



Medtronic

YOUR MEDTRONIC[®] DEEP
BRAIN STIMULATION THERAPY
Patient Therapy Guide



!USA Rx only



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

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.



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.



Authorized representative in the European community



Manufacturer



For USA audiences only

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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.

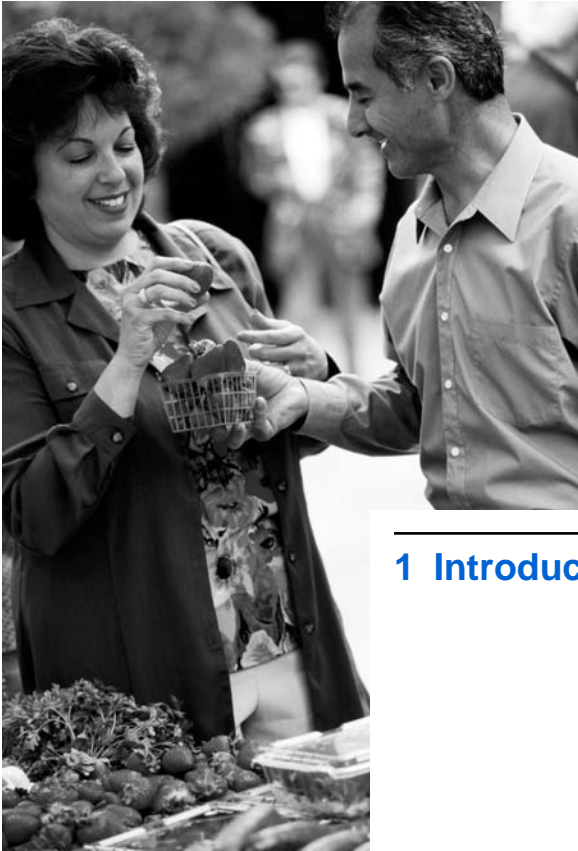
Stimulation - The delivery of electrical pulses to the brain.

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.



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

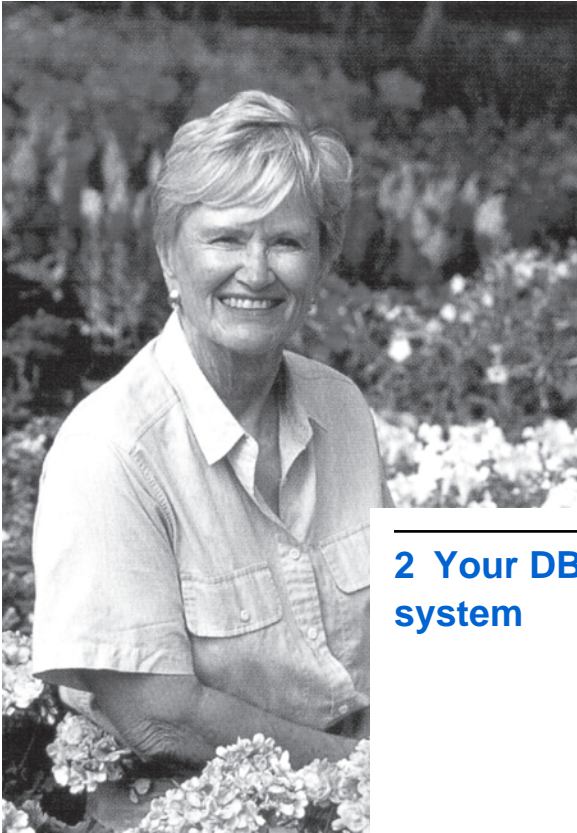
Patient guides	DBS system
<i>DBS Patient Therapy Guide</i> provides basic DBS therapy information	Nonrechargeable and rechargeable systems
<i>DBS Therapy-specific Patient Booklet</i> provides DBS therapy information specific to your medical condition	Nonrechargeable and rechargeable systems

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

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

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

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



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 programmer¹—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—You should not have certain types of MRI if you have an implanted DBS System or any part of the DBS System implanted in your body.

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 complete information regarding these MRI guidelines, (see the addresses at the back of this manual).

 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, or swelling at the surgery sites
- Infection
- Headache
- Confusion or attention problems
- 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. 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 69, 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 69.

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 55.

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 placement¹

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

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

After surgery

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

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.

 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 55.

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

² Rechargeable DBS systems only.

these activities. You should also discuss your activities with your doctor.

Activities requiring excessive twisting or stretching—Avoid activities that may put undue stress on the implanted components of your DBS System. Activities that include sudden, excessive, or repetitive bending, twisting, or stretching can cause component fracture or dislodgement. Component fracture or dislodgement may result in loss of stimulation, intermittent stimulation, stimulation at the fracture site, and additional surgery to replace or reposition the component.

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

Skydiving, skiing, or hiking in the mountains—High altitudes should not affect the DBS System, however, you should consider the movements involved in any planned activity and 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

Additional information 5

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 PC, Activa RC, and Activa SC Neurostimulators	Titanium Parylene Silicone rubber Silicone medical adhesive Polyurethane
Soletra Model 7426	Sheet Titanium Urethane Titanium Silicone rubber Polymeric insulating film Silicone medical adhesive
Kinetra Model 7428	Sheet Titanium Tecothane Titanium Silicone rubber Polymeric insulating film Silicone medical adhesive
Lead	Polyurethane Platinum iridium
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 83.

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.

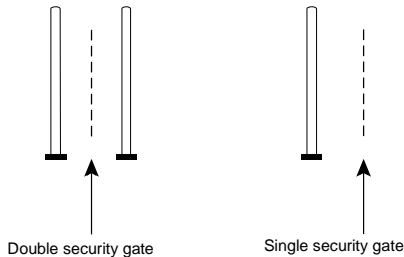


Figure 6.1 Walking through security gates.

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:

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 83, for more information.

- Antennas of citizen band (CB) or ham radios
- Electric arc welding equipment
- Electric induction heaters
- Electric steel furnaces (not home furnaces)
- Electric substations
- High-power amateur transmitters
- High-voltage areas (safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment
- Magnets and other equipment that generate strong magnetic fields
- Microwave communication transmitters (safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (safe if outside the fenced area)

Safe from interference

Most household appliances and equipment that work properly and are properly grounded will not interfere with the neurostimulation system. The following equipment is safe if you follow these guidelines:

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

- **Sewing machine or salon hair dryers:**
Keep your implanted neurostimulator away from the motors.
- **Stereo speakers and radios for the home or car:** Do not lift or carry them close to or touching the part of your body where the neurostimulator is located.

Medical and dental environments

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

If they have any questions, they should contact Medtronic. 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.

 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 Solettra DBS systems.

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