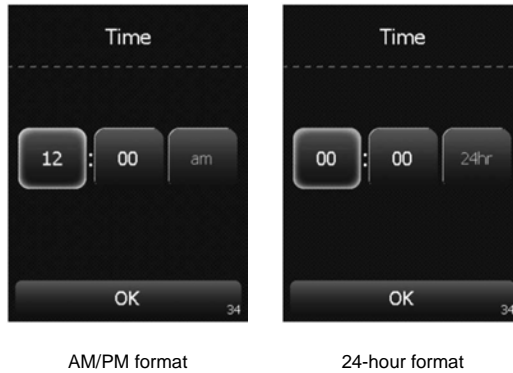
## Changing the time

1. Select the **Time** button from the Menu (Figure 68).



**Figure 68.** *Selecting the Time button.*

2. To change the hour, the minute, or the time format, press the touchscreen button with the incorrect value, then use the **Increase** and **Decrease** keys to change the value. Once the hour, minute, and time format are set correctly, press the **OK** button to exit (Figure 69).



AM/PM format

24-hour format

*Figure 69. Changing the time on the controller.*

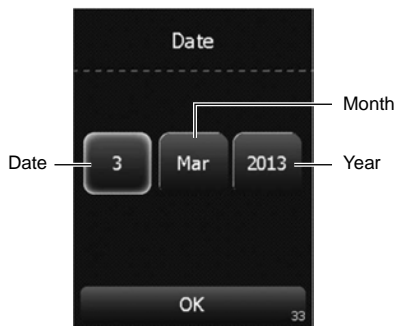
### Changing the date

1. Select the **Date** button from the Menu (Figure 70).



*Figure 70. Selecting the Date button.*

2. To change the date, the month, or the year, press the touchscreen button with the incorrect value, then use the **Increase** and **Decrease** keys to change the value. Once the date, month, and year are set correctly, press the **OK** button to exit (Figure 71).



*Figure 71. Changing the date on the controller.*

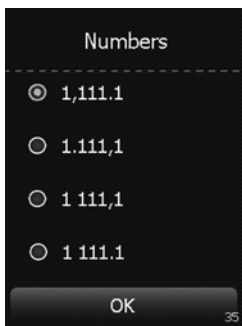
### Changing the number format

1. Select the **Numbers** button from the Menu (Figure 72).



*Figure 72. Selecting the Numbers button.*

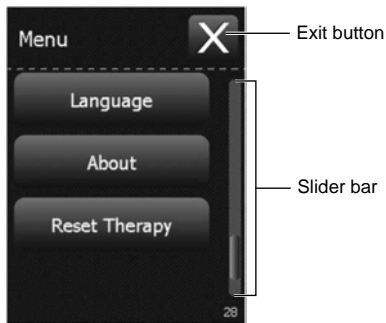
- Using the touchscreen, press the radio button next to the desired number format for the controller, then press the **OK** button to exit (Figure 73).



*Figure 73. Changing the number format of the controller.*

### Changing the language

- Select the **Language** button from the Menu (Figure 74).



**Figure 74.** Selecting the Language button.

- Using the touchscreen, select the desired language from the options available, then press the **OK** button to exit (Figure 75).

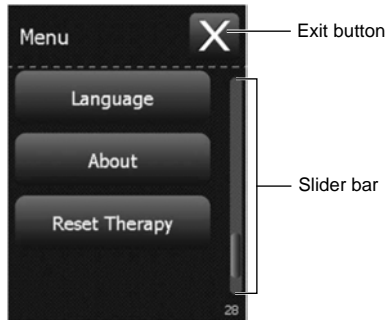


**Figure 75.** Changing the language on the controller.

**Note:** Use the slider bar to scroll up or down to see more languages.

### Viewing information about the controller and the external neurostimulator

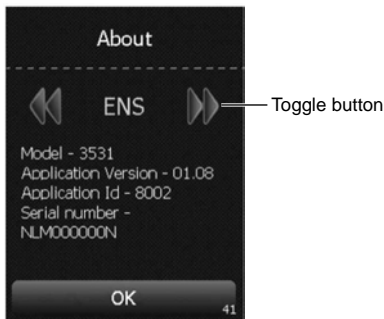
1. To view information about the controller or the external neurostimulator, use the touchscreen to select the **About** button from the Menu (Figure 76).



**Figure 76.** *Selecting the About button.*

2. When finished reading the information about the controller, press the **OK** button to exit (Figure 77).

**Note:** To view information about the controller, press the **Toggle** button (Figure 77).



*Figure 77. The About screen.*

## Checking and replacing batteries




Always keep 2 new AA alkaline batteries available for replacement.

### Checking the external neurostimulator and controller batteries

**Note:** You can see the battery levels of the controller and the external neurostimulator at the top of the **Home** screen (Figure 78). For more detailed information on battery levels, follow the steps below.

Table 1 lists several examples of external neurostimulator battery levels and whether action is required.

**Table 1. Battery level definitions for the external neurostimulator**

	External neurostimulator battery icon is green. Battery level is full. No action is needed.
	External neurostimulator battery icon is green. Consider replacing the external neurostimulator batteries.
	External neurostimulator battery icon is orange. Battery level is low. Do not send a patient home with low batteries. Replace the external neurostimulator batteries.

**Table 1. Battery level definitions for the external neurostimulator**



External neurostimulator battery icon is red. Stimulation may no longer be available. Do not send a patient home with low batteries. Replace the external neurostimulator batteries.

Table 2 lists several examples of controller battery levels and whether action is required.

**Table 2. 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.



Controller battery icon is orange. The controller batteries are low. Consider changing controller batteries soon.



Controller battery icon is red. The controller batteries are nearly depleted and programming will not be possible soon. Replace the controller batteries.

You can check the controller batteries at any time. Complete the following steps to check the controller batteries.

1. From the **Therapy Home** screen, press the **Battery status** button (Figure 78).

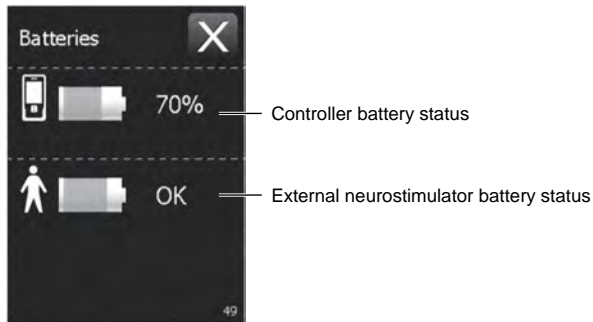


Battery status button



**Figure 78.** Viewing the battery status on the Home screen.

**Note:** Two battery icons are displayed (Figure 79). The upper battery icon shows the battery status of the controller. The lower battery icon shows the battery status of the external neurostimulator.



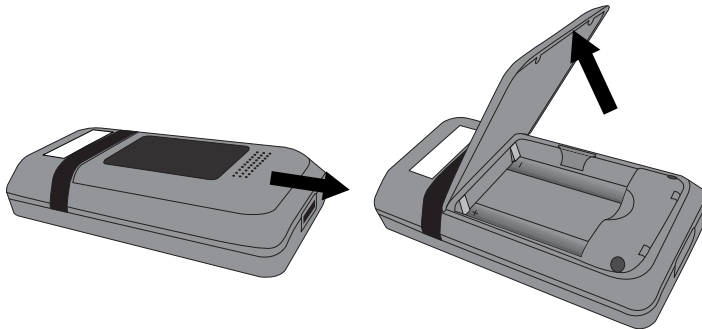
**Figure 79.** Viewing the detailed battery status.

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

## Replacing the controller batteries

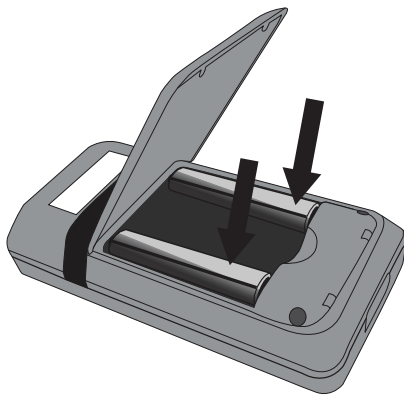
### Notes:

- For information on replacing the external neurostimulator batteries, refer to the *Model 3531 External Neurostimulator Technical Manual*.
  - If not using the controller for an extended period of time, remove the batteries from the controller to prevent battery depletion.
1. Open the battery compartment cover (Figure 80).



**Figure 80.** Opening the battery cover.

2. Remove the depleted batteries.
3. Insert the new batteries as shown on the battery compartment label (Figure 81).

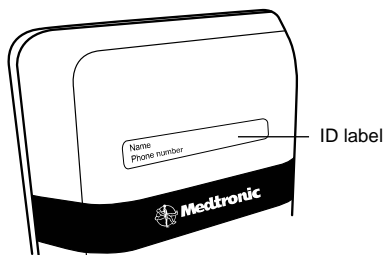


**Figure 81.** Inserting new batteries.

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

### Labeling the controller

Write your clinic contact information on an identification label and place the label on the back of the controller so the controller can be returned if lost (Figure 82).



**Figure 82.** Place the adhesive label on the back of the controller.

### Troubleshooting

This section lists basic troubleshooting for the controller.

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' (i).

If you experience an issue not described in this section, contact your Medtronic representative.

## Troubleshooting reference guide

**Table 3. Warning messages**

Message	Explanation and Solution
<b>System Problem</b> Cannot continue. Please call your clinician.	<p>Explanation: The system is not working correctly. Stimulation may have stopped.</p> <ol style="list-style-type: none"><li>1. <b>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 "Checking and replacing batteries" on page 55.</b></li><li>2. <b>If the issue persists, remove and reinsert the external neurostimulator batteries, then retry the action that caused the error screen to appear. For instructions on removing and inserting external neurostimulator batteries, refer to the manual packaged with the external neurostimulator.</b></li><li>3. <b>If the issue persists and if using the Model 3093/3889 Lead, remove all electrode configurations by setting all electrodes to blank for all programs, then reprogram electrode configurations and retry the action that caused the error screen to appear. For instructions on programming electrodes, refer to "Adjusting stimulation parameters for the Model 3093 or Model 3889 Tined Lead" on page 37.</b></li><li>4. <b>If the steps above do not resolve the issue, the external neurostimulator and/or controller need to be replaced.</b></li></ol>

**Table 3. Warning messages**

<b>Message</b>	<b>Explanation and Solution</b>
<b>Software Problem</b> Cannot continue. Please call your clinician.	Explanation: The software is not working correctly. Stimulation may have stopped. <ol style="list-style-type: none"><li><b>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 "Checking and replacing batteries".</b></li><li><b>2. If the issue persists, replace the controller and refer to "Pairing a new controller to an external neurostimulator" for instructions on pairing the new controller to the external neurostimulator.</b></li></ol>
<b>Button Jammed</b> Cannot provide stimulation. Release the external device button.	Explanation: The ENS button on the external neurostimulator is stuck in the pressed position. <b>Solution: Press and release the ENS button, then press the OK button. If the problem persists, the external neurostimulator may need to be replaced.</b>
<b>Batteries Empty (external device)</b> External device batteries need to be changed. Call your clinician.	Explanation: The external neurostimulator batteries are depleted and stimulation is not available. <b>Solution: Replace the external neurostimulator batteries. For more information on replacing the external neurostimulator batteries, refer to the Model 3531 External Neurostimulator Technical Manual.</b>
<b>Battery Empty (controller)</b> Cannot continue. Replace the controller batteries.	Explanation: The controller batteries are depleted. Programming is not available. <b>Solution: Replace the controller batteries. For instructions on replacing the controller batteries, see "Checking and replacing batteries" on page 55.</b>
<b>Change External Device</b> Cannot provide stimulation. Call your clinician.	Explanation: The external neurostimulator has reached the end of service. This is related to device function, not to battery level. This external neurostimulator can no longer provide stimulation. <b>Solution: Replace the external neurostimulator.</b>

*Table 4. Alert messages*

<b>Message</b>	<b>Explanation</b>
<b>No Device Found</b> Try the following: Move the controller closer to the external device.	<p>Explanation: 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>Solution: 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><b>If the issue persists, the external neurostimulator batteries may need to be replaced. For instructions on replacing the external neurostimulator batteries, see the appropriate technical manual packaged with the external neurostimulator.</b></p>
<b>Change External Device</b> Call your clinician. Stimulation hour(s) remaining: XX	<p>Explanation: The external neurostimulator is nearing the end of service. Stimulation will not be available soon.</p> <p><b>Solution: Replace the external neurostimulator.</b></p>
<b>Batteries Low (external device)</b> External device batteries need to be changed. Call your clinician.	<p>Explanation: The external neurostimulator batteries are low and stimulation will not be available soon.</p> <p><b>Solution: Replace the external neurostimulator batteries. For more information on replacing the external neurostimulator batteries, refer to the Model 3531 External Neurostimulator Technical Manual.</b></p>
<b>Battery Low (controller)</b> Replace the controller batteries soon.	<p>Explanation: The controller batteries are low and programming will not be available soon.</p> <p><b>Solution: Replace the controller batteries. For instructions on replacing the controller batteries, see "Checking and replacing batteries" on page 55.</b></p>
<b>Incomplete Settings</b> Valid electrodes configuration, pulse width, and rate settings required.	<p>Explanation: One or more stimulation parameters, including electrode configuration, was left unprogrammed.</p> <p><b>Solution: Check stimulation parameters. Ensure that at least one electrode is negative and at least one electrode is positive, or that all electrodes are blank.</b></p>
<b>Incompatible Device</b> Change external device.	<p>Explanation: You are attempting to connect to an incompatible external neurostimulator.</p> <p><b>Solution: Replace the external neurostimulator with a compatible model.</b></p>

*Table 4. Alert messages*

<b>Message</b>	<b>Explanation</b>
<b>Incompatible System Component</b> Ensure batteries and other system components are compatible.	<b>Explanation:</b> You are attempting to connect to an incompatible system component. <b>Solution: Verify that all components are compatible. Remove any incompatible system components.</b> <b>If the issue persists, the controller batteries may need to be replaced. For instructions on replacing the controller batteries, see "Checking and replacing batteries".</b>
<b>Connection Changed</b> Cable or lead changed. Therapy settings were reset.	<b>Explanation:</b> The external neurostimulator has detected that a different cable type has been connected. <b>Solution: Press the OK button. Stimulation parameters for the new connection need to be programmed to desired settings.</b>
<b>Check Connection</b> Ensure all cable and lead connections are secure.	<b>Explanation:</b> The external neurostimulator has detected that either a cable or a lead is not connected. <b>Solution: Ensure all cable and lead connections are secure. Press the OK button.</b>

*Table 5. Notification messages*

<b>Message</b>	<b>Explanation and solution</b>
<b>Stimulation is off</b> Settings cannot be changed with stimulation off.	<b>Explanation:</b> You tried to adjust stimulation/therapy when stimulation/therapy was off. <b>Solution: Turn stimulation/therapy on, then try adjusting stimulation/therapy again.</b>
<b>Upper limit</b> Settings cannot be increased any higher.	<b>Explanation:</b> You tried increasing a stimulation parameter above the highest value allowed. You can not increase the stimulation any higher. <b>Solution: Press the OK button and consider adjusting other stimulation parameters.</b>
<b>Lower limit</b> Settings cannot be decreased any lower.	<b>Explanation:</b> You tried decreasing a stimulation parameter below the lowest value allowed. You can not decrease the amplitude below zero. <b>Solution: Press the OK button and consider adjusting other stimulation parameters.</b>

**Table 5. Notification messages**

<b>Message</b>	<b>Explanation and solution</b>
<b>Settings Not Available</b> Cannot provide your desired settings. Call your clinician.	<p>Explanation: Your combined settings can not currently be delivered by the external neurostimulator.</p> <p><b>Solution: Press the OK button and try the following:</b></p> <ol style="list-style-type: none"><li><b>1) Consider adjusting other stimulation parameters, including electrode configuration.</b></li><li><b>2) Ensure that lead and cable connections are secure.</b></li></ol>
<b>Retry ENS</b> Unable to find device	<p>Explanation: 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>Solution: 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><b>If this does not work, the external neurostimulator batteries may need to be replaced. For instructions on replacing the external neurostimulator batteries, see the appropriate technical manual packaged with the external neurostimulator.</b></p> <p><b>Note: If you wish to pair the controller to a new external neurostimulator, see "Pairing the controller to the external neurostimulator" on page 11</b></p>
<b>Memory Problem</b> Data has been lost. Repeat set-up process.	<p>Explanation: Controller settings are not available, but telemetry is still available. The controller batteries may have been removed or depleted for an extended period of time.</p> <p><b>Solution: Follow the on-screen prompts to reconfigure controller settings, including pairing to the external neurostimulator.</b></p>



**Table 6. Additional scenarios**

Scenario	Explanation
The controller is unresponsive.	<p>Explanation: the controller has encountered a problem and must be reset.</p> <ol style="list-style-type: none"><li><b>1. Solution: Remove and reinsert the batteries. For instruction on battery removal and placement, see "Replacing the controller batteries" on page 58.</b></li><li><b>2. If batteries are inserted correctly, the batteries are depleted. Replace the controller batteries. For instructions on replacing controller batteries, see "Replacing the controller batteries" on page 58.</b></li><li><b>3. If the issue persists, replace the controller.</b></li></ol>
The controller screen goes blank, then returns to the <b>Unlock</b> screen.	<p>Explanation: The controller encountered a problem and has automatically reset.</p> <p><b>Solution: Unlock the controller. If necessary, navigate back to the screen that was in use when the controller was reset and continue the intended task.</b></p>

## Device specifications

**Table 7. Model 3537 Controller specifications<sup>a</sup>**

Parameter	Specification
Power source	Two alkaline AA batteries (nonrechargeable)
Operating temperature	9 °C to 43 °C (49 °F to 110 °F)
Temperature limitation	-30 °C to 57 °C (-22 °F to +135 °F)
Controller size	12.0 x 6.0 x 2.4 cm (4.7 x 2.4 x 0.9 in)
Controller weight, including batteries	150 g (5.3 oz)
Battery life	4–6 weeks average for alkaline batteries
Operating time	Short

<sup>a</sup> All measurements are approximate.

## Device care and storage

- Keep new alkaline batteries available.
- Use the controller to check the battery level daily.
- Replace low or depleted batteries.

- 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 battery contacts may be cleaned periodically with a cotton swab dampened with alcohol. Do not use a pencil eraser or sandpaper.
- Store the device at room temperature. Avoid extreme hot or cold temperatures and direct sunlight.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Dispose of depleted batteries and worn out devices according to local requirements.

Filename Date Time  
UC2001xxxx EN  
4.625 x 6 inches (117 mm x 152 mm)

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**Contacts:**

**Asia:**

Medtronic International Ltd.  
Tel. 02919-1362  
Fax 02907-3998

Medtronic Asia Ltd.

Tel. (02)-548-1148  
Fax (02)-518-4786

**Australia:**

Medtronic Australasia Pty. Ltd.  
97 Waterloo Road  
North Ryde, NSW 2113  
Australia  
Tel. +61-2-9857-9000  
Fax +61-2-9878-5100  
Toll free 1-800-668-6700

**Austria:**

Medtronic Österreich GmbH  
Tel. 01-240440  
Fax 01-24044-100

**Belgium:**

Medtronic Belgium S.A.  
Tel. 02-456-0900  
Fax 02-460-2667

**Canada:**

Medtronic of Canada Ltd.  
Tel. (1-905)-460-3800  
Fax (1905)-826-6620

**Czech Republic:**

Medtronic Czechia s.r.o.  
Tel. 2-965-795-80  
Fax 2-965-795-89

**Denmark:**

Medtronic Danmark A/S  
Tel. 45-32-48-18-00  
Fax 45-32-48-18-01

**Finland:**

Medtronic Finland Oy/LTD  
Tel. (09)-755-2500  
Fax (09)-755-25018

**France:**

Medtronic France S.A.S.  
Tel. 01-5538-1700  
Fax 01-5538-1800

**Germany:**

Medtronic GmbH  
Tel. (02159)-81490  
Fax (02159)-8149100

**Greece:**

Medtronic Hellas S.A.  
Tel. 210-67-79-099  
Fax 210-67-79-399

**Hungary:**

Medtronic Hungária Kft.  
Tel. 1-889-06-00  
Fax 1-889-06-99

**Ireland:**

Medtronic Ireland Ltd.  
Tel. (01)-890-6522  
Fax (01)-890-7220

**Italy:**

Medtronic Italia SpA  
Tel. 02-241371  
Fax 02-241381  
Tel. 06-328141  
Fax 06-3215812

**Japan:**

Medtronic Japan  
Tel. 03-6430-2016  
Fax 03-6430-7110

**Latin America:**

Medtronic, Inc.  
Tel. (1305)-500-9328  
Fax (1786)-709-4244

**Norway:**

Medtronic Norge AS  
Tel. 067-10-32-00  
Fax 067-10-32-10

**Poland:**

Medtronic Poland Sp. z o.o.  
Tel. (022)-465-69-00  
Fax (022)-465-69-17

**Portugal:**

Medtronic Portugal, Lda.  
Tel. 21-724-5100  
Fax 21-724-5199

**Russia:**

Medtronic Russia  
Tel. (8495) 580-7377  
Fax (8495) 580-7378

**Slovakia**

Medtronic Slovakia, o.z.  
Tel. 0268 206 911  
Fax 0268 206 999

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**Template version: 08-08-2011**

**Spain:**

Medtronic Ibérica, S.A.  
Tel. 91-625-0400  
Fax 91-650-7410

**Sweden:**

Medtronic AB  
Tel. 08-568-585-00  
Fax 08-568-585-01

**Switzerland:**

Medtronic (Schweiz) AG  
Tel. 031-868-0100  
Fax 031-868-0199

**The Netherlands:**

Medtronic B.V.  
Tel. (045)-566-8000  
Fax (045)-566-8668

**U.K.:**

Medtronic U.K. Ltd.  
Tel. 01923-212213  
Fax 01923-241004

**USA:**

Medtronic, Inc.  
Tel. (1763)-505-5000  
Fax (1763)-505-1000  
Toll-free: (1-800)-328-0810



# Medtronic

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## **Manufacturer**

Medtronic, Inc.  
710 Medtronic Parkway  
Minneapolis, MN 55432-5604  
USA  
www.medtronic.com  
Tel. +1-763-505-5000  
Fax +1-763-505-1000

## **Medtronic E.C. Authorized** EC REP **Representative/Distributed by**

Medtronic B.V.  
Earl Bakkenstraat 10  
6422 PJ Heerlen  
The Netherlands  
Tel. +31-45-566-8000  
Fax +31-45-566-8668

## **Europe/Africa/Middle East**

### **Headquarters**

Medtronic International Trading Sàrl  
Route du Molliau 31  
Case Postale 84  
CH-1131 Tolochenaz  
Switzerland  
www.medtronic.eu  
Tel. +41-21-802-7000  
Fax +41-21-802-7900

### **Asia-Pacific**

Medtronic International Ltd.  
Suite 1106-11 16/F, Tower 1, The Gateway  
25 Canton Road, Tsimshatsui  
Kowloon  
Hong Kong  
Tel. +852-2919-1362  
Fax +852-2907-3998

Contacts for specific countries are listed inside this cover.



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