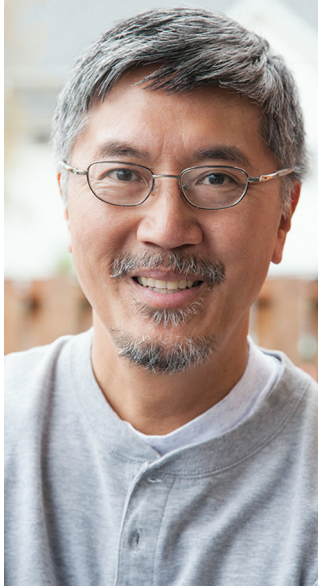


A620

Patient Programming Application for Deep Brain Stimulation With TM91 Communicator

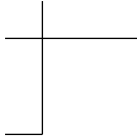
Patient User Guide for Model
B35200 and Model B35300
Percept™ neurostimulators with
Adaptive Therapy



Application version 3.0

! USA Rx only

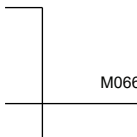
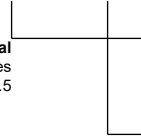
Medtronic



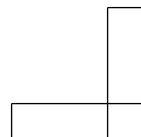
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2025/FEB/12 at 8:30 p.m.
Template Version: 1.96.0



Medtronic Confidential
Printspec [Patient] pm46x76 - 4.6 x 7.6 inches
DTD Version: 1.1.5



M066529C001 Rev B 2025-02-14



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The Bluetooth[®] word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by Medtronic is under license.



**Refer to your handset quick start guide
for information about:**

- Charging your handset
- Handset buttons and controls
- Setting your handset language
- Wi-Fi® connection



**Refer to the contents of this Patient
User Guide for information about:**

- Using your patient programming application
- Using your communicator
- Viewing and adjusting therapy
- Preparing for an MRI scan
- Checking battery status
- Troubleshooting your application



**Refer to the patient therapy guide
and therapy-specific patient booklet for
warnings, precautions, risks, and benefits
of your deep brain stimulation (DBS)
system.**

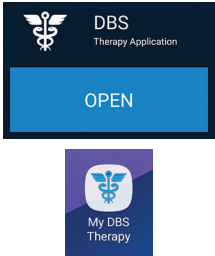
Quick Start Overview

Quick Start Overview

Every time you connect to your neurostimulator, you must use two devices:

- **Handset** – the device with a screen that has the Patient Programming Application.
- **Communicator** – the smaller, blue and white device.

To view your therapy, follow these steps:

	1. Turn on the handset and communicator. Check that they are charged. For handset charging instructions, refer to the handset quick start guide. For communicator charging instructions, refer to "Charging Instructions", page 102.
	2. If the app is not already open, tap the DBS Therapy Application OPEN button or the My DBS Therapy app icon on the handset.
	3. Ensure the communicator is within 1 meter of the neurostimulator and tap the

Quick Start Overview

(continued)

	CONNECT button on the handset.
	4. Tap the THERAPY button on the HOME screen.

HOME Screen

Note: Depending on your settings, your **HOME** screen may not look exactly like this.

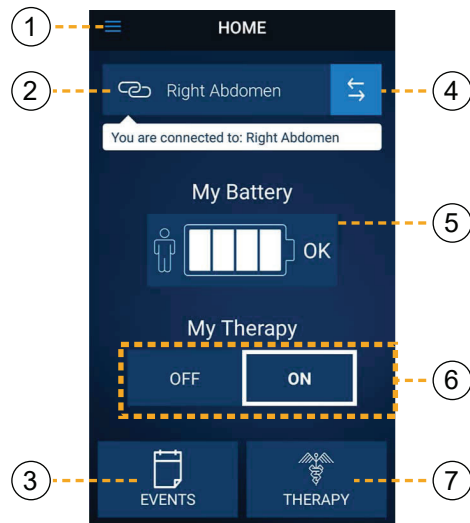


Figure 1. HOME screen.

Quick Start Overview

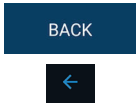
Item	Definition
①	Menu button ( – Refer to "Menu Screen", page 43.
②	The neurostimulator connected to your handset (only displays if you have two neurostimulators).
③	EVENTS button – Event recording.
④	OTHER DEVICE button – Switch neurostimulator (only displays if you have two neurostimulators).
⑤	My Battery button and display – View the status of all batteries.
⑥	My Therapy ON/OFF indicator.
⑦	THERAPY button – Therapy settings.

Buttons and Icons

Icon	Description
	GO HOME button – Go to the HOME screen.
	EVENTS button – Record events.
	THERAPY button – View or adjust your therapy.

Quick Start Overview

(continued)

Icon	Description
	OTHER DEVICE button – Switch neurostimulators (only displays if you have two neurostimulators).
	REVERT GROUP button – Change a group back to the way it was when your DBS clinician set it up, before you made any changes.
	GROUP button – Change groups.
	BACK buttons – Return to the previous screen.
	My Battery button – View detailed battery status.
	Neurostimulator battery icon.
	Communicator battery icon.
	Handset battery icon.

Reference Guide

My Therapy (OFF and ON) – To turn your therapy OFF or ON, refer to page 45 or page 47.

Quick Start Overview

THERAPY – To view or adjust your therapy, refer to page 55 or page 57.

OTHER DEVICE – To switch between neurostimulators, refer to page 60 (only if you have two neurostimulators).

Menu button – By tapping on the **Menu** (≡) button, you can access these features:

- **Battery** – To view battery status, refer to page 48.
- **Tutorial** – To watch videos about how to use the app, refer to page 84.
- **My Links** – To set up your communicator or neurostimulator, remove links, or set up a new link, refer to page 28.
- **MRI Mode** – To prepare for an MRI scan, refer to page 68.
- **Reminders** – To customize the time for your battery reminder, refer to page 86.
- **About** – To look up information about your system, refer to page 88.

Explanation of Symbols

Refer to the appropriate product to see symbols that apply.



Authorized Representative in the European Community



Importer



Reorder number



Model number



Serial number



Pin number



Manufacturer



Medical device

Rx only

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

 Conformité Européenne
(European Conformity). This
symbol means that the device
fully complies with applicable
European Union Acts.



www.medtronic.com/manuals

Consult electronic instructions for
use at this website



Deep Brain Stimulation



Date of manufacture



Use by



Consult instructions for use



Follow instructions for use



Class II equipment



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



Keep dry

IP22 This product meets the basic safety and essential performance requirements indicated in the IP22 conditioning test.



Magnetic Resonance (MR)
Unsafe



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
“e” in this logo signifies none
of the restricted substances are
present above permitted levels.)



For USA audiences only

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Glossary

Glossary

Adaptive Therapy

A mode that adjusts therapy automatically, based on certain signals in your brain. These adjustments occur within limits defined by your DBS clinician.

Application (app)

The software program that allows you to view or adjust your therapy.

Bluetooth® wireless technology

A wireless communication technology that allows computers, smartphones, and other devices to communicate with each other.

Button

A symbol or graphic in the app that you tap to initiate an action or respond to information on the screen.

Caution

A statement that describes an action or situation which could harm you or damage the device.

Clinician

A healthcare professional such as a doctor or nurse.

Communicator

A hand-held device that lets your handset communicate with your neurostimulator.

Glossary

DBS clinician

The clinician you visit for setting up and programming your DBS therapy.

Deep brain stimulation (DBS)

The delivery of electrical pulses to a targeted area or areas of the brain.

Elective replacement indicator (ERI)

An alert that your neurostimulator is near its end of service (EOS). If you see an ERI alert on your app, contact your DBS clinician.

End of service (EOS)

An alert that your neurostimulator has reached its end of service (EOS) and is no longer providing therapy. If you see an EOS alert on your app, contact your DBS clinician immediately.

Group

A therapy option that your clinician creates for you. If changing groups is available to you, it is a way for you to quickly adjust your therapy.

Handset

A hand-held device with the app installed, that lets you view or adjust your therapy. The handset looks like a smartphone, but cannot be used to make calls (including emergency calls).

Icon

A symbol or graphic shown in the app that helps you understand information shown on the screen.

Glossary

Link

The wireless connection between your handset and your neurostimulator. This wireless connection is enabled by your communicator.

Magnetic Resonance Imaging (MRI)

A type of medical procedure that scans your body using magnetic fields to provide detailed pictures of your anatomy.

MRI mode

A way for you to temporarily change your system settings, so you can safely get an MRI scan under certain conditions.

Neurostimulator

An implanted device that provides your DBS therapy.

Precaution

See Caution.

Recharger

The component of the neurostimulation system that is used to recharge your rechargeable neurostimulator battery.

Recharging Session

Time spent charging the rechargeable neurostimulator.

Stimulation

See Therapy.

Therapy

The treatment of your disease or condition with deep brain stimulation.

Glossary

Tutorial

A feature within the app that teaches you how to use the app.

Warning

A statement that describes an action or situation which could seriously harm you.

Wi-Fi®

A wireless communication technology that allows computers, smartphones, and other devices to communicate with each other within a particular area.

Wireless

Communication technologies that send data between devices with a wireless signal (rather than a cord or cable).



Part 1: Introduction

Your Therapy System

Your Therapy System

The Model A620 DBS Patient Programming Application, along with the handset and communicator, is meant to be used to view or adjust your therapy, as prescribed by your DBS clinician.

To view or adjust your therapy, you need to use these products together:

- Model HH90 Handset
- Model A620 Patient Programming Application (also known as the “app”)
- Model TM91 Communicator

Handset

The Model HH90 handset has a screen, like a smartphone, and contains the patient programming app.

Notes:

- The handset has screens, settings, and menus that are **NOT** part of the patient programming app (eg, for changing the handset language). Refer to the handset quick start guide for more information.
- The handset is not a phone and therefore cannot be used to make any calls, including emergency calls.
- Make sure to keep your handset, communicator, and charging cable with you at all times in the event that you need to

Your Therapy System

adjust your therapy or turn your therapy off or on.

Patient Programming Application

Intended Purpose: The patient programming application provides the user interface for patients to adjust therapy and obtain system information from an implantable neurostimulator as part of a neurostimulation system for deep brain stimulation therapy.

The Model A620 Patient Programming Application is preinstalled on your handset. You can view or adjust your therapy with this app, as enabled by your DBS clinician.

Communicator

Intended Purpose: The communicator provides a communication bridge between the handset and an implantable neurostimulator.

The Model TM91 communicator (Figure 2) allows the app on the handset to connect to your neurostimulator.

⚠ **Warning: Wound contact**—Do not use the communicator on an unhealed wound. The communicator is not sterile and contact with the wound may cause an infection.

⚠ **Caution: Communicator damage**—Avoid causing damage to the communicator and check the communicator for damage before use. If you notice damage to your

Your Therapy System

communicator, including case punctures or breakage, do not use the communicator. A damaged communicator may result in exposure to chemicals or sharp edges.

△ **Caution: Electric shock**—Do not handle the communicator near water. Allowing the communicator to be submerged in water could damage the device, resulting in electric shock.



Figure 2. TM91 Communicator.

Item	Definition
①	Battery indicator light ■ Blinks yellow (battery is low) ■ Flashes yellow rapidly for about 2 seconds (battery is fully depleted; communicator cannot be used unless it is charging) ■ Blinks green (battery is charging)

Your Therapy System

(continued)

Item	Definition
	■ Solid green (battery is ready for use)
②	BLUETOOTH® wireless technology indicator light ■ Blinks blue (connecting in progress) ■ Solid blue (connected to the handset)
③	Power (Stand-by) button ■ Turn On (press and release button) ■ Turn Off (press and hold button until multiple colors flash simultaneously) ■ Reset communicator (press and hold button until multiple colors stop flashing)

Notes:

- After 3 minutes of inactivity, the communicator will enter a sleep state, but can still communicate with the handset. When entering sleep state, the battery indicator light will pulse green approximately every 10 seconds for approximately 15 minutes, after which all indicator lights will turn off to further preserve battery.
- When plugged in and charging, the communicator will remain awake and able to communicate with the handset. Indicator lights will turn off after 3 minutes of inactivity. Pressing a button, disconnecting the charging cable, or

Your Therapy System

starting a communication session will turn the indicator lights back on.

- If the battery is low, the communicator will move from sleep state to off. If this happens, you will need to press and release the power (stand-by) button before using the communicator.
- The communicator contains a lithium-ion battery that will need to be charged at least every 6 months (even if device is not used).
- After approximately 6 months without charging, the battery will be in a depleted state and may no longer be able to be charged. If this happens, the communicator will no longer function and will need to be replaced.
- Keep your communicator nearby (within 1 meter) when using the app.
- Once the communicator is set up, the app will connect to the communicator automatically if the communicator is on or asleep, within 1 meter of the handset, and BLUETOOTH is enabled on the handset.
- If prompted by the app, place your communicator over your neurostimulator (Figure 3).
- The communicator can be used in a home or health care setting.

Your Therapy System



Figure 3. Position the communicator over neurostimulator (if prompted).

System Setup

System Setup

Before using the handset, it must be paired with the communicator and linked to your neurostimulator(s). If your handset can already connect to your neurostimulator, then your clinician has completed the pairing and linking for you, and additional setup is not necessary.

For most operations, your communicator needs to be on and within 1 meter of the neurostimulator (unless the app prompts you to hold it directly over your neurostimulator).

If you get a new handset or communicator that is not set up, complete the steps in the following sections:

- System Preparation (page 28)
- Communicator Setup (page 29)
- Neurostimulator Setup (page 32)

System Preparation

1. Unpack everything from the handset and communicator packages.
2. Before using the communicator for the first time, plug it in with the charging cable to activate it.
3. Charge the communicator. Keep the communicator plugged in with the charging cable. While it is charging, the battery indicator light will blink green (Figure 2). You can use the communicator while it is

System Setup

charging. Refer to "Charging Instructions", page 102, for detailed charging information.

Notes:

- Do not touch the AC adaptor when using the communicator for its intended medical use. The AC adaptor should remain outside of the patient environment.
 - To disconnect from mains power, unplug the communicator from the power source.
4. Charge the handset (refer to the handset quick start guide).
 5. Power on the handset and communicator.

Communicator Setup

To set up your communicator, follow these steps:

1. Start the app by tapping the **OPEN** button or the **My DBS Therapy** app icon (Figure 4 or Figure 5) on the handset's main screen.

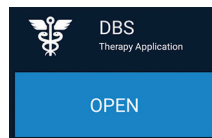


Figure 4. OPEN button.

System Setup



Figure 5. My DBS Therapy app icon.

2. On the **DBS THERAPY APPLICATION** screen, tap the **CONNECT** button (Figure 6).



Figure 6. CONNECT button.

If your links are not already set up, you will see either the **Set Up Links** screen or the **Select Communicator** screen.

- If you see the **Set Up Links** screen, refer to "Neurostimulator Setup", page 32.
- If you see the **Select Communicator** screen (Figure 7), tap the **TM91** communicator, then tap the **CONTINUE** button.
- If you see the **HOME** screen, your links are already set up. You can skip the "Communicator Setup" and "Neurostimulator Setup" sections.

System Setup

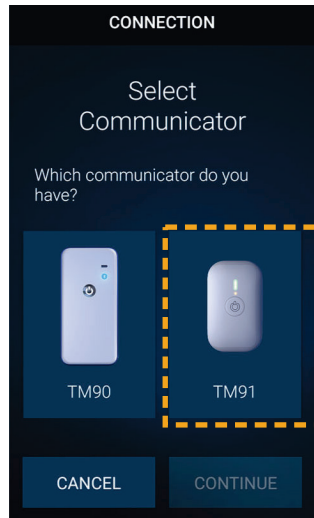


Figure 7. Select Communicator screen.

3. On the **CONNECTION** screen, watch the video that appears. It will help you locate the code and serial number on the back of your communicator. After watching the video, you can either scan the code above the serial number with the handset camera by tapping the **SCAN CODE** button, or enter the serial number manually by tapping the **ENTER MANUALLY** button and typing the serial number on the screen.

Note: If you choose to scan the code above the serial number using the handset camera, place the communicator with the blue side facing up. Hold the handset over

System Setup

the communicator and point the camera on the back of the handset at the code on the communicator. Hold the handset far enough away from the communicator that it can focus on the scan code.

4. After scanning the code or typing the serial number, tap **CONTINUE** and follow the remaining on-screen instructions to complete the connection to pair the handset with the communicator.

Neurostimulator Setup

A “link” is a wireless connection between your handset and your neurostimulator. You must be “linked” to your neurostimulator to view or adjust therapy.

If you receive a new handset and communicator, or if you removed your existing links, you should set up your neurostimulator links by following these steps:

1. Open the app (if it is not already open). Refer to "Opening the Application", page 40.
2. On the **Set Up Links** screen (Figure 8), tap the **START** button to search for the neurostimulator.

Note: Make sure your communicator is on and place it over your neurostimulator.

System Setup

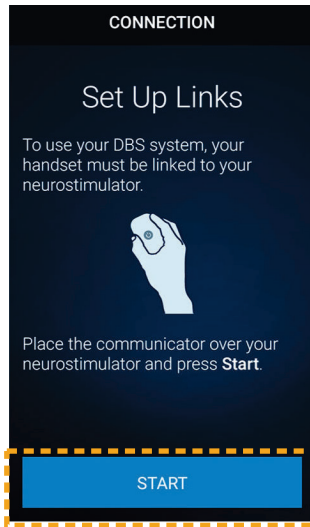


Figure 8. Set Up Links screen.

- If the **Device Found** screen (Figure 9) appears, compare the serial number displayed on the screen with your neurostimulator's serial number (which can be found on your Patient ID Card).
 - If the serial numbers match, tap **YES**. Then tap **CONTINUE** when the **DEVICE LINKED** confirmation screen appears.
 - If they do not match, tap **NO** and try again. If they still don't match after trying again, contact your DBS clinician.

System Setup

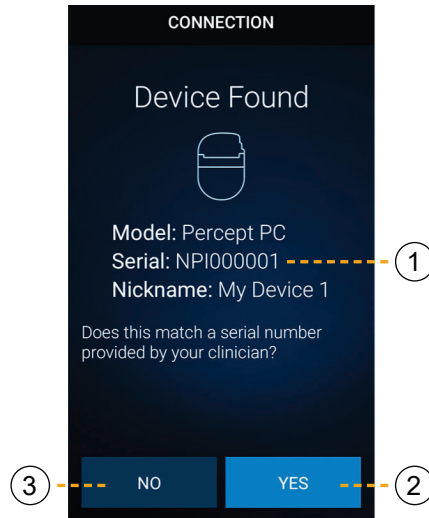


Figure 9. Device Found screen.

Item	Definition
①	Serial number.
②	YES button.
③	NO button.

- After tapping **CONTINUE** on the **DEVICE LINKED** confirmation screen, you will reach the **Linked Devices** screen (Figure 10).
 - If you have one neurostimulator implanted, tap **DONE**. You have finished linking your neurostimulator.

System Setup

- If you have two neurostimulators implanted, tap **LINK OTHER DEVICE**, repeat step 2, and tap **DONE**.

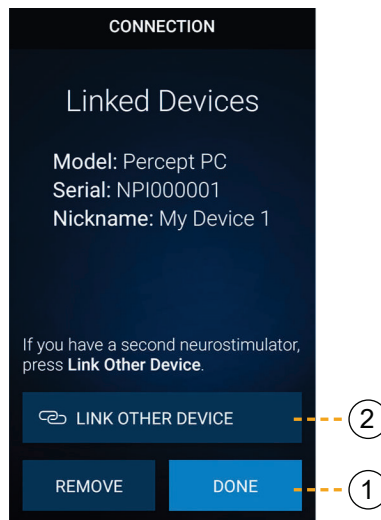


Figure 10. Linked Devices screen.

Item	Definition
①	DONE button.
②	LINK OTHER DEVICE button.

Removing Neurostimulator Links

If you get a replacement neurostimulator, or if you receive a second neurostimulator implant, you need to remove the link to your old

System Setup

neurostimulator before you can set up a link with the new neurostimulator.

Note: If you remove links with a neurostimulator, you will not be able to view or adjust your therapy until you set up links again.

To remove the link to your neurostimulator, follow these steps:

1. On the **HOME** screen, tap the **Menu** button  and then tap **My Links** on the menu (Figure 11).

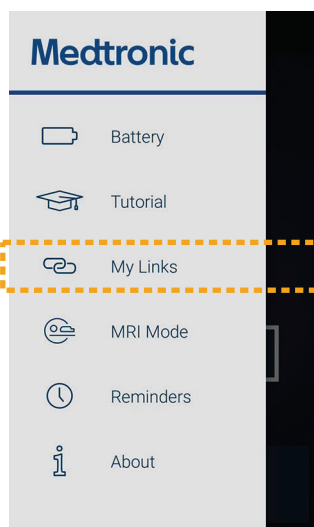


Figure 11. Selecting My Links from the menu.

System Setup

2. To unlink all neurostimulators, tap the **REMOVE LINKS** button on the **Linked Devices** screen (Figure 12).

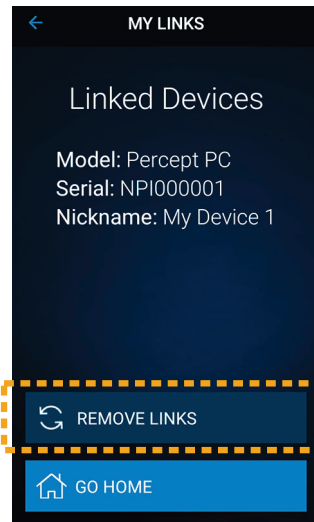


Figure 12. REMOVE LINKS.

3. On the **REMOVE LINKS** confirmation screen, tap **REMOVE** if you are sure you want to remove your links, or tap **CANCEL** to keep your links.

Note: For instructions on how to add links, refer to "Neurostimulator Setup", page 32.

System Setup

Adding a Second Neurostimulator Link

To add a second link, you must first remove your current link and then add them both.

1. Refer to "Removing Neurostimulator Links", page 35.
2. Once links are removed, refer to "Neurostimulator Setup", page 32.



Part 2: Using the Application

Opening the Application

Opening the Application

To open the app, follow these steps:

1. Tap the **OPEN** button or the **My DBS Therapy** app icon (Figure 13 or Figure 14) on the handset's main screen.

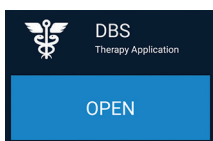


Figure 13. OPEN button.

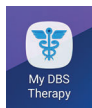


Figure 14. My DBS Therapy app icon.

2. When you see the **CONNECT** button, ensure your communicator is nearby (within 1 meter) and tap the **CONNECT** button to continue.
3. If you have two neurostimulators linked, tap the neurostimulator you want the app to connect to, on the **Select Device** screen.

Note: You cannot use the programming app while you are in a recharging session.

The Application

The Application

HOME Screen (Therapy ON)

When therapy is ON, your **HOME** screen will look like this (Figure 15).

Note: Depending on your settings, your **HOME** screen may not look exactly like this.

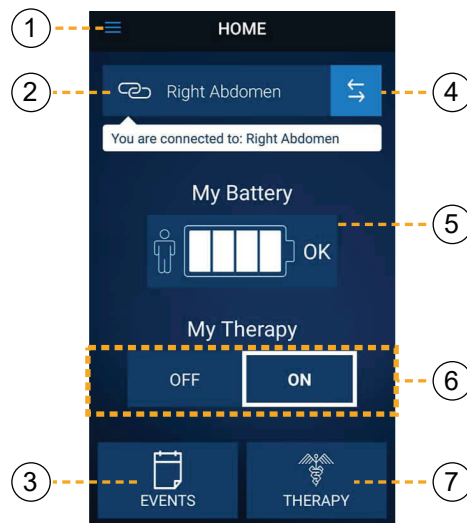


Figure 15. HOME screen when therapy is ON.

The Application

Item	Definition
①	Menu button (☰ – Refer to "Menu Screen", page 43.
②	The neurostimulator connected to your handset (only displays if you have two neurostimulators).
③	EVENTS button – Event recording.
④	OTHER DEVICE button – Switch neurostimulator (only displays if you have two neurostimulators).
⑤	My Battery button and display – View the status of all batteries.
⑥	My Therapy ON/OFF indicator.
⑦	THERAPY button – Therapy settings.

HOME Screen (Therapy OFF)

When therapy is OFF, your **HOME** screen will look like Figure 16.

Notes:

- Depending on your settings, your **HOME** screen may not look exactly like Figure 16.
- If your neurostimulator is in MRI Mode, your **HOME** screen will look like Figure 38, page 77.

The Application

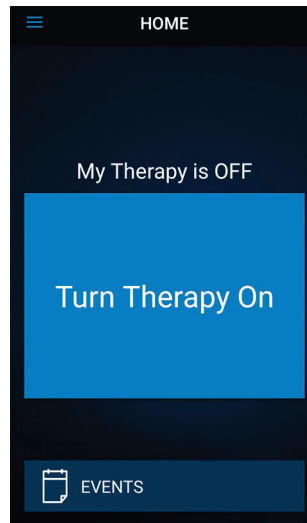


Figure 16. HOME screen when therapy is OFF.

Finding the HOME Screen

To return to the **HOME** screen from another screen, tap the back button in the top-left corner of the screen. You might need to tap the back button more than once.

Note: The **GO HOME** button, which you will find on some screens, will also bring you directly to the **HOME** screen.

Menu Screen

The **Menu** screen is accessed by tapping the **Menu** button (☰) on the **HOME** screen.

The Application

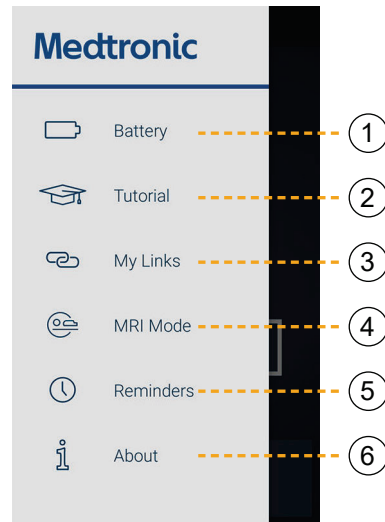


Figure 17. Menu screen.

Item	Definition
①	Battery - View the status of all batteries.
②	Tutorial - View information about how to use your handset and patient application.
③	My Links - Set up links between the neurostimulator and communicator.
④	MRI Mode - Check eligibility for an MRI scan.
⑤	Reminders - Set reminders to check your battery.
⑥	About - View information about your DBS system.

How to Turn Therapy Off

How to Turn Therapy Off

Effects of Turning Therapy Off

⚠ Warning: Avoid turning your therapy off without first talking with your clinician, because your symptoms might return. For some, this can cause a serious medical emergency. Refer to your therapy-specific patient booklet for more information.

If your therapy is turned off by accident, turn your therapy back on. Refer to "How to Turn Therapy On", page 47.

To Turn Therapy Off

There may be times when your DBS clinician instructs you to turn your therapy off.

- For steps on preparing for an MRI, refer to "MRI Workflow and MRI Mode", page 68.
- For steps on turning your therapy off for other reasons, continue reading this section.

To turn therapy off, follow these steps:

1. Turn on your communicator.
2. On the **HOME** screen, tap the **OFF** button (Figure 18).

How to Turn Therapy Off

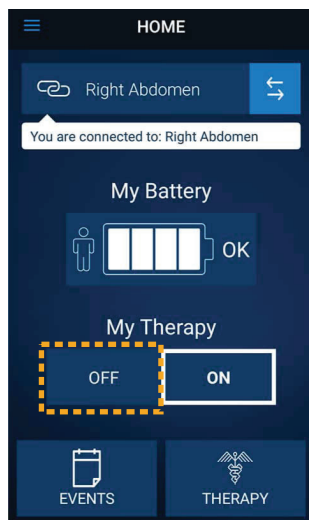


Figure 18. Turn Therapy OFF.

3. An alert will appear prompting you to confirm you want to turn therapy off. To turn therapy off, tap the **TURN OFF THERAPY** button. Or to keep therapy on, tap the **CANCEL** button.

Note: If configured by your DBS clinician, the app will prompt you to place your communicator directly over the neurostimulator to confirm you want to turn therapy off.

How to Turn Therapy On

How to Turn Therapy On

To turn therapy on, follow this step:

- On the **HOME** screen, tap the **Turn Therapy On** button (Figure 19).

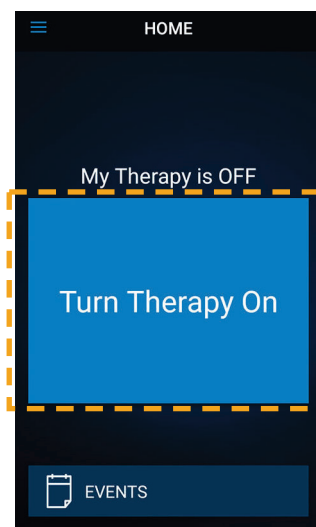


Figure 19. Turn Therapy ON.

BATTERY Screen

BATTERY Screen

Checking Your Batteries

If a low battery alert appears, refer to "Troubleshooting", page 90.

To check your batteries, follow these steps:

1. On the **HOME** screen, the **My Battery** button (Figure 20) displays the battery level of your neurostimulator. Tap the **My Battery** button to open the **BATTERY** screen.

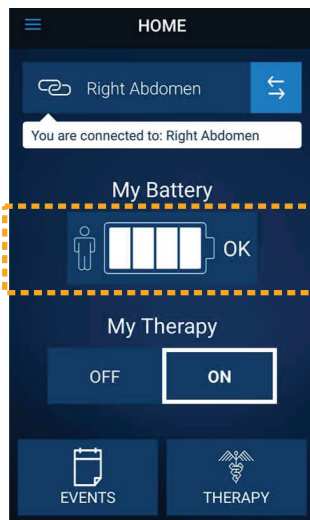


Figure 20. My Battery button.

2. The **BATTERY** screen (Figure 21) shows the status of three different batteries.

BATTERY Screen

Note: Depending on your settings and your neurostimulator, your **BATTERY** screen may not look exactly like this.

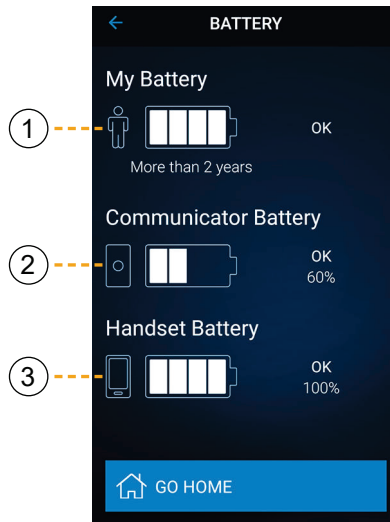


Figure 21. BATTERY screen.

Item	Definition
①	My Battery – the battery level of the neurostimulator, the device implanted in your body. If you have two neurostimulators implanted, you can view the battery level of the other device

BATTERY Screen

(continued)

Item	Definition
	by switching to the other device (refer to "Switching Neurostimulators", page 60).
②	Communicator Battery – the battery level of the communicator, the device that communicates with your neurostimulator.
③	Handset Battery – the battery level of the handset, the device that runs the My DBS Therapy app.

Understanding Battery Levels

Your communicator and your handset are rechargeable. Some neurostimulators are rechargeable too. If you are not sure if your neurostimulator is rechargeable, ask your DBS clinician.

On the **BATTERY** screen, the battery icons show the approximate level of the batteries. The status of the battery is displayed next to the battery icon.

- For rechargeable neurostimulator battery levels, refer to Table 1.
- For non-rechargeable neurostimulator battery levels, refer to Table 2.
- For handset battery levels, refer to Table 3.
- For communicator battery levels, refer to Table 4.

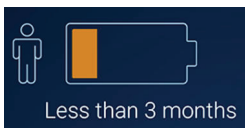
BATTERY Screen

Table 1. Rechargeable neurostimulator

Battery level icon	Battery percentage next to icon	Meaning
	90% or 100%	Your battery is OK. You do not need to do anything now, but you can recharge your battery if you would like.
	60%, 70%, or 80%	Your battery level is between 60% and 80%. You do not need to do anything now, but you can recharge your battery if you would like.
	30%, 40%, or 50%	Your battery level is between 30% and 50%. Consider recharging your battery.
	10% or 20%	Your battery is low. Recharge your battery.
	0% or 10%	Your battery is nearly empty. Recharge your battery immediately. You may not be getting therapy. If your battery does not recharge, call your clinician.

BATTERY Screen

Table 2. Non-rechargeable neurostimulator

Battery level icon	Text next to icon	Meaning
 More than 2 years	OK	Your battery is OK. You do not need to do anything now.
 Less than 3 months Note: The text under the icon eg, “More than 2 years,” “Less than 3 months”) is the estimated time before your neurostimulator reaches EOS (End of Service).	LOW	Your battery has reached ERI (Elective Replacement Indicator) status. Discuss your battery status with your clinician.
	EOS	Your battery has reached End of Service (EOS) status. Call your clinician right away. You are not getting therapy.

BATTERY Screen

Table 3. Handset

Battery level	Meaning
	The battery is OK. You do not need to do anything now.
	The battery is about 75% full. You do not need to do anything now.
	The battery is about half full. Consider recharging the handset.
	The battery is about 25% full. Recharge the handset.
	The battery is nearly empty. Recharge the handset soon. If it does not recharge, call your clinician.

Table 4. Communicator

Battery level	Meaning
	The battery is OK. You do not need to do anything now.
	The battery is about 75% full. You do not need to do anything now.

BATTERY Screen

Table 4. Communicator (continued)

Battery level	Meaning
	The battery is about half full. Consider recharging the communicator.
	The battery is about 25% full. Consider recharging the communicator.
	The battery is less than 20% full. Recharge the communicator.
	The battery is nearly empty. Recharge the communicator soon. If it does not recharge, call your clinician.

THERAPY Screen

THERAPY Screen

On the **HOME** screen, tap the **THERAPY** button (Figure 22) to open the **THERAPY** screen.

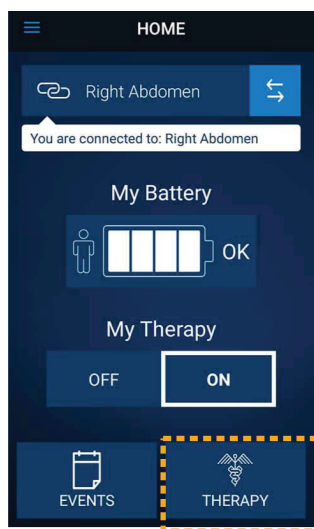


Figure 22. THERAPY button.

Figure 23 presents an example of what the **THERAPY** screen looks like with two neurostimulators.

Note: Depending on your settings, your **THERAPY** screen may not look exactly like Figure 23.

THERAPY Screen

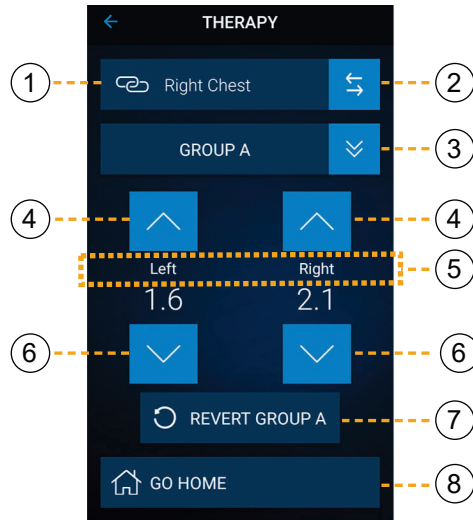


Figure 23. THERAPY screen (with two neurostimulators).

Item	Definition
①	The neurostimulator connected to your handset (only available if you have two neurostimulators).
②	OTHER DEVICE button (only displays if you have two neurostimulators).
③	GROUP button.
④	Adjust therapy up buttons.
⑤	Left/Right refers to the side of your body receiving therapy.

THERAPY Screen

(continued)

Item	Definition
⑥	Adjust therapy down buttons.
⑦	REVERT GROUP button.
⑧	GO HOME button.

Changing Groups

Your clinician may have set up groups, which are preset therapy options that you can choose from. If available, changing groups is a way for you to quickly adjust your therapy.

To change groups, follow these steps:

1. On the **HOME** screen, tap **THERAPY**.
2. Tap the **GROUP** button (✓) on the **THERAPY** screen.
3. Tap the group that you want to change to.

After choosing a group, the **THERAPY** screen for that group will appear. This means you have successfully changed groups.

Adjusting Therapy

If it is available, you can change your therapy settings. Your DBS clinician will decide whether to provide you with this option.

To adjust your therapy, follow these steps:

1. On the **HOME** screen, tap **THERAPY**.

THERAPY Screen

2. On the **THERAPY** screen, adjust your therapy up or down using the arrow buttons (Figure 24).



Figure 24. Adjusting your therapy.

Item	Definition
①	Adjust therapy up.
②	Adjust therapy down.

Reverting to Clinician Settings

If adjusting therapy is available, you can revert a group back to clinician settings. This means changing a group back to the way it was when

THERAPY Screen

your DBS clinician set it up, before you made any changes.

To revert a group back to clinician settings, follow these steps:

1. On the **HOME** screen, tap **THERAPY**.
2. Tap the **REVERT GROUP** button (Figure 25).

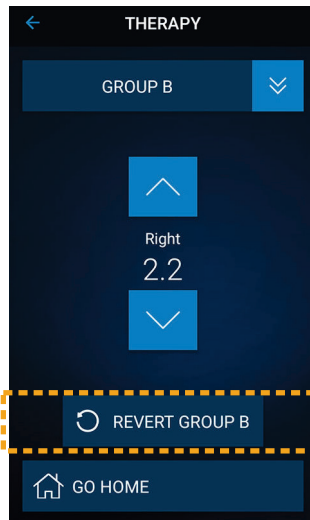


Figure 25. REVERT GROUP button.

3. An alert will appear. Tap **REVERT** to confirm the change.

Your therapy is now changed back to the way it was when your DBS clinician set it up.

THERAPY Screen

Switching Neurostimulators

If you have two neurostimulators implanted, your clinician may have given you the option to view or adjust therapy on both neurostimulators.

You can only view or adjust therapy for one neurostimulator at a time.

To switch to your other neurostimulator, follow this step:

- On the **HOME** screen, tap the **OTHER DEVICE** button (Figure 26).

Note: You can use any screen that has the **OTHER DEVICE** button at the top.



Figure 26. OTHER DEVICE button.

The **HOME** screen for the other neurostimulator will appear, which means you have successfully switched to the other neurostimulator.

Note: If you have two neurostimulators implanted, but you cannot switch between them, refer to "Adding a Second Neurostimulator Link", page 38.

Adaptive Therapy

Adaptive Therapy

Notes:

- Pausing and resuming Adaptive Therapy is NOT the same as turning your therapy off and on. When you pause Adaptive Therapy, your therapy reverts to a fixed level defined by your DBS clinician. Refer to "Pause Adaptive Therapy", page 63 for instructions on pausing and resuming Adaptive Therapy.
- Adaptive therapy has only been studied in patients with a single Percept neurostimulator for Parkinson's disease. Using Adaptive Therapy when you have multiple neurostimulators may interfere with the sensing of brain signals which could result in unwanted adjustments to your therapy. However, any adjustments to your therapy will occur within the limits defined by your DBS clinician.
- You might not have Adaptive Therapy. This depends on whether your DBS clinician set it up for you. Your clinician will discuss with you whether you are a candidate for Adaptive Therapy.

About Adaptive Therapy

Adaptive Therapy is a mode that automatically adjusts therapy based on certain signals in your brain. These adjustments occur within limits defined by your DBS clinician.

Adaptive Therapy

You may have to return to the clinic a few times during the first few months after turning on Adaptive Therapy in order for your DBS clinician to personalize your Adaptive Therapy settings. Those who are programmed with Adaptive Therapy may need to return to the clinic more often if they experience therapy-related side effects, or for adjustments to therapy settings.

When Adaptive Therapy is enabled, you cannot adjust your therapy because your therapy adjusts automatically based on how your DBS clinician configured your device.

If you experience any therapy-related side effects, contact your DBS clinician or pause Adaptive Therapy.

You can pause or resume Adaptive Therapy at any time—unless you are in MRI Mode.

Electromagnetic interference (EMI) is a field of energy made by equipment found in the home, work, medical, or public environments. EMI may interfere with the sensing of brain signals which could result in adjustments to your therapy. However, any adjustments to your therapy will occur within the limits defined by your DBS clinician. If EMI causes any discomfort, you can move away from the EMI, pause Adaptive Therapy, change groups, or turn off your therapy.

Adaptive Therapy

Pause Adaptive Therapy

Notes:

- Pausing Adaptive Therapy is NOT the same as turning your therapy off. When you pause Adaptive Therapy, your therapy reverts to a fixed level defined by your DBS clinician. Refer to "How to Turn Therapy Off", page 45 for instructions on turning your therapy off.
- Adaptive Therapy is automatically paused during a recharging session. Adaptive Therapy automatically resumes when the recharging session ends.

To pause Adaptive Therapy, follow these steps:

1. On the **HOME** screen, tap the **THERAPY** button (Figure 27).

Adaptive Therapy

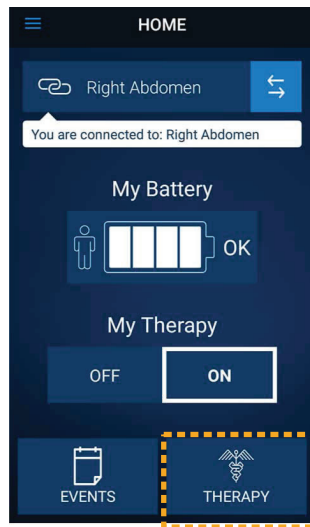


Figure 27. THERAPY button.

2. On the **THERAPY** screen, tap the **PAUSE ADAPTIVE THERAPY** button (Figure 28).

Adaptive Therapy



Figure 28. PAUSE ADAPTIVE THERAPY button.

When Adaptive Therapy is paused, your screen will look like Figure 30.

Resume Adaptive Therapy

Notes:

- Resuming Adaptive Therapy is NOT the same as turning your therapy on.
- When you resume Adaptive Therapy, your therapy automatically adjusts based on certain signals in your brain.

To resume Adaptive Therapy, follow these steps:

Adaptive Therapy

1. On the **HOME** screen, tap the **THERAPY** button (Figure 29).

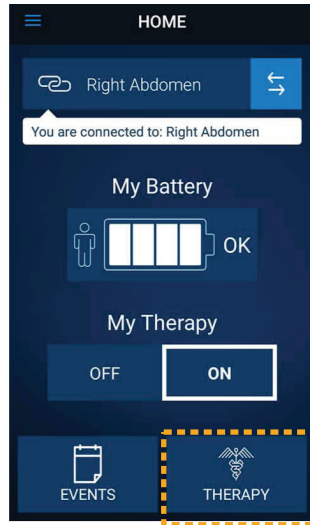


Figure 29. THERAPY button.

2. On the **THERAPY** screen, tap the **RESUME ADAPTIVE THERAPY** button (Figure 30).

Adaptive Therapy



Figure 30. RESUME ADAPTIVE THERAPY button.

When Adaptive Therapy is resumed, your screen will look like Figure 28.

MRI Workflow and MRI Mode

MRI Workflow and MRI Mode

Refer to your patient therapy guide and therapy-specific patient booklet for warnings, cautions, and important safety information about MRI scans.

The MRI workflow provides information about settings and checks your eligibility for an MRI scan. If the workflow determines you can have an MRI scan, you will be prompted to enter MRI mode. In some cases, the MRI workflow may indicate that no MRI scan may be performed.

Once you are in MRI Mode, you cannot change therapy settings until you exit MRI Mode. This helps you stay safely in MRI Mode until after the MRI scan. MRI Mode should only be used at an MRI facility.

Effects of Turning Off MRI Mode Early

⚠ Warning: Stay in MRI mode until after your MRI scan is complete and you have exited the MRI (magnet) room. Leaving MRI mode before your MRI scan is complete could lead to discomfort or injury during the scan.

Notes:

- Do not take the handset or communicator into the MRI (magnet) room. If you have a recharger device, do not take the recharger into the MRI (magnet) room either.

MRI Workflow and MRI Mode

- Your DBS clinician may activate MRI Mode for you, prior to your MRI scan appointment.

Entering MRI Mode

To start the MRI workflow, follow these steps:

1. On the **HOME** screen, tap the **Menu** button  (Figure 31) and then tap **MRI Mode** on the menu, to begin the MRI workflow.

Note: MRI Mode should only be used for an MRI scan.

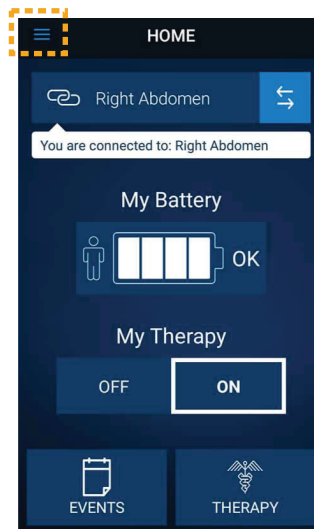


Figure 31. Menu button.

2. If you don't have an **MRI Eligibility Report**, ask the MRI clinician if they

MRI Workflow and MRI Mode

received a report. Your DBS clinician may have already completed an **MRI Eligibility Report** and sent it directly to the MRI facility. If you or the MRI clinician have a report, tap **YES** on the **MRI Report** screen (Figure 32). Otherwise, tap **NO** on the **MRI Report** screen.

← MRI MODE

MRI Report

Does your MRI clinician have an MRI Eligibility Report for this neurostimulator?

Model: B35200
Serial: NPI000001H
Location: Left Chest

NO YES

GO HOME

Figure 32. MRI Report screen.

- If you tapped **YES** on the **MRI Report** screen, tap the scan eligibility type selected on your report (Full Body or Head Only), then tap **CONTINUE** on the **Scan Eligibility** screen (Figure 33) and proceed to step 3.

MRI Workflow and MRI Mode

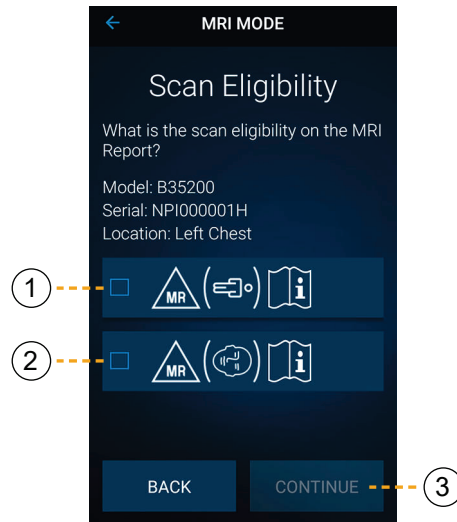


Figure 33. Scan Eligibility screen.

Item	Definition
①	Full Body eligibility.
②	Head Only eligibility.
③	CONTINUE button.

- If you tapped **NO** on the **MRI Report** screen, the app will prompt you to test your system to determine your MRI eligibility. Tap **START TEST** on the **Test System** screen to continue with

MRI Workflow and MRI Mode

the test. To cancel and return to the previous screen, tap **BACK** (Figure 34).

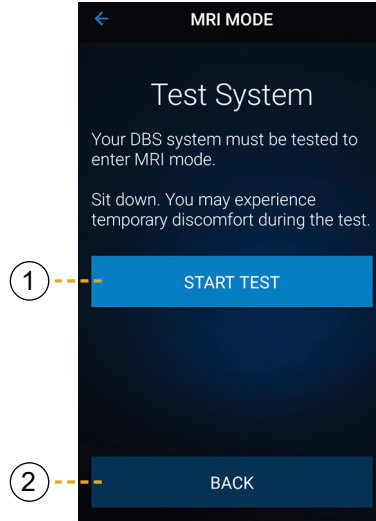


Figure 34. Test System screen.

Item	Definition
①	START TEST button.
②	BACK button.

Note: Sit down. You may experience temporary discomfort during the test because the settings used may differ from your normal therapy settings. Once the test starts, you can stop the test at any time by tapping **STOP**

MRI Workflow and MRI Mode

TEST on the **Testing System** screen
(Figure 35).

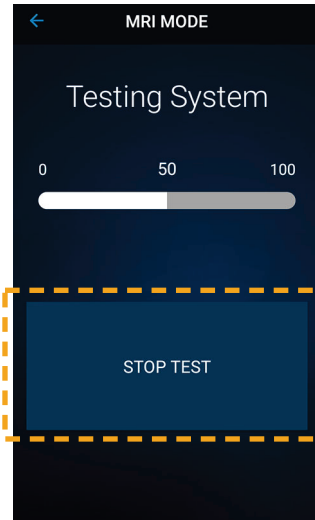


Figure 35. Stop Test.

Notes:

- Upon completion of the test, if you see the **MRI Mode Not Available** screen (Figure 36), contact your DBS clinician. This screen indicates your DBS system cannot enter MRI Mode as currently configured. Your DBS clinician may be able to make adjustments to allow MRI Mode.
- If you have multiple neurostimulators and cannot get both neurostimulators prepared for

MRI Workflow and MRI Mode

an MRI, exit MRI Mode on the neurostimulator that is in MRI Mode before contacting your DBS clinician. Otherwise, proceed to step 3.

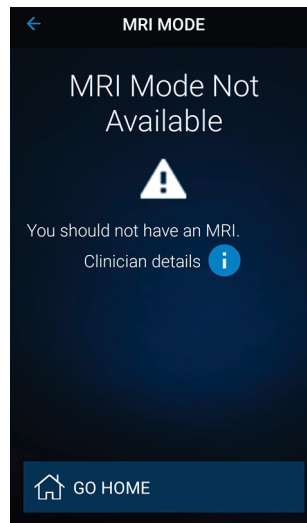


Figure 36. MRI Mode Not Available.

3. On the **Therapy for MRI** screen (Figure 37), only settings that are available for an MRI scan are shown. Select a therapy option and tap the **CONTINUE** button. If you selected the **THERAPY OFF** option, then tap **TURN THERAPY OFF** on the **THERAPY OFF** alert. To cancel and return to the previous screen, tap **BACK**.

MRI Workflow and MRI Mode

Note: In some cases, you may not have any groups to select and your only option will be to turn therapy off.

Warning: Avoid turning your therapy off without first talking with your clinician, because your symptoms might return. For some, this can cause a serious medical emergency. Refer to your therapy-specific patient booklet for more information.

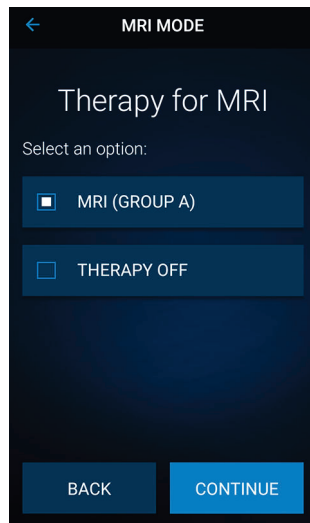


Figure 37. Therapy for MRI screen (screen may vary).

Note: If you have two neurostimulators, both neurostimulators must be assessed for an MRI scan.

- If this app only controls one neurostimulator, you will see the **MRI**

MRI Workflow and MRI Mode

Mode Active screen (Figure 38), confirming your neurostimulator is in MRI Mode. Depending on your settings, your **MRI Mode Active** screen may not look exactly like Figure 38.

- If this app is used to control two neurostimulators, tap the **CONTINUE** button to check whether the second neurostimulator is in MRI Mode. If it is not in MRI Mode, put it into MRI Mode by repeating the steps in this section. If the second neurostimulator is not controlled by this app, prepare the DBS system according to the information on the MRI Eligibility Report provided by your DBS clinician.

MRI Workflow and MRI Mode

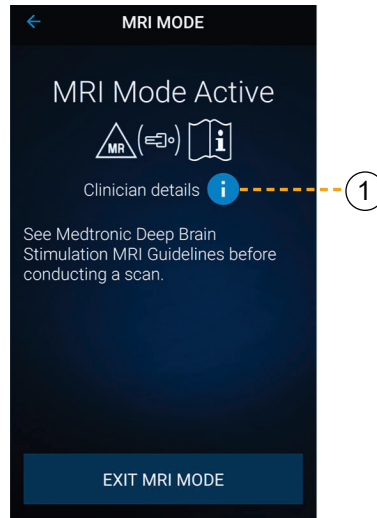


Figure 38. MRI Mode Active.

Item	Definition
①	Clinician details button.

Note: If you have two neurostimulators, both neurostimulators must be assessed for an MRI scan.

- On the **MRI Mode Active** screen (Figure 38), tap the **Clinician details** button to open the **Clinician Details** screen. The **Clinician Details** screen contains eligibility information needed by the MRI clinician to review the correct information in the MRI Guidelines manual.

MRI Workflow and MRI Mode

5. This DBS system is now ready for an MRI scan.

Exiting MRI Mode

To exit MRI Mode after an MRI scan, follow these steps:

1. Tap the **EXIT MRI MODE** button on the **MRI Mode Active** screen (Figure 39). Depending on your settings, your **MRI Mode Active** screen may not look exactly like Figure 39.

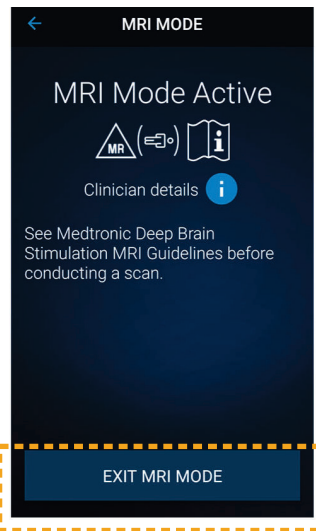


Figure 39. EXIT MRI MODE button.

2. On the **EXIT MRI MODE** confirmation screen, tap **EXIT MRI MODE** to exit MRI Mode and go to the **HOME** screen. If you

MRI Workflow and MRI Mode

wish to go back and keep MRI Mode active, tap **CANCEL**.

3. If this app is used to control two neurostimulators, tap the **CONTINUE** button to check whether the second neurostimulator is out of MRI Mode. If it is still in MRI Mode, take it out of MRI Mode.
4. If the second neurostimulator is not controlled by this app, return to the previous therapy settings using the appropriate controller or see your DBS clinician.
5. Ensure that your therapy returns to the original settings.

Note: See your clinician if you have questions about your therapy after your MRI scan.

Events

Events

Your clinician may set up events for you to record in the app (eg, Took Medication). When you record an event, the app will automatically record other information that may be helpful to your DBS clinician, such as your current therapy settings. Your clinician may also program event recording to adjust the stimulation cycle.

To record an event:

1. On the **HOME** screen, tap the **EVENTS** button (Figure 40).

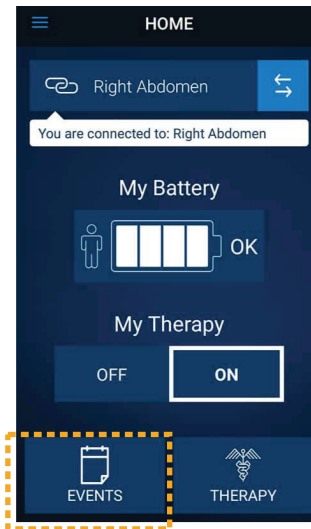


Figure 40. EVENTS button.

Events

2. On the **Events** screen, tap an event button that you want to record (eg, Took Medication) (Figure 41), then tap **OK** on the **EVENT RECORDED** confirmation screen.

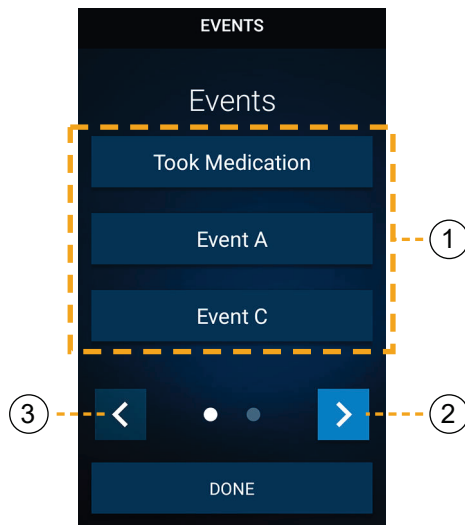


Figure 41. EVENTS screen (with example event buttons).

Item	Definition
①	Record event buttons.
②	Forward button.
③	Back button.

Events

Notes:

- The events set up by your DBS clinician may differ from those in Figure 41.
- If your DBS clinician set up more than four events, you can see additional events by tapping the **Forward** or **Back** buttons (Figure 41).
- If you see an **EVENT NOT RECORDED** alert, this indicates your DBS clinician removed the selected event from the app.
- If your therapy is off, you can record an event by tapping the **EVENTS** button on the **HOME** screen (Figure 42).

Events

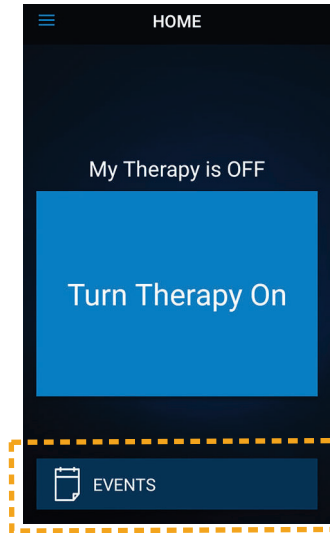


Figure 42. EVENTS button.

Tutorial

Tutorial

The tutorial has short videos on the following topics:

- Turn therapy on or off
- Check system battery levels
- Adjust settings (if available)
- Revert settings (if available)
- Switch group (if available)
- Switch device (if you have two neurostimulators)

You can view tutorials by following these steps:

1. On the **HOME** screen, tap the **Menu** (≡) button and then tap **Tutorial** on the menu.
2. On the **TUTORIAL** screen, tap **NEXT** to continue to the tutorial videos.
3. The first tutorial video will play on its own. Use the controls at the bottom of the screen to pause, play, and skip between videos (Table 5).
4. After all videos have been played or skipped, you will reach the final tutorial screen.
5. Tap **DONE** to complete the tutorial.

Tutorial

Table 5. Tutorial video controls

Button	Definition
	Skip to next video
	Go back to previous video
	Pause the video
	Play the video

Battery Reminder

Battery Reminder

The Battery Reminder feature lets you set the time of your battery check reminder. This helps you remember to check your neurostimulator battery every day.

To set the time of your battery check reminder, follow these steps:

1. On the **HOME** screen, tap the **Menu** (≡) button, and then tap **Reminders** on the menu.

Note: If you see a message that says “Battery reminder is disabled,” then this feature is not available. Tap the **GO HOME** button. If you have questions, contact your DBS clinician.

2. On the **BATTERY REMINDER** screen (Figure 43), tap, hold, and drag the numbers up and down to change the battery reminder time. If you are using the 12-hour clock time format, you can also adjust between AM and PM. To adjust the time format (12-hour or 24-hour clock), use the Settings menu on the handset. Refer to the handset quick start guide for more information.
3. Tap **CONFIRM** to save the battery reminder time.

Battery Reminder

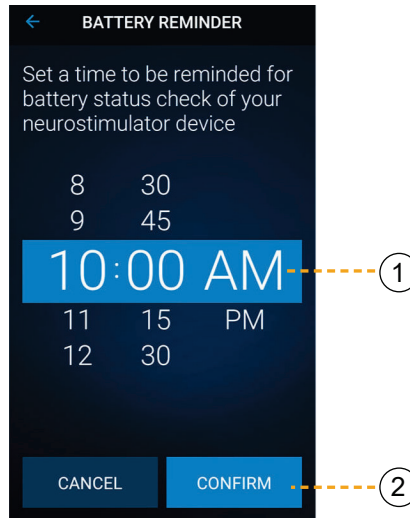


Figure 43. BATTERY REMINDER screen.

Item	Definition
①	Reminder time.
②	CONFIRM button.

ABOUT Screen

ABOUT Screen

The **ABOUT** screen has detailed information about the parts of your system. If you call your DBS clinician or Medtronic for help, they may ask for information on this screen.

To view the **ABOUT** screen, follow these steps:

1. On the **HOME** screen, tap the **Menu** (≡) button, and then tap **About** on the menu.

Note: You can also access the **ABOUT** screen from the **Settings** menu on the **DBS THERAPY APPLICATION** screen.

2. While on the **ABOUT** screen, tap the left arrow (◀) and right arrow (▶) buttons to view information about other parts of your system.
3. When you are done, tap **GO HOME** to go back to the **HOME** screen.

M066529C001
2025/FEB/12 at 8:30 p.m.
Template Version: 1.96.0

Medtronic Confidential
Printspec [Patient] pm46x76 - 4.6 x 7.6 inches
DTD Version: 1.1.5



Part 3: Troubleshooting & Maintenance

Troubleshooting

Troubleshooting

Problems with the App

If you have problems with the app but you don't get an alert screen, contact Medtronic.

When an alert screen pops up on the app, follow the on-screen instructions carefully. If an alert screen says to contact your clinician or Medtronic, make contact as soon as you can.

Table 6 lists some important alert screens and what to do if you see them.

Table 6. Alerts and actions

Alert	Action
No Communicator Found or Not Found Is power on? Is communicator charged? Is communicator near handset?	Turn on your communicator, hold it near your handset, then try again. If you continue to see the No Communicator Found or Not Found screen, verify that your system is set up correctly (refer to "System Setup", page 28). If the problem persists, call your DBS clinician. Your system may not be set up correctly.
No Device Response Place the communicator over your neurostimulator and press Retry.	Reposition and hold your communicator directly over your neurostimulator and try again. Metal surfaces can interfere with the communication between the communicator and the neurostimulator. If the

Troubleshooting

Table 6. Alerts and actions (continued)

Alert	Action
If you continue to get this message, check that your neurostimulator is linked.	communicator is on a metal table or metal tray, move the communicator to a nonmetal surface. If your neurostimulator has been replaced recently, you may need to link your handset to the new neurostimulator. Refer to "Removing Neurostimulator Links", page 35. Note: You cannot use the programming app while you are in a recharging session. If you continue to see the No Device Response screen, call your DBS clinician. Your system may not be set up correctly.
LOW BATTERY Recharge your neurostimulator battery to prevent future loss of therapy. Service Code: 626	Recharge your neurostimulator. Call your clinician if you have trouble recharging.
BATTERY VERY LOW Recharge your neurostimulator battery to restore therapy. Battery level is too low to provide therapy.	Recharge your neurostimulator. Call your clinician if you have trouble recharging.

Troubleshooting

Table 6. Alerts and actions (continued)

Alert	Action
Service Code: 634	
LOW COMMUNICATOR BATTERY Recharge your communicator soon to continue using your DBS therapy application. Communicator Battery: __% Service Code: 808	Recharge your communicator.
NO THERAPY Select a different group. Current group is not providing therapy. Service Code: 809	Go to the THERAPY screen and select a new group. Refer to "Changing Groups", page 57.
NO THERAPY Contact your clinician as soon as possible to fix your therapy settings. Service Code: 810	Contact your DBS clinic immediately and read the alert message to your clinician.
NO VALID THERAPY Contact your clinician for initial setup. Your neurostimulator	Contact your DBS clinic immediately and read the alert message to your clinician.

Troubleshooting

Table 6. Alerts and actions (continued)

Alert	Action
cannot provide therapy yet. Service Codes: 1714, 2714	
DEVICE NOT ACTIVATED Contact your clinician for initial setup. Your neurostimulator cannot provide therapy yet. Service Codes: 1708, 2708	Contact your DBS clinic and read the alert message to your clinician.
REPLACEMENT NEEDED (ERI) Contact your clinician to prevent future loss of therapy. Neurostimulator battery is nearing End of Service EOS). Service Code: 1710	Contact your DBS clinic and read the alert message to your clinician.
NO THERAPY Contact your clinician as soon as possible. Neurostimulator	Call your clinician immediately and read the alert message to your clinician.

Troubleshooting

Table 6. Alerts and actions (continued)

Alert	Action
can no longer provide therapy because it has reached End Of Service (EOS). Service Codes: 1035, 1709	
THERAPY OFF Your therapy has been turned off. Press continue and turn therapy back on. If this condition persists, contact your clinician. Service Code: 2718	Contact your DBS clinic immediately and read the alert message to your clinician.

Problems with the Handset

If you have problems with the handset device, contact your DBS clinician or call Medtronic.

If you have problems with software that is NOT the Medtronic app, contact your clinician or call Medtronic.

Handset Disposal

To dispose of a handset that is broken or no longer needed, contact Medtronic.

Troubleshooting

Ordering a New Handset or Communicator

If the handset or communicator is lost or broken, contact Medtronic.

Getting Help with the Handset

When to call your clinician

Call your clinician if any of these things happen:

- An alert screen says to contact your clinician.
- Your battery is running low and you cannot recharge it.
- Your therapy is off, and you cannot turn it back on.
- You have repeating problems that your manuals cannot help you solve.

When to contact Medtronic

Contact Medtronic if your DBS clinician is unavailable, or if your DBS clinician tells you to call Medtronic.

How to contact Medtronic

For assistance in the US, call +1 800 510 6735, Monday through Friday, 8 AM to 5 PM (Central Time).

Outside the US, refer to the contact information on the back cover.

Software Information

Software Information

Data Security

The Model A620 Patient Programming app uses and stores data about your medical device. This information is protected by the app and handset. Personal files or data you choose to store or access elsewhere on the handset are not protected. You are ultimately responsible for protecting the data stored on the handset.

The Model TM91 Communicator does not store any personal information.

Network Connectivity

You do not need to connect to a network to use your patient programming system. Network connectivity is required only in the event of a software update for your handset or communicator.

Software Updates

If a software update for your handset or communicator is needed, Medtronic will notify you and will provide the necessary support and instructions.

During updates, you temporarily may not be able to make changes to your therapy. Plan for updates accordingly.

Software Information

Wi-Fi Connection

Some handsets may support Wi-Fi connection. Wi-Fi is initially turned off on these handsets and should remain off, unless instructed by Medtronic.

Note: Refer to the handset quick start guide to help determine if Wi-Fi is supported on your handset.

Additional Security Measures

If your handset is lost or stolen, contact Medtronic right away using the contact information at the end of this guide.

If you suspect the security of your handset has been compromised, stop using the app (if possible) and contact Medtronic to document and respond to the suspected incident.

If you no longer need the handset to manage your therapy, refer to "Handset Disposal", page 94.

If more details are needed about the system software, hardware, or firmware (such as a Software Bill of Materials), contact Medtronic.

Communication Manager App

The Model A901 Communication Manager app works with the Model A620 Patient Programming app to manage communication between the handset and the neurostimulator. You do not need to open or use this app.



Part 4: Model TM91 Communicator

About the Communicator

About the Communicator

Troubleshooting

Use of the communicator is specific to the medical device. Refer to "Problems with the App", page 90, to troubleshoot possible issues while using the communicator with the app.

Software updates are sent to the communicator if needed.

Electromagnetic Interference

Electromagnetic interference (EMI) is a field of energy made by equipment found in the home, work, medical, or public environments. EMI may be strong enough to interfere with the connection between the handset and implanted device.

Refer to the DBS Patient Therapy Manual for more information about EMI.

Safety and Technical Checks

Safety checks are not required for the Model TM91 Communicator. Maintenance is not necessary, because the communicator does not contain serviceable components.

Device Care

- Do not dismantle or tamper with the communicator.

About the Communicator

- Clean the communicator with a damp cloth or sponge. Mild household cleaners will not damage the device.
- Handle the communicator with care. Do not drop, strike, or step on it.
- The communicator is not waterproof. Do not allow moisture to get inside the communicator.
- Keep the communicator and USB charging cable out of the reach of children and pets, to prevent risk of strangulation.

Communicator Disposal

△ **Caution:** Disposal—Dispose of the communicator according to local regulations, or consult <http://recycling.medtronic.com>. Failure to dispose of the communicator correctly may lead to environmental damage.

Communicator Specifications

Table 7. Communicator specifications

Item	Specification
Power Source	Rechargeable battery, USB 2.0 compliant cable
Input	4.75V-5.25V  1.0A
Expected Battery life - Patient use	Up to 4 days with power on

About the Communicator

Table 7. Communicator specifications (continued)

Item	Specification
Service life	4 years minimum ^a
Operating temperature	5°C to 40°C (41°F to 104°F) ^{b, c}
Long-term storage temperature	20°C to 25°C (68°F to 77°F)
Short-term transport temperature	-35°C to 70°C (-31°F to 158°F) ^{d, e, f}
Size (approximate) Note: Size does not include lanyard.	53.57 mm x 87.25 mm x 19.77mm (2.1 in x 3.4 in x 0.78 in)
Weight (approximate)	61 g (2.2 oz)
Mode of operation	Continuous
Classification	Internally Powered
Communicator materials	Polycarbonate/ABS Blend, Polycarbonate, Stainless Steel A1 or A2, Thermoplastic Polyurethane, Polyester
^a Communicator can continue to be used after the minimum service life has elapsed. ^b A relative humidity range of 15% to 90%, noncondensing, but not requiring a water vapor partial pressure greater than 50 hPa; and an atmospheric pressure range of 700 hPa to 1060 hPa. ^c At the upper range of operating temperature, the communicator may reach 43°C (109°F). ^d 5°C to 35°C at a relative humidity up to 90%, noncondensing; and >35°C to 70°C at a water vapor pressure up to 50 hPa. ^e Allow 25 minutes for the communicator to warm up before use, after being transported at or near the minimum short-term transport temperature. ^f Allow 45 minutes for the communicator to cool down before use, after being transported at or near the maximum short-term transport temperature.	

About the Communicator

Charging Instructions

When the battery indicator light (Figure 44) is blinking yellow, it is time to charge the communicator.

Effects of Using a Damaged/ Incompatible Charger

⚠ Warning: Do not use a damaged or incompatible USB cable or AC adaptor when charging your communicator. Use of a damaged or incompatible USB cable or AC adaptor can result in electric shock, which may result in patient discomfort, pain, injury, or death.



Figure 44. Battery indicator light.

About the Communicator

Item	Definition
①	Battery indicator light.

To charge the communicator, use the USB 2.0 cable and AC adaptor provided by Medtronic. If other adaptors or cables are used, they must meet the following specified requirements:

Rated Input	100-240V 50-60Hz
Minimum Rated Output	5.0V — 1.0A
Agency Certification	Class II I.T.E Power Supply (IEC 60950-1) or equivalent

The use of other chargers or equipment not provided by Medtronic has not been tested for safety and could lead to serious injury and/or damage to parts of your system. All configurations shall comply with the requirements for Medical Electrical Systems per clause 16 of IEC 60601-1:2012. Anyone connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for that medical electrical system.

For best results, charge the communicator overnight, so it is fully charged and ready for use at the beginning of the day.

About the Communicator

While charging, the lights on the communicator will turn off after 3 minutes, if it is not communicating with the handset. The communicator will continue to charge, and can communicate with the handset in this state.

Notes:

- The communicator can be used while charging. Do not touch the AC adaptor when using the communicator for its intended medical use. The AC adaptor should remain outside of the patient environment.
- Do not charge the communicator at temperatures below 5°C (41°F) or above 40°C (104°F).

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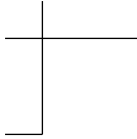
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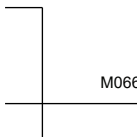
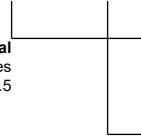
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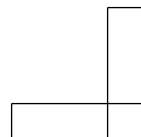
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2025/FEB/12 at 8:30 p.m.
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DTD Version: 1.1.5



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2025/FEB/12 at 8:30 p.m.
Template Version: 1.96.0

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DTD Version: 1.1.5

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Your Medtronic Deep Brain Stimulation Therapy for Movement Disorders



Therapy-specific Patient Manual

 Rx only

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Information for family members or caregivers

Read this patient manual thoroughly so you can assist the patient living with Deep Brain Stimulation (DBS) Therapy.

In addition to this manual, the patient should have a patient therapy guide.

If you do not have these manuals, contact the patient's doctor.

If you are living in certain countries, you may also receive additional patient information.

Always tell any medical personnel that the patient has an implanted neurostimulator and tell them where it is located. If medical personnel have any questions, they should contact Medtronic. Refer to the Medtronic contacts at the end of this manual.

[! USA] For assistance in the US, call Medtronic patient services at 1-800-510-6735.

Have the name and telephone number of the patient's doctor at hand if you have any questions or problems.

Label symbols

The following symbols appear on or within this manual.



Authorized Representative in the European Community



Manufacturer



For USA audiences only



Importer

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Glossary

Caution - A statement that describes an action or situation which could harm you or damage the device.

Clinician - A health care professional such as a doctor or nurse.

Contraindications - A medical term meaning that a procedure, device, or drug, etc. should always be avoided because the risk is greater than any possible benefit.

Electromagnetic interference (EMI) - Electrical or magnetic energy that is strong enough to interfere with or disrupt your therapy.

Essential tremor - A movement disorder in which the only symptom is rhythmic shaking produced by muscle contractions. The tremor often occurs in the hands, head, legs, trunk, or voice.

Extension - A thin wire covered with a protective coating that connects the neurostimulator to a lead.

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

Neurostimulator - The neurostimulator is the implanted device that generates and controls your DBS therapy.

“On Time” - The time period when you are receiving relief from your Parkinson’s disease symptoms.

“On Time” with dyskinesia - The time period when you are receiving relief from your Parkinson’s disease symptoms, but have uncontrolled movements caused by Parkinson’s disease medications.

Parkinson’s disease - A movement disorder with four typical symptoms: tremor (involuntary rhythmic shaking), rigidity (stiffness of the limbs), bradykinesia/akinesia (slowness of movement/no movement), and postural instability (problems with balance or coordination).

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

Precaution - See Caution.

Stimulation - The delivery of electrical pulses to the brain.

Test stimulation - During the implant procedure, the surgeon tests the appropriate area of the brain with electrical stimulation to determine how well it controls your symptoms.

Therapy settings - Your Medtronic DBS Therapy can be adjusted by changing the rate, amplitude, or pulse width of the electrical stimulation. Your clinician will adjust the programming of these therapy settings if appropriate.

Warning - A statement that describes an action or situation which could seriously harm you.

Medtronic DBS Patient Manual for Movement Disorders

This DBS Therapy-specific Patient Manual provides important DBS therapy information specific to your medical condition.

It supplements the information found in your DBS Patient Therapy Guide. These two guides should be kept together.

You should also receive a manual instructing you how to operate your patient control device. Keep all your patient information together.

If you are living in certain countries, you may also receive additional patient information.

DBS Therapy for Movement Disorders

Some of your symptoms are caused by abnormal electrical messages generated by your brain. Your DBS system delivers

mild electrical therapy to block some of the abnormal electrical messages as they travel inside the brain. This may relieve the symptoms of your disease.

Medtronic DBS therapy helps control your symptoms; however, it is not a cure. When you turn on the DBS system, it delivers therapy that may decrease your symptoms. If the DBS system is turned off or stops working, your symptoms will return. Some symptoms return quickly. Other symptoms may take longer to return.

Description of the device

Depending upon your medical condition, you may have 1 or 2 implanted neurostimulators.

Treating one side of your body

If you are receiving stimulation for only one side of your body, 1 neurostimulator, 1 lead, and 1 extension is implanted (Figure 1).

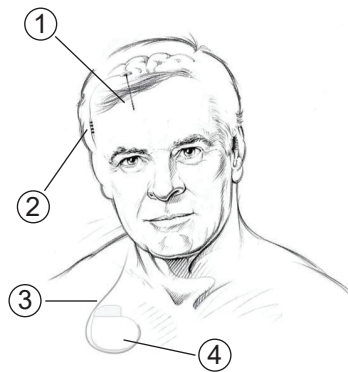


Figure 1. Implanted system for treating symptoms on one side of your body.

- | | |
|-----------------------------|-------------------|
| ① Lead | ③ Extension |
| ② Lead-extension connection | ④ Neurostimulator |

Treating both sides of your body

If you are receiving stimulation for both sides of your body, you may have 1 neurostimulator or 2 neurostimulators implanted.

You may have 2 neurostimulators, 2 leads, and 2 extensions implanted (Figure 2) or you may have 1 neurostimulator, 2 leads, and 2 extensions implanted (Figure 3).

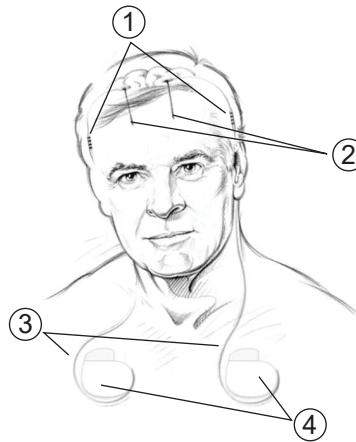


Figure 2. Implanted system for treating symptoms on both sides of your body with 2 neurostimulators.

- | | |
|------------------------------|----------------------|
| ① Lead-extension connections | ③ 2 Extensions |
| ② 2 Leads | ④ 2 Neurostimulators |

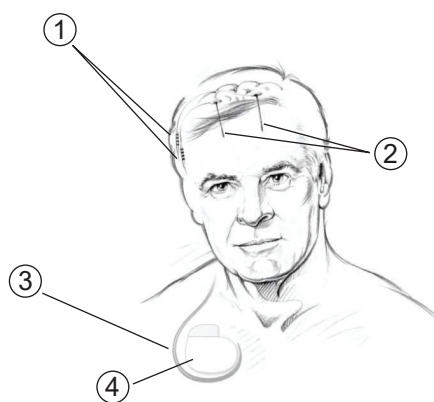


Figure 3. Implanted system for treating symptoms on both sides of your body with 1 neurostimulator.

- | | |
|------------------------------|---------------------|
| ① Lead-extension connections | ③ 2 extensions |
| ② 2 leads | ④ 1 neurostimulator |

Treating both sides of your body

Contraindications

There are no therapy-specific contraindications for Medtronic DBS Therapy for Movement Disorders.

Refer to the DBS Patient Therapy Guide for an additional list of warnings, precautions, risks, and contraindications.

Warnings

Rebound effect—If your DBS system ceases to function for any reason (eg, battery depletion or exposure to EMI sources that may shut off the system), your symptoms may 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.

If your DBS system ceases to function, contact your physician immediately so the status of your system can be assessed and your therapy restored.

Please follow your doctor's advice for taking medications when your neurostimulator is not working. Medications may help control your symptoms until your therapy is restored.

If your neurostimulator has a rechargeable battery, it is very important to check every day that your neurostimulator battery is charged. If the therapy provided by your neurostimulator should stop due to the battery not being charged, this could cause your symptoms to return. It is important for you to recharge your battery on a regular, frequent basis as recommended by your doctor (for example weekly or daily), to avoid your battery not being charged. If you have technical problems while charging your battery, contact your clinician or Medtronic customer support.

Risk of depression, suicidal thoughts, and suicide—New onset or worsening depression which may be temporary or permanent is a risk that has been reported with DBS therapy. Suicidal thoughts, suicide attempts, and suicide are events that have

also been reported. Patients and caregivers should consider the following:

- Before the procedure, be sure you talk to your treating physician(s) if you have a history of depression, suicidal thoughts, or have attempted suicide. Be sure you understand the possible risks of new onset or worsening depression (including suicidal thoughts) as well as the potential clinical benefits of DBS therapy.
- After the procedure, if you notice unusual changes in mood or behavior such as increased anxiety, sleeping problems, loss of interest in activities, feeling of hopelessness, mood swings, weight loss or weight gain) or impulse control contact your physician. If you are having thoughts of suicide, contact your physician or emergency services immediately.
- It is important to attend on-going follow-up visits to manage your therapy.

Precautions

DBS therapy precautions that are specific to movement disorders include the following:

Battery longevity and brain target selection—DBS Systems implanted in the globus pallidus (GPI) may have shorter battery life than systems implanted in the subthalamic nucleus (STN).

Possible side effects after surgery

For potential risks and side effects related to DBS therapy, refer to the DBS Patient Therapy Guide. There are no known additional side effects associated with DBS Therapy for Movement Disorders.

Expected battery life for your neurostimulator

The expected battery life for an implanted neurostimulator is different for rechargeable and non-rechargeable models.

The rechargeable batteries – The Aactiva™ RC rechargeable battery can last for 15 years, but has a preset battery life of 9 years. Your clinician can extend the battery life from 9 years to 15 years.

The Percept™ RC rechargeable battery can last for 15 years.

The non-rechargeable batteries – used by Percept™ PC, Aactiva™ PC, and Aactiva™ SC models are influenced by the programmed therapy settings of the neurostimulator.

Depending on your individual therapy settings, the non-rechargeable battery will typically last between 2 to 5 years. Consult with your clinician for exact information as it relates to your medical condition because the life of your neurostimulator battery may be outside of this range.

What to expect from your implant procedure

Your doctor can provide greater detail about your implant procedure; however, the

procedure normally includes the following stages.

Before surgery

The evening before surgery, you may be instructed to stop taking all of your medications. This will enable the doctor to evaluate the effect of the DBS therapy on your symptoms without the influence of medication. You will be admitted to the hospital either the night before or the morning of your surgery. You may have your head shaved prior to surgery.

During surgery

During the surgery to implant your DBS system for movement disorders, your doctor may use the following techniques to locate the appropriate place in the brain for the DBS lead.

1. Before placing the DBS lead, your surgeon may use test stimulation to determine the exact placement for the lead.
 - You will be awake, but lightly sedated. This is so you can help determine, along with your doctor, when your symptoms are best controlled.
 - Your doctor may ask you to move your arms or legs, tap your fingers, move your hands, or pretend to drink from a cup.

This will help your surgeon to determine if the DBS system is controlling symptoms like rigidity, slowness of movement, or tremor.

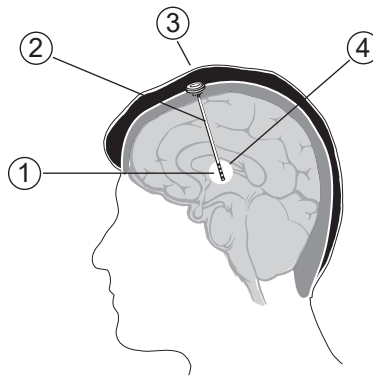


Figure 4. The location of the lead in your brain.

- | | |
|--------------|----------------------|
| ① Electrodes | ③ Hole cap |
| ② Lead | ④ Stimulation target |

2. When the best area for stimulation in the brain is located, the lead is passed into the brain. The control of your symptoms will be checked again.

Changes in therapy

There may be changes in the level of your symptom suppression over time. These changes may include:

- Less relief or no symptom relief
- Loss of effective stimulation

In many cases, your doctor can correct these changes by programming the DBS system again. However, surgery may be required to reposition or replace the lead, replace the system, or remove the system.

Because your disease changes with time, your condition may improve, may worsen, or may remain unchanged with stimulation.

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Your Medtronic Deep Brain
Stimulation Therapy
Patient Therapy Guide



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Information for family members or caregivers

Read this patient manual thoroughly so you can assist the patient living with Deep Brain Stimulation (DBS) Therapy.

In addition to this manual, the patient should have a Therapy-specific Patient Manual, which contains therapy information specific to your medical condition.

If you do not have these manuals, contact the patient's doctor.

If you are living in certain countries, you may also receive additional patient information.

Always tell any medical personnel that the patient has an implanted neurostimulator and tell them where it is located. If medical personnel have any questions, they should contact Medtronic.

[! USA] For assistance in the US, call Medtronic patient services at 1-800-510-6735.

Have the name and telephone number of the patient's doctor at hand if you have any questions or problems.

Label symbols

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For USA audiences only



Magnetic Resonance (MR) Conditional



Warning



Importer

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Glossary

Caution - A statement that describes an action or situation which could harm you or damage the device.

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

Clinician programmer - A small device used by your doctor or nurse to program the DBS system. If necessary, your doctor or nurse can change your therapy settings using this programmer.

Contraindications - A medical term meaning that a procedure, device, or drug, etc. should always be avoided because the risk is greater than any possible benefit.

DBS system (Deep brain stimulation system) - Components that deliver, control, and maintain electrical pulses to provide therapy to the brain.

Diathermy - A medical treatment applied to the outside of the body that delivers energy into the body. Three types of energy that can be used are shortwave, microwave, and ultrasound. Depending on the power level used, diathermy devices may or may not produce heat within the body. This treatment is typically used to relieve pain, stiffness and muscle spasms, reduce joint contractures, reduce swelling and pain after surgery, and promote wound healing.

Electromagnetic interference (EMI) - Electrical or magnetic energy that is strong enough to interfere with or disrupt your DBS therapy.

Extension - A thin wire covered with a protective coating that connects the neurostimulator to a lead.

Lead - A thin wire with protective coating that has metal electrodes on one end. The electrodes are placed in your brain and the other end of the lead is connected to the DBS system extension.

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

Neurostimulator - The neurostimulator is the implanted device that generates and controls your DBS therapy.

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

Precaution - See Caution.

Psychotherapeutic procedures - Therapies or procedures that treat mental health problems.

Recharger - The component of the neurostimulation system that is used to recharge your rechargeable neurostimulator battery.

Stimulation - The delivery of electrical pulses to the brain.

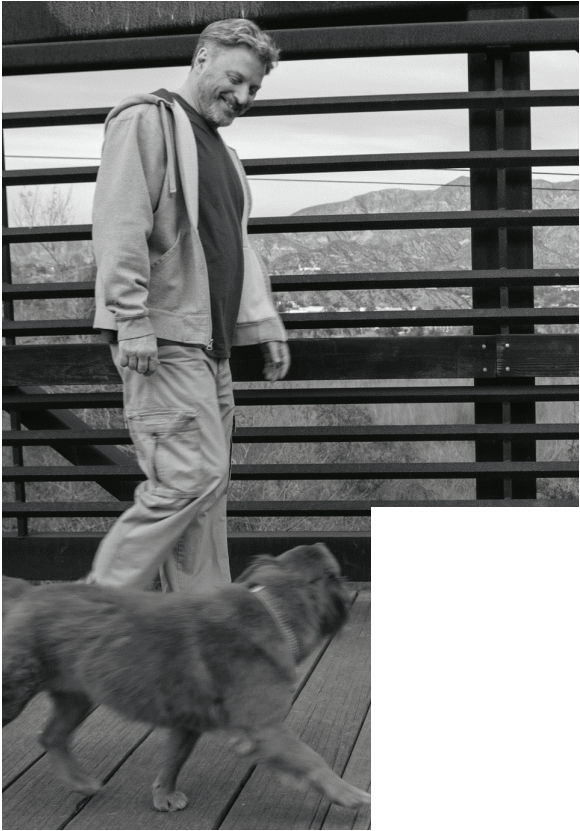
Therapy settings - Your Medtronic DBS

Therapy can be adjusted by changing the rate, amplitude, or pulse width of the electrical stimulation. Your clinician will adjust the programming of these therapy settings if appropriate.

Transcranial magnetic stimulation (TMS) -

The use of magnetic energy to stimulate the brain for diagnostic or therapeutic purposes.

Ultrasound - The use of high frequency sound waves for diagnostic or therapeutic purposes.**Warning** - A statement that describes an action or situation which could seriously harm you.



Medtronic DBS Patient Therapy Guide

Your therapy guide is designed to provide information about your Medtronic deep brain stimulation (DBS) system. Ask your clinician to explain anything that may be unclear.

The DBS Therapy-specific Patient Manual provides important DBS therapy information specific to your medical condition.

You should also receive a manual instructing you how to operate your patient control device.

If you do not have these manuals, contact your doctor.

If you are living in certain countries, you may also receive additional patient information.

Keep all your patient information together because they both provide important information for you and for your health care providers.

Most of the information you need to know is found in this DBS Patient Therapy Guide, however be sure to read the DBS Therapy-specific Patient Manual for important information regarding DBS therapy and your specific medical condition.

DBS patient guides

In addition to the DBS Patient Therapy Guide and the DBS Therapy-specific Patient Manual, you will receive the following manuals:

- Patient control device user guide
- Quick reference card
- Patient implant card or patient identification card (or both)
- Purpose of DBS therapy (indications) sheet

Table 1.1 lists all the patient materials that you should receive with your DBS therapy system.

The patient materials may vary depending upon geography.

Table 1.1 Patient guides provided with the Medtronic DBS therapy system

Patient guides	DBS system
<i>DBS Patient Therapy Guide</i> provides basic DBS therapy information	Nonrechargeable and rechargeable systems
<i>DBS Therapy-specific Patient Manual</i> provides DBS therapy information specific to your medical condition	Nonrechargeable and rechargeable systems
<i>Patient Programmer or Therapy Controller User Guide</i> describes the patient programmer and how to use it with your implanted neurostimulator.	Nonrechargeable and rechargeable systems
<i>Patient Programmer or Therapy Controller Quick Reference Card</i> provides quick instructions for common patient programmer tasks.	Nonrechargeable and rechargeable systems

Table 1.1 Patient guides provided with the Medtronic DBS therapy system (continued)

Patient guides	DBS system
<i>Implant Card or Identification Card</i> provides information about you, your implanted neurostimulator, and your doctor.	Nonrechargeable and rechargeable systems
<i>Purpose of DBS Therapy (Indication) Sheet</i> provides information about the purpose of your brain stimulation system.	Nonrechargeable and rechargeable systems
<i>Charging System User Manual</i> describes the charging system and how to use it with your implanted neurostimulator.	Rechargeable system only
<i>Charging System Quick Reference Card</i> provides quick instructions for common charging system tasks.	Rechargeable system only



Purpose of your DBS system

Refer to the Purpose of DBS Therapy (Indication) Sheet for information specific to your DBS system.

Your DBS system

Your DBS system is implanted inside your body and includes 3 major parts:

The 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. Approximately 10 cm (4 in) of the lead is implanted inside the brain. The rest of the lead is implanted under the skin of the scalp. Whether you have 1 or 2 leads depends upon your medical condition.

The extension—The extension is a set of thin wires covered with a protective coating that connects the lead to the neurostimulator. The extension is connected to the end of the

lead, just behind the ear (or where your doctor decides is the best placement). The connection point between the lead and the extension is placed under the scalp. The remaining length of the extension is placed under the skin down the neck to the upper chest area and connects to the neurostimulator. For each lead, you will have 1 extension.

The neurostimulator—The neurostimulator contains the power source of your DBS system. The neurostimulator generates and controls the therapy stimulation. The neurostimulator is typically implanted just under the skin in the upper chest area.

Additional DBS system components

The Medtronic DBS system includes an external patient control device and if you have a rechargeable neurostimulator you will also receive a charging system.

Patient control device—A patient control device is a hand-held device that you use to:

- Turn your therapy on and off.

- Check the neurostimulator battery.
- In some cases, make adjustments to your therapy settings or perform therapy-specific tasks.

Charging system—The charging system is used to charge the battery of a rechargeable neurostimulator.

Medical procedures that are not allowed (contraindications)

You should not have the following medical procedures if you have an implanted Medtronic DBS System.

Note: Make sure to inform all your doctors and medical professionals that you have an implanted DBS system.

You can show them the information in your DBS Patient Therapy Guide and DBS Therapy-specific Patient Manual. Please request that they contact Medtronic for detailed information about the compatibility of

the DBS system and other medical procedures.

[! USA] In the US, they can call 1-800-510-6735.

Diathermy—Patients who will be exposed to diathermy (deep heat treatment). Inform anyone treating you that you **CANNOT** have any shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) anywhere on your body because you have an implanted neurostimulation system. Energy from diathermy can be transferred through your implanted system, can cause tissue damage and can result in severe injury or death.

Diathermy can also damage parts of your neurostimulation system. This can result in loss of therapy from your neurostimulation system, and can require additional surgery to remove or replace parts of your implanted system.

Personal injury or device damage can occur during diathermy treatment when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on your body (not just where your neurostimulation system is located).
- diathermy is used to deliver heat or no heat.
- any component of your neurostimulation system (lead, extension, neurostimulator) remains in your body.

Certain MRI procedures—Use of a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with any the following implanted DBS systems or system components:

- Activa SC Model 37602 Neurostimulator
- Model 64001 and Model 64002 pocket adaptors implanted with any DBS system

If an MRI is prescribed for you, make sure to tell your doctor that you have an implanted DBS system and that you cannot have an MRI procedure that involves the use of:

- a full body transmit radio-frequency (RF) coil.
- a receive-only head coil.
- a head transmit coil that extends over the chest area.

These types of MRI can cause the electrode tip of the implanted lead or leads to generate heat, resulting in serious and permanent injury (including coma, paralysis, or death).

Medtronic provides detailed guidelines to physicians about performing MRI on patients who have an implanted DBS system. Refer your doctor to Medtronic for the latest MRI guidelines, or to www.medtronic.com/mri (where available).

 In the US, your doctor can call 1-800-510-6735.

Additional safety information about MRI is located later in this manual. For information on the types of MRI scans you may be eligible to receive, refer to the "Probable interference" section under medical and dental environments in "Appendix A: Electromagnetic interference".

For information on what you should do if you have an MRI examination, refer to "Appendix B: MRI examinations".

Transcranial magnetic stimulation therapy

—Transcranial magnetic stimulation therapy (TMS) is contraindicated for patients with any implanted DBS System or system component.

Other contraindications—Patients who are unable to properly operate the DBS System should not have the system implanted.

Refer to your DBS Therapy-specific Patient Manual for any additional contraindications that relate to your specific therapy.

Risks

Medtronic DBS therapy includes risks from surgery and possible side effects after surgery, both of which may include device complications.

Risks from surgery

Implanting the brain stimulation system carries risks similar to other brain surgeries and surgeries not involving the brain.

Risks may include:

- Stroke due to bleeding or blockage of blood flow inside the brain, which can result in coma, paralysis, or death
- Anesthesia-related complications such as low blood pressure, nausea, vomiting, headache, and allergic reaction
- Complications of the lead, neurostimulator, extension, or equipment related to the implant or explant procedure, including mechanical or electrical device complications

- Complications of the extension implant procedure may result in damage to nerves, blood vessels, or other areas of the body near the surgery site
- Leakage of fluid surrounding the brain
- Air may get into or around the brain
- Seizures

Possible side effects after surgery

For additional possible side effects associated with your specific therapy, consult your DBS Therapy-specific Patient Manual.

The following side effects can occur and may be temporary or permanent. Some side effects may be more applicable depending on your medical condition being treated.

- Stroke due to bleeding or blockage of blood flow inside the brain, which can result in coma, paralysis, or death

- Pain, lack of healing, inflammation (redness), swelling, discharge, or drainage at the surgery sites
- Infection, including symptoms of fever or chills
- Infection in the brain or spinal cord
- Swelling or fluid in the brain around the DBS lead that may occur weeks to months after implant and usually presents as new neurological symptoms (weakness, walking difficulties, dizziness, numbness, confusion, speech difficulties, and visual disturbances). Surgical removal of the lead may reduce the amount of swelling and fluid and decrease the neurological symptoms.
- The brain stimulation system parts may wear through your skin, which can cause an infection or scarring.
- The lead or lead-extension connector may move or require readjustment. You may need surgery to readjust the location.

- DBS Therapy could stop because of mechanical/electrical problems or battery depletion. These complications may require surgery.
- Tightening or pulling of tissue underneath the skin that can cause pain, disfigurement, discomfort, and limit head mobility that may occur weeks to years after implant and may require surgery.
- Temporary or permanent neurological symptoms:
 - Worsening of disease symptoms
 - Double vision and other vision problems
 - Trouble swallowing
 - Speech problems, such as trouble speaking louder than a whisper (dysarthria) and/or difficulty forming words (dysphasia)
 - Dizziness or lightheadedness (disequilibrium)

- Facial and limb muscle weakness or partial paralysis (paresis)
- Abnormal, involuntary movements (chorea, dystonia, dyskinesia)
- Movement problems or reduced coordination, including "freezing" and difficulty walking
- Sensations such as tingling or burning (paresthesia)
- Numbness (hypoesthesia)
- Headache
- Confusion, attention problems, memory problems (change in mental status)
- Difficulty with sleeping, unusual dreams
- New or worsening abnormal behaviors, moods, or thoughts that may be temporary or permanent, including:
 - Suicidal thoughts and attempts, suicide, depression
 - Anxiety or panic

- Hyperactivity, sad or happy mood that is very excessive or inappropriate for the situation, hearing or seeing things that are not reality, unusual behaviors that are noticed by family or caregivers, obsessive-compulsive disorder
- Abnormal thoughts
- Moods or behaviors that are new or unusual, such as aggression, impulsiveness, apathy, agitation
- Seizures
- Your body may have an allergic reaction to the brain stimulation system. Your body could also reject the system (as a foreign body).
- Stomach and digestion problems
- Cough associated with DBS
- Jolting, shocking, vibration, or buzzing sensation
- There is the possibility of tissue damage resulting from the programming

parameters or a malfunction of one of the parts of the brain stimulation system.

- Weight gain or loss

Note: Contact your doctor if you experience any of these side effects.

For EU only: The Summary of Safety and Clinical Performance (SSCP) can be found at <https://ec.europa.eu/tools/eudamed>. Search for the SSCP using the manufacturer (Medtronic), device name (trade name), and device model number.

Warnings

Also refer to "Medical procedures that are not allowed (contraindications)" on page 24.

Refer to "Physical activities" on page 53 for additional warnings.

Certain MRI procedures—Some types of MRI could possibly result in movement, heating or damage to the implanted DBS System. This can cause serious and

permanent injury including coma, paralysis, or death.

Additional safety information about MRI is located later in this manual. For information on the types of MRI scans you may be eligible to receive, refer to the "Probable interference" section under medical and dental environments in "Appendix A: Electromagnetic interference".

For information on what you should do if you have an MRI examination, refer to "Appendix B: MRI examinations".

Electromagnetic interference (EMI)—

Electromagnetic interference is a field (electrical, magnetic or a combination of both) that is generated by various equipment found in medical, work, and home environments.

Electromagnetic interference could cause:

- **serious injury or death**, resulting from heating of the implanted system components, which can damage surrounding tissue.

- **system damage**, requiring surgical replacement; or result in a loss of, or change in, symptom control.
- **changes in your neurostimulator function**, causing it to switch on or off, or reset to factory settings, which may result in loss of stimulation, return of symptoms, and require reprogramming by your doctor.
- **unexpected changes in stimulation**, causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as “jolting” or “shocking.”

For complete information regarding EMI warnings, please see "Appendix A: Electromagnetic interference" on page 73.

Case damage—If the neurostimulator is ruptured or pierced after implant due to outside forces, severe burns could result from exposure to battery chemicals.

Excessive stimulation—There is the possibility of brain tissue damage from high

stimulation settings or a malfunction of one of the parts of the neurostimulator.

Medications that slow blood clotting—If you are a candidate for implant surgery and are taking medications that slow clotting of the blood (anticoagulants such as aspirin or warfarin), inform your doctor. These medications increase the risk of bleeding during surgery.

Medications, over-the-counter drugs, and nutritional supplements—Inform your doctor about any medications, over-the-counter drugs, or nutritional supplements that you are taking. Some may have harmful effects when combined with DBS Therapy.

Psychotherapeutic procedures—Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (such as electroconvulsive therapy) in patients who have an implanted DBS System.

Component failures—The DBS System may unexpectedly stop working due to the battery wearing out or other causes. The symptoms you had before your system was implanted will likely return if the device stops working.

Patient activities and environmental warnings—You should exercise reasonable caution to avoid items that generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause your neurostimulator to switch on or off. Your implanted system also may unexpectedly cease to function due to battery depletion or other causes. For these reasons, you should use caution while performing any activities that would be potentially unsafe if your symptoms unexpectedly return.

Refer to "Appendix A: Electromagnetic interference" on page 73, for more information about possible sources of EMI.

DBS System explant and EMI considerations—If any DBS System components (neurostimulator, lead,

extension, or lead-extension fragment) remain implanted in your body after a partial system explant, the remaining components may be affected by EMI. These effects include induced current and component heating, which may result in shocking or jolting, or tissue damage resulting in serious injury or death. Therefore, if your DBS System is surgically removed, ask your doctor if any components still remain in your body. If so, be sure to always tell any medical personnel that you have an implanted DBS System so they can take the necessary precautions.

Pushing or twisting the implanted parts of your system—Avoid pushing or twisting the implanted parts of your system, such as the neurostimulator. This can damage the system or cause skin erosion. This may require surgery.

Precautions

Multiple implants—The long-term safety associated with implanting more than one

lead on the same side of the brain is unknown.

Activities requiring coordination—Loss of coordination is a possible side effect of DBS Therapy. You should use caution when doing activities that require coordination, even if you were able to do them before receiving DBS Therapy (for example, swimming).

Bathing—Patients should exercise reasonable caution when bathing.

Expected battery life

The length of time the battery will last depends on your programmed settings and the amount of time you use your neurostimulator.

For a rechargeable neurostimulator, battery life can be influenced by how well you have maintained the battery charge level. For more information see, Chapter 4 "Important information about rechargeable neurostimulators" page 59.

The battery is a permanent part of the neurostimulator. To replace the battery, your doctor must replace the neurostimulator. This is a minor surgical procedure and is typically done as an outpatient surgery, using a local anesthetic. It does not require the use of a head frame.



Your implant procedure

The DBS implant procedure may vary depending on the medical condition being treated.

Before surgery

Preparation for the implant procedure varies depending on the type of DBS therapy you are receiving. Refer to the DBS Therapy-specific Patient Manual for information on what to expect before surgery.

The day of surgery

Your surgery may consist of these steps:

1. A metal frame will be attached to your head. The frame is a special instrument that allows your surgeon to find the correct path to the target site in your brain.
2. Your surgeon will review MRI (magnetic resonance imaging) and CT (computer-aided tomography) scans of your brain to

determine where the lead or leads will be placed.

3. You will then go to the operating room. Your doctor will numb an area of your scalp before creating a small hole in your skull for each lead. This hole is needed to place the lead in your brain. Later in the surgery, a cap will be placed over this hole.
4. Your doctor will place the lead or leads inside your brain.

Note: How the doctor locates the appropriate area of your brain for placing the lead depends on the type of DBS therapy you receive. Refer to your DBS Therapy-specific Patient Manual for more information about this step.

5. The lead will be locked in place on the outside of your skull with a specially-designed cap. After each lead is secured in a cap, the metal frame will be removed from your head.

Extension and neurostimulator placement¹

If you do not have the extension and the neurostimulator implanted at the same time as the lead, you will typically be allowed to go home in approximately 24 to 48 hours. Your doctor will decide the length of your hospital stay.

When you have the extension and neurostimulator implanted, you will be sedated and asleep. You will typically be allowed to go home in approximately 24 to 48 hours. Your doctor will decide the length of your hospital stay.

After surgery

Your doctor will decide when to turn on your DBS therapy. It may be turned on immediately after surgery or after you have had time to heal (about four weeks).

¹ For a description of the complete DBS system, see "Your DBS system" on page 21.

First programming

Your doctor will use a device called a clinician programmer to turn on your neurostimulator and adjust your therapy settings. Depending on the type of DBS therapy you are receiving, you may have to return to the clinic a few times during the first few months after surgery in order for your doctor to fine tune your therapy settings.

Patient implant card and patient identification card

Depending on your geography, you may receive more than one card. Talk to your doctor about the type of patient implant card or patient identification card that you should receive when you leave the hospital. These cards provide information about you, your implanted device, and your doctor. Your patient cards may allow you to bypass security devices. Carry these cards with you at all times and bring them with you to all MRI appointments (see "Appendix B: MRI examinations" on page 93).

If you move, change doctors, or lose your card, contact Medtronic for a replacement card. Refer to the Medtronic contacts at the end of this manual.

[! USA] A temporary identification card will be provided at the hospital. After Medtronic receives your implant registration from the hospital, you will receive a permanent identification card.

Recovering at home

After your surgery, your doctor or nurse will give you instructions about care at home. These instructions often include information about the healing process after surgery, medication to take, and when to return to your daily activities.

Healing

It takes several weeks to heal from surgery. You may feel some discomfort from the incision site, and discomfort or pain at the neurostimulator site during the healing

process. If you notice unusual symptoms, contact your doctor.

Medication

Always follow your doctor's instructions for taking medication.

Daily activities and exercise

During your recovery, follow your doctor's instructions. On the advice of your doctor, you should be able to return to your normal lifestyle after a period of healing.

Returning to your daily activities should make you feel better, not worse. Ask your doctor about activities that include bending of your neck, raising your arms over your shoulders, or strenuous activities such as lifting heavy objects.

Use care when you choose any activities that may result in accidents or falls. Sudden jerky movements may cause the lead(s) to move. Falls may damage parts of the implanted system. Surgery may be needed to repair or replace the components of your DBS system.

For more information about your activities, see the following sections in this chapter.

What you should know

The following guidelines about your DBS system will help to ensure that you receive the safest and most effective treatment.

Note: Make sure to read Chapter 2 "Your DBS system" for additional precautions.

- **Always tell any medical personnel that you have an implanted brain stimulation system and tell them where it is located.** If they have any questions, they should contact Medtronic.

[! USA] In the US, they can call 1-800-510-6735.

- If you experience any unusual symptoms that you think may be related to your neurostimulator, contact your doctor.
- If you have a family member or caregiver, ask them to read your DBS patient therapy manuals along with you. There

may be situations when you need their assistance.

- Go to all follow-up appointments. This will ensure that you get the best care.
- Check your neurostimulator battery. The instructions are found in your Patient Programmer User Manual.
 - If you have a nonrechargeable neurostimulator, your doctor will tell you how often to check your battery status.
 - If you have a rechargeable neurostimulator, read Chapter 4 "Important information about rechargeable neurostimulators" on page 59.

When to call your doctor

Call your doctor if any of the following situations occur:

- You experience pain, redness, or swelling along the scalp, neck, or chest where the stimulation system is implanted.

- You are not receiving relief from your symptoms and it appears that the neurostimulator is turned on.
- You feel uncomfortable or painful sensations during stimulation. First, turn off the neurostimulator, then call your doctor.
- You cannot turn on or turn off the neurostimulator.
- You experience unexpected changes in your symptoms.
- You experience any unusual symptoms that you think may be caused by electromagnetic interference (eg, theft detectors).
- You lose your patient control device or any charging system component.²

² Rechargeable DBS systems only.

Reporting a serious incident

If you experience any unusual side effects related to your therapy or encounter a serious incident with your device, report it immediately to your clinician. Your clinician will help manage your symptoms and may report the incident to Medtronic and to the applicable competent authority.

Physical activities

Make sure to protect your implanted DBS system by avoiding the following activities or following the warnings associated with these activities. You should also discuss your activities with your doctor.

- ⚠ **Activities requiring excessive twisting or stretching**—Avoid activities that may put undue stress on the implanted components of your DBS System. Activities that include sudden, excessive, or repetitive bending, twisting, or stretching can cause component fracture

or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component.

 Scuba diving or hyperbaric chambers

—You should not dive below 10 meters (33 feet) of water or enter hyperbaric chambers above 2.0 atmospheres absolute (ATA). Pressures below 10 meters (33 feet) of water (or above 2.0 ATA) could damage the DBS System. Before diving or using a hyperbaric chamber, discuss the effects of high pressure with your doctor.

 Skydiving, skiing, or hiking in the mountains—High altitudes should not affect the DBS System, however, you should consider the movements involved in any planned activity and avoid putting undue stress on the implanted system. For example, during skydiving, the sudden jerking that occurs when the

parachute opens may cause lead dislodgement or fractures, which may require surgery to repair or replace the lead.

Commonly asked questions

Will the neurostimulator show through my clothes?

Depending on your body build, the neurostimulator may be noticeable as a small bulge under the skin. However, your doctor will try to place the neurostimulator in a place that is most comfortable and cosmetically acceptable.

What does stimulation feel like?

You may not feel stimulation. You will experience the effects of stimulation when it reduces the symptoms of your medical condition. Some people may feel a brief tingling sensation when the therapy is first turned on. Higher levels of stimulation have

been described as uncomfortable, “jolting” or “shocking” by some patients.

Does the brain stimulation system make any noise?

No.

What happens if the neurostimulator stops working?

The symptoms of your medical condition will return. If you can’t determine the possible cause and correct the problem, contact your doctor.

Will I be able to increase or decrease the strength of stimulation?

In many cases, the strength of stimulation can only be changed by your doctor. Some patients with an implanted neurostimulator can change stimulation settings by using a patient control device. Consult with your doctor to determine if you can increase or decrease the strength of stimulation.

Will I be able to resume my normal daily activities?

For the first few weeks after surgery, you should avoid strenuous activity, and arm movements over your shoulder, and excessive stretching of your neck. You may gradually want to try activities that were difficult before your surgery. Talk about this with your doctor first.

Can stimulation be used during pregnancy?

The safety of using DBS Therapy during pregnancy or delivery is not known. If you learn, or think, that you are pregnant, call your doctor immediately.

What should I do if the stimulation changes or becomes uncomfortable?

Contact your doctor immediately.

More about Medtronic DBS Therapy

For additional information about DBS Therapy, use these resources:

- Medtronic website: www.medtronic.com
- Medtronic contacts listed at the end of this manual.
- Your doctor.



The information in this chapter is only applicable for rechargeable neurostimulators. If you have a rechargeable neurostimulator, your clinician will show you how to recharge the internal battery.

If you do not have a rechargeable neurostimulator, then you do not need to read this chapter.

Your responsibilities

A rechargeable neurostimulator should only be implanted if:

- you are willing and able to incorporate the required recharging activities into current activities of daily living.
- you can use the patient control device and understand the icons that appear on the screen.
- you can regularly check the status of the rechargeable battery and respond appropriately.

- you can accurately locate the implanted neurostimulator, properly position the recharger over the neurostimulator, and monitor progress while recharging the battery.
- you can perform charging activities for sufficient duration and frequency to maintain therapy and to perform charging activities on an ongoing basis.
- you are willing to use the patient control device alert or a different method that will be effective in reminding you to check the battery status on a daily basis.
- you (and your caregiver) are willing to continue recharging activities as necessary under all circumstances, eg power outages, travel, and hospitalizations, and recognize the high importance of maintaining a charged battery in the neurostimulator.

Checking the neurostimulator battery

You should check the neurostimulator battery charge level status every day.

 **Warning:** It is very important to check every day that your neurostimulator battery is charged. If the therapy provided by your neurostimulator should stop due to the battery not being charged, 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 that meets your needs, and is recommended by your doctor (for example, weekly or daily) to keep your battery charged. If you have technical problems while charging your battery, contact your physician or Medtronic customer support.

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. 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.

Check and charge: make it a habit

Because this habit is so important, make it a priority to check and charge your neurostimulator battery on a regular schedule.

- Check your battery charge level at the same time every day (your doctor can set

the patient control device 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 one night).
- Allow enough time to fully charge the neurostimulator. Depending on the charge level of the battery when you begin recharging, this could take up to 2 hours for Percept RC, or up to 4 hours for Activa RC. If the charge level is completely depleted or the charging session is not efficient, charging the neurostimulator may require more than 12 hours for Activa RC.

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 when your therapy is turned off, the neurostimulator battery is still working. 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.

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



Neurostimulator disposal

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

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

Specifications

Table 5.1 DBS System Neurostimulator specifications^{ab}

Neurostimulator model	Size	Weight	Power source
Percept PC Model B35200	6.8 cm x 5.1 cm x 1.1 cm (2.6 in x 2.0 in x 0.4 in)	61 g (2.2 oz)	3.2 V Hybrid combined silver vanadium oxide battery
Percept RC Model B35300	5.7 cm x 4.7 cm x 0.6 cm (2.2 in x 1.9 in x 0.2 in)	29 g (1.0 oz)	Lithium ion rechargeable battery
Activa PC Model 37601	6.5 cm x 4.9 cm x 1.5 cm (2.6 in x 1.9 in x 0.6 in)	67 g (2.4 oz)	3.2 V Hybrid combined silver vanadium oxide battery

Additional information 5

Table 5.1 DBS System Neurostimulator specifications^{ab} (continued)

Neurostimulator model	Size	Weight	Power source
Activa RC Model 37612	5.4 cm x 5.4 cm x 1.1 cm (2.1 in x 2.1 in x 0.4 in)	40 g (1.4 oz)	Lithium ion rechargeable battery
Activa SC Model 37602	5.5 cm x 6.0 cm x 1.1 cm (2.2 in x 2.4 in x 0.4 in)	45 g (1.6 oz)	3.2 V Hybrid combined silver vanadium oxide battery
Activa SC Model 37603	5.5 cm x 6.0 cm x 1.1 cm (2.2 in x 2.4 in x 0.4 in)	45 g (1.6 oz)	3.2 V Hybrid combined silver vanadium oxide battery

^a For information about your neurostimulator battery life, see your DBS Therapy-specific Patient Manual.

^b All measurements are approximate.

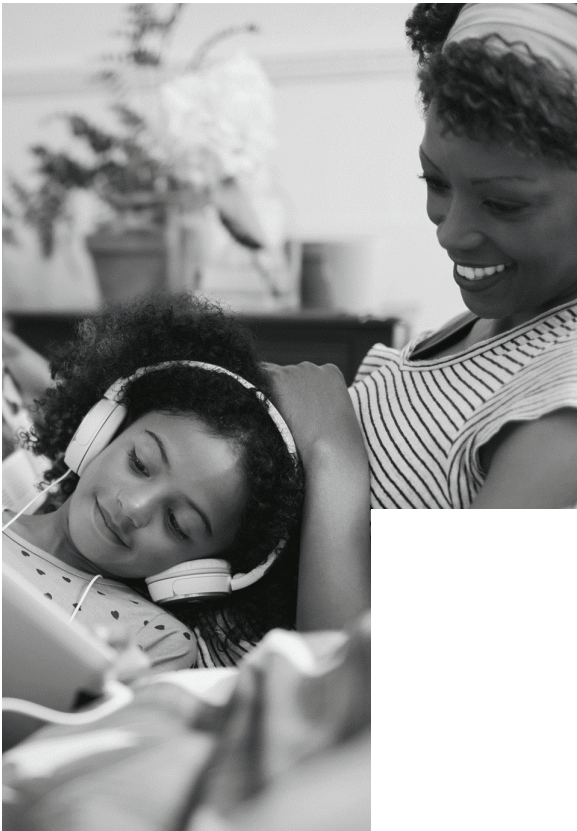
Table 5.2 Materials and substances to which you can be exposed^a

Description	Specification
Percept PC Model B35200	Titanium Silicone rubber
Activa RC Model 37612	Silicone medical adhesive
Activa SC Model 37603	Polysulfone
Percept RC Model B35300	Titanium Polysulfone with titanium dioxide Silicone
Activa SC Model 37602	Titanium
Activa PC Model 37601	Silicone rubber Silicone medical adhesive Polyurethane
Lead	Polyurethane Platinum iridium
Extension	Polyurethane Silicone rubber Stainless steel Titanium Titanium dioxide
Burr hole device	Polyamide Titanium Titanium dioxide
Connector plug	Polyurethane

Table 5.2 Materials and substances to which you can be exposed^a

Description	Specification
-------------	---------------

^a For a complete list of materials, contact your doctor.



About electromagnetic interference

Electromagnetic interference (EMI) is a field (electrical, magnetic or a combination of both) that is generated by various equipment or environmental devices found in medical, work, and home environments.

These EMI sources may create enough interference to:

- turn your neurostimulator off or on.
- cause stimulation that can result in an uncomfortable sensation.
- reset your neurostimulator to factory settings, which will require reprogramming by your doctor.

Your neurostimulator is designed to protect against most sources of EMI. However, strong electromagnetic fields and permanent magnets can interfere with your system.

Even if your therapy is turned off, EMI can affect your implanted system.

If you think that EMI is interfering with your DBS Therapy, you should do the following:

- Move away from the equipment or object causing the EMI.
- If possible, turn off the equipment or object causing the EMI.
- If necessary, use the patient control device to return your neurostimulator to the desired on or off state.
- Inform the equipment owner or operator of what happened.

If these actions do not correct the effects of the interference, or if you think that your DBS Therapy is not effective after exposure to EMI, then contact your doctor.

Note: To help you quickly locate information about an item, refer to "EMI lookup table" page 89.

Theft detectors and security gates

Walking through some theft detectors or security gates can cause an increase in stimulation or additional stimulation. It could also turn on or turn off your neurostimulator.

Use care when approaching security arches or gates (such as those found in airports, libraries, and some department stores). If an airport security wand is used, ask the security personnel to avoid placing the wand over your neurostimulator.

When approaching these devices, do the following:

1. If security personnel are present, show them your neurostimulator identification card and request a hand search.
2. If you must pass through the security device, approach the center of the device and walk normally.

3. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.
4. If one gate is present, walk as far away as possible from it.

Note: Some theft detectors might not be visible.

5. Proceed through the security arch or gate. Do not touch, lean on, or linger near the security arch or gate.

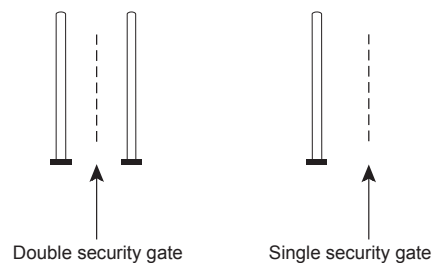


Figure 6.1 Walking through security gates.

6. If you suspect that your neurostimulator was turned off, make sure someone is able to turn on your system again. (The

person could be you, if your medical condition allows it. Or, it could be someone who has been taught how to use the system.)

Home and work environments

Most home appliances and office equipment will not affect your therapy if they are installed properly and in good working order.

Probable interference

Electromagnetic field devices—EMI from electromagnetic field devices may affect or damage the neurostimulator.

The following equipment or environments should be avoided:

- Antennas of citizen band (CB) or ham radios
- Electric arc welding equipment
- Electric induction heaters

- Electric steel furnaces (not home furnaces)
- Electric substations
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets and other equipment that generate strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (safe if outside the fenced area)

Safe from interference

Most household appliances and equipment that work properly and are properly grounded

will not interfere with the neurostimulation system. The following equipment is safe if you follow these guidelines:

- **Computer disk drives:** Keep any disk drives away from your implanted neurostimulator.
- **Freezer, refrigerator, or storm doors:** Do not lean against the magnetic strip that holds the door closed.
- **Induction range:** Keep your implanted neurostimulator away from the burners while the burners are turned on.
- **Power tools:** Keep the power tool motor away from your implanted DBS System.
- **Radio-frequency sources:** Keep AM/FM radios, and cellular, cordless, and conventional telephones at least 10 cm (4 in) away from your implanted neurostimulator.
- **Sewing machine or salon hair dryers:** Keep your implanted neurostimulator away from the motors.

- **Stereo speakers and radios for the home or car:** Do not lift or carry them close to or touching the part of your body where the neurostimulator is located.

Medical and dental environments

Always tell any medical personnel that you have an implanted DBS system and tell them where it is located.

If they have any questions, they should contact Medtronic.

[! USA] In the US, they can call 1-800-510-6735.

Note for medical professional

Turning the neurostimulator off—The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures may result in unforeseen consequences and should therefore be carefully considered based on the patient's underlying medical

condition. Consultation with the appropriate medical professionals (prescribing or implanting clinicians) is recommended.

For more information, contact Medtronic.

 In the US, you can call 1-800-510-6735.

Most routine diagnostic procedures, such as fluoroscopy and x-ray do not affect the implanted DBS System and other procedures can be done when precautions are taken.

However, interference from some medical procedures can:

- damage a component of your system requiring surgery to replace it.
- affect your brain stimulation system, for example, turning your neurostimulator on or off.
- cause harm to you, for example, heating a system component enough that it can cause tissue damage.

Probable interference

The following procedures can damage the neurostimulator or cause harm to you.

Cardioversion—Tell your clinician that you have an implanted device. If you need a scheduled cardioversion, inform both the clinician treating your heart condition (for example, cardiologist) and the clinician managing your DBS system. They can determine the proper programming of the implantable system before the cardioversion procedure.

Diathermy (deep heat treatment)—You should not have diathermy if you have an implanted DBS System. Additional safety information about diathermy is located in the front of this manual.

Refer to the contraindications on page 24.

 **MR Conditional (MRI)** – Depending on the neurostimulation system components implanted, you may be eligible for either an MRI scan of the head only or eligible for an

MRI scan on any part of your body (this is referred to as full-body eligible).

Your clinician managing your neurostimulation system will determine the MRI scan eligibility for your implanted neurostimulation system before your MRI scan.

For your MRI scan, the MRI clinician must follow all conditions given in the *MRI guidelines for Medtronic neurostimulation systems for deep brain stimulation instructions for use* manual.

- **Full-body eligible MRI scans**

The neurostimulation system that is full-body eligible has been designed to minimize the risks associated with an MRI scan of the head, torso, or extremities. An MRI scan may be safely performed under certain specific conditions.¹ Not following the specific conditions can possibly result

¹ Please have your health care professional contact Medtronic for the latest MRI guidelines for your neurostimulation system for deep brain stimulation. Contact information is found at the back of this

in movement, heating, or damage to the implanted system. This can cause serious and permanent injury including coma, paralysis, or death.

- **Head-only eligible MRI scans**

An MRI scan of the head only may be safely performed under certain specific conditions.² However, Medtronic recommends that an MRI should not be prescribed using a radio-frequency (RF) transmit body coil, receive-only head coil, or a head transmit coil that extends over the chest area if you have a head-only eligible implanted neurostimulation system. Exposing you to an MRI using a radio-frequency (RF) transmit body coil, receive-only head coil, or a head transmit

manual, or the health care professional can go to www.medtronic.com/mri (where available).

² Please have your health care professional contact Medtronic for the latest MRI guidelines for your neurostimulation system for deep brain stimulation. Contact information is found at the back of this manual, or the health care professional can go to www.medtronic.com/mri (where available).

coil that extends over the chest area, or not following the specific conditions can possibly result in movement, heating, or damage to the implanted system. This can cause serious and permanent injury including coma, paralysis, or death.

Medtronic provides detailed guidelines to physicians about performing MRI on patients who have an implanted DBS system. Refer your doctor to Medtronic for the latest MRI guidelines or to www.medtronic.com/mri (where available).

For information on what you should do if you have an MRI examination, refer to "Appendix B: MRI examinations" on page 93.

Other procedures – If you require any of the following procedures, please inform your treating doctor that you have an implanted neurostimulator. Your doctor should contact Medtronic for more information.

[! USA] In the US, your doctor can call 1-800-510-6735.

- **Cautery or Electrocautery** (Stops the bleeding of blood vessels. It is used during most surgeries).
- **External defibrillation** (Strong electrical shock that slows a fast heartbeat).
- **Lithotripsy** (The crushing of stones using electricity. These stones are usually in the gallbladder or urinary tract).
- **Recording procedures** Safety has not been established for recording procedures using equipment that generates electromagnetic interference (eg, electromyography, electroencephalogram, or positron emission tomography) in patients with an implanted DBS System.
- **Radiation therapy** (Often used in cancer treatment).

Possible interference

The following procedures may cause possible EMI interference for your DBS System.

- **Dental drills and ultrasonic probes** (used to clean teeth)
- **Electrolysis** (removes unwanted hair)

The following procedures and devices require safeguards:

- **Computerized axial tomography (CT or CAT) scans** (A special type of x-ray equipment that gives a cross-section view).
- **Implanted cardiac devices** (medical device placed inside the body to regulate the heart rate, such as a pacemaker or defibrillator).
Note: Tell your cardiac doctor that you have a neurostimulator.
- **Mammography** (x-ray of breast tissue).
Note: When an x-ray requires tight pressure around the neurostimulator, such as during mammography, tell the person using the equipment that the brain stimulation system should not be squeezed tightly. Too much pressure can

permanently damage the system, which will require replacement surgery.

Safe from interference

The following medical procedures should not affect your therapy:

- **Diagnostic ultrasound** (An imaging technique that uses high-frequency sound waves).
- **Diagnostic x-rays** Diagnostic x-rays do not interfere with the system. However, tight pressure can affect the system, as described above in Mammography.

EMI lookup table

Table 6.1 Potential for interference from EMI^a

Item or procedure	Safe	Possible	Probable
Arc welding equipment			X
CAT (or CT) scan		X	
Cardioversion			X
Cautery			X

Table 6.1 Potential for interference from EMI^a
(continued)

Item or procedure	Safe	Possible	Probable
Cellular phone	X		
Computer disk drive	X		
Defibrillation			X
Defibrillation, implanted		X	
Dental drill or ultrasonic probe		X	
Diagnostic ultrasound	X		
Diathermy treatment			X
Electric power generator			X
Electric substation			X
Electrocautery			X
Electrolysis		X	
Fluoroscopy	X		
Freezer door (magnet)	X		
Furnaces, industrial			X
Hair dryers, salon		X	
Ham radio antennas			X

Table 6.1 Potential for interference from EMI^a
(continued)

Item or procedure	Safe	Possible	Probable
Induction heater, industrial			X
Induction range	X		
Lithotripsy			X
Magnets, industrial			X
Magnetic Resonance Imaging (MRI) - see page 24 and page 93			X
Mammography		X	
Microwave communication transmitter			X
Pacemaker		X	
Power lines			X
Power tool		X	
Psychotherapeutic procedures			X
Perfusion systems			X
Radiation therapy			X
Radios, AM and FM	X		

Table 6.1 Potential for interference from EMI^a
(continued)

Item or procedure	Safe	Possible	Probable
Refrigerator door (magnet)	X		
Resistance welder			X
Security gates		X	
Sewing machine	X		
Smooth top range	X		
Stereo speaker (magnet)	X		
Storm door	X		
Telephone (magnet)	X		
Theft detector		X	
Transmission towers for television and radio signals			X
Ultrasound, diagnostic	X		
Ultrasound, therapeutic			X
X-ray, CAT scan		X	
X-ray, diagnostic	X		

^a Assuming equipment is in proper working order.



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 including your head, torso, and extremities (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

- If you have a rechargeable neurostimulator, be sure to recharge it before the MRI appointment.
- If you have a patient implant card or patient identification (ID) card given to you by Medtronic for your implanted neurostimulation system, be sure to bring your most **current** cards to every MRI appointment.

The patient ID cards show the MRI clinician that Medtronic is the manufacturer of your implanted neurostimulation system. The patient ID cards also identify your lead and neurostimulator models and serial numbers.

The MRI clinician can use this information to obtain instructions to confirm the eligibility of your implanted

neurostimulation system for the MRI scan and the MRI scan safety conditions required by your neurostimulation system.

Note: If you have 2 neurostimulation systems implanted in your body, bring both ID cards and MRI eligibility reports to your MRI appointment.

- Bring the MRI eligibility report for each implanted neurostimulation system to the MRI appointment if you were given one by the clinician managing your neurostimulation system.
- Bring your patient control device to every MRI appointment. However, you cannot take the patient control device into the MRI scanner (magnet) room.

At the MRI appointment

- If you have a patient implant card or patient identification (ID) card given to you by Medtronic for your implanted neurostimulation system(s), present your most **current** card(s) to the MRI clinician.

- Be sure to inform the MRI center that you have an implanted neurostimulation system for deep brain stimulation when you arrive for the appointment.
- If you no longer have an implanted neurostimulator, be sure to inform the MRI clinician of any leads or other components that still remain implanted.
- To obtain the MRI guidelines, the MRI clinician can refer to the contact information at the back of this manual, or the MRI clinician can go to www.medtronic.com/mri (where available).

 **Warning:** Inform the MRI clinician before you enter the MRI scanner (magnet) room that you have an implanted neurostimulation system. If you do not provide this important information, you may be given an inappropriate MRI scan, which could cause you injury or could cause damage to your implanted medical device. The MRI clinician conducting your MRI scan needs to be aware of all

medical implants in order to assess the conditions for safely performing your MRI scan.

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, MRI mode activated, or the system reprogrammed to allow the system to safely remain on during your MRI scan. This will depend on the lead and neurostimulator models 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, which program to select, and if MRI mode should be active during the MRI scan.

If your clinician managing your neurostimulation system instructs you to turn

off therapy, activate MRI mode or change your therapy settings before you receive an MRI scan, refer to your patient programmer user manual for instructions.

If the clinician managing your neurostimulation system has activated MRI mode or changed therapy settings in preparation for the MRI scan, do not change the settings until after the MRI scan, unless instructed to do so.

After the MRI scan

Change the therapy settings (or deactivate MRI mode) when the MRI scan is complete, and you are outside of the MRI scanning area. If you have two implanted neurostimulation systems, remember to change the therapy settings for both systems.

Contact the clinician managing your neurostimulation system if have any concerns about your MRI scan or questions about your implanted neurostimulation system.

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