

PATIENT PROGRAMMER 37642 Medtronic[®] DBS™ Therapy user manual Activa[®] PC Model 37601 Activa[®] RC Model 37612 Activa[®] SC Model 37602 Activa[®] SC Model 37603



USA Rx only



Medtronic[®], Activa[®], and SoftStart/Stop[®] are trademarks of Medtronic, Inc., registered in the U.S. and other countries.

DBS[™] is a trademark of Medtronic, Inc.

IUSA FCC Information

The following is communications regulation information on the Model 37642 Patient Programmer.

FCC ID: LF537741

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

IMPORTANT: Changes or modifications to this product not authorized by Medtronic, Inc., could void the FCC Certification and negate your authority to operate this product.

This device complies with Industry Canada licenseexempt 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.

CEO123 Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.



Consult instructions for use



Manufacturer



Temperature limitation



Keep dry



Ingress protection rating IP22, per 60601-1-11



Serial number



PIN number



Authorized representative in the European community

I USA For USA audiences only

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

Non-ionizing electromagnetic radiation

Antenna jack

Magnetic Resonance (MR) Conditional

Magnetic Resonance (MR) Unsafe

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.)





★

(('**_**'))







Table of contents

Label Symbols 3

Glossary 10

1 Introduction 18

How to use this manual 18 For important safety information 20 Purpose of your patient programmer 20 Purpose of the neurostimulation system (indications) 21 Precautions 21

2 Using your patient programmer 26

How the patient programmer works 26 Multiple neurostimulators 29 Simple and advanced therapy modes 29 Summary of keys 32 Using the Navigator key 36 The Therapy screen 38

5

Synchronizing the patient programmer and your neurostimulator 41 Turning your therapy on or off 44 The neurostimulator battery 46 About rechargeable batteries 46 Checking the nonrechargeable battery status 47 Possible nonrechargeable battery status conditions 48 Customizing your patient programmer 50 Changing preferences 51 Patient programmer alert 57 Patient programmer accessories 58 Carrying case and patient programmer ID label 58 Detachable antenna 60 Using the detachable antenna 61

3 Adjusting therapy settings with Advanced mode 66

Adjusting your therapy settings 66 Therapy settings 68 Changing therapy settings in Advanced

mode 69

Selecting a new group 73 Returning your therapy to original settings 77 Understanding therapy parameter limits 81

4 MRI examinations 84

If you have an MRI appointment 84 Responsibilities of the patient in preparing for the MRI appointment 84

Preparing your neurostimulation system for the MRI scan 85

Turning off therapy before the MRI scan 86

Using the patient programmer to turn off therapy 87

Using the clinician programmer to turn off therapy 88

Turning therapy back on after the MRI scan 89

Activating settings to allow therapy on during the MRI scan 90

Using the patient programmer to activate a new group 91

Using the clinician programmer to activate a new group 92 Returning therapy to your original group setting after the MRI scan 94

5 Important information about your rechargeable neurostimulator 98

The rechargeable neurostimulator battery 98 Check and charge: make it a habit 100

Checking the rechargeable neurostimulator battery 102

Low battery status 103

Rechargeable battery overdischarge 105 Charging the neurostimulator battery 106 Patient programmer alert 108

6 Troubleshooting 110

Patient Programmer screens 110 Warning screens 110 Communication screen 113 Information screens 114 Possible problems and solutions 121

7 Maintenance 128

Patient programmer batteries 128 Checking the patient programmer batteries 129 Replacing the patient programmer batteries 132
Cleaning and care 134
Safety and technical checks 135
Battery and patient programmer disposal 136
Declaration of conformity 136
Specifications 137

8 Assistance for the patient programmer 140

Index 142

9

Glossary

- Active Group Available in Advanced mode only, the active group is the current group selected for your neurostimulator. See "Group" for more information.
- 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.
- **Charging system -** Equipment used to charge the battery inside a rechargeable implanted neurostimulator.
- Clinician A healthcare professional such as a doctor or nurse.
- **Clinician programmer -** A device used by a clinician to send instructions to a neurostimulator.
- **Contraindication -** A condition or circumstance when a person should not have a neurostimulation system.

Cycling - See Stimulation cycling.

Deep Brain Stimulation (DBS) - The delivery of electrical pulses to a targeted area or areas of the brain.

- Discharged battery status (rechargeable battery only) - The rechargeable battery is depleted and should be charged as soon as possible. When the battery is in a discharged state, therapy is not available.
- Electrode A metal piece near the tip of the lead. Electrodes deliver electrical pulses to a targeted area or areas of the brain.
- Electromagnetic interference (EMI) A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly.
- EOS (End of Service) A notification that the neurostimulator has reached its end of service. At EOS, the neurostimulator no longer delivers the electrical pulses that provide therapy.

- ERI (Elective replacement indicator) A notification that the neurostimulator is nearing its end of service.
- **Group -** A group is a collection of therapy settings on your patient programmer that your doctor creates for you. Each group may be defined for a different activity, symptom, or time of day. Available in Advanced mode only, this feature allows you to adjust your therapy for different situations or for personal preference.
- **Group status row -** The Parameter row on the **Therapy** screen displays the active group.
- Implantable neurostimulator (INS) See Neurostimulator.
- **Indication -** The purpose of the neurostimulation system and the medical condition for which it may be implanted.
- Lead The lead is a set of thin wires covered with a protective coating. It carries the therapy signal to the electrodes that deliver stimulation to the brain tissue.

Magnetic Resonance Imaging (MRI) - A type of medical procedure that scans your body using magnetic fields to provide detailed pictures of your anatomy.

- **Neurostimulation system -** Components that deliver, control, and maintain electrical pulses to provide therapy to the brain.
- **Neurostimulator -** The neurostimulator is the implanted device that generates and controls your DBS therapy.
- Overdischarge (rechargeable battery only)

 The rechargeable battery cannot be recharged when it is overdischarged. Once the battery is in a discharged state, if it is not recharged it continues to lose charge. Eventually, the battery loses enough charge to permanently affect the neurostimulator. If this occurs, the battery is overdischarged.
- **Parameter -** One of three therapy settings that adjust the electrical pulse: amplitude, pulse width, and rate of the electrical stimulation.

Parameter/Group row - The bottom row on the Therapy screen showing the parameter and active group settings (only available in Advanced mode).

Parameter settings - See Therapy settings.

Patient programmer - A hand-held device that allows you to turn your therapy on and off. It may also be used to adjust some therapy settings.

Precaution - See Caution.

Preferences - Adjustable settings on your patient programmer including audio, contrast, and text or icon display format. Preferences do not affect your therapy.

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

Glossary

- **SoftStart/Stop -** This feature, programmed by your clinician, starts and stops your therapy gradually by slowly increasing or decreasing to the programmed amplitude or until turned off.
- Status row The top row on the Therapy screen. This row displays if your therapy is on or off.
- **Stimulation -** The delivery of electrical pulses to an appropriate area of the brain. Your therapy is actually mild electrical stimulation.
- Stimulation cycling This feature turns your stimulation on and off at regular intervals and is programmed by your doctor.
- **Synchronize -** The process of sending and receiving information between the patient programmer and neurostimulator.
- **Therapy -** Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to one or more areas of the brain.

Therapy screen - The main screen displayed on the patient programmer.

- Therapy settings Your therapy can be adjusted by changing the rate, amplitude, or pulse width of the electrical stimulation. Your clinician programs all therapy settings. You may be able to adjust some therapy settings within clinician-defined limits. Available in Advanced mode only.
- **Warning -** A statement describing an action or situation that could harm the patient.
- Warning screen A screen displayed on the patient programmer that alerts you to a problem with the programmer, antenna, or neurostimulator.

Glossary

1 Introduction

How to use this manual

Refer to this manual after you receive an implanted neurostimulator. Ask your doctor 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", on page 17, describes how to use this manual, the purpose of the patient programmer, and provides general precautions related to using your patient programmer.
- Chapter 2 "Using your patient programmer", on page 25, describes the patient programmer and how to perform specific tasks.
- Chapter 3 "Adjusting therapy settings with Advanced mode", on page 65, explains

how to use your patient programmer to adjust your therapy settings.¹

- Chapter 4 "MRI examinations", on page 83, provides information about what you should do if you have an MRI examination.
- Chapter 5 "Important information about your rechargeable neurostimulator", on page 97 emphasizes the importance of checking and recharging your neurostimulator battery (for rechargeable devices only).
- Chapter 6 "Troubleshooting", on page 109, describes patient programmer warning and information screens, how to solve possible problems, and who to contact if your device is lost or broken.
- Chapter 7 "Maintenance", on page 127 describes how to care for your patient
- ¹ Your doctor has programmed your implanted neurostimulator to provide the correct therapy settings for your medical condition and will activate Advanced mode if appropriate.

programmer, including how to change the batteries.

For important safety information

Please see your DBS Patient Therapy Guide and DBS Therapy-specific Patient Booklet for important safety information, related warnings and precautions, and additional information about your therapy.

Purpose of your patient programmer

The Medtronic Model 37642 Patient Programmer is designed to operate with the following Medtronic neurostimulators:

- Activa PC Model 37601 (nonrechargeable battery)
- Activa RC Model 37612 (rechargeable battery)
- Activa SC Model 37602 (nonrechargeable battery)

 Activa SC Model 37603 (nonrechargeable battery)

Purpose of the neurostimulation system (indications)

Refer to the indications sheet that is packaged with your patient programmer for the purpose of the neurostimulation system and related information.

Precautions

Patient control devices may affect other implanted devices—Do not place the patient control device (ie, patient programmer) over another type of active implanted medical device (eg, pacemaker, defibrillator, another type of neurostimulator). The patient control device could unintentionally change the operation of the other device.

Patient programmer handling—To avoid damaging the patient programmer, do not immerse the device in liquid; do not clean it

with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or handle it in a way that might damage it.

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

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

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

37642 2015-04 English 23

Introduction 1





2 Using your programmer

How the patient programmer works

The patient programmer is used to control and monitor your implanted neurostimulator or neurostimulators. For example, you will use your patient programmer to:

- Turn your therapy on or off.
- Check the neurostimulator and patient programmer battery status.
- Alert you when you need to check the status of the neurostimulator battery.¹
- Change therapy settings.²

Note: Make sure to keep your patient programmer with you at all times in the event that you need to adjust your therapy or turn your therapy off.

- ¹ Your clinician will turn this feature on or off and also set the time of day that it will alert you.
- ² Your clinician will set up the therapy settings you will be able to adjust depending on your specific therapy requirements. Discuss this with your doctor.

The patient programmer communicates with your neurostimulator by sending signals to and receiving signals from your implanted neurostimulator.

When you use the patient programmer, hold it directly over your implanted neurostimulator so that the programmer screen is facing out. The back of the patient programmer should be as close to the neurostimulator as possible, as shown in Figure 2.1.



Figure 2.1 Place the patient programmer directly over your neurostimulator.

A detachable antenna is available for use with your neurostimulator system. The detachable antenna makes it easier to view the patient programmer screen while adjusting your therapy settings or checking the neurostimulator battery status. See "Using the detachable antenna" on page 61 for more information.

Multiple neurostimulators

Some patients have decided with their doctors to have two neurostimulators implanted.

If you have two neurostimulators implanted, you can use one patient programmer to communicate with both neurostimulators, but only with one neurostimulator at a time. The patient programmer only displays information about the neurostimulator with which it is currently synchronized.

The patient programmer must be turned off prior to sychronizing with the other neurostimulator or you may not be viewing the desired information.

Simple and advanced therapy modes

There are two therapy modes available for your patient programmer: Simple mode and Advanced mode. Your doctor will discuss which mode you will use.

- Simple mode uses the therapy settings selected by your doctor. Only your doctor can adjust your therapy settings.
- Advanced mode uses therapy settings selected by your doctor and also may allow you to change certain therapy settings and/or select preset therapy groups.

Table 2.1 Tasks available for Simple andAdvanced therapy modes

Tasks	Simple	Advanced
Check neurostimulator battery	Yes	Yes
Check patient programmer battery	Yes	Yes
Check status of neurostimulator (on or off)	Yes	Yes
Turn audio on or off. This does not change the Patient alert.	Yes	Yes
Adjust time	Yes	Yes
Adjust screen contrast	Yes	Yes
Adjust therapy settings	No	Yes ^a
Change active group	No	Yes ^a

^a This advanced feature is determined by your doctor.

For details about Advanced mode, see "Adjusting therapy settings with Advanced mode" on page 65.

Summary of keys



Figure 2.2 Keys used to operate the patient programmer.

Refer to Table 2.2 for a description of the patient programmer keys.

Table 2.2 Summary of keys

Кеу	Function
Therapy On/Off	Turns your therapy on or off.
	 The patient programmer (or detachable antenna) must be held directly over the neurostimulator while pressing the Therapy On/Off key.
	• After using the Therapy On/Off key, verify your therapy status by viewing the displayed Therapy screen.
	Press this key to turn your therapy on or off.
	Synchronizes the neurostimulator and patient programmer.
Check	Activates a selected group (Advanced mode only).
	Activates the "Return to Clinician Settings" (Advanced mode only).
	The patient programmer (or detachable antenna) must be held directly over the neurostimulator while pressing the Check \checkmark key.
	Press this key to synchronize the patient programmer and neurostimulator.

Table 2.2 Summary of keys (continued)

Кеу	Function
Dower/ backlight On/Off	Turns the patient programmer and the backlight on or off. The backlight provides more light to the display.
	Press and release this key once to turn the patient programmer power on or off.
	Press and hold this key to turn the backlight on or off.

Table 2.2 Summary of keys (continued)

Кеу	Function
Selection	Selects parameter setting for the left or right side of body (Therapy screen).
	Increases or decreases setting values (Parameter screen).
	When increasing or decreasing values, hold the patient programmer (or detachable antenna) directly over the neurostimulator and press the appropriate Selection key.
	You have two options to increase or decrease the settings with the Selection key.
	 Press and release the Selection key multiple times to increase or decrease the settings.
	 Press and hold the Selection key to increase or decrease the settings which will change approximately every half-second.
	Press the Selection key under an option displayed on the screen to select that option.

Table 2.2 Summary of keys (continued)

Key	Function
	Moves the selection box up or down on the Therapy screen or to the next
Navigator	available screen.
	The Options () icon at the end of a row on the Therapy screen indicates that the row continues on the next screen.
	Press the left \blacktriangleleft or right \triangleright arrows on this key to navigate to the next screen.
	Press the up \land or down \bigtriangledown arrows on this key to move the selection box to the next row.

Using the Navigator key

The **Navigator** key moves the selection box on the patient programmer screen to the right or left and up or down (Figure 2.3).



Figure 2.3 Navigator key.
- To move the selection box to a new row, press the up ▲ and down ▼ arrows on the Navigator key.

The image below is an example of how the **Options** (→) icon is displayed. The **Options** (→) icon is displayed at the end of a row when that row has additional items to view to the right or left (Figure 2.4).



Figure 2.4 The Options icon and selection box.

When moving the selection box with the **Navigator** key, you do not need to hold the patient programmer over your neurostimulator.

The Therapy screen

The **Therapy** screen displays your neurostimulator settings and battery status.

• In Simple mode:

The **Therapy** screen shows whether your neurostimulator is on or off and the status of the neurostimulator battery. The Simple mode screen appears the same for Activa PC, RC, and SC models (Figure 2.5).



Figure 2.5 The Therapy screen in Simple mode for Activa PC, RC, and SC models

• In Advanced mode:

The **Therapy** screen shows whether your neurostimulator is on or off, the battery status, and the specific parameters set for your therapy.

In most cases, the Advanced mode screen appears differently for Activa SC models than the Activa PC and Activa RC models (Figure 2.6). In most cases, one Activa PC or RC neurostimulator stimulates two sides of the brain. In contrast, one Activa SC neurostimulator stimulates one side of the brain.

Advanced mode



Activa PC and RC

Activa SC models

Figure 2.6 The Therapy screen in Advanced modes Activa PC, RC, and SC models.

Table 2.3 Therapy screen icons

Row	Icons	Description	
Status	Č s	Therapy is on	
	\bigcirc	Therapy is off	
Battery (Activa RC)	ſ	Neurostimulator battery charge level (rechargeable) ^a	•
		Needs Charge Full Charge	
Battery (Activa PC and SC models)	Ċ	Neurostimulator battery status (nonrechargeable)	
		🖆 OK 🗂 ERI	
		Battery OK Battery near end of service	Э
Parameter/ group ^b	Ä	Active group ^c	
		Amplitude	
	\leftrightarrow	Pulse width	
		Rate	

^a For complete rechargeable battery information, see Chapter 5 "Important information about your rechargeable neurostimulator".

^b The **Parameter/group** row only appears in Advanced mode.

Table 2.3 Therapy screen icons

Row Icons Description

^c If only one group is available, this row displays only the parameter setting icon.

Synchronizing the patient programmer and your neurostimulator

In order to check your neurostimulator status, change therapy settings, or turn your neurostimulator on and off, you must first synchronize the patient programmer and the neurostimulator.

Complete the following steps to synchronize the patient programmer and neurostimulator.

- **1.** Locate the **Check** \checkmark key.
- 2. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
- **3.** Press the **Check** \checkmark key.

Note: Pressing the **Check** \checkmark key also turns on the patient programmer (Figure 2.7).

Use the Check Ckey to synchronize



Figure 2.7 Press the **Check** key to synchronize your neurostimulator and patient programmer.

4. After pressing the **Check** *→* key, the **Communication** screen appears briefly.



Figure 2.8 Communication screen.

a. If synchronization is successful, the **Therapy** screen appears (Figure 2.9).



Figure 2.9 Therapy screen (Simple mode).

 b. If synchronization is not successful, the Position antenna screen or the Poor communication screen appears (Figure 2.10 and Figure 2.11). See Table 6.3 on page 115 for information on how to proceed when these screens appear.



Figure 2.10 Position antenna screen



Figure 2.11 Poor communication screen.

Note: See Chapter 6 "Troubleshooting" for more information about synchronizing the patient programmer and neurostimulator.

Turning your therapy on or off

Complete the following steps to turn your therapy on. Be sure to talk to your doctor about turning your therapy on or off before following this procedure.

- 1. Synchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
 - **b.** Press the **Check** *I* key. The **Therapy** screen appears.

The **Status** icon on the **Therapy** screen indicates whether your therapy is turned on or off (Figure 2.12).

🥙 On

🗅 Off

Therapy is turned On

Therapy is turned Off

Figure 2.12 Therapy status is displayed.

2. Press the Therapy On/Off key (.

If your therapy is currently off, pressing the **Therapy On/Off** key will turn the therapy on.

If your therapy is currently on, pressing the **Therapy On/Off** key will turn the therapy off.

The display flashes **Off** when the therapy is turned off. If the display is set to icon mode, a warning symbol (\bigwedge) flashes when the therapy is turned off.



Figure 2.13 Therapy off in icon mode.

Note: See "Changing preferences" on page 51 for more information about icon mode.

The neurostimulator battery

Your neurostimulator battery may be either a rechargeable battery or a nonrechargeable battery. Check with your doctor if you do not know what type of neurostimulator battery you have.

About rechargeable batteries

The rechargeable neurostimulator battery needs to be checked daily to make sure the charge level is adequate for your therapy.

Note: For complete information about the rechargeable neurostimulator battery, see Chapter 5 "Important information about your rechargeable neurostimulator" on page 97.

Checking the nonrechargeable battery status

1. Synchronize the patient programmer and neurostimulator.

Note: For information on checking and charging the rechargeable neurostimulator battery, see Chapter 5 "Important information about your rechargeable neurostimulator".

- a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
- b. Press the Check ☑ key. The Therapy screen appears (Figure 2.14).



🗅 Off

Therapy is turned On

Therapy is turned Off

Figure 2.14 Therapy status is displayed.

- 2. Check the current status reading for the battery:
 - Simple Mode: Press the left

 or right
 arrow on the Navigator key to display the Battery status screen (Figure 2.15).
 - Advanced mode: press the up ▲ or down ▼ arrow on the Navigator key to select the Battery row. Press the left ◄ or right ▶ arrow on the Navigator key to display the Battery status screen (Figure 2.15).

Figure 2.15 Battery Status screen.

Possible nonrechargeable battery status conditions

The patient programmer displays an information screen if the neurostimulator battery needs your attention (Table 2.4).

See Chapter 6 "Troubleshooting" for more information about battery-related screens.

Table 2.4 Nonrechargeable neurostimulator battery screens

CON * ERI ERI condition	If the Therapy screen displays ERI, the neurostimulator battery is close to its end of service date. ^a
	to report.
Nonrecharge-able battery status is low	This information screen appears when you synchronize your neurostimulator and patient programmer when the nonrechargeable battery status is low. This means that your therapy will not be available soon.
	Press any key to clear this message. Call your doctor to report this message.

Table 2.4 Nonrechargeable neurostimulator battery screens (continued)



EOS condition

If the EOS screen displays, then the battery is at end of service (EOS), therapy has stopped, and the neurostimulator needs to be replaced.

Call your doctor immediately.

^a If your nonrechargeable neurostimulator battery is approaching ERI condition, your doctor may set up an alert on the patient programmer to remind you to check your neurostimulator battery voltage once a day. For more information see, "Patient programmer alert" on page 57.

Customizing your patient programmer

You can adjust the audio and display settings for your patient programmer by changing the preferences. Preferences can be reached from the **Status** row of the **Therapy** screen. Changing the preferences for the patient programmer do not affect your therapy. See Table 2.5 for a list of the available preference settings.

Table 2.5 Preference icons

Icons	Preference
4	Audio
\bigcirc	Contrast
$\underbrace{}$	Time ^a
	Time and number format
Abc 🖄 💼	Text or icon only display

^a The Patient alert feature is based on the time set in your patient programmer. For more information, see "Patient programmer alert" on page 57.

Changing preferences

Complete the following steps to adjust the patient programmer preferences.

- 1. Synchronize the patient programmer and neurostimulator.
 - **a.** Hold the patient programmer (or antenna) directly over your

neurostimulator with the screen facing outward.

b. Press the **Check** *✓* key. The **Therapy** screen appears (Figure 2.16).



Figure 2.16 Access preferences from the Status row.



Figure 2.17 Desired preference (audio in this example).

Press the down
 ▼ arrow on the
 Navigator key to move the selection box to the Change row (Figure 2.18).



Figure 2.18 Change row (audio in this example).

5. Follow the steps in Table 2.6 to change the selected preference.

Table 2.6 Changing programmer preferences

4 »	•

Audio preference

- a. Press the left ◀ or right ▶ arrow on the Navigator key to move the selection box to audio on ◀» or off 术.
- **b.** Continue to step 6 through step 8 on page 56.

Note:The Patient alert will play even if the **Audio** preference is turned off.



Contrast preference

- a. Press the left delti or right ▶ arrow on the **Navigator** key to move the selection box to the contrast slider bar.
- b. Press the Selection keys to make the contrast lighter O or darker ●.
- c. Continue to step 6 through step 8 on page 56.

2

Table 2.6 Changing programmer preferences (continued)



Time preference

- a. Press the left ◀ or right ▶ arrow on the Navigator key to move the selection box to the hour, minutes, or time of day (A or P).
- Press the Selection keys to increase or decrease the displayed time.
- c. Continue to step 6 through step 8 on page 56.



Time and number format preference

- a. Press the left ◀ or right ▶ arrow on the Navigator key to move the selection box to a 12-hour clock or to a 24-hour clock.
- **b.** Continue to step 6 through step 8 on page 56.

Table 2.6 Changing programmer preferences (continued)

Text on	Text or icon display format	
Abc ७⊆	a.	Press the left ◀ or right ▶ arrow on the Navigator key to move the selection box to the Text on or Text off/icon only display setting.
Text off/icon only	b.	Continue to step 6 through step 8 on page 56.
Abc ੴ ┗━ [ੴ ┗━ ▲•		Note: The text displayed on the patient programmer will always be in English.

- Press the up ▲ arrow on the Navigator key to return the selection box to the Status row.

Patient programmer alert

Your doctor may set up an alert on the patient programmer to remind you to check your neurostimulator battery once a day (rechargeable neurostimulator batteries only).

Note: For nonrechargeable neurostimulator batteries, your doctor may set up this alert for you when your battery is near its end of service.

The default setting for the alarm is 11:00 a.m. However, your doctor may change this to a different time of day if appropriate.

The alert time is based on the time set for the patient programmer. To adjust this time, see Table 2.6 on page 54.

The patient programmer alert beeps for 30 seconds, with a pause every 10 seconds. The **Patient alert** screen displays while the alarm is beeping (see Figure 2.19). The Patient alert sounds even if the audio preference is turned off.



Figure 2.19 Patient alert screen.

This alert repeats every 15 minutes until the neurostimulator battery status has been checked.

To check battery status, see "Checking the nonrechargeable battery status" on page 47 or "Checking the rechargeable neurostimulator battery" on page 102.

Patient programmer accessories

Carrying case and patient programmer ID label

A carrying case and identification label are included with your patient programmer. Two AAA alkaline batteries that provide the power for your patient programmer are also included. The carrying case has a pouch to hold the patient programmer and the quick reference guide.



Figure 2.20 Insert the patient programmer into the case.

You can attach the patient programmer to a belt using the loop on the back of the case.

Place the provided identification label on the back of your patient programmer just in case the patient programmer is lost (Figure 2.21).



Figure 2.21 Place the adhesive label on the back of the patient programmer.

Detachable antenna

A detachable antenna (Model 37092) is useful for viewing the patient programmer screen while you are adjusting therapy. When the antenna is connected to the patient programmer, hold the antenna or attach it to your clothing directly over the neurostimulator to adjust settings or check the neurostimulator battery.

Using the detachable antenna

1. Place the antenna directly over your neurostimulator (Figure 2.22).



Figure 2.22 Place the antenna directly over your neurostimulator.

2. Pull the fabric of your clothing through the large opening in the antenna. Then, wedge the fabric in the narrow slit to secure the antenna in place (Figure 2.23).



Figure 2.23 Pull the fabric through the slit (a) and wedge in place (b).

 Push the antenna plug firmly into the antenna jack (Ÿ) on the patient programmer (Figure 2.24).



Figure 2.24 Insert the antenna plug into the antenna jack.

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

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

△ Caution: Do not pull directly on the antenna cable to disconnect the cable from the programmer because this may damage the antenna cable.

Using your patient programmer 2

64 English 37642 2015-04



3 Adjusting therapy settings with Advanced

Adjusting your therapy settings

You may find that on some days, in order to receive the most effective therapy, you need to adjust your therapy several times. On other days you may not need to adjust it at all. Your doctor will provide complete guidelines about when you may want to adjust your therapy.

- Ask your doctor to print a report with your programmed settings.
- When a therapy setting is changed, you will see the change on the **Therapy** screen.
- If your patient programmer audio is turned on, you will hear one tone that means the change was effective.
- Three rapid tones means that the change could not be confirmed or that the synchronization was not successful.
- Verify the current therapy settings by pressing the Check key and viewing the Therapy screen.

Tips for adjusting your therapy:

- Always adjust the therapy settings to the lowest possible setting that provides symptom relief.
 - High therapy settings use more rechargeable battery charge which may force you to charge the battery more frequently.
 - High therapy settings may shorten the service life of the nonrechargeable battery.
- Before changing any therapy settings with your patient programmer, you need to synchronize the patient programmer with the neurostimulator.

Note: If you have two neurostimulators implanted, you can use one patient programmer to communicate with both neurostimulators, but only with one neurostimulator at a time. To communicate with another neurostimulator, turn the patient programmer off and then press the **Check** ☑ key to synchronize while holding over the desired neurostimulator.

 If you experience uncomfortable therapy or unwanted side effects when increasing the amplitude, pulse width, or rate, decrease the setting to a comfortable therapy setting. You may also use the Therapy On/Off (key to stop the therapy.

Therapy settings

If your neurostimulator is set to Simple mode, you will not be able to adjust your therapy settings. Your doctor can adjust your settings when necessary.

Notes:

- To increase amplitude, pulse width, or rate, your therapy must be turned on.
- To decrease amplitude or pulse width, your therapy may be turned on or off.
- To decrease rate, your therapy must be turned on.

- For each group, only one parameter can be changed. For example, group A may allow you to change only the amplitude of the therapy and group B may allow you to change only the rate of the therapy.
- A group may also be programmed for view only and you will not be able to adjust any settings. Discuss your settings with your doctor. For more information about groups, see "Selecting a new group" on page 73.

Changing therapy settings in Advanced mode

The ability to change therapy settings is only available in Advanced mode.

You can only change the settings of the active group. If you want to change settings available for a non-active group, you will need to make that group active first. See "Selecting a new group" on page 73 for complete instructions.

- 1. Synchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
 - **b.** Press the **Check** *✓* key. The **Therapy** screen appears.
- Press the down ▼ arrow on the Navigator key to move the selection box to the Parameter row (Figure 3.1).



Figure 3.1 Parameter row for Activa PC, RC, and SC models.

3. Press the **Selection** key directly under the displayed setting you want to adjust (Figure 3.2).



Figure 3.2 Select the appropriate Selection key on Activa PC, RC, and SC models. က Adjusting therapy settings with Advanced mode

37642 2015-04 English 71

 Press the Selection keys again to increase or decrease the selected therapy setting as needed (Figure 3.3).¹



Figure 3.3 Increasing or decreasing a therapy setting.

Notes:

 Hold the patient programmer or detachable antenna over your neurostimulator when increasing or decreasing your settings. The therapy settings will immediately change as you press the **Selection** keys.

¹ If you attempt to increase or decrease the therapy setting beyond the available limits, an information screen appears, see Table 3.1 on page 81.
က Adjusting therapy settings with Advanced mode

- Press and hold down the Selection key to increase or decrease the setting which will change approximately every half-second.
- 5. Press any arrow on the **Navigator** key to return to the **Therapy** screen.
- 6. Repeat steps 2-5 for the other side of your body if desired.

Note: If you have multiple neurostimulators, the patient programmer must be turned off prior to synchronizing with the other neurostimulator.

Selecting a new group

The group feature is only available in Advanced mode.

- △ Caution: Select the group that your clinician has recommended for your specific needs.
- 1. Synchronize the patient programmer and neurostimulator.

- a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
- **b.** Press the **Check** *I* key. The **Therapy** screen appears.
- Press the down
 ▼ arrow on the
 Navigator key to move the selection box to the Parameter row (Figure 3.4).



Figure 3.4 Parameter row.

 Press the right
 ■ arrow on the Navigator key to display the available groups. (Figure 3.5).

Figure 3.5 Group screen.

 Press the up ▲ or down ▼ arrow on the Navigator key to move the selection box the desired group (Figure 3.6).



Figure 3.6 Select the desired group.

- **5.** Resynchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
 - b. Press the Check with the patient programmer and activate the selected group.

6. The **Communication** screen briefly appears, followed by the **Therapy** screen (Figure 3.7).



Figure 3.7 Communication screen.

The **Therapy** screen will display your new therapy parameters and group setting (Figure 3.8).



Activa PC and RC models

Figure 3.8 Therapy screen with new group setting.

Returning your therapy to original settings

If you have changed your therapy settings and want to return to the settings selected by your doctor, follow these steps:

- 1. Synchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
 - **b.** Press the **Check** *✓* key. The **Therapy** screen appears.
- Press the down
 ▼ arrow on the
 Navigator key to move the selection box to the Parameter row (Figure 3.9).



Activa PC and RC models

Activa SC models

Figure 3.9 Parameter row.

 Press the right
 arrow on the Navigator key to display the available groups. The Group settings screen appears (Figure 3.10).

Figure 3.10 Group settings screen.

To change from the current group settings back to the doctor default settings:

a. With the selection box highlighting the current group, press the right
 ■ arrow on the Navigator key. The Group reset screen appears (Figure 3.11).



Figure 3.11 Group reset screen.

b. Press the **Check** \checkmark key.

To change an inactive group back to the doctor default settings:

a. Press the up ▲ or down ▼ arrow on the Navigator key to move the selection box to the desired inactive group (Figure 3.12).



Figure 3.12 Select new group.

b. Press the right ▶ arrow on the
 Navigator key. The Group options screen appears (Figure 3.13).



Figure 3.13 Group options screen.

c. Press the down ▼ arrow on the Navigator key to move the selection box to the Clinician setting option (Figure 3.14).



Figure 3.14 Change group to clinician settings.

d. Press the right
 ▶ arrow on the
 Navigator key to display the Group
 reset screen (Figure 3.15).



Figure 3.15 Group reset screen

e. Press the **Check** \checkmark key.

4. The patient programmer beeps when the group settings are changed (if the audio is turned on).

Understanding therapy parameter limits

Each therapy parameter will have a default limit set by your doctor. If you attempt to change a therapy parameter outside these set limits, you will see one of the screens shown in Table 3.1.

Lower limit	You tried to decrease a parameter (amplitude, pulse width, or rate) below the lowest value allowed.	
	Press any arrow on the Navigator key to clear the screen.	
ب		

Table 3.1 Parameter limit screens

Table 3.1 Parameter limit screens (continued)





4 MRI examinations

If you have an MRI appointment

MR Conditional—Depending on what kind of neurostimulation system components that you have implanted, you may be eligible for one of the following types of magnetic resonance imaging (MRI) scans:

- MRI scans of the head only (this is referred to as head-only eligible).
- MRI scans of any part of your body (this is referred to as full-body eligible).

Note: You should inform your clinician managing your neurostimulation system that an MRI examination has been prescribed for you and that you need him or her to determine what type of MRI scan you are eligible to receive.

Responsibilities of the patient in preparing for the MRI appointment

Bring the following to every MRI appointment:

• Your patient identification (ID) card for your neurostimulation system if you received one from Medtronic.

Note: If you have two neurostimulation systems implanted in your body, bring both ID cards to your MRI appointment.

- Your MRI scan eligibility sheet if you were given one from your clinician managing your neurostimuation system.
- Your patient programmer.

For more information about how MRI can affect your neurostimulation system and what you should do if you have an MRI appointment, refer to the *DBS Patient Therapy Guide*.

Preparing your neurostimulation system for the MRI scan

Your implanted neurostimulation system (ie, therapy) may need to be turned off prior to your MRI scan or reprogrammed to allow the

system to safely remain on during your MRI scan. This will depend on the neurostimulator model implanted in your body, the therapy settings of your neurostimulator, and the type of MRI scan you are eligible to receive.

Your clinician managing your neurostimulation system will inform you whether your system should be on or off during the MRI scan.

If therapy should be turned off prior to your MRI scan, refer to "Turning off therapy before the MRI scan" on page 86.

If therapy can remain on during your MRI scan, refer to "Activating settings to allow therapy on during the MRI scan" on page 90.

Turning off therapy before the MRI scan

If your clinician managing your neurostimulation system indicates that therapy should be off during the MRI scan, therapy can be turned off with the patient programmer (see page 87) or the clinician programmer (see page 88).

Using the patient programmer to turn off therapy

If you brought your patient programmer to the MRI appointment, you can turn off therapy before your MRI scan and outside of the MRI scanner (magnet) room.

For instructions on turning off therapy, go to "Turning your therapy on or off" on page 44.

During the MRI scan, keep therapy off.

△ Caution: Do not turn therapy back on before your MRI scan. Leaving therapy on during the scan could increase the potential for unintended stimulation.

After the MRI scan and outside of the MRI scanner (magnet) room, you can turn therapy back on using your patient programmer or you can return to the clinician managing your neurostimulation system to have therapy turned back on (refer to "Turning therapy back on after the MRI scan" on page 89). **Note:** Do **not** take the patient programmer into the MRI scanner (magnet) room. If you brought the recharger with you to the MRI appointment, do not take the recharger into the MRI scanner (magnet) room either.

Using the clinician programmer to turn off therapy

Your clinician managing your neurostimulation system can turn off therapy before your MRI examination using the clinician programmer.

Do not turn therapy back on before your MRI scan.

△ Caution: Do not turn therapy back on before your MRI scan. Leaving therapy on during the scan could increase the potential for unintended stimulation.

The clinician may give you an MRI scan eligibility sheet to bring to your MRI appointment. Give the eligibility sheet to the MRI clinician.

During the MRI scan, keep therapy off.

After the MRI scan and outside of the MRI scanner (magnet) room, you can turn therapy back on using your patient programmer or you can return to the clinician managing your neurostimulation system to have therapy turned back on (refer to "Turning therapy back on after the MRI scan" on page 89).

Turning therapy back on after the MRI scan

Turn therapy back on when the MRI scan is complete and you are **outside** of the MRI scanner (magnet) room.

Therapy can be turned on with the patient programmer or the clinician programmer:

- If you do not have your patient programmer with you, go to the clinician managing your neurostimulation system to turn on therapy using the clinician programmer.
- If you brought your patient programmer to the MRI appointment, turn therapy back on using the patient programmer. For

instructions on turning on therapy, go to "Turning your therapy on or off" on page 44.

Note: If a power-on-reset (POR) screen appears on the patient programmer, see Table 4.1 on page 95.

Activating settings to allow therapy on during the MRI scan

Depending on your therapy settings, your clinician managing your neurostimulation system may create a new group that should be activated prior to your MRI scan. This will allow your system to safely remain on during the scan.

If your clinician managing your neurostimulation system creates a new group setting so that therapy can remain on during your MRI scan, the new group can be activated with the patient programmer (see page 91) or the clinician programmer (see page 92).

Using the patient programmer to activate a new group

If you brought your patient programmer to the MRI appointment, you can activate the new group before your MRI scan and outside of the MRI scanner (magnet) room. This will allow you to keep therapy on during your MRI scan.

For instructions on activating a new group, go to "Selecting a new group" on page 73.

During the MRI scan, keep therapy on, but do not return therapy to your original group setting.

△ Caution: Do not return therapy to your original group setting before your MRI scan. Returning therapy to your original group setting could increase the potential for unintended stimulation during the scan.

After the MRI scan and outside of the MRI scanner (magnet) room, you can return therapy to your original group setting using

your patient programmer or you can return to the clinician managing your neurostimulation system to reprogram therapy to your original group setting (refer to "Returning therapy to your original group setting after the MRI scan" on page 94).

Note: Do **not** take the patient programmer into the MRI scanner (magnet) room. If you brought the recharger with you to the MRI appointment, do not take the recharger into the MRI scanner (magnet) room either.

Using the clinician programmer to activate a new group

The clinician managing your neurostimulation system can activate the new group before your MRI examination using the clinician programmer. This will allow you to keep therapy on during your MRI scan.

Do not change therapy to your original group setting before the MRI scan.

 \triangle **Caution:** Do not return therapy to your original group setting before your MRI

scan. Returning therapy to your original group setting could increase the potential for unintended stimulation during the scan.

The clinician may give you an MRI scan eligibility sheet to bring to your MRI appointment. Give the eligibility sheet to the MRI clinician.

During the MRI scan, keep therapy on, but do not return therapy to your original group setting.

After the MRI scan and outside of the MRI scanner (magnet) room, you can return therapy to your original group setting using your patient programmer or you can return to the clinician managing your neurostimulation system to reprogram therapy to your original group setting (refer to "Returning therapy to your original group setting after the MRI scan" on page 94).

Returning therapy to your original group setting after the MRI scan

Return therapy to your original group setting when the MRI scan is complete and you are **outside** of the MRI scanner (magnet) room.

Group settings can be changed with the patient programmer or the clinician programmer:

- If you do not have your patient programmer with you, go to the clinician managing your neurostimulation system to return therapy to your original group setting using the clinician programmer.
- If you brought your patient programmer to the MRI appointment, return therapy to your original group setting using the patient programmer. For instructions on returning therapy to your original group setting, go to "Selecting a new group" on page 73.

Note: If a power-on-reset (POR) screen appears on the patient programmer, see Table 4.1.

Table 4.1 POR screens

Screen	Description and action
Warning POR	Error code POR: Your therapy has
(hazard triangle	stopped.
symbol in the	Call your clinician to restart
upper left corner)	your therapy.

Table 4.1 POR screens (continued)

Screen



Informational POR (small "i" icon in the upper left corner)

Description and action

The neurostimulator has been reset. Your therapy has stopped.

- 1. Press any arrow on the Navigator key to clear the screen
- 2. Reset the time, if prompted (for instructions, see Table 2.6). Before resetting the time, confirm the patient programmer or antenna is directly over the neurostimulator.
- 3. Press the up arrow on the patient programmer. This action will clear the POR.
- 4. Press the Therapy on/off () key to turn your therapy on.

Call your clinician to report the reset.



5 Important information about your rechargeable neurostimulator

The rechargeable neurostimulator battery

The following chapter explains the importance of maintaining the battery charge level of your rechargeable neurostimulator.¹

▲ Warning: It is very important to check your neurostimulator battery every day. If the therapy provided by your neurostimulator should stop abruptly this could cause your symptoms to return. In some cases, your symptoms may return at a greater intensity than before your implant. In rare situations, this could result in a medical emergency.

It is important for you to recharge your battery on a regular, frequent basis as recommended by your doctor to make sure that the neurostimulator battery remains charged. Depending on your therapy settings this may mean charging your battery once a day or once a week,

¹ This information only applies to implantable neurostimulators that use a rechargeable battery.

ask your doctor for his recommendation. If you have technical problems while charging your battery, contact your doctor, nurse, or Medtronic patient services.

If you notice that your symptoms return, check your battery status first. If it indicates that your battery is not charged, recharge your battery immediately. Please follow your doctor's advice for taking medications when your neurostimulator is not working. Medications may help control your symptoms while or until your battery is charged. Please contact your doctor immediately if your symptoms get worse and do not return to where they were when your neurostimulator was working, or if your device battery is not indicating a need to recharge, please contact your doctor immediately. Your doctor can check the status of your neurostimulator system and monitor your condition.

Note: For contact information, see Chapter 8 "Assistance for the patient programmer" on page 139.

Check and charge: make it a habit

Because this is so important, make it a priority to check and charge your neurostimulator battery on a regular schedule. See Table 5.1 on page 107 for rechargeable battery alert screens that indicate a low battery charge level.

Recommendations:

- Check your battery charge level at the same time every day (your doctor can set the patient programmer alert for this time).
- Combine checking your battery charge level with something else you do every day in order to make it a convenient habit.
- Make sure to bring your neurostimulator recharging system with you when you travel or are hospitalized (even for overnight).
- Allow enough time to fully charge the neurostimulator. Depending on the charge level of the battery when you begin

S Important information about your rechargeable neurostimulator

charging, this could take up to four hours. If the charge level is completely depleted, charging may require more than four hours.

Note: For more information, see the manual packaged with your recharging device.

- Make sure that the charging antenna is held securely against the implanted neurostimulator. If the devices are not aligned correctly or if there is open space between the devices, it may take longer to charge the neurostimulator battery.
- Charge your neurostimulator battery before it is depleted. The battery should be charged before it has only 25% power remaining.

You do not need to wait until the battery charge level is low. If it's more convenient, you can charge the battery every day.

Note: Remember that even when your therapy is turned off, the neurostimulator battery charge will still deplete over time. You

should continue to check the battery daily and charge it when necessary.

Consult with your doctor about how often you should charge your neurostimulator battery based on your individual therapy settings.

Checking the rechargeable neurostimulator battery

- 1. Synchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.

Press the **Check** \checkmark key. The **Therapy** screen appears displaying the neurostimulator battery charge level (Figure 5.1).



Figure 5.1 The neurostimulator battery charge level is displayed on the **Therapy** screen.

Low battery status

△ Caution: Charge the neurostimulator when you see a Low battery screen displayed on the patient programmer or recharger. If LOW is flashing, the battery charge level is at 0 and your therapy will stop soon unless you recharge the battery.

If you see the following screen (Figure 5.2), the neurostimulator battery is

in a discharged state and your therapy has stopped.



Figure 5.2 Neurostimulator battery is in a discharged state.

You should charge the battery as soon as possible. If the battery remains in a discharged state, it continues to lose charge and it will become overdischarged.

If the neurostimulator battery is allowed to overdischarge, you may not be able to recharge or communicate with the neurostimulator; however, your doctor may be able to restore the battery function.

Allowing the neurostimulator battery to overdischarge will permanently affect the neurostimulator in one of the following ways:

- Battery function is restored; however, charging sessions may be more frequent because battery capacity has been reduced.
- Battery function is not restored and the neurostimulator must be surgically replaced. Battery function is not restored because:
 - the neurostimulator battery is permanently damaged.
 - the neurostimulator battery has been overdischarged and restored twice before. The third time the battery is overdischarged, the neurostimulator will reach end of service. Surgery is required to replace the neurostimulator.

Rechargeable battery overdischarge

You can avoid the consequences of an overdischarged battery and the loss of therapy by keeping the battery charged.

Charging the neurostimulator battery

When the neurostimulator battery charge level is low, charge the battery as described in the manual packaged with the charging system.

Note: You can charge your battery more often, even daily. You do not need to wait until the battery charge level is low.

Your neurostimulator battery can be charged many times; however, eventually the neurostimulator will need to be replaced.

If the neurostimulator battery needs charging, you will see one of the screens shown in Table 5.1.

Table 5.1 Rechargeable neurostimulator battery screens

Low	The neurostimulator battery charge level is low. When the "Low" message is flashing, therapy will not be available soon.
Charge battery screen	Charge your neurostimulator battery. Refer to the manual packaged with the charging system.
	Press any arrow on the Navigator key to clear this message from the screen.
A ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓	The neurostimulator battery charge level is depleted and needs immediate charging. The battery is in a discharged state and therapy has stopped when the battery is depleted.
	Charge the neurostimulator battery now. Refer to the manual packaged with the charging system. ^a

Table 5.1 Rechargeable neurostimulator battery screens (continued)



If this screen displays, the battery is at the end of service, therapy has stopped, and the neurostimulator needs to be replaced.

If the EOS screen displays, call your doctor immediately.

^a If necessary, you can stop charging the battery before it is completely recharged in order to turn the therapy back on. Finish charging the battery after your therapy is turned back on.

Patient programmer alert

Your doctor may set up an alert on the patient programmer to remind you to check your neurostimulator battery once a day.

For more information, see "Patient programmer alert" on page 57.
6 Troubleshooting

This chapter will help you solve problems with your patient programmer. It also provides information on when to call your doctor.

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

Patient Programmer screens

After you synchronize your patient programmer with your implanted neurostimulator, the patient programmer may display a Warning \bigwedge , Communication \mathbb{X} , or Information (i) screen to provide you with information about your system, alert you to a problem with your system, or to guide you while using the patient programmer.

Warning screens

Warning screens indicate a problem with the patient programmer, the antenna, or the neurostimulator. If the patient programmer audio preference is turned on, three tones alert you when a warning screen is displayed on the patient programmer.

Table 6.1 describes warning screens and provides instructions (see blue text) on how to resolve the problem and clear the screen.

Screen	Cause and action
Replace patient	The patient programmer batteries are depleted. Programming is not possible. Replace the patient
programmer batteries	programmer batteries now.
	The implanted device that you are attempting to communicate with is not compatible with the patient programmer.
Device not supported	Call your doctor.
	The patient programmer and the neurostimulator must be synchronized.
Synchronize patient programmer and neurostimulator	Synchronize the patient programmer and neurostimulator.

Table 6.1 Warning screens

Table 6.1 Warning screens (continued)

Cause and action
The system is not working correctly. Therapy may have
stopped.
Read the error code at the bottom of the screen.
Error codes 0 to 252:
Remove batteries from the patient programmer, wait several seconds, then re- insert the batteries. If the error message appears again, call your doctor.
Error code EOS: Your neurostimulator has reached its end of service. Therapy is not available.
Call your doctor.
Error code POR: Your therapy has stopped.
Call your doctor to restart your therapy.
Other codes: Write down the code shown on the screen.
Call your doctor.

Table 6.1 Warning screens (continued)

Screen	Cause and action
Rechargeable battery only	The rechargeable neurostimulator battery is in a discharged state and therapy has stopped.
Rechargeable battery is in a discharged state	Charge the neurostimulator battery now. Refer to the manual packaged with the charging system.

▲ Warning: If the neurostimulator battery is allowed to overdischarge, you may not be able to recharge it. However, your doctor may be able to restore the battery function.

Refer to "The rechargeable neurostimulator battery" on page 98 for more information.

Communication screen

The **Communication** screen appears when the patient programmer is trying to communicate with your neurostimulator. If there is a problem, the displayed screen provides instructions (see blue text) on how to resolve the problem and clear the screen.

Table 6.2 describes the **Communication** screen. Unless there is a problem with the communication, the **Communication** screen automatically clears when the process is finished.

Table 6.2 Communication screens

Screen	Description and action
X Cw	The patient programmer is communicating with the neurostimulator.
Communication	Continue to hold the patient programmer over your neurostimulator.

Information screens

The information screens provide status information about therapy settings, error conditions, and patient programmer and neurostimulator battery levels. If the patient programmer audio setting is turned on, three tones alert you to the message.

Table 6.3 describes information screens and instructions on how to proceed (see blue text) when these messages appear.

Note: Press any arrow on the **Navigator** key to clear an information screen.

Screen	Description and action
	You tried to increase the amplitude, pulse width, or rate parameters with your therapy off.
Turn therapy on	Turn your therapy on and try communication again.
	You tried to decrease rate with your therapy off.
	Turn your therapy on and try decreasing rate again.

Table 6.3 Information screens





Screen

Description and action



Poor communication

The patient programmer attempted to communicate with the neurostimulator, but communication was unsuccessful.

For patients with two neurostimulators, you may have attempted to synchronize with another neurostimulator without first turning the patient programmer off.

Reposition the patient programmer over the neurostimulator with the screen facing outward and try communication again.

If using the detachable antenna, check that the antenna is connected properly, reposition the antenna and try communication again.

Press any arrow on the Navigator key to clear the screen.

Screen	Description and action
Û II ↑ Upper limit (amplitude shown)	You tried increasing a parameter (amplitude, pulse width, or rate) above the highest value allowed.
	Press any arrow on the Navigator key to clear the screen.
Cull ↓ Lower limit (amplitude shown)	You tried decreasing a parameter (amplitude, pulse width, or rate) below the lowest value allowed.
	Press any arrow on the Navigator key to clear the screen.
	The patient programmer batteries are low. You can finish programming.
Programmer batteries are low	Replace the patient programmer batteries before the batteries become depleted.

Screen



Power on reset error detected

Description and action

The neurostimulator has been reset. Your therapy has stopped.

Press any arrow on the Navigator key to clear the screen, then press the Therapy on/off (key to turn your therapy on.

Call your doctor to report the reset.

Note: This information screen has a small information icon in the upper left corner. Compare this POR screen to the warning screens explained on page 110. The warning POR screen has a hazard triangle symbol in the upper left corner.

Screen	Description and action
Out of Regulation error	The neurostimulator cannot provide the programmed therapy or perform the requested parameter increase.
	Reduce the requested parameter increase.
	(Rechargeable battery only) Recharge your neurostimulator.
	Call your doctor if these steps do not resolve the issue.
Rechargeable battery only	The rechargeable neurostimulator battery charge level is low and therapy will not be available soon.
Low	Charge your neurostimulator battery. Refer to the manual packaged with the charging system.
Rechargeable	

Rechargeable neurostimulator battery charge level is low

120 English 37642 2015-04

Screen	Description and action
Nonrechargeable battery only	This information screen appears when you synchronize your neurostimulator and patient programmer and the nonrechargeable neurostimulator battery status is low.
	This means that your therapy will not be available soon.
	Press any arrow on the Navigator key to clear the

screen and call your doctor to report this message.

Possible problems and solutions

Table 6.4 will help you solve problems or identify when to call your doctor. 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 doctor.

Table 6.4 Troubleshooting problems

Problems	Ca	uses and actions
Uncomfortable or Intolerable therapy You are experiencing side effects from the therapy.	The are acti	e selected therapy settings not suitable for your current vity.
	1.	Turn your therapy off (see page 44).
	2.	Call your doctor.
	lf yo usir try you	our patient programmer is ng Advanced mode, you can the following before calling rr doctor.
	•	Reduce the amplitude or pulse width setting for both sides of your body (see page 66).
	•	If necessary, select a different group (see page 73).

Table 6.4 Troubleshooting problems (continued)		
Problems	Causes and actions	
Delayed therapy changes You do not notice	Your doctor may have programmed SoftStart/Stop which gradually starts and stops your therapy	
the therapy right away after turning your therapy on or you notice therapy- like sensations after turning your therapy off.	Your doctor can advise you as to how long it takes to feel the effects of the therapy. This time can be different from patient to patient. It also depends upon your medical condition.	
	In general, allow about 8 seconds for your neurostimulator to turn on and off.	
	You may also notice a residual effect after the neurostimulator is turned off.	
Intermittent therapy	Your doctor may have programmed your therapy to	
You only notice your therapy some of the time.	turn on and off at regular intervals.	
	However, if you are not receiving adequate symptom relief, contact your doctor.	

Table 6.4 Troubleshooting problems (continued)	
Problems	Causes and actions
No therapy	Therapy is off.
You cannot notice your therapy but you think that therapy should be on.	Use your patient programmer to turn your therapy on (see page 44).
	The amplitude setting for the active group is set too low to feel. (The effect of the amplitude setting may take up to 10 minutes or more to notice.)
	If you do not feel the desired effect from a change in amplitude, call your doctor.
	If your patient programmer is using Advanced mode, you can try the following before calling your doctor.
	Use your patient programmer to increase the amplitude for one or both sides of your body (see page 69).

Table 6.4 Troubleshooting problems (continued)		
Problems	Causes and actions	
Patient programmer is unresponsive The display screen is blank when you press a key.	The patient programmer batteries are depleted.	
	Replace the patient programmer batteries (see page 128).	
	The patient programmer batteries are in backwards.	
	Check the battery polarity and reinstall the patient programmer batteries (see page 128).	
Dropped patient programmer Your patient programmer falls off	The patient programmer is designed to withstand a short drop to a hard surface and still operate normally, even if the	
a cabinet or table.	Try the patient programmer; it should work.	

Table 6.4	Troubleshooting problems
	(continued)

Problems	Causes and actions
Fluid on the patient programmer	The patient programmer is not waterproof, and water can damage the device.
onto the patient programmer or the patient programmer was dropped into	Immediately remove the patient programmer from the water, then dry with a soft towel.
water.	Remove the batteries, then allow the battery compartment to air dry at room temperature for 24 hours.
	Note: If you need to check your rechargeable neurostimulator battery while your patient programmer is drying, you can use the recharger device.

7 Maintenance

This chapter descibes how to care for your patient programmer and accessories.

Patient programmer batteries

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

You can check your patient programmer batteries at any time. The patient programmer also monitors its own battery charge and will display the following screens when the batteries are low or depleted (Figure 7.1).

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





Patient programmer batteries are low Patient programmer batteries are depleted

Figure 7.1 Patient programmer battery screens.

Checking the patient programmer batteries

The images in this procedure are an example and show how to check the patient programmer batteries:

- 1. Synchronize the patient programmer and neurostimulator.
 - a. Hold the patient programmer (or antenna) directly over your neurostimulator with the screen facing outward.
 - **b.** Press the **Check** *✓* key. The **Therapy** screen appears (Figure 7.2).



Simple mode

[™] On C OK 2.85 Ă 4.60

Advanced mode

Figure 7.2 Therapy screen.

- 2. To display the current patient programmer battery status:
 - Simple mode: Press the right
 ■ arrow on the Navigator key once to display the patient programmer battery status (Figure 7.3).
 - Advanced mode: Press the up ▲ arrow on the Navigator key once to highlight the Status row, then press the right ▶ arrow (Figure 7.3).



Figure 7.3 Status row and Therapy screen.

 Review the status of the patient programmer battery (Figure 7.4).



Figure 7.4 Patient programmer battery level.

If the batteries are low, see "Replacing the patient programmer batteries" on page 132 for replacement instructions.

Table 7.1 Patient programmer battery replacement screens

Patient programmer batteries are low	The patient programmer batteries are low. You can finish programming.
	Press any arrow on the Navigator key to clear the screen; then continue programming.
	Replace the patient programmer batteries before the batteries become depleted.
	See page 132.
	The patient programmer batteries are depleted. Programming is not possible.
Replace patient programmer batteries	Replace the patient programmer batteries now.
	See page 132.

Maintenance 7

Replacing the patient programmer batteries

1. Open the battery compartment cover by sliding the cover down and pulling it up.



Figure 7.5 Opening the battery cover.

- 2. Remove the depleted batteries.
- **3.** Insert the new batteries as shown on the battery compartment label.
- 4. Close the battery compartment cover.
- **5.** Dispose of old batteries according to local requirements.

Maintenance 7

Cleaning and care

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

- △ Caution: If the device will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, causing damage to the electronic components.
 - Keep the device out of the reach of children and pets. Keep the batteries away from children. If children or pets swallow the batteries, contact a doctor at once.
 - Use the device only as explained to you by your doctor 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 patient programmer are not required. The patient programmer contains no user-serviceable parts. If repair or service is needed, contact your doctor or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

Battery and patient programmer disposal

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

Declaration of conformity

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

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

Maintenance 7

Specifications

Table 7.2 Patient programmer specifications

Item	Specification
Power source	2 AAA alkaline batteries (non- rechargeable, LR03)
Operating	9 °C to 43 °C
temperature	(49 °F to 110 °F)
Temperature	-34 °C to 57 °C
limitation ^a	(-30 °F to 135 °F)
Ingress protection	IP22 rating for solid objects greater than or equal to 12.5 mm, and for vertically dripping water when the device is tilted 15 degrees, per 60601-1-11.
Size	Approximately
	9.4 cm x 5.6 cm x 2.8 cm
	(3.7 in x 2.2 in x 1.1 in)
Weight, including batteries	Approximately 111 g (3.9 oz.)
Battery life	2 months (average) for alkaline batteries
Service life	Up to 5 years
Mode of operation	Continuous

Table 7.2 Patient programmer specifications

Item

Specification

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



8 Assistance for the patient programmer

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

IUSA For assistance in the US, call Medtronic patient services at 1-800-510-6735.

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

 If your patient programmer stops working, first try the steps in Chapter 6 "Troubleshooting" on page 109.

Contact your doctor if indicated by the troubleshooting information. If the problem persists, contact your doctor.

• If you lose your patient programmer, contact your doctor to order a new patient programmer.

IUSA Note: To register the patient programmer for service covered by the warranty, complete and mail the warranty registration.

37642 2015-04 English 141

Index

About rechargeable batteries 46 Adjusting therapy adjustment limits 81 guidelines for 81 settings 66-82 Adjustment stimulation see Adjusting therapy Alerts patient programmer 57, 108 Amplitude increasing or decreasing 81,82 Audio tones 66, 111, 115 Backlight (Power/Backlight On/Off) key 34 Batteries (patient programmer) battery charge level (low) screen 118 checking 128 disposing of 136 replacing 132 Battery icons 40

Battery neurostimulator see Neurostimulator battery Button descriptions 32 Changing a group 73 Charging the Neurostimulator battery (rechargeable) 106 Checking batteries patient programmer 128 Checking the nonrechargeable battery 47 Communication screen 114 Decreasing therapy settings 69 limits 81 Disposing of patient programmer batteries 136 patient programmer 136 EOS (end of service) error code 112 Error codes 112 Group, changing 73 Icons battery 40 Parameter/Group 40 Status 40

Identification label 60 Increasing therapy settings limits 82 Indications 21 Information screen 114 Keys (patient programmer) 32 Low battery level screen neurostimulator 102 patient programmer 118 Lower limit screens 81 Magnetic resonance imaging (MRI) 84 MRI examinations activating a new group 86, 91, 92 MRI scan eligibility sheet 85, 88, 93 preparing for an MRI appointment 85 returning therapy to your original group settings 94 turning off therapy 86, 87, 88 turning therapy back on 89 MRI scan eligibility types of 84 Navigator key 36
Neurostimulator battery 46 Neurostimulator battery (rechargeable) automatic alert 57, 108 charging the battery 106 checking battery level (charge level) 98 low battery charge level screen 49, 120, 121 overdischarge 105 rechargeable battery screens 106 recharge warning screen 113 warning 98 when to check and charge 100 Nonrechargeable neurostimulator battery 47 Options icon 37 Overdischarge 105 Parameter/Group row icons 40 Parameter increasing or decreasing limits 81 limit screens 81 Parameter row 38 Patient programmer alert 57, 108

Patient programmer batteries 128-133 buttons 32 cleaning and care 134 description 26 disposing of 136 keys 32 low battery level screen 118 purpose 20 replacing batteries 132 screens 110 troubleshooting 110-126 turning on and off 34 POR 96 Possible battery status conditions (nonrechargeable) 48 Power/Backlight On/Off key 34 Precautions 21 Preference icons 51 Pulse Width increasing or decreasing 81,82

Index

Rate

increasing or decreasing 81,82 Rebound effect 98 Recharge warning screen 113 Repair 135 Serial number 140 Settings adjusting therapy 66-82 limits 81 SoftStart/Stop 123 Specifications 137 Status row icons 40 Stimulation limits when adjusting settings 81 stops suddenly 98 troubleshooting 124 uncomfortable 122 Synchronize Patient programmer and implanted neurostimulator 41 warning screen 111

Therapy settings 37 decreasing 69 increasing 69 turning therapy on or off 33 Therapy adjusting settings 66-82 guidelines for adjusting 81 On/Off key 33 Tones, audio 66, 111, 115 Turning neurostimulator on or off see Turning your therapy on or off Turning patient programmer on and off 34 Turning your therapy on or off 33 Uncomfortable stimulation troubleshooting 122 Upper limit screens 82 Warning screens 111-112 When to check your rechargeable neurostimulator battery 100

Index

37642 2015-04 English 149

Contacts:

Asia: Medtronic International Ltd. Tel. 02919-1300 Fax 02891-6830

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 1-800-668-670

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 I td. 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. 67-10-32-00 Fax 67-10-32-10 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 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

Turkey: Medtronic Turkey Tel. +90 216 636 1000 Fax +90 216 636 1008

U.K.: Medtronic U.K. Ltd. Tel. 01923-212213 Fax 01923-241004 **USA:** Medtronic, Inc. Tel. (1-763)-505-5000 Fax (1-763)-505-1000 Toll-free: (1-800)-328-0810



Manufacturer

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

Authorized Representative | EC | REP

in the European Community

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, 11/F, Tower 1, The Gateway, 25 Canton Road, Tsimshatsui, Kowloon, Hong Kong Tel. +852-2919-1300 Fax +852-2891-6830

Contacts for specific countries are listed inside this cover.



© Medtronic, Inc. 2015 All Rights Reserved

M929532A026