For the patient – Rx only

Purpose of Medtronic® DBS™ Therapy for Epilepsy

Indications

Medtronic DBS Therapy for Epilepsy is an adjunctive therapy (used along with medications) that delivers electrical stimulation to an area in your brain to reduce the frequency of seizures. The brain stimulation system is used in individuals 18 years of age or older who are diagnosed with epilepsy characterized by partial-onset seizures, with or without secondary generalization, that are not adequately controlled by three or more antiepileptic medications.

The Medtronic DBS System for Epilepsy has demonstrated safety and effectiveness for patients who average six or more seizures per month over the three most recent months prior to implant of the DBS system (with no more than 30 days between seizures). The Medtronic DBS System for Epilepsy has not been evaluated in patients with less frequent seizures.

Use in specific populations

The safety and effectiveness of this therapy is not known for:

- Patients without partial-onset seizures
- Patients who are pregnant or nursing
- Patients younger than 18 years
- Patients at high risk for bleeding (eg, coagulopathies)

Medtronic

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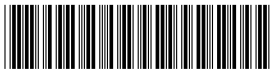

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Medtronic

Your Medtronic® Deep Brain Stimulation Therapy
Patient Therapy Guide

! USA Rx only

CE0123

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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.

You should have two patient therapy manuals:

- The DBS Patient Therapy Guide, which contains information about all DBS therapies.
- The DBS Therapy-specific Patient Booklet, which contains important DBS therapy information specific to your medical condition.

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

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 your doctor at hand if you have any questions or problems.

Label symbols

The following symbols appear within the manual or on the back cover.

CE 0123	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.
EC REP	Authorized representative in the European Community
	Manufacturer
! USA	For USA audiences only

Label symbols

Table of contents

Glossary

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 programmer - A hand-held device that allows you to turn your neurostimulator on and off. It is also used to adjust some stimulation settings.

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 describing an action or situation that could harm you.

Glossary

1 Introduction

Why a 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.

Your patient therapy guide is provided to you in two parts:

- The *DBS Patient Therapy Guide*, which contains information about all DBS therapies.
- The *DBS Therapy-specific Patient Booklet*, which contains important DBS therapy information specific to the patient's medical condition.

If you do not have both the therapy guide and the patient booklet, contact your doctor.

You should keep the guide and the booklet 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 Booklet* for important information regarding DBS therapy and your specific medical condition.

Patient Therapy Guide overview

This guide includes the following information:

- A glossary, provided at the beginning of this guide, explains terms that may not be familiar to you.
- Chapter 1 "Introduction" describes the patient information that you should receive with your DBS system.
- Chapter 2 "Your DBS system" describes the DBS system, including the risks, benefits, warnings, and precautions related to your system.
- Chapter 3 "Living with your DBS system" provides information you need to know

about your implant procedure, living with your DBS system, when you should call your doctor, answers to some commonly asked questions, and information about your patient ID card.

- Chapter 4 "Important information about the rechargeable neurostimulator" provides information for patients with an Activa RC Rechargeable Neurostimulator.
- Chapter 5 "Additional information" provides information about disposal of the neurostimulator and the DBS system specifications.
- "Appendix A: Electromagnetic interference" provides information about electromagnetic interference and how it may affect your DBS therapy.

DBS patient guides

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

- a patient programmer user guide
- a quick reference card
- a patient identification card
- a purpose of DBS therapy (indications) sheet

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

Table 1.1 Patient guides provided with the Medtronic DBS therapy system

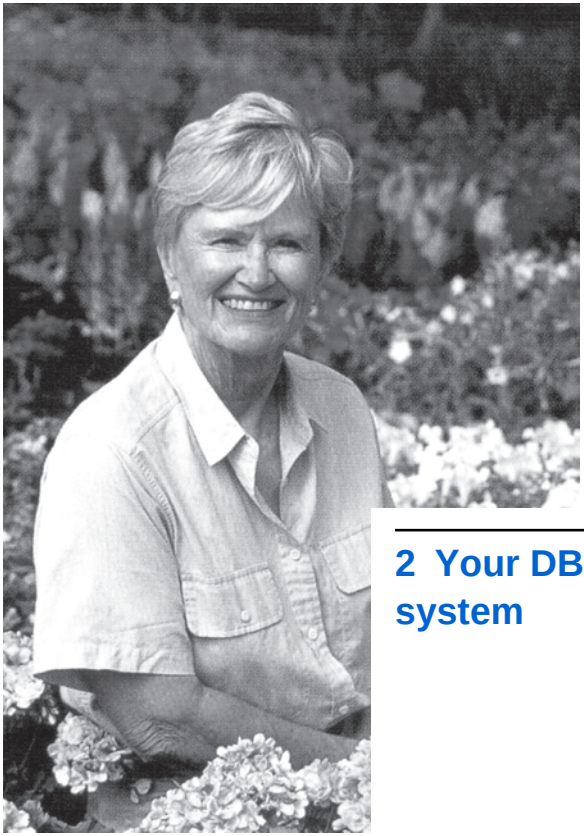
Patient guides	DBS system
DBS Patient Therapy Guide provides basic DBS therapy information	Nonrechargeable and rechargeable systems
DBS Therapy-specific Patient Booklet provides DBS therapy information specific to your medical condition	Nonrechargeable and rechargeable systems

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

Patient guides	DBS system
Patient Programmer or Therapy Controller User Manual describes the patient programmer and how to use it with your implanted neurostimulator.	Nonrechargeable and rechargeable systems
Patient Programmer or Therapy Controller Quick Reference Card provides quick instructions for common patient programmer tasks.	Nonrechargeable and rechargeable systems
Identification Card provides information about you, your implanted neurostimulator, and your doctor.	Nonrechargeable and rechargeable systems
Purpose of DBS Therapy (Indication) Sheet provides information about the purpose of your brain stimulation system.	Nonrechargeable and rechargeable systems

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

Patient guides	DBS system
Charging System User Manual describes the charging system and how to use it with your implanted neurostimulator.	Rechargeable system only
Charging System Quick Reference Card provides quick instructions for common charging system tasks.	Rechargeable system only



2 Your DBS system

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 three 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 (about 38 cm or 15 in) is implanted under the skin of the scalp. Whether you have one or two 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 one extension.

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

Additional DBS system components

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

Patient programmer[1]—A patient programmer 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.

How DBS therapy works

Please read your *DBS Therapy-specific Patient Booklet* for the details of how the DBS system works for your specific medical condition.

[1] The patient programmer used with the Soletra Model 7426 and Kinetra Model 7428 DBS systems is referred to as the Therapy Controller.

The DBS Therapy-specific Patient Booklet also describes additional system components such as the patient programmer.

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 Booklet*. Please request that they contact Medtronic for detailed information about the compatibility of the DBS system and other medical procedures.

See the Medtronic contact information on the back cover of this guide.

! 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:

- Soletra Model 7426 Neurostimulator
- Kinetra Model 7428 Neurostimulator
- 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, (see the addresses at the back of this manual) or to www.medtronic.com/mri.

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

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 Booklet for any additional contraindications that relate to your specific therapy.

Risks

Risks of the Medtronic DBS therapy include the risks of surgery, and possible side effects or device complications.

Risks of surgery

Implanting the brain stimulation system carries the same risks associated with any other brain surgery.

Risks may include:

- Pain, inflammation (redness), swelling, discharge, or drainage at the surgery sites
- Infection, including symptoms of fevers or chills
- Headache
- Confusion or attention problems (change in mental status)
- Bleeding inside the brain (stroke)
- Temporary or permanent neurologic complications
- Leakage of fluid surrounding the brain
- Seizures
- Paralysis, coma, or death
- Allergic response to implanted materials

Possible device complications

- There may be pain, lack of healing, or infection where the brain stimulation system parts are implanted.

- 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 or electrical problems. Either of these would require surgery.
- Your body may have an allergic reaction to the brain stimulation system. Your body could also reject the system (as a foreign body).
- 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.

Possible side effects

Refer to your DBS Therapy-specific Patient Booklet for information about possible side effects of DBS therapy.

Warnings

Also refer to "Medical procedures that are not allowed (contraindications)" on page 27.

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.

Precautions

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.

Lead materials—Over time, there is some risk that the lead could break down. If this would happen, the breakdown materials are known to cause nerve damage or cancer in animals. The chance of these effects occurring in patients who receive the device are not yet known.

Multiple implants—The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the same area of the brain, and lead explant is unknown.

Patient activities and environmental precautions—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 71, 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.

Electromagnetic interference (EMI)

Also refer to "Medical procedures that are not allowed (contraindications)" on page 27.

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.”

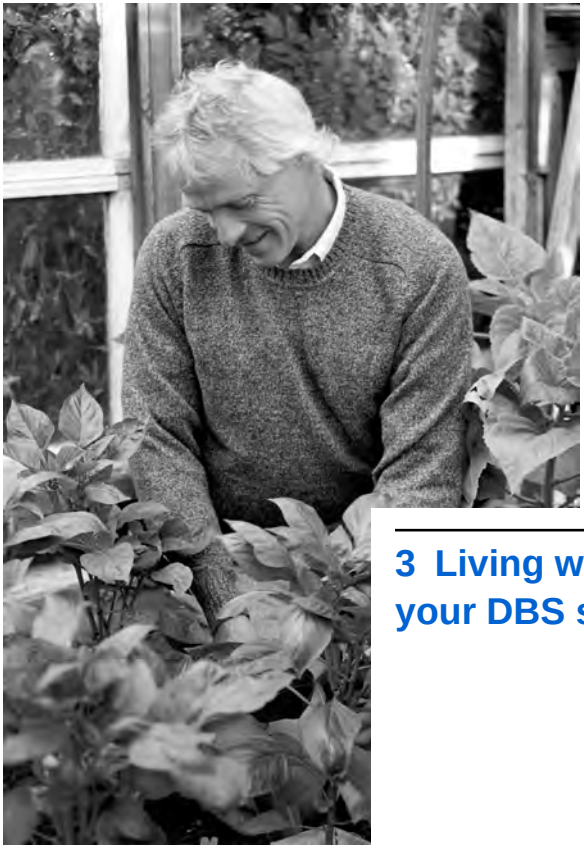
For complete information regarding EMI warnings, please see "Appendix A: Electromagnetic interference" on page 71.

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 the rechargeable Activa RC 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 the rechargeable neurostimulator" page 57.

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.



3 Living with your DBS system

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 Booklet* 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 Booklet* 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 placement[1]

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).

First programming

[1] For a description of the complete DBS system, see "Your DBS system" on page 23.

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 identification card

When you leave the hospital, your doctor will give you a patient identification card. This card supplies information about you, your implanted device, and your doctor. Your identification card may allow you to bypass security devices. Carry this card with you at all times. 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. Refer to the addresses at the back of this manual.

  ! 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 rechargeable neurostimulator, read Chapter 4 "Important information about the rechargeable neurostimulator" on page 57.

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 programmer or any charging system component.[2]

Physical activities

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

[2] Rechargeable DBS systems only.

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 take precautions to 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 programmer. 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.

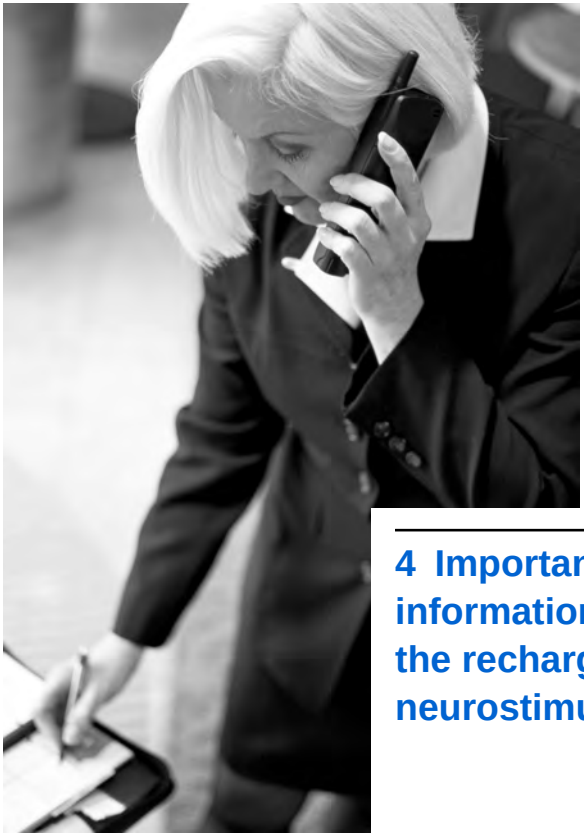
What should I do if the stimulation changes or becomes uncomfortable?

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.



4 Important information about the rechargeable neurostimulator

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

The Activa RC 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 programmer 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 recharge antenna for recharging the battery, put on the recharge holster/belt, 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 programmer 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 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 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 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 programmer alert for this time).

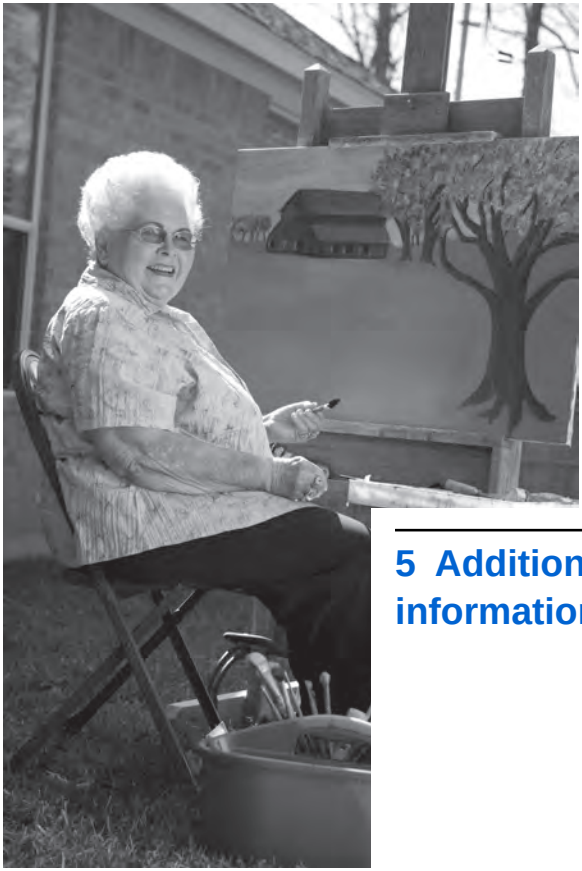
- Combine checking your battery charge level with something else you do every day in order to make it a convenient habit.
- Make sure to bring your neurostimulator recharging system with you when you travel or are hospitalized (even for overnight).
- Allow enough time to fully charge the neurostimulator. Depending on the charge level of the battery when you begin recharging, this could take up to four hours. If the charge level is completely depleted or the charging session is not efficient, charging the neurostimulator may require more than twelve hours.

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.



5 Additional information

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.

Declaration of conformity

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

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

Specifications

Table 5.1 DBS System Neurostimulator specifications[a]

Neurostimulator model	Size (approximate)	Weight	Power source
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
Activa RC Model 37612	5.4 cm x 5.4 cm x 1.0 cm (2.1 in x 2.1 in x 0.4 in)	40 g (1.6 oz)	Lithium ion rechargeable battery
Activa SC Model 37602	6.0 cm x 5.5 cm x 1.1 cm (2.4 in x 2.2 in x 0.4 in)	45 g (1.6 oz)	3.2 V Hybrid combined silver vanadium oxide battery
Activa SC Model 37603	6.0 cm x 5.5 cm x 1.1 cm (2.4 in x 2.2 in x 0.4 in)	44 g (1.6 oz)	3.2 V Hybrid combined silver vanadium oxide battery

Table 5.1 DBS System Neurostimulator specifications[a] (continued)

Neurostimulator model	Size (approximate)	Weight	Power source
Soletra Model 7426	55 mm x 60 mm x 10 mm (2.2 in x 2.4 in x 0.4 in)	42 g (1.5 oz)	3.7 V Lithium-thionyl chloride
Kinetra Model 7428	61 mm x 76 mm x 15 mm (2.4 in x 3.0 in x 0.6 in)	83 g (2.8 oz)	3.2 V Combined silver vanadium oxide

[a] For information about your neurostimulator battery life, see your DBS Therapy-specific Patient Booklet.

Table 5.2 Typical materials in contact with human tissue[a]

Description	Specification
Activa RC Model 37612 Activa SC Model 37603	Titanium Silicone rubber Silicone medical adhesive Polysulfone
Activa SC Model 37602 Activa PC Model 37601	Titanium Silicone rubber Silicone medical adhesive Polyurethane
Kinetra Model 7428	Sheet Titanium Tecothane Titanium Silicone rubber Polymeric insulating film Silicone medical adhesive
Soletra Model 7426	Sheet Titanium Urethane Titanium Silicone rubber Polymeric insulating film Silicone medical adhesive
Lead	Polyurethane Platinum iridium

Table 5.2 Typical materials in contact with human tissue[a] (continued)

Description	Specification
Extension	Polyurethane Silicone rubber Stainless steel

[a] For a complete list of materials in contact with human tissue, contact your doctor.

6 Appendix A: Electromagnetic interference

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

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

Note: To help you quickly locate information about an item, refer to "EMI lookup table" page 85.

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.

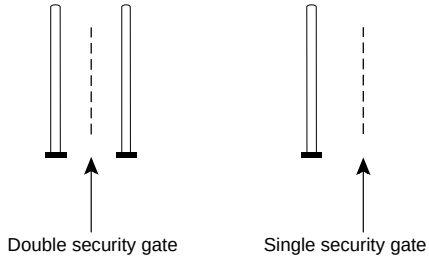


Figure 6.1 Walking through security gates.

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.[1]

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

[1] The Soletra DBS system may be susceptible to interference from household items that contain strong magnets, such as stereo speakers or magnets in appliance doors. See "EMI lookup table" on page 85, for more information.

- 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. Refer to the addresses at the back of this manual.

! 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; refer to the addresses at the back of this manual.

! USA 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.

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 27.

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 in the front of this manual.

Refer to the contraindications on page 27.

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, refer to the addresses at the back of this manual.

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).
- **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.

- **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).

- **Implantable device that senses electrical signals** (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	
Cautery			X
Cellular phone	X	See footnote[b]	
Computer disk drive	X		
Defibrillation, external			X
Defibrillation, implanted		X	
Dental drill or ultrasonic probe		X	
Diagnostic ultrasound	X		
Diathermy treatment			X

Table 6.1 Potential for interference from EMI[a] (continued)

Item or procedure	Safe	Possible	Probable
Electronic power generator			X
Electric substation			X
Electrocautery			X
Electrolysis		X	
Fluoroscopy	X		
Freezer door (magnet)	X	See footnote[b]	
Furnaces, industrial			X
Hair dryers, salon		X	
Ham radio antennas			X
Induction heater, industrial			X
Induction range	X		
Lithotripsy			X
Magnets, industrial			X
Magnetic Resonance Imaging (MRI) - see page 29			X
Mammography		X	

Table 6.1 Potential for interference from EMI[a] (continued)

Item or procedure	Safe	Possible	Probable
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		
Refrigerator door (magnet)	X	See footnote[b]	
Resistance welder			X
Security gates		X	
Sewing machine	X		
Smooth top range	X		
Stereo speaker (magnet)	X	See footnote[b]	
Storm door	X		

Table 6.1 Potential for interference from EMI[a] (continued)

Item or procedure	Safe	Possible	Probable
Telephone (magnet)	X	See footnote[b]	
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.
[b] Possible interference for Soletra DBS systems.

Index

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Medtronic

PATIENT PROGRAMMER 37441

Intercept™ Model 37441 Patient Programmer User Manual for Medtronic® DBS™ Therapy for Epilepsy

! USA Rx only

CE 0123
2010

! USA FCC Information

The following is communications regulation information on the Model 37441 Patient Programmer.

FCC ID: LF537741

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

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

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

Label symbols

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

CE 0123	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.
	Consult instructions for use
	Manufacturer
	Temperature limitation
	Keep dry
IP22	Ingress protection rating IP22, per 60601-1-11
SN	Serial number
PIN No.	PIN number
EC REP	Authorized representative in the European community

Label symbols

! USA	For USA audiences only
	IEC 60601-1/EN60601-1, Type BF Equipment
	Non-ionizing electromagnetic radiation
	Antenna jack
	Magnetic Resonance (MR) Conditional
	Magnetic Resonance (MR) Unsafe
	System meets the applicable (CAN/CSA-C22.2 No. 60601-1) electrical safety standard requirements.
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.
	Chinese Standard (SJ/T11364-2006) Logo: Electronic Information Products Pollution Control Symbol. (The date in this logo means the environmental protection use period of the product.)

Table of contents

Glossary

Active group - Available in Advanced mode only, the active group is the current group selected for your neurostimulator.

Amplitude - The strength or intensity of an electrical pulse.

Aura - A sensation experienced before a seizure.

Caution - A statement describing potentially hazardous situations which may result in minor or moderate injury to the patient or damage to the device.

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

Clinician programmer - A device used by a clinician to send instructions to a neurostimulator.

Contraindication - A condition or circumstance when a person should not have a neurostimulation system.

Cycling - See Stimulation cycle.

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

Electrode - A metal piece near the tip of the lead. Electrodes deliver electrical pulses to a targeted area or areas of the brain.

Electromagnetic interference (EMI) - A strong field of energy near electrical or magnetic devices that could prevent the neurostimulator from functioning properly.

EOS - End of service (EOS). A notification that the neurostimulator has reached its end of service. At EOS, the neurostimulator no longer delivers the electrical pulses that provide therapy.

ERI - Elective replacement indicator (ERI). A notification that the neurostimulator is nearing its end of service.

Group - A group is a collection of therapy settings that your clinician creates for you. Available in Advanced mode only, this feature allows you to choose between the available groups to adjust your therapy as needed.

Implantable neurostimulator (INS) - See Neurostimulator.

Indication - The purpose of the neurostimulation system and the medical condition for which it may be implanted.

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

Neurostimulation system - Components that deliver electrical pulses to provide therapy to the brain.

Neurostimulator - The power source of a neurostimulation system. It contains the battery and electronics that control the therapy that you receive. The neurostimulator is implanted inside the body.

Parameter - One of three therapy settings that adjust the electrical pulse: amplitude, pulse width, and rate of the electrical stimulation.

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

Parameter settings - See Therapy settings.

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

Precaution - See Caution.

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

Program - Therapy directed to a specific brain site.

Pulse width - The length or duration of an electrical pulse.

Rate - The number of electrical pulses delivered each second.

Seizure key - The top left key on the Intercept Patient Programmer. Press this key when you want to record a seizure event or both record a seizure event and reset the stimulation cycle.

Seizure row - The middle row on the Therapy screen. This row displays the number of times you have pressed the Seizure key since your last clinic visit.

Settings - See Therapy settings.

SoftStart/Stop - This feature, programmed by your clinician, starts and stops your therapy gradually by slowly increasing or decreasing to the programmed amplitude or until turned off.

Status row - The top row on the Therapy screen. This row indicates if your therapy is on or off.

Stimulation - The delivery of electrical pulses to an appropriate area of the brain.

Stimulation cycle - This feature, programmed by your clinician, turns your stimulation on and off at regular intervals.

Synchronize - The process of sending and receiving information between the patient programmer and neurostimulator.

Therapy - Treatment of a disease or condition. When neurostimulation therapy is prescribed, a neurostimulation system is used to deliver stimulation to one or more areas of the brain.

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

Therapy settings - Your therapy can be adjusted by changing the rate, amplitude, or pulse width of the electrical stimulation. Your clinician programs all therapy settings. You may be able to adjust some therapy settings within clinician-defined limits. Available in Advanced mode only.

Warning screen - A screen displayed on the patient programmer that alerts you to a problem with the patient programmer, antenna, or neurostimulator.

1 Introduction

How to use this manual

Refer to this manual after you receive an implanted neurostimulator. Ask your clinician to explain anything that is unclear.

- A glossary is provided at the beginning of the manual to describe terms that may be unfamiliar to you.
- Chapter 1 "Introduction", on page 17, describes how to use this manual and the purpose of the patient programmer. It also provides general precautions related to using the patient programmer.
- Chapter 2 "Using your patient programmer", on page 23, describes the patient programmer and how to perform specific tasks.
- Chapter 3 "Using your patient programmer in Advanced mode", on page 71, describes how to perform specific tasks in Advanced mode.
- Chapter 4 "MRI examinations", on page 113, provides information about

what you should do if you have an MRI examination.

- Chapter 5 "Maintenance", on page 127 describes how to care for the patient programmer and lists the patient programmer specifications.
- Chapter 6 "Troubleshooting", on page 139, describes the patient programmer warning and information screens and how to solve possible problems.
- Chapter 7 "User assistance", on page 155 describes where to find the patient programmer serial number and who to contact if the patient programmer is lost or broken.

Note: The values shown in the screen images in this manual are examples only and may not be representative of the

values that appear on your patient programmer.

For important safety information

Please see the DBS patient therapy guide and your DBS therapy-specific patient booklet for important safety information, related risks, warnings and precautions, and additional information about your therapy.

Purpose of your patient programmer

The Intercept Model 37441 Patient Programmer is designed to program the Medtronic Activa PC Model 37601 Neurostimulator.

Purpose of the neurostimulation system (indications)

Refer to the indications sheet that is packaged with the patient programmer for the

purpose of the neurostimulation system and related information.

Precautions

Patient control devices—Do not place your patient programmer over any other implanted device (such as a pacemaker, defibrillator, another neurostimulator). The patient control device could accidently change the operation of another device.

Patient programmer handling—To avoid damaging the patient programmer, do not immerse the device in liquid; do not clean it with bleach, nail polish remover, mineral oil, or similar substances; and do not drop it or handle it in a way that might damage it.

Patient control device use—When operating a patient control device, use special care near flammable or explosive atmospheres (eg, a dentist office). An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using a battery-powered device near

flammable or explosive atmospheres are unknown.

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

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

2 Using your patient programmer

How the patient programmer works

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

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

- Turn your therapy on or off.
- Change therapy settings.[1]
- Record a seizure or aura.
- Reset the stimulation cycle.[2]
- Check the neurostimulator and patient programmer batteries.
- Alert you when you need to check the neurostimulator battery.[1]

[1] Your clinician will program the therapy settings you can adjust depending on your specific therapy needs. Discuss this with your clinician.

[2] Your clinician will turn this feature on or off.

Note: Keep your patient programmer accessible at all times.

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

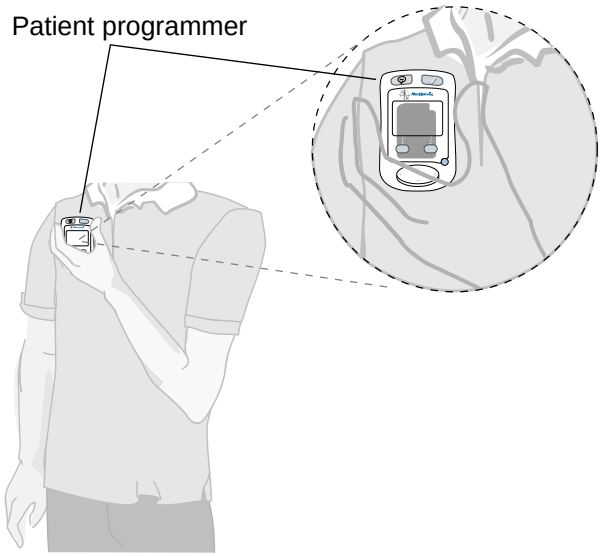


Figure 2.1 Place the patient programmer directly over the neurostimulator.

If you have trouble viewing the patient programmer screen while adjusting your therapy settings or while checking the neurostimulator battery, a detachable antenna is available for use with your neurostimulator system. Contact your

clinician or see "Using the detachable antenna" on page 65 for more information.

Therapy modes

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

- Simple mode uses the therapy settings selected by your clinician. You can adjust the patient programmer preference settings, but only your clinician can adjust your therapy settings.
- Advanced mode uses therapy settings selected by your clinician and also may allow you to change certain therapy settings or select from preset therapy groups. See "Using your patient programmer in Advanced mode" on page 71 for detailed instructions.

Table 2.1 Tasks available for Simple mode and Advanced mode

Tasks	Simple	Advanced
Record a seizure or aura (and reset the stimulation cycle)	Yes	Yes
Turn therapy on or off	Yes	Yes
Check neurostimulator battery	Yes	Yes
Check patient programmer battery	Yes	Yes
Turn audio on or off. This does not change battery alert beeping.	Yes	Yes
Adjust screen contrast	Yes	Yes
Set display to text and icon or icon-only format	Yes	Yes
Adjust therapy settings	No	Yes
Change the active group	No	Yes

The Therapy screen

The **Therapy** screen displays icons and numbers that indicate your therapy settings and the number of times you have pressed the **Seizure** key. See Table 2.2 on

page 30 for a description of these icons and numbers.

There are two versions of the **Therapy** screen: one for Simple mode and one for Advanced mode.

If the patient programmer is set to Simple mode, then the **Therapy** screen displays the **Status** row and the **Seizure** row (Figure 2.2).

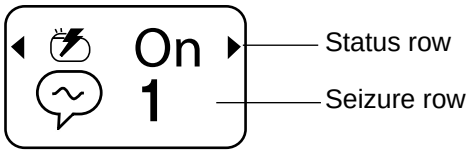


Figure 2.2 **Therapy** screen (Simple mode).

See "Using your patient programmer in Advanced mode" on page 71 for information about the **Therapy** screen in Advanced mode.

Table 2.2 Therapy screen icons and numbers in Simple mode

Row	Icons	Description
Status		Therapy is on
		Therapy is off
Seizure		**Seizure** key count. The number beside this icon indicates the total number of times you have pressed the **Seizure** key since the last time your clinician checked your neurostimulator.

Summary of keys

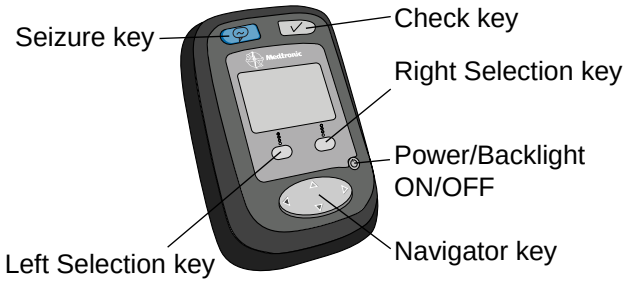


Figure 2.3 Patient programmer keys.

Refer to Table 2.3 for a description of the patient programmer keys.

Table 2.3 Summary of keys

Key	Function
Seizure	Records a seizure or aura. Your clinician may also program the **Seizure** key to reset the stimulation cycle. Raised bumps on the **Seizure** key help you identify the key by touch. The patient programmer (or detachable antenna) must be held directly over the neurostimulator while pressing the **Seizure** key. **Press this key to record a seizure or aura.**
Check	Sychronizes the neurostimulator and patient programmer. The patient programmer (or detachable antenna) must be held directly over the neurostimulator while pressing the **Check** key. **Press this key to synchronize the patient programmer and the neurostimulator.**

Table 2.3 Summary of keys (continued)

Key	Function
 Power / Backlight on/off	Turns the patient programmer and the backlight on or off. The backlight provides more light to the display. **Press and release this key to turn the patient programmer on or off.** **Press and hold this key to turn the backlight on or off.**
 Selection	Turns your therapy on or off. Clears the **Seizure confirmation** screen. See Figure 2.5 on page 36. Selects the patient programmer preference settings. **Press the Selection key under an option displayed on the screen to select that option.**
 Navigator	Navigates to the next available screen. Clears the information screens. See Table 6.3 on page 144. **Press the left ◀ or right ▶ arrows on this key to navigate to the next screen.** **Press any arrow on this key to clear an information screen.**

Using the Seizure key

The **Seizure** key is used to record seizures or auras. Raised bumps on this key help you identify it by touch.

In most cases, your clinician will instruct you to press the **Seizure** key at the first sign of a seizure. Your clinician will discuss with you when to use the patient programmer to record a seizure or aura.

If you are already using a paper journal to record information about your seizures, you should continue to do so. The patient programmer does not replace your paper journal.

The **Seizure** key has two possible settings: 1) to record seizures or auras only, or 2) to record seizures or auras and reset the stimulation cycle. Resetting the stimulation cycle has not been shown to stop a seizure or aura.

Only your clinician can adjust your **Seizure** key settings. Your clinician will decide which

settings are appropriate for you and will program the settings.

You do not need to turn on your patient programmer before using the **Seizure** key or before synchronizing. Using the **Seizure** key to record a seizure or aura automatically turns on the patient programmer.

Complete the following steps to record a seizure or aura.

1. Locate the **Seizure** key.
2. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
3. Press the **Seizure** key (Figure 2.4).

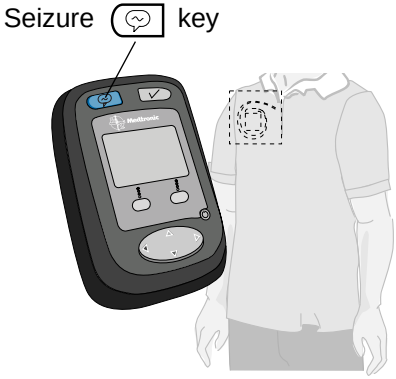


Figure 2.4 Recording a seizure or aura.

If communication between the patient programmer and the neurostimulator is successful, the **Seizure Confirmation** screen appears (Figure 2.5).

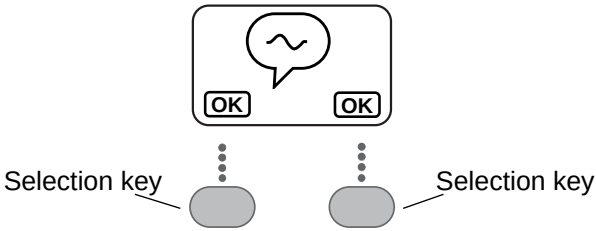


Figure 2.5 **Seizure confirmation** screen.

4. Press either **Selection** key to continue (Figure 2.5).

   The **Therapy** screen appears and the **Seizure** key count increases by one (Figure 2.6).

Figure 2.6 **Therapy** screen (Simple mode).

Notes:

- You do not need to press the **Check** ☑ key (see "Summary of keys" on page 30) before you press the **Seizure** key.
- You must hold the patient programmer over the neurostimulator when you press the **Seizure** key.
- You do not need to hold the patient programmer directly over the neurostimulator to clear the **Seizure Confirmation** screen (Figure 2.5).
- If communication between the patient programmer and the neurostimulator is not successful, the **Position antenna** screen (Figure 2.7) or the **Poor communication** (Figure 2.8) screen appears. See Table 6.3 on page 144 for information on how to proceed when these screens appear.

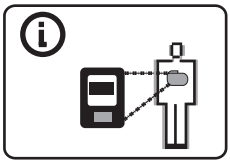


Figure 2.7 Position antenna screen.

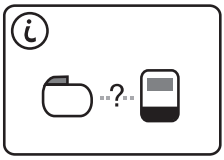


Figure 2.8 Poor communication screen.

Synchronizing the patient programmer and neurostimulator

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

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

1. Locate the **Check** ☑ key.

2. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
3. Press the **Check** ☑ key (Figure 2.9).

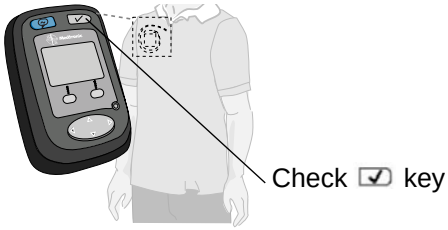


Figure 2.9 Synchronizing the neurostimulator and patient programmer.

Note: Pressing the **Check** ☑ key also turns on the patient programmer.

a. After pressing the **Check** ☑ key, the **Communication** screen (Figure 2.10) appears briefly.

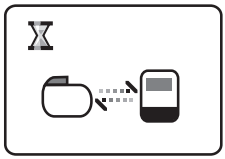


Figure 2.10 Communication screen.

b. If synchronization is successful, the **Therapy** screen appears (Figure 2.11).

Figure 2.11 Therapy screen (Simple mode).

c. If synchronization is not successful, the **Position antenna** screen (Figure 2.12) or the **Poor communication** screen (Figure 2.13) appears. See Table 6.3 on page 144 for information on how to proceed when these screens appear.

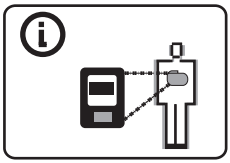


Figure 2.12 Position antenna screen

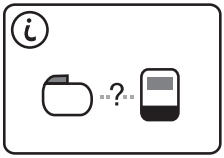


Figure 2.13 Poor communication screen.

For more information about the screens associated with synchronizing the patient programmer and neurostimulator, see "Troubleshooting" on page 139.

Using the Navigator key

The **Navigator** key has left ◀, right ▶, up ▲, and down ▼ arrows (Figure 2.14).

Figure 2.14 Navigator key.

When the Options ◀ ▶ icons appear on a screen, this means more screens are available and can be reached by pressing the left ◀ or right ▶ arrows on the **Navigator** key.

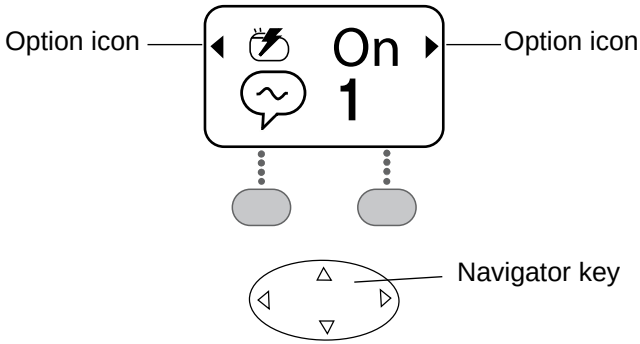


Figure 2.15 Options icons (Simple mode).

To move to a new screen, press the left ◀ or right ▶ arrows on the **Navigator** key.

When pressing the arrows on the **Navigator** key, you do not need to hold the patient programmer directly over the neurostimulator.

Navigating from the Therapy screen

Any of the status or preference screens can be reached from the **Therapy** screen by pressing the left ◀ or right ▶ arrows on the **Navigator** key.

Figure 2.16 Therapy screen.

Some screens can be reached more quickly from the **Therapy** screen by pressing the right ▶ arrow and some can be reached more quickly by pressing the left ◀ arrow.

Navigation from the **Therapy** screen is the same for Simple mode and Advanced mode. Figure 2.17 shows the order in which the screens appear when you press the left ◀ or right ▶ arrows on the **Navigator** key.

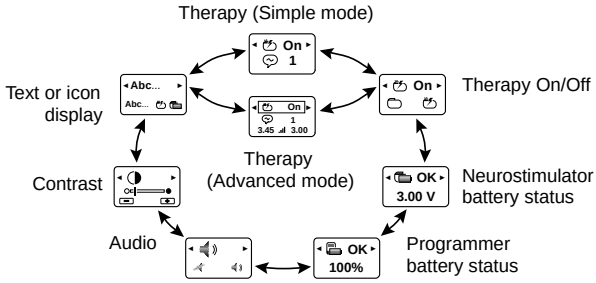


Figure 2.17 Navigating from the **Therapy** screen.

Turning your therapy on

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

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

neurostimulator with the screen facing outward.

b. Press the **Check** ☑ key.

The **Therapy** screen appears. The **Status** icon on the **Therapy** screen indicates whether your therapy is turned on or off (Figure 2.18).

Figure 2.18 **Therapy** screen showing therapy turned off.

2. From the **Therapy** screen, press the right ▶ arrow on the **Navigator** key until you reach the **Therapy on/off** screen (Figure 2.19).

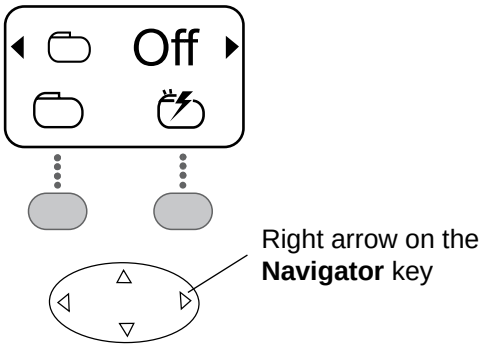


Figure 2.19 Therapy on/off screen.

3. Turn therapy on.

a. Locate the **Selection** key under the therapy **on** icon (Figure 2.20).

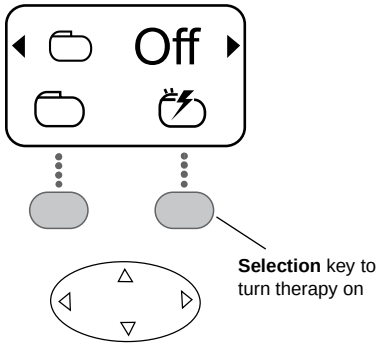


Figure 2.20 Therapy on/off screen.

b. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.

c. Press the **Selection** key under the therapy **on** icon .

4. Press the left ◀ arrow on the **Navigator** key to move back to the **Therapy** screen.

Figure 2.21 **Therapy** screen showing therapy turned on.

Turning your therapy off

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

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears. The **Status** icon on the **Therapy** screen indicates

whether your therapy is turned on or off (Figure 2.22).

Figure 2.22 **Therapy** screen showing therapy turned on.

2. From the **Therapy** screen, press the right arrow on the **Navigator** key until you reach the **Therapy on/off** screen (Figure 2.23).

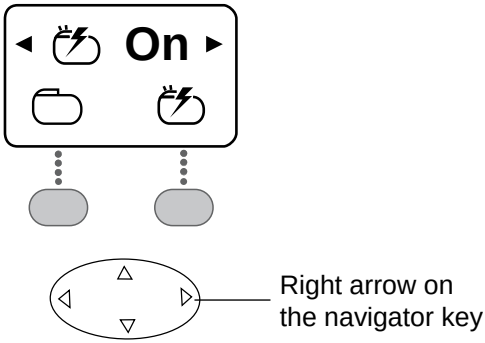


Figure 2.23 Therapy on/off screen.

3. Turn therapy off.

a. Locate the **Selection** key under the therapy **off** icon (Figure 2.24).

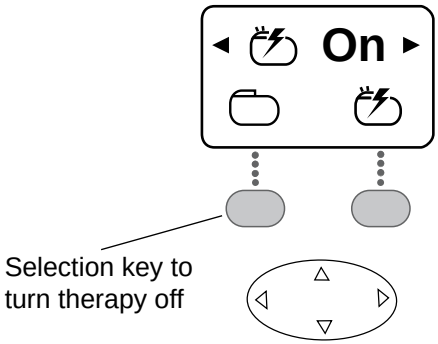


Figure 2.24 Therapy on/off screen.

b. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.

c. Press the **Selection** key under the therapy **off** icon.

4. Press the left arrow on the **Navigator** key to move back to the **Therapy** screen.

Figure 2.25 **Therapy** screen showing therapy turned off.

Note: You do not need to hold the patient programmer directly over the neurostimulator to move back to the **Therapy** screen.

When your therapy is turned off, either the word "Off" (Figure 2.25) or a warning symbol (⚠) flashes on the **Therapy** screen (depending on the patient programmer display preference setting).[3]

Checking the neurostimulator battery

Complete the following steps to check the voltage reading and neurostimulator battery.

[3] See "Changing preferences" on page 60 for more information about display preferences.

Note: Patient programmer batteries are different from the neurostimulator batteries. For information on checking your patient programmer batteries, see "Checking the patient programmer batteries" on page 59.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 2.26).

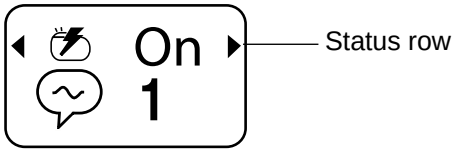


Figure 2.26 **Status** row on the **Therapy** screen.

2. Press the right ▶ arrow on the **Navigator** key until you reach the **Neurostimulator battery status** screen (Figure 2.27).

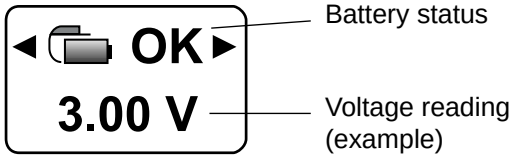


Figure 2.27 Neurostimulator battery status screen.

3. Review the voltage reading and neurostimulator battery status (Figure 2.27). See Table 2.4 on page 56 for possible neurostimulator battery status screens.

Possible neurostimulator battery conditions

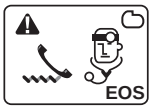
Table 2.4 lists the screens associated with the neurostimulator battery.

For more information about the screens associated with the neurostimulator battery, see "Troubleshooting" on page 139.

Table 2.4 Neurostimulator battery screens

 OK condition	The **Neurostimulator battery status** screen displays OK when the battery is at an acceptable level. The number on the screen indicates the battery voltage level. The voltage reading is used for clinician reference only. **You do not need to take any action.**
 ERI condition	The **Neurostimulator battery status** screen displays ERI when the battery is close to its end of service date. ERI stands for elective replacement indicator. This means that soon your therapy will not be available. **Call your clinician.**

Table 2.4 Neurostimulator battery screens (continued)

 EOS condition	EOS stands for end of service. This warning screen appears when the neurostimulator battery is at the end of service, your therapy has stopped, and the neurostimulator needs to be replaced. **Call your clinician immediately.**
 Neurostimulator battery is low	This information screen appears when you synchronize your neurostimulator and patient programmer and the neurostimulator battery is low. This means that soon your therapy will not be available. **Press any arrow on the Navigator key to clear the screen. Call your clinician to report this message. After you clear this screen, it will appear again once every 24 hours.**

Patient programmer alert

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

The default setting for the alarm is 11:00 am. However, your clinician may change this to a different time of day.

The alert beeps for a total of 30 seconds, with pauses at 10 and 20 seconds. The **Synchronize** screen displays while the alarm is beeping (see Figure 2.28).

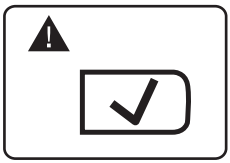


Figure 2.28 Synchronize screen.

This 30-second alert repeats every 15 minutes until the neurostimulator battery status has been checked. Follow the steps in "Checking the neurostimulator battery" on

page 53 to check the neurostimulator battery and automatically clear the alert.

Checking the patient programmer batteries

See "Checking the patient programmer batteries in Simple mode" on page 128 or "Checking the patient programmer batteries in Advanced mode" on page 83.

Changing preferences: audio, contrast, and display format

Preferences are settings for the patient programmer that do not affect your therapy. Preferences you can adjust include audio, contrast, and text or icon display format. Preferences can be reached from the **Status** row of the **Therapy** screen. See "Navigating from the Therapy screen" on page 43 for more information. Table 2.5 lists the preference icons.

Table 2.5 Preference icons

Icons	Preference
	Audio
	Contrast
	Text or icon display format

Changing preferences

Complete the following steps to adjust the patient programmer preferences.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 2.29).

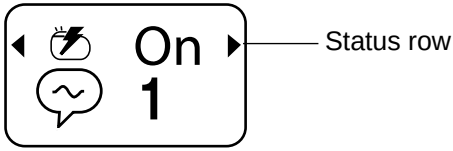


Figure 2.29 **Status** row on the **Therapy** screen.

2. Press the left ◀ arrow on the **Navigator** key until you reach the screen with the desired preference (Figure 2.30)

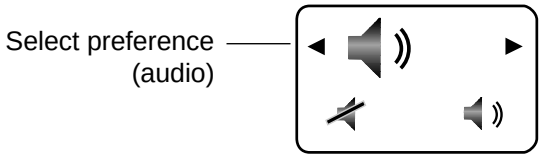
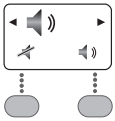
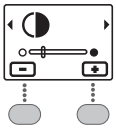
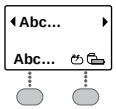


Figure 2.30 Desired preference (audio in this example).

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

Table 2.6 Changing preferences

	**Audio** **a.** Press the appropriate **Selection** key to turn audio off or on . **b.** Continue to step 4.
	**Contrast** **a.** Press the appropriate **Selection** key to make the contrast lighter (○) or darker (●). **b.** Continue to step 4.
	**Text or icon display format**[a] **a.** Press the appropriate **Selection** key to choose whether the patient programmer displays both text and icons Abc... or displays icons only . **b.** Continue to step 4.

[a] The text displayed by the patient programmer will always be in English.

4. Press the left or right arrow on the **Navigator** key to return to the **Therapy** screen.

Note: The **Therapy** screen will show the selected text or icon display format preference that was selected. Additionally, you do not need to hold the patient programmer directly over the neurostimulator to adjust and set preferences.

Accessories

A carrying case and identification label are included with your patient programmer. Two AAA alkaline batteries that provide the power for your patient programmer are also included. Refer to "Checking the patient programmer batteries in Simple mode" on page 128 and "Checking the patient programmer batteries in Advanced mode" on page 83 for information on replacing the patient programmer batteries.

Using the carrying case and labeling the patient programmer

The carrying case has a pouch to hold the patient programmer and the quick reference guide (Figure 2.31).

The carrying case also has a clip on the back that attaches to a belt.

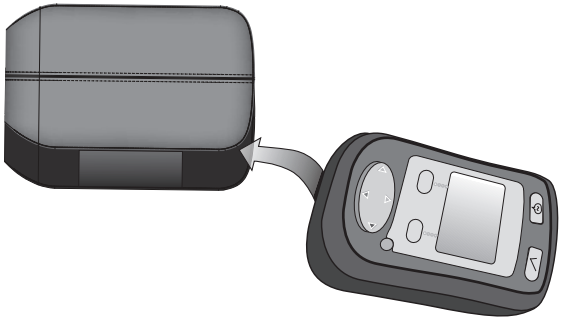


Figure 2.31 Insert the patient programmer into the case.

Place a label on the back of your patient programmer with your clinician's name and phone number in case of an emergency (Figure 2.32). Your clinician may have already done this for you.

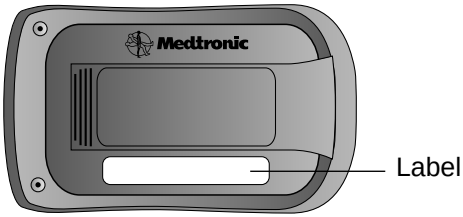


Figure 2.32 Place the adhesive label on the back of the patient programmer.

Using the detachable antenna

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

Complete the following steps to use the detachable antenna.

1. Place the antenna directly over the neurostimulator (Figure 2.33).

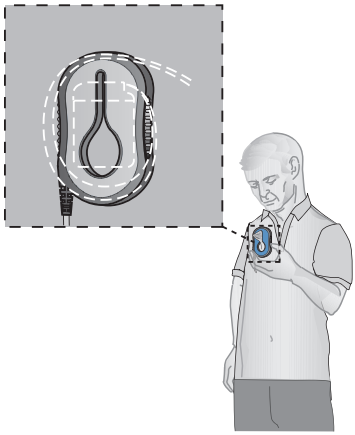


Figure 2.33 Place the antenna directly over your neurostimulator.

2. Pull the fabric of your clothing through the large opening in the antenna. Then, wedge the fabric in the narrow slit to secure the antenna in place (Figure 2.34).

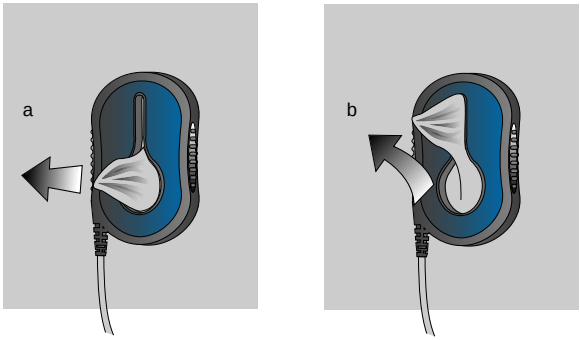


Figure 2.34 Pull the fabric through the slit (a) and wedge in place (b).

3. Push the antenna plug firmly into the antenna jack (Y) on the patient programmer (Figure 2.35).

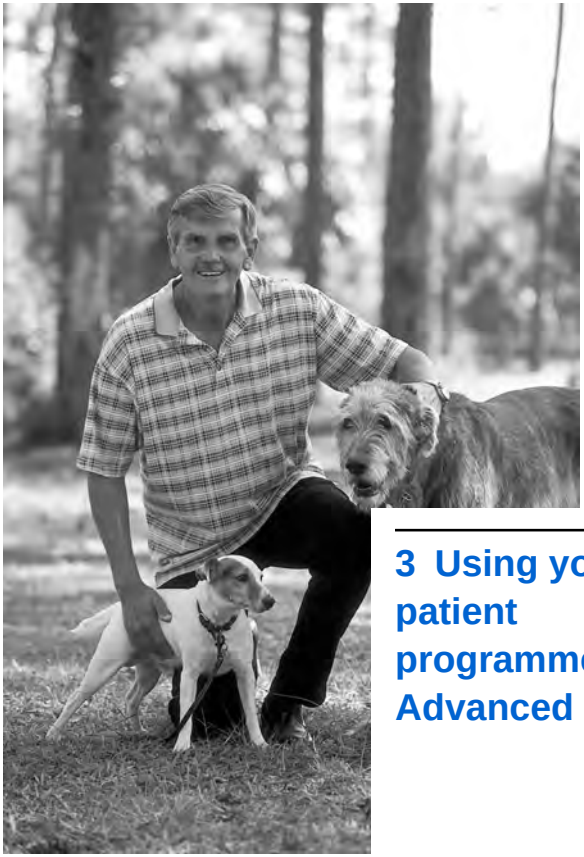
Figure 2.35 Insert the antenna plug into the antenna jack.

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

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

△ **Caution:** Do not pull directly on the antenna cable to disconnect the cable

from the programmer because this may damage the antenna cable.



3 Using your patient programmer in Advanced mode

How the patient programmer works in Advanced mode

There are two therapy modes available for the patient programmer: Simple mode and Advanced mode. The other chapters in this manual explain how to use the patient programmer in Simple mode and describe the features that are identical in both modes. This chapter explains how to use the patient programmer in Advanced mode.

See "Therapy modes" on page 27 for more information about the differences between Simple mode and Advanced mode.

The Therapy screen in Advanced mode

In Advanced mode, the **Therapy** screen displays icons and numbers that indicate your therapy setting, the setting values, and the number of times you have pressed the **Seizure** key. See Table 3.1 on page 73 for a description of these icons and numbers.

If the patient programmer is set to Advanced mode, the **Therapy** screen displays the **Status** row, the **Seizure** row, and the **Parameter/group** row.

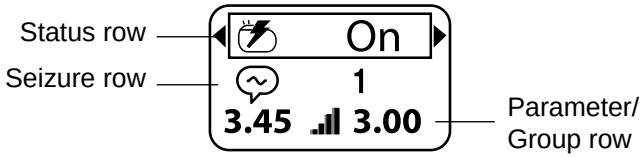


Figure 3.1 **Therapy** screen (Advanced mode).

Table 3.1 **Therapy screen icons and numbers in Advanced mode**

Row	Icons	Description
Status		Therapy is on
		Therapy is off
Seizure		**Seizure** key count. The number beside this icon indicates the total number of times you have pressed the **Seizure** key since your last clinic visit.

Table 3.1 Therapy screen icons and numbers in Advanced mode (continued)

Row	Icons	Description
Parameter/ group[a]		Active group. The numbers beside this icon indicate the parameter settings for that group.
		Amplitude parameter. The numbers beside this icon indicate the amplitude setting.
		Pulse width parameter. The numbers beside this icon indicate the pulse width settings.
		Rate parameter. The numbers beside this icon indicate the rate settings.

[a] The **Parameter/group** row appears only in Advanced mode. If more than one group is available, then the active group is displayed. If only one group is available, no group icon is displayed. Instead, this row displays the adjustable parameter icon for the group.

Summary of keys in Advanced mode

The patient programmer keys have all the same functions in Advanced mode that they do in Simple mode. However, some keys have additional functions available in Advanced mode only. See "Summary of keys" on page 30 for information about patient programmer keys in both Simple mode and Advanced mode.

Table 3.2 Summary of keys (Advanced mode only)

Key	Advanced mode function
☑ Check	Activates a selected group. Activates the "Return to clinician settings".

Table 3.2 Summary of keys (Advanced mode only) (continued)

Key	Advanced mode function
 Selection	Selects the parameter setting for the left or right side of the body. Increases or decreases the setting values. When increasing or decreasing values, the patient programmer (or detachable antenna) must be held directly over the neurostimulator while pressing the **Selection** key. You can either press the **Selection** key multiple times or press and hold the **Selection** key to increase or decrease the settings.
 Navigator	Moves the selection box (Figure 3.2) up or down on the **Therapy** screen.

Using the Navigator key in Advanced mode

In Advanced mode, the **Navigator** key also controls the selection box. The selection box

(Figure 3.2) can be moved to a new row on the screen by pressing the up ▲ or down ▼ arrows on the **Navigator** key. The selection box will only appear in Advanced mode.

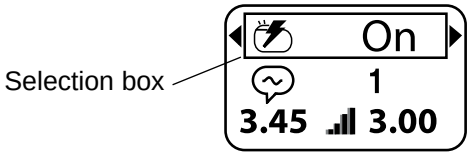


Figure 3.2 The selection box on the **Therapy** screen (Advanced mode only).

To move the selection box to a new row, press the up ▲ or down ▼ arrows on the **Navigator** key.

When pressing the arrows on the **Navigator** key, you do not need to hold the patient programmer directly over the neurostimulator.

Navigating from the Therapy screen in Advanced mode

In both Advanced and Simple modes, any of the status or preference screens can be

reached from the **Status** row on the **Therapy** screen by pressing either the left ◀ or right ▶ arrow on the **Navigator** key. See "Navigating from the Therapy screen" on page 43 for a diagram of status screen navigation.

Turning your therapy on or off in Advanced mode

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

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.3). The **Status** icon on the **Therapy** screen indicates whether your therapy is turned on or off.

2. Confirm that the selection box is on the **Status** row on the **Therapy** screen (Figure 3.3).

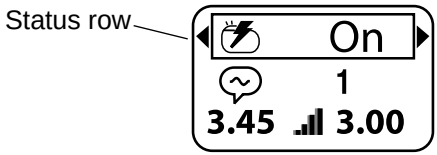


Figure 3.3 **Status** row on the **Therapy** screen.

3. Press the right ▶ arrow on the **Navigator** key until you reach the **Therapy on/off** screen (Figure 3.4).

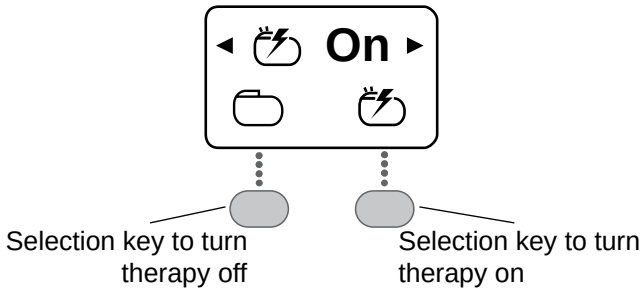


Figure 3.4 **Therapy on/off** screen.

4. Press the appropriate **Selection** key (Figure 3.4) to turn your therapy on or off .
5. Hold the patient programmer or antenna directly over your neurostimulator with the screen facing outward.
6. Press the left or right arrows on the **Navigator** key to move back to the **Therapy** screen.

   Note: You do not need to hold the patient programmer directly over the neurostimulator to move back to the **Therapy** screen.

   When your therapy is turned off, either the word "Off" flashes (Figure 3.5) or a warning symbol ( ) flashes on the **Therapy** screen (depending on the patient programmer display preference setting).[1]

[1] See "Changing preferences in Advanced mode" for more information about display preferences.

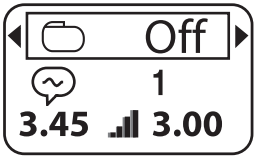


Figure 3.5 **Therapy** screen showing therapy turned off.

Checking the neurostimulator battery in Advanced mode

Complete the following steps to check the neurostimulator battery.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.6).

2. Confirm that the selection box is on the **Status** row on the **Therapy** screen (Figure 3.6).

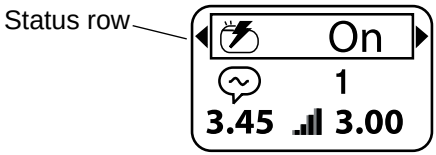


Figure 3.6 **Status** row on the **Therapy** screen.

3. Press the right ▶ arrow on the **Navigator** key until you reach the **Neurostimulator battery status** screen (Figure 3.7).

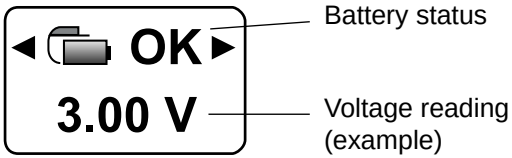


Figure 3.7 **Neurostimulator battery status** screen.

4. Review the voltage reading and the neurostimulator battery status displayed

on the screen (Figure 3.7). See Table 2.4 on page 56 for possible neurostimulator battery status screens.

Patient programmer alert

See "Patient programmer alert" on page 58 for information about alerts.

Checking the patient programmer batteries in Advanced mode

Complete the following steps to check the patient programmer batteries.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.8).

2. Confirm that the selection box is on the **Status** row on the **Therapy** screen (Figure 3.8).

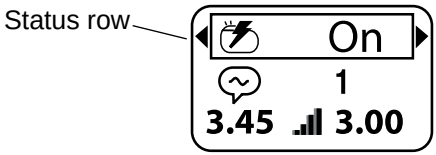


Figure 3.8 **Status** row on the **Therapy** screen .

3. Press the right ▶ arrow on the **Navigator** key until you reach the **Patient programmer battery status** screen (Figure 3.9).

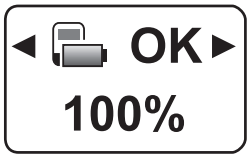


Figure 3.9 **Patient programmer battery status** screen.

4. Review the patient programmer battery status and battery level (Figure 3.10).

The **Patient programmer battery status** screen (Figure 3.9) displays an icon indicating the patient programmer battery level and the percentage of the battery energy remaining (Figure 3.10).

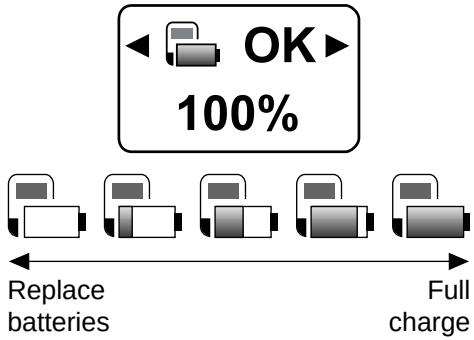


Figure 3.10 Patient programmer battery level.

See "Possible patient programmer battery conditions" on page 132 for more information about battery status screens. If the batteries are low, see "Replacing the patient programmer batteries" on page 133 for replacement instructions.

Changing preferences in Advanced mode

See "Changing preferences: audio, contrast, and display format" on page 59 for information about patient programmer preferences. Complete the following steps to adjust the patient programmer preferences.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.11).
2. Confirm that the selection box is on the **Status** row on the **Therapy** screen (Figure 3.11).

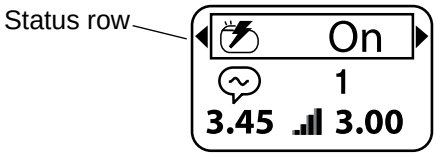


Figure 3.11 **Status** row on the **Therapy** screen.

3. Press the left ◀ arrow on the **Navigator** key until you reach the screen with the desired preference (Figure 3.12)

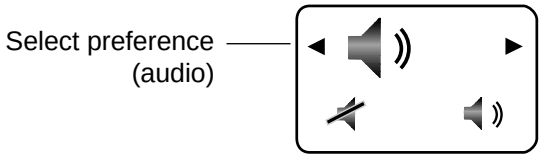
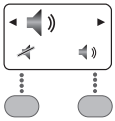
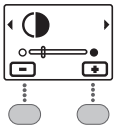
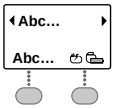


Figure 3.12 Desired preference (audio in this example).

4. Follow the steps in Table 3.3 to change the selected preference.

Table 3.3 Changing preferences

	**Audio** **a.** Press the appropriate **Selection** key to turn audio off or on . **b.** Continue to step 5.
	**Contrast** **a.** Press the appropriate **Selection** key to make the contrast lighter (○) or darker (●). **b.** Continue to step 5.
	**Text or icon display format**[a] **preference** **a.** Press the appropriate **Selection** key to choose whether the patient programmer displays both text and icons Abc... or displays icons only . **b.** Continue to step 5.

[a] The text displayed by the patient programmer will always be in English.

5. Press the left ◀ or right ▶ arrow on the **Navigator** key to return to the **Therapy** screen.

Note: You do not need to hold the patient programmer directly over the neurostimulator to adjust and set preferences.

Understanding your therapy settings (Advanced mode only)

Advanced mode allows you to adjust some of your therapy settings with the patient programmer. Your clinician will provide complete guidelines about when you may want to adjust your therapy.

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

Notes:

- Ask your clinician to print a report with your clinician-programmed settings.
- When a therapy setting is changed, you will see the change on the **Therapy** screen.

- When a therapy setting is changed, and the audio preference on the patient programmer is turned on, you will hear one tone that means the change was effective.
- When a therapy setting is changed, and the audio preference on the patient programmer is turned on, three rapid tones mean that the change could not be confirmed or that the synchronization was not successful.
- Verify the current therapy settings by pressing the **Check** ☑ key and viewing the **Therapy** screen.

Guidelines for adjusting your therapy

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

- For each group, only one parameter can be changed. For example, group A may allow you to change only the amplitude of the therapy and group B may allow you to change only the rate of the therapy.

  Note: A group may also be programmed for viewing only and you will not be able to adjust any settings. Discuss your settings with your clinician. For more information about groups, see "Understanding groups" on page 99.

Tips for adjusting your therapy

- Always adjust the therapy settings to the lowest possible settings that provide effective therapy.

  High therapy settings may shorten the long-term use of the neurostimulator battery.

- Before changing any therapy settings, you need to synchronize the patient programmer and neurostimulator.

- If you experience uncomfortable therapy or unwanted side effects when increasing the amplitude, pulse width, or rate, decrease the setting until your therapy is comfortable. You may also stop the therapy by navigating to the **Therapy on/off** screen and turning the therapy off (see "Turning your therapy on or off in Advanced mode" on page 78).

Adjusting your therapy settings (Advanced mode only)

Your therapy settings can be adjusted in several ways. The following sections explain how to change group settings and how to change individual settings for each side of your body.

In most cases, your clinician will instruct you to adjust therapy equally for both sides of your body.

Adjusting therapy settings

The ability to change therapy settings is only available in Advanced mode. For more information on the icons and numbers displayed on the patient programmer screen, see Table 3.1 on pages 73-74.[2]

The amplitude and pulse width therapy settings can only be adjusted on one side of the body at a time. The **Selection** key and the therapy setting displayed on the left side of the patient programmer screen correspond to the left side of your body. The **Selection** key and the therapy setting displayed on the right side of the patient programmer screen correspond to the right side of your body (Figure 3.14).

Complete the following steps to adjust therapy settings for one side of your body. If desired, repeat the steps for the other side of

[2] You can only change the settings of the active group. If you want to change settings for a nonactive group, you will need to make that group active first. See "Understanding groups" on page 99 for complete instructions.

your body. **In most cases, your clinician will instruct you to adjust therapy equally for both sides of your body.**

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.13).
2. Press the down ▼ arrow on the **Navigator** key to move the selection box to the **Parameter/group** row (Figure 3.13).

Figure 3.13 **Parameter/group** row on the **Therapy** screen.

3. Press the **Selection** key directly under the therapy setting you want to adjust (Figure 3.14).
   - Press the left **Selection** key to adjust the therapy setting for the left side of your body.

     or
   - Press the right **Selection** key to adjust the therapy setting for the right side of your body.

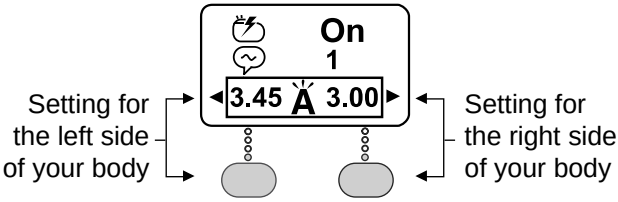


Figure 3.14 **Selection** key for the left or right side of your body.

A new screen appears with the therapy setting for the selected side of the body (Figure 3.15 and Figure 3.16).

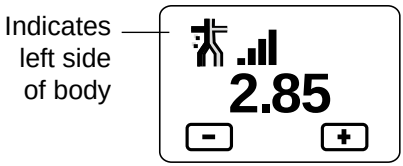


Figure 3.15 Screen displaying settings for the left side of the body.

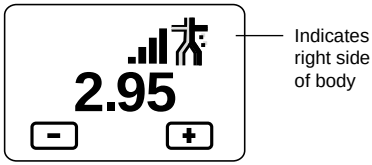


Figure 3.16 Screen displaying settings for the right side of the body.

4. Press the **Selection** keys again to increase or decrease the selected therapy setting as needed (Figure 3.17).

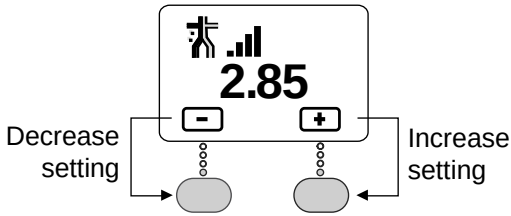


Figure 3.17 **Selection** keys for increasing or decreasing a setting.

5. Hold the patient programmer (or antenna) over the neurostimulator with the screen facing outward.

Notes:

- Hold the patient programmer (or antenna) over your neurostimulator when increasing or decreasing your settings. The therapy settings will immediately change as you press the **Selection** keys.
- Press and hold the **Selection** key to increase or decrease the setting approximately every half-second.
- If you attempt to increase or decrease the setting beyond the programmed limits, a **Parameter limit** screen appears. See Table 3.4 on page 111.

6. Press any arrow on the **Navigator** key to return to the **Therapy** screen.

   If your clinician has instructed you to adjust therapy for both sides of your body, then repeat steps 2-6 for the other side.

   In most cases, your clinician will instruct you to adjust therapy equally for both sides of your body.

Understanding groups

A group is a unique set of therapy settings that your clinician has selected for you. Your clinician may have selected several groups for you to try. You may be able to adjust the therapy settings within a group. See "Adjusting therapy settings" on page 93 for more information. The group feature is only available in Advanced mode.

Selecting a new group

Complete the following steps to select a group. The images in this procedure are an example and show the active group changing from group A to group B.

△ **Caution:** Select the group that your clinician has recommended for your specific needs.

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

neurostimulator with the screen facing outward.

b. Press the **Check** ☑ key.

The **Therapy** screen appears (Figure 3.18).

2. Press the down ▼ arrow on the **Navigator** key to move the selection box to the **Parameter/group** row (Figure 3.18).

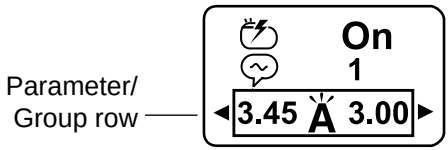


Figure 3.18 Move the selection box to the **Parameter/group** row.

3. Press the left ◀ or right ▶ arrow on the **Navigator** key to display the **Group** screen. (Figure 3.19).

The **Group** screen appears with the active group checked (Figure 3.19).

Figure 3.19 **Group** screen.

4. Press the up ▲ or down ▼ arrow on the **Navigator** key to move the selection box to the desired group (Figure 3.20).[3]

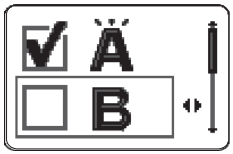


Figure 3.20 Move the selection box to the desired new group.

5. Press the right ▶ arrow on the **Navigator** key. The **Group settings** screen appears (Figure 3.21).

[3] A software shortcut allows you to skip steps 5 and 6 in this procedure. After step 4, go right to step 7 to synchronize and confirm the new active group.

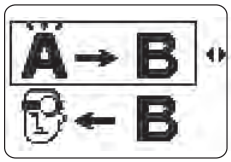


Figure 3.21 **Group settings** screen.

6. Press the right ▶ arrow on the **Navigator** key. The **Confirm new group** screen appears (Figure 3.22).

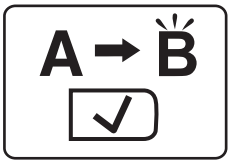


Figure 3.22 **Confirm new group** screen.

7. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

The **Therapy** screen appears displaying the new group (Figure 3.23).

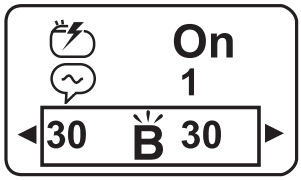


Figure 3.23 **Therapy** screen with the new active group.

Returning your therapy to the clinician settings

If you have changed your therapy settings and want to return to the settings selected by your clinician, complete the steps in the following sections.

Returning the active group to original clinician settings

Complete the following steps to change the therapy settings for the active group back to the original settings selected by your clinician. The images in this procedure are an

example. In this example the active group is group A.

1. Synchronize the patient programmer and neurostimulator.

   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.

   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.24).

2. Press the down ▼ arrow on the **Navigator** key to move the selection box to the **Parameter/group** row (Figure 3.24).

Figure 3.24 Move the selection box to the **Parameter/group** row.

3. Press the left ◀ or right ▶ arrow on the **Navigator** key to display the **Group** screen. (Figure 3.25).

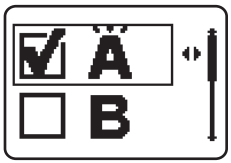


Figure 3.25 **Group** screen with active group checked.

a. Confirm that the selection box is highlighting the active group and that the active group is checked.

b. Press the right ▶ arrow on the **Navigator** key.

The **Clinician Settings** screen appears (Figure 3.26).

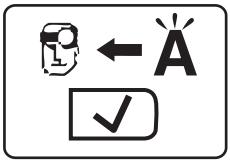


Figure 3.26 Clinician settings screen

4. Synchronize the patient programmer and neurostimulator.

   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.

   b. Press the **Check** ☑ key.

   The **Therapy** screen appears and the patient programmer beeps when the group settings are changed.

Returning an inactive group to the clinician settings

Complete the following steps to change the therapy settings for an inactive group back to the original settings selected by your clinician. The images in this procedure are an example. In this example, group B is the inactive group.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

   The **Therapy** screen appears (Figure 3.27).
2. Press the down ▼ arrow on the **Navigator** key to move the selection box to the **Parameter/group** row (Figure 3.27).

Figure 3.27 Move the selection box to the **Parameter/group** row.

3. Press the left ◀ or right ▶ arrow on the **Navigator** key to display the **Group** screen. (Figure 3.28).

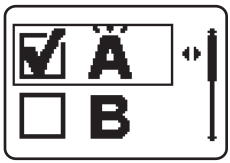


Figure 3.28 **Group** screen with active group checked.

4. Press the up ▲ or down ▼ arrow on the **Navigator** key to move the selection box to the desired inactive group (Figure 3.29).

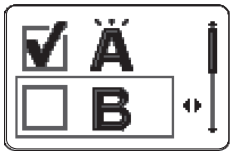


Figure 3.29 Move the selection box to the desired inactive group.

5. Press the right ▶ arrow on the **Navigator** key. The **Group selection** screen appears (Figure 3.30).

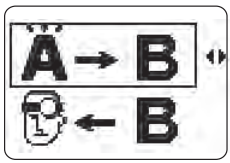


Figure 3.30 **Group selection** screen.

6. Press the down ▼ arrow on the **Navigator** key to move the selection box to the clinician settings option (Figure 3.31).

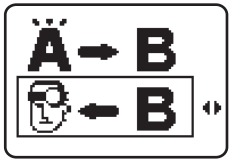


Figure 3.31 Move the selection box to the clinician settings option.

7. Press the right ▶ arrow on the **Navigator** key to display the **Clinician settings** screen (Figure 3.32).

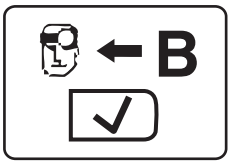


Figure 3.32 **Clinician settings** screen.

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

b. Press the **Check** ☑ key.

The **Therapy** screen appears with the active group displayed and the patient programmer beeps when the group settings are changed.

Understanding the programmed parameter limits

Each parameter has an upper and lower limit programmed by your clinician. If you attempt to change a parameter to a value outside these limits, you will see one of the screens shown in Table 3.4.

Table 3.4 Parameter limit screens

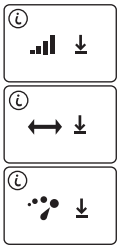
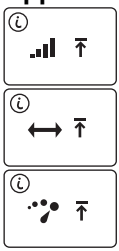
Lower limit 	You tried to decrease a parameter (amplitude, pulse width, or rate) below the lowest value allowed. **Press any arrow on the Navigator key to clear the screen.**

Table 3.4 Parameter limit screens (continued)

Upper limit 	You tried to increase a parameter (amplitude, pulse width, or rate) above the highest value allowed. **Press any arrow on the Navigator key to clear the screen.**

4 MRI examinations

If you have an MRI appointment

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

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

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

Responsibilities of the patient in preparing for the MRI appointment

Bring the following to every MRI appointment:

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

  Note: If you have two neurostimulation systems implanted in your body, bring both ID cards to your MRI appointment.
- Your MRI scan eligibility sheet if you were given one from your clinician managing your neurostimuation system.
- Your patient programmer.

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

Preparing your neurostimulation system for the MRI scan

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

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

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

If therapy should be turned off prior to your MRI scan, refer to "Turning off therapy before the MRI scan" on page 116.

If therapy can remain on during your MRI scan, refer to "Activating settings to allow therapy on during the MRI scan" on page 120.

Turning off therapy before the MRI scan

If your clinician managing your neurostimulation system indicates that therapy should be off during the MRI scan, therapy can be turned off with the patient

programmer (see page 117) or the clinician programmer (see page 118).

Using the patient programmer to turn off therapy

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

For instructions on turning off therapy, go to "Turning your therapy off" on page 49.

During the MRI scan, keep therapy off.

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

After the MRI scan and outside of the MRI scanner (magnet) room, you can turn therapy back on using your patient programmer or you can return to the clinician managing your neurostimulation system to have therapy turned back on (refer to "Turning therapy back on after the MRI scan" on page 119).

Note: Do **not** take the patient programmer into the MRI scanner (magnet) room.

Using the clinician programmer to turn off therapy

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

Do not turn therapy back on before your MRI scan.

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

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

During the MRI scan, keep therapy off.

After the MRI scan and outside of the MRI scanner (magnet) room, you can turn therapy

back on using your patient programmer or you can return to the clinician managing your neurostimulation system to have therapy turned back on (refer to "Turning therapy back on after the MRI scan" on page 119).

Turning therapy back on after the MRI scan

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

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

- If you do not have your patient programmer with you, go to the clinician managing your neurostimulation system to turn on therapy using the clinician programmer.
- If you brought your patient programmer to the MRI appointment, turn therapy back on using the patient programmer. For instructions on turning on therapy, go to "Turning your therapy on" on page 45.

Note: If a power-on-reset (POR) screen appears on the patient programmer, see Table 4.1 on page 126.

Activating settings to allow therapy on during the MRI scan

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

If your clinician managing your neurostimulation system creates a new group setting so that therapy can remain on during your MRI scan, the new group can be activated with the patient programmer (see page 121) or the clinician programmer (see page 122).

Using the patient programmer to activate a new group

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

For instructions on activating a new group, go to "Selecting a new group" on page 99.

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

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

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

your patient programmer or you can return to the clinician managing your neurostimulation system to reprogram therapy to your original group setting (refer to "Returning therapy to your original group setting after the MRI scan" on page 124).

Note: Do **not** take the patient programmer into the MRI scanner (magnet) room.

Using the clinician programmer to activate a new group

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

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

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

for unintended stimulation during the scan.

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

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

After the MRI scan and outside of the MRI scanner (magnet) room, you can return therapy to your original group setting using your patient programmer or you can return to the clinician managing your neurostimulation system to reprogram therapy to your original group setting (refer to "Returning therapy to your original group setting after the MRI scan" on page 124).

Returning therapy to your original group setting after the MRI scan

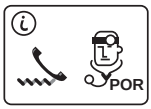
Return therapy to your original group setting when the MRI scan is complete and you are **outside** of the MRI scanner (magnet) room.

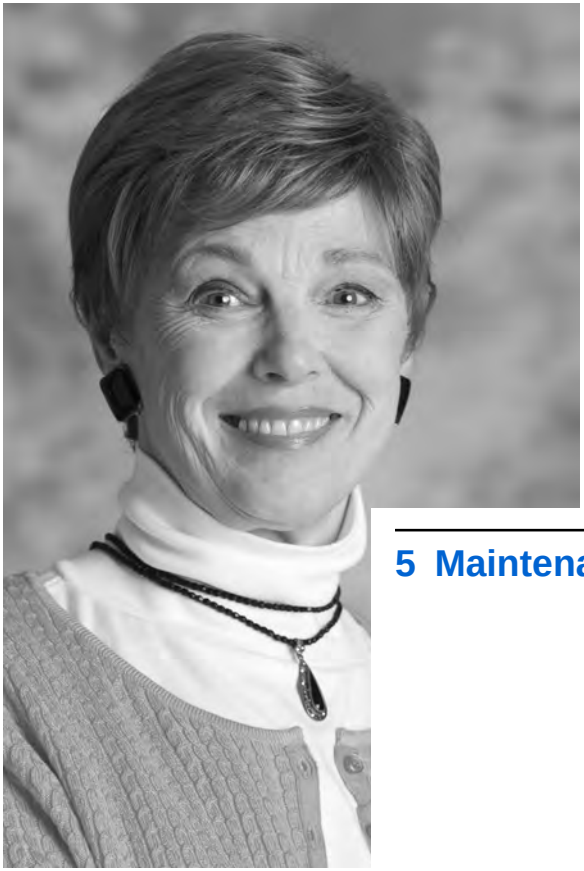
Group settings can be changed with the patient programmer or the clinician programmer:

- If you do not have your patient programmer with you, go to the clinician managing your neurostimulation system to return therapy to your original group setting using the clinician programmer.
- If you brought your patient programmer to the MRI appointment, return therapy to your original group setting using the patient programmer. For instructions on returning therapy to your original group setting, go to "Selecting a new group" on page 99.

Note: If a power-on-reset (POR) screen appears on the patient programmer, see Table 4.1 on page 126.

Table 4.1 POR screens

Screen	Description and action
 Warning POR (hazard triangle symbol in the upper left corner)	Error code = POR. Your therapy has stopped. **Call your clinician to restart your therapy.**
 Informational POR (small "i" icon in the upper left corner)	The neurostimulator has been reset. Your therapy has stopped. **Press any arrow on the Navigator key to clear the screen. Then turn your therapy on by following the instructions in "Turning your therapy on" on page 45.** **Call your clinician to report the reset.**



5 Maintenance

This section describes how to care for and dispose of your patient programmer and accessories.

Patient programmer batteries

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

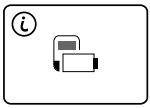
△ **Caution:** If the device will not be used for several weeks, remove the batteries from the device. A battery left in the device may corrode, causing damage to the electronic components.

Checking the patient programmer batteries in Simple mode

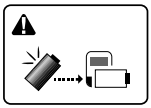
You can check the patient programmer batteries at any time. The **Patient programmer battery status** screen can be reached from the **Status** row of the **Therapy** screen. See "Navigating from the Therapy

screen in Advanced mode" on page 77 for more information.

The patient programmer displays the following screens when the patient programmer batteries are low or depleted.



Patient programmer batteries are low



Patient programmer batteries are depleted

Figure 5.1 Patient programmer battery screens.

Complete the following steps to check the patient programmer batteries.

1. Synchronize the patient programmer and neurostimulator.
   a. Hold the patient programmer (or antenna) directly over the neurostimulator with the screen facing outward.
   b. Press the **Check** ☑ key.

The **Therapy** screen appears (Figure 5.2).

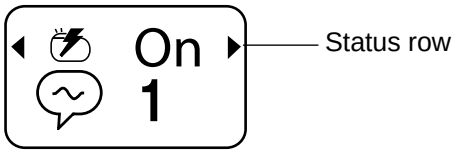


Figure 5.2 Status row on the **Therapy** screen .

2. Press the right ▶ arrow on the **Navigator** key until you reach the **Patient programmer battery status** screen (Figure 5.3).

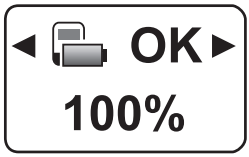


Figure 5.3 Patient programmer battery status screen.

3. Review the patient programmer battery status and battery level (Figure 5.3).

The **Patient programmer battery status** screen (Figure 5.3) displays an icon indicating the patient programmer battery level and the percentage of the battery energy remaining (Figure 5.4).

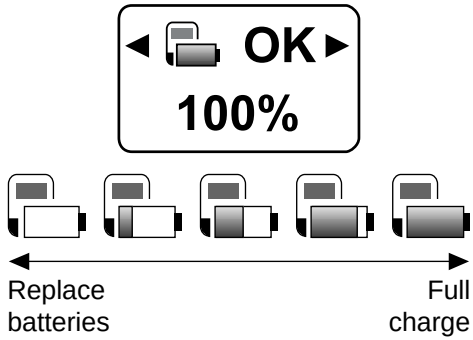


Figure 5.4 Patient programmer battery level.

If the batteries are low, see "Replacing the patient programmer batteries" on page 133 for replacement instructions.

Possible patient programmer battery conditions

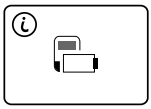
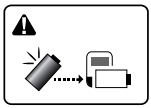
Table 5.1 lists the screens associated with the patient programmer battery.

For more information about the screens associated with the patient programmer battery, see "Troubleshooting" on page 139.

Table 5.1 Patient programmer battery screens

 Batteries are OK	The **Patient programmer battery status** screen displays OK when the patient programmer batteries are at an acceptable level. The number on the screen indicates the battery level or the percentage of energy left in the batteries. **You do not need to take any action.**

Table 5.1 Patient programmer battery screens (continued)

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

Replacing the patient programmer batteries

1. Open the battery compartment cover (Figure 5.5).

Figure 5.5 Opening the battery cover.

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

Cleaning and care

The intent of these guidelines is to ensure proper care of your patient programmer and accessories.

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

- Keep the device out of the reach of children and pets. Keep the batteries away from children. If children or pets swallow the batteries, contact a doctor at once.
- Use the device only as explained to you by your clinician or as discussed in this manual.
- Handle the device with care. Do not drop, strike, or step on the device.
- Do not dismantle or tamper with the device.

- Clean the outside of the device with a damp cloth when necessary. Mild household cleaners (eg, dish soap) will not damage the device or labels.
- The device is not waterproof. Do not allow moisture to get inside the device.
- Keep fresh batteries available.
- Replace low or depleted batteries.

Safety and technical checks

Periodic safety and technical checks or periodic maintenance of the patient programmer are not required. The patient programmer contains no user-serviceable parts. If repair or service is needed, contact your clinician or a Medtronic sales office. Refer to the Medtronic contacts at the end of this manual.

Battery and patient programmer disposal

Dispose of depleted batteries and worn out devices according to local requirements. If

you no longer need your patient programmer and would like to donate it, contact your clinician.

Specifications

Table 5.2 Patient programmer specifications

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

Table 5.2 Patient programmer specifications (continued)

Item	Specification
Battery life	2 months (average) for alkaline batteries
Service life	Up to 5 years
Mode of operation	Continuous

[a] Batteries should be removed from the device for storage.

6 Troubleshooting

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

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

Patient programmer screens

The patient programmer displays **warning** ⚠, **communication** ⧗, and **information** ⓘ screens to provide you with information about your system, or to guide you while using the patient programmer.

Warning screens

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

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

Table 6.1 Warning screens

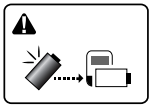
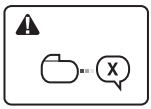
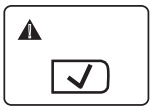
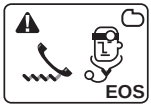
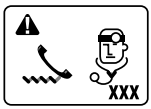
Screen	Cause and action
 Replace batteries	The patient programmer batteries are depleted. Programming is not possible. **Replace the patient programmer batteries now.**
 Device not supported	The implanted device that you are attempting to communicate with is not compatible with the patient programmer.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

Table 6.1 Warning screens (continued)

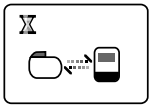
Screen	Cause and action
 End of service error	Error code = EOS. Your neurostimulator has reached the end of service. Therapy is not available. **Call your clinician.**
 Power on reset error	Error code = POR. Your therapy has stopped. **Call your clinician to restart your therapy.**
 Call your clinician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

Communication screen

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

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

Table 6.2 Communication screen

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

Information screens

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

If the patient programmer audio setting is turned on, three tones alert you when an information screen is displayed on the patient programmer.

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

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

Table 6.3 Information screens

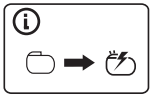
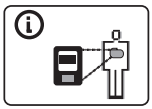
Screen	Description and action
 Turn therapy on	You tried to increase the amplitude, pulse width, or rate parameters with your therapy off. **Press any arrow on the Navigator key to clear the screen.** **Turn your therapy on and try communication again.** You tried to decrease rate with your therapy off. **Turn your therapy on and try decreasing rate again.**
 Position patient programmer over neurostimulator	The patient programmer is trying to communicate with the neurostimulator. **Hold the patient programmer or detachable antenna over the neurostimulator.**

Table 6.3 Information screens (continued)

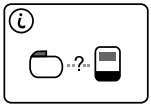
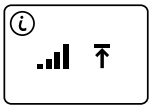
Screen	Description and action
 Poor communication	The patient programmer attempted to communicate with the neurostimulator, but communication was unsuccessful. **Reposition the patient programmer over the neurostimulator with the screen facing outward and try communication again.** **If using the detachable antenna, check that the antenna is connected properly, reposition the antenna and try communication again.** **Press any arrow on the Navigator key to clear the screen.**
 Upper limit (amplitude shown)	You tried increasing a parameter (amplitude, pulse width, or rate) above the highest value allowed. **Press any arrow on the Navigator key to clear the screen.**

Table 6.3 Information screens (continued)

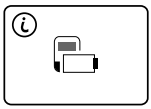
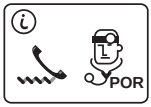
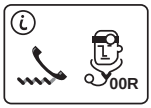
Screen	Description and action
 Lower limit (amplitude shown)	You tried decreasing a parameter (amplitude, pulse width, or rate) below the lowest value allowed. **Press any arrow on the Navigator key to clear the screen.**
 Neurostimulator battery is low	The neurostimulator battery is low and therapy will not be available soon. **Call your clinician to report this message screen. Press any arrow on the Navigator key to clear the screen.**
 Patient programmer batteries are low	The patient programmer batteries are low. You can finish programming. **Press any arrow on the Navigator key to clear the screen.** **Replace the patient programmer batteries before the batteries become depleted.**

Table 6.3 Information screens (continued)

Screen	Description and action
 Power on reset error detected	The neurostimulator has been reset. Your therapy has stopped. **Press any arrow on the Navigator key to clear the screen. Then turn your therapy on by following the instructions in "Turning your therapy on" on page 45.** **Call your clinician to report the reset.**
 Out of regulation error	The neurostimulator cannot provide the programmed therapy or increase the parameter to the value that you requested. **Press any arrow on the Navigator key to clear the screen. Then lower the parameter setting.** **Call your clinician if this step does not resolve the issue.**

Possible problems and solutions

Table 6.4 will help you solve possible problems associated with the patient programmer or identify when to call your clinician. Problems are described in the left column (see **bold black text**). The right column lists possible causes of the problem (see plain text) and how to correct the problem (see **bold blue text**).

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

Table 6.4 Troubleshooting

Problems	Causes and actions
Uncomfortable or Intolerable therapy You are experiencing side effects from the therapy.	The selected therapy settings are not suitable for your current activity. **1. Turn your therapy off (see page 49 and page 78).** **2. Call your clinician.** If your patient programmer is using Advanced mode, you can try the following before calling your clinician. • **Reduce the amplitude or pulse width setting for both sides of your body (see page 92).** • **If necessary, select a different group (see page 99).**

Table 6.4 Troubleshooting (continued)

Problems	Causes and actions
No therapy You think you are not getting therapy but you think that therapy should be on.	Therapy is off. **Use your patient programmer to turn your therapy on (see page 45 and page 78).** The amplitude setting of the active group for each lead is too low to provide effective therapy. **Call your clinician.** If your patient programmer is using Advanced mode, you can try the following before calling your clinician. **Use your patient programmer to increase the amplitude(s) (see page 93).**

Table 6.4 Troubleshooting (continued)

Problems	Causes and actions
Patient programmer is unresponsive The display screen is blank when you press a key.	The patient programmer batteries are depleted. **Replace the patient programmer batteries (see page 133).** The patient programmer batteries are in backwards. **Check the battery polarity and reinstall the patient programmer batteries (see page 133).**
Dropped patient programmer Your patient programmer falls off a cabinet or table.	The patient programmer is designed to withstand a short drop to a hard surface and still operate normally, even if the case is chipped or nicked. **Try the patient programmer; it should work.**

Table 6.4 Troubleshooting (continued)

Problems	Causes and actions
Fluid on the patient programmer Fluid was spilled onto the patient programmer or the patient programmer was dropped into water.	The patient programmer is not waterproof, and water can damage the device. **Immediately remove the patient programmer from the water, then dry the patient programmer with a towel dampened with clean tap water.** **Remove the batteries (see page 133), then allow the battery compartment to air dry at room temperature for 24 hours.**

7 User assistance

User assistance

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

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

If your patient programmer stops working, first try the steps in "Possible problems and solutions" on page 149. Then contact your clinician.

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

! USA To register the patient programmer for service covered by the warranty, complete and mail the warranty registration.

Declaration of conformity

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

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

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Contacts for specific countries are listed inside this cover.

M933209A027

Medtronic

Your Medtronic® Deep Brain Stimulation Therapy

Therapy-specific Patient Booklet

Specific DBS™ therapy information for epilepsy

Patient Manual

! USA Rx only

CE0123

Information for family members or caregivers

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

You should have two patient therapy manuals:

- The DBS Patient Therapy Guide, which contains information about all DBS therapies.
- The DBS Therapy-specific Patient Booklet, which contains important DBS therapy information specific to the patient's medical condition.

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

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.

CE 0123	Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.
EC REP	Authorized representative in the European Community
	Manufacturer
! USA	For USA audiences only

Table of contents

Glossary

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

Epilepsy - A neurological disorder with recurrent seizures, which may include episodes of sensory disturbance, loss of consciousness, or convulsions.

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 power source of a brain stimulation system.

Status epilepticus - A seizure that lasts too long or when seizures occur close together and the patient does not recover between seizures.

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.

Vagus nerve stimulation - The delivery of electrical pulses to the vagus nerve for therapeutic purposes.

Warning - A statement describing an action or situation that could harm the patient.

Medtronic DBS *Therapy-Specific patient Booklet* for Epilepsy

This DBS *Therapy-specific Patient Booklet* provides important DBS Therapy information specific to your medical condition.

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

DBS Therapy for Epilepsy

Research has shown that a specific part of the brain, called the thalamus, may control certain types of seizure activity because it receives and sends nerve signals to and from many areas of the brain. Clinical research has also shown that if this area of the brain receives electrical stimulation, then seizure frequency may be reduced. Based on your seizure history, your doctor believes that you may benefit from this therapy to help control your seizures.

This therapy is not a cure. When you turn on the brain stimulation system, it will deliver stimulation that may reduce the number or intensity of your seizures. Seizures may also increase with stimulation, but usually improve with changes in stimulation settings. Seizure numbers or intensity may return when the system is not delivering stimulation.

SANTÉ Clinical Study

The SANTÉ clinical study assessed the risks and benefits of the Medtronic Deep Brain Stimulation (DBS) System for Epilepsy. Participants were adults with partial-onset seizures who had tried at least 3 different antiepileptic medications to control their seizures. On average, they had at least 6 partial seizures per month and were taking 1 to 4 antiepileptic medications when they started the study.

Patients were implanted with a DBS system if they met all the required criteria. To understand the benefits of stimulation, there

was a 3-month comparison period where about half of the subjects had their device turned on (active group) and the other half continued with their device turned off (control group). At the end of the comparison period, seizure frequency was compared between the two groups.

The main goal of the study was to show that patients with stimulation turned on had fewer seizures than patients that had their device turned off. Subjects kept daily seizure diaries and filled out questionnaires about their seizure severity and quality of life. Patients who remained in the study were followed for at least 7 years after the implant of their DBS system.

Benefits

The clinical study showed that the Medtronic DBS System for Epilepsy reduced the frequency of seizures in the participants. During the comparison period, the active group (device turned on) experienced 17% fewer seizures than patients in the control group (device turned off). Seizures were

reduced by 41% one year after implant and 75% seven years after implant.

Seizure severity and quality of life also improved long term. Between the first year and the seventh year, almost half of the patients were experiencing clinically meaningful improvements in their quality of life (46% in the first year and 43% in the seventh year).

Risks

During the comparison period of the study, more patients in the active group (device turned on) reported adverse events of depression or memory problems as compared to the control group (device turned off).

During the study, the most frequent events related to the device, therapy, or surgery included implant site pain, tingling sensations, ineffective stimulation, and implant site infection.

Adverse events related to the therapy are summarized in the section "Possible side

effects from DBS Therapy for Epilepsy" of this manual starting on page 20.

Adverse events related to the DBS surgical procedure and possible device complications are summarized in the *DBS Patient Therapy Guide*.

System components

The Medtronic DBS System for Epilepsy includes two leads and two extensions connected to one neurostimulator. Refer to the DBS *Patient Therapy Guide* for more information about system components (Figure 1).

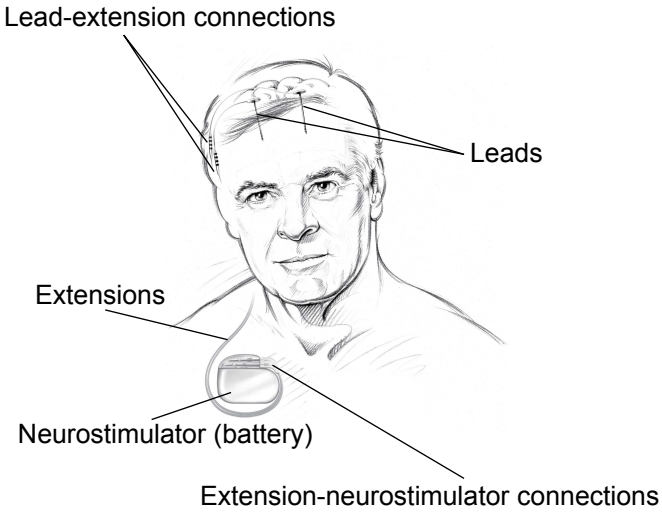

Figure 1. Implanted system for Medtronic DBS Therapy for Epilepsy.

Warnings

Risk of depression, suicidal thoughts, and suicide—Depression, suicidal thoughts, and suicide have been reported in patients receiving DBS therapy. It is not known why these events occur in patients receiving DBS

therapy. However, the seriousness of these adverse events requires attention from patients and caregivers. When considering DBS therapy be sure to discuss any history of depression or suicidal thoughts or behaviors with your physician to determine if this therapy is an appropriate option for you. If you have an implanted DBS system, it is important to attend on-going follow-up visits and to immediately notify your physician of any episodes of depression or suicidal thoughts or behaviors, so that they can help manage these symptoms appropriately.

Increase in seizures—Stopping, reducing, or starting stimulation may potentially lead to an increased number of seizures, seizures that are more intense, new types of seizures, and the potential for status epilepticus. Be sure to check that your neurostimulator has not been accidentally turned off. Contact your doctor if you experience an increase in seizure symptoms.

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

Precautions

Memory impairment—Memory problems have been reported in patients receiving DBS therapy. Contact your doctor if you experience new or worsening symptoms of memory impairment.

Possible side effects from DBS Therapy for Epilepsy

Side effects of brain stimulation may include the following:

- Depression
- Memory problems (memory impairment or déjà vu)
- Status epilepticus
- Changes in seizures: new seizure type or worsening seizures (increased seizure frequency, duration, and/or severity)

- Anxiety, panic attack
- Agitation, anger
- Confusion
- Abnormal thoughts
- Dizziness
- Abnormal face or body movements
- Trouble sleeping
- Pain at implant site
- Paresthesia (tingling, shocking, vibration, or buzzing sensation)
- Abnormal feelings or sensations
- Discomfort
- Headaches
- Stimulation not effective, insufficient seizure control

Battery life for DBS Therapy for Epilepsy

The neurostimulator battery life is influenced by its programmed therapy settings. Depending on your individual therapy settings, the battery will typically last between 2.5 to 5 years. Consult with your clinician for exact information as it relates to your medical condition because the battery life of your neurostimulator may be outside 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.

Note: Refer to the DBS *Patient Therapy Guide* for additional information of what to expect from your implant procedure.

Before surgery

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 to help prevent infection.

MRI procedure

Your doctor will perform an MRI procedure before surgery to get an image of where the DBS leads will be placed in the brain.

During surgery

Vagus nerve stimulation system

If you already have a vagus nerve stimulation (VNS) system implanted, the power source for your VNS system will be removed and the lead will be removed or trimmed and capped. Some tests, such as MRI, may not be safe if you have part of your VNS system still implanted. Your doctor will follow the manufacturer's instructions for explant.

Details of your DBS surgery

During the surgery to implant your Medtronic DBS System for Epilepsy, your surgeon will use the images from the MRI procedure to guide the placement of the DBS leads in the brain.

When the area to be stimulated is located, the leads are passed into the brain.

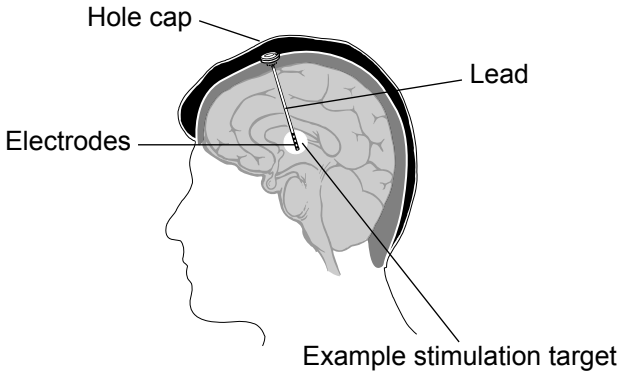

Figure 2. Location of the lead in your brain.

After surgery

MRI procedure

Your doctor may perform an MRI procedure after the leads have been placed in the brain to confirm that the leads have been placed in the appropriate location.

When to call your doctor

Call your doctor if any of the following situations occur:

- You experience unexpected changes in your symptoms or seizures, including an increase in seizure frequency, a change in seizure characteristics, a new seizure type, signs of infection, or new neurological symptoms.
- You experience new or worsening symptoms of depression or have suicidal thoughts.

Note: Refer to the DBS *Patient Therapy Guide* for an additional list of when to call your doctor.

Changes in therapy

There may be changes in the level of your seizure reduction over time. These changes may include:

- A decrease in seizures
- An increase in seizures
- Loss of effective stimulation

If your seizures are worsening, check to ensure that your neurostimulator is on. Your doctor may also be able to help by reprogramming the brain stimulation system. However, surgery may be required to reposition or replace the lead, replace the system, or remove the system.

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