

PATIENT LABELING



YOUR RECLAIM™ DBS™ THERAPY FOR OCD
With a Kinetra® or Soletra® Neurostimulator



Patient Manual
Rx Only

Humanitarian Device: Authorized by Federal (U.S.A.) law for use as an adjunct to medications and as an alternative to anterior capsulotomy for the treatment of chronic, severe, treatment-resistant obsessive compulsive disorder (OCD) in adult patients who have failed at least three selective serotonin reuptake inhibitors (SSRIs). The effectiveness of this device for this use has not been demonstrated.

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FAMILY MEMBERS OR CAREGIVERS

Please remember the following:

- Read this patient manual thoroughly so you can assist the patient living with Reclaim DBS Therapy.
- **Always tell any medical personnel that the patient has an implanted brain stimulator and tell them where it is located.** If medical personnel have any questions, they should contact Medtronic 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. Also, keep the telephone number of Medtronic's Patient Services Department (1-800-510-6735) in case you or medical or dental personnel have any questions. In the case of a medical emergency, always dial 911.

4 | FAMILY MEMBERS OR CAREGIVERS

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1 GLOSSARY

Amplitude – Amplitude is the strength of stimulation for your specific therapy. The amplitude is measured in volts. The amplitude setting is 1 of several that can be adjusted by your doctor in the office or clinic using the clinician programmer.

Autonomic effects – Involuntary physical effects of neurostimulation such as facial flushing or increased heart rate.

Battery – A part of the neurostimulator that provides the power for your brain stimulation system. Neurostimulator service life depends on individual use. Neurostimulator service life for obsessive compulsive disorder (OCD) therapy typically ranges from 6 months to 16 months.

Capsulotomy – A surgical technique that is intended to lessen the symptoms of obsessive compulsive disorder that involves the destruction of specific groups of cells within a place in the brain called the internal capsule.

Clinician Programmer – A small computer that is used to program the Reclaim DBS

System. The doctor can change the therapy settings using this programmer.

Cognitive behavior therapy (CBT) – Psychotherapy that emphasizes the substitution of undesirable thinking patterns with desirable thinking patterns.

Comorbid Psychiatric Disorder – A psychiatric disorder that exists simultaneously with and usually independently of another psychiatric disorder.

Computerized Axial Tomography (CT or CAT) Scans – A test that can see inside the brain and other parts of the body, into areas that cannot be seen with regular x-ray.

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.

Control magnet – A magnet used to turn your neurostimulator on and off.

Disinhibition – The lessening of inhibition that results in behavior not normally engaged

in that may go beyond accepted cultural norms.

Electroconvulsive therapy – Therapy that uses electrodes placed on the outside of the head to send electric current to the brain for the treatment of certain mental disorders. Also called electroshock therapy.

Electrode – A metal piece near the tip of the lead. Electrodes deliver electrical pulses to an area of your brain that may alter the way you feel.

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

Explant – The removal of an implanted device. Explantation requires surgery.

Fluoroscopy – An x-ray procedure that makes it possible to see internal organs in motion.

Hole cap – A component covering the hole in your skull that secures your lead in place.

Hypomania – A mild form of mania, characterized by hyperactivity or euphoria.

Inappropriate euphoria – Feeling very good even when it isn't justified.

Lead – Implantable component that consists of a small cable with a set of electrodes through which the electrical stimulation is delivered to a specific area of the brain.

Magnetic Resonance Imaging (MRI) – A type of scan using magnetic fields that provides detailed pictures of your anatomy.

Neurostimulator – Device for treating a neurological condition by sending electrical impulses to a specific area of the brain.

Paraphilias – Psychosexual disorders characterized by deviant sexual thoughts or actions.

Service life – Amount of time that the device battery is expected to work based on the programmed parameters, clinician-selectable features, and how often the device is used by the patient.

Somatic psychiatric therapies – Therapies such as electroconvulsive therapy (sometimes

called electroshock therapy), transcranial magnetic stimulation, or vagus nerve stimulation that may generate electromagnetic interference.

Stimulation – The delivery of electrical signals to the brain cells. The electrical signals may alter some of the incorrect messages processed by the brain in the areas that control mood and anxiety.

Stimulation target – The area of the brain where the application of stimulation is most effective.

Suboptimal electrodes – Electrodes on the lead that may be less effective than other electrodes on the lead because of their location in the brain.

Surgical ablation – Surgical destruction of brain tissue intended to lessen the symptoms of obsessive compulsive disorder. An example is a capsulotomy, which is an alternative to neurostimulation therapy.

Test Stimulation – The time period during the system implant procedure when brain stimulation is evaluated to determine how well it controls your symptoms.

Therapy controller – An electronic remote control device used to turn your neurostimulator on and off.

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.

2 DESCRIPTIVE INFORMATION

Purpose of the Device

The Reclaim DBS System delivers electrical stimulation to the area in your brain to help control symptoms of obsessive compulsive disorder (OCD). Electrical stimulation is delivered to both sides of your brain to help relieve the effects of OCD.

You may be a candidate for the brain stimulation system for OCD if you:

- have a diagnosis of OCD with a documented duration of at least 5 years.
- have OCD rated as severe or extreme illness.
- have comorbid depression and anxiety.
- have failed to improve following treatment with at least 3 selective serotonin reuptake inhibitors (SSRIs).
- do not have hoarding as your primary subclassification.
- have completed or tried to complete Cognitive Behavior Therapy (CBT).

- have no serious psychiatric disorder in addition to OCD (e.g. comorbid personality disorder) or substance abuse issues.
- meet established criteria for implantation of a deep brain stimulation system.
- are 18 years old or older.
- have not had a previous surgery to destroy the region of the brain that will be the target of stimulation.
- are not pregnant.
- have no other neurological disorders, including dementia.
- do not have a bleeding disorder or are not taking blood thinners.
- do not require routine MRIs.

Description of the Device

The brain stimulation system is implanted inside your body. Refer to Figure 2.1. A control magnet or therapy controller is used to turn the therapy on and off. The Reclaim DBS System is made up of 3 major parts:

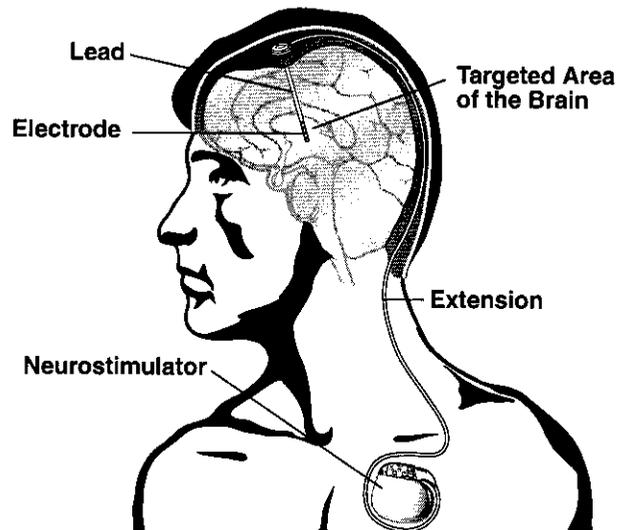


Figure 2.1 Parts of the brain stimulation system implanted inside your body.

- The **lead** is made of 4 wires contained in a plastic tube. It carries the stimulation signal

to the 4 electrodes (platinum rings) that deliver stimulation to the brain tissue. About 4 inches of the lead is implanted inside the brain. The rest of the lead (about 15 inches) is implanted under the skin of the scalp.

- The **extension** is made of 4 wires contained in a tube 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 extension is then tunneled under the skin of the neck down to the upper chest area to connect to the neurostimulator. For each lead, you will have 1 extension.
- The **neurostimulator** contains a battery that is the power source of your system. The neurostimulator controls the stimulation. It is implanted just under the skin in the upper chest area. The Kinetra Model 7428 neurostimulator is about 3 inches long, 2.4 inches high, and 0.6 inches thick. The Soletra Model 7426 neurostimulator is about 2.4 inches long, 2.2 inches high, and 0.4 inches thick.

Your System Components

One or 2 Kinetra Model 7428 or 2 Soletra Model 7426 implanted neurostimulators provide stimulation for the treatment of OCD. Your system consists of 2 leads and 2 extensions. Each lead connects to an extension and each extension connects to a neurostimulator.

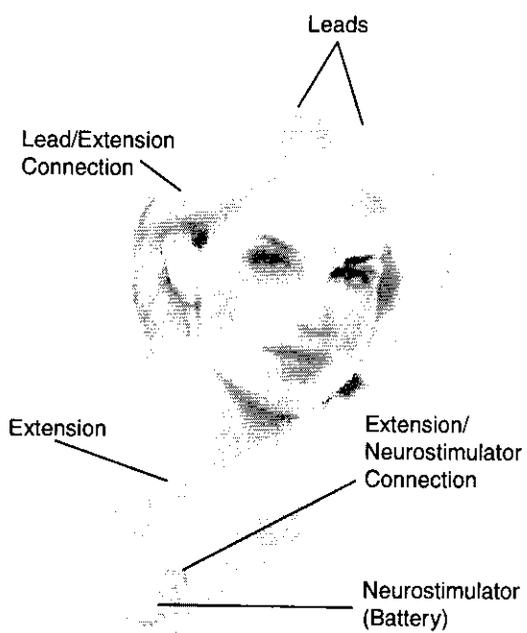


Figure 2.2 The Implanted Reclaim DBS System (with 1 neurostimulator).

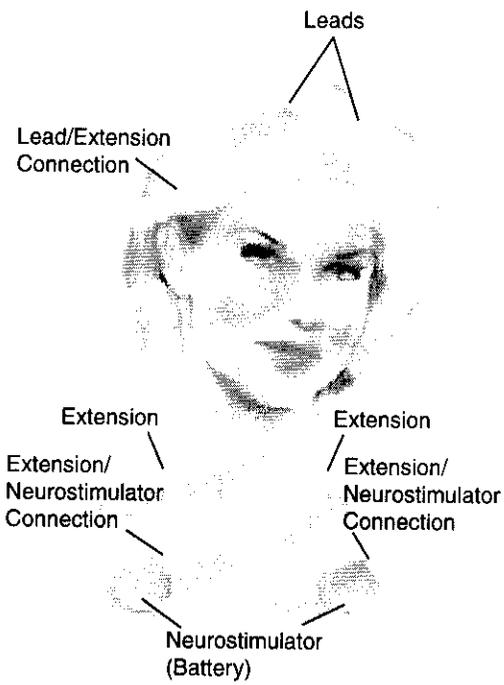


Figure 2.3 The Implanted Reclaim DBS System (with 2 neurostimulators).

How Does Your Brain Stimulation System Work?

Some of your symptoms are caused by abnormal messages being processed by your brain. Your brain stimulation system delivers mild electrical stimulation to an area in the brain that controls mood and anxiety. Stimulation alters some of the messages as they are being processed by the brain. This may relieve the symptoms of your disease.

Your therapy helps you control symptoms. **It is not a cure.** When you turn on the brain stimulation system, it will deliver stimulation that may decrease your symptoms. Symptoms will return when the system is turned off.

Significant OCD symptoms are likely to persist following Reclaim DBS Therapy.

The brain stimulation system is one therapy that helps you control the symptoms of your disease. Other therapies and options include cognitive behavior therapy (CBT), medication therapy, and capsulotomy.

When the Device Should Not be Used (Contraindications)

Reclaim DBS Therapy for OCD should not be used for:

- 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 may require additional surgery to remove or replace parts of your implanted device. Injury or damage can occur during diathermy treatment whether

your neurostimulation system is turned “on” or “off.”

- Patients who will be exposed to Magnetic Resonance Imaging (MRI). Performing MRI can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death.
- Patients who are unable to properly operate the neurostimulator.

Transcranial magnetic stimulation (TMS) is contraindicated for use in patients with an implanted DBS system.

Risks

Electroconvulsive Therapy (ECT) – The safety of ECT in patients who have an implanted deep brain stimulation (DBS) system has not been established. Induced electrical currents may interfere with the intended stimulation or damage the neurostimulation system components resulting in loss of therapeutic effect, clinically significant undesirable stimulation effects, additional surgery for system explantation and replacement, or neurological injury.

Risks of Reclaim DBS Therapy can include risks of surgery, side effects, or device complications.

Risks of Surgery

Implanting the neurostimulator system carries the same risks associated with any other brain surgery. Risks may include:

- Paralysis, coma, and/or death
- Bleeding inside the brain (stroke)

- Leakage of fluid surrounding the brain
- Seizures
- Infection
- Allergic response to implanted materials
- Temporary or permanent neurologic complications
- Confusion or attention problems
- Pain at the surgery sites
- Headache

Possible Side Effects

Side effects of brain stimulation may include the following:

- Suicidal ideation and depression
- Increased OCD symptoms
- Changes in mood (positive and negative)
- Increased anxiety
- Gastrointestinal disturbances
- Sensations such as tingling (paresthesia), smell, or taste

- Dizziness or lightheadedness (disequilibrium)
- Facial and limb muscle weakness or partial paralysis (paresis)
- Facial flushing or facial muscle contractions
- Jolting or shocking sensation
- Numbness (hypoesthesia)
- Increased heart rate
- Hyperactivity or euphoria (hypomania)

Your doctor should carefully monitor you for symptoms of depression, anxiety, and/or hypomania/mania. Such symptoms may include changes in sleep or eating behavior, disinhibition, anger, aggression, and a predisposition to accidents.

There is also potential for brain tissue damage if the stimulation parameters are set too high. Your physician will be warned when the stimulation parameters exceed a certain charge density.

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 re-adjust the location.
- The brain stimulation system could stop because of mechanical or electrical problems. Either of these would require surgery. Neurostimulator service life depends on individual use. Neurostimulator service life for OCD typically ranges from 6 months to 16 months.
Note: Refer to “Risks of Surgery” on page 27 and “Expected Battery Life” on page 60.
- Your body may have an allergic reaction to the brain stimulation system. The system materials coming in contact with your

tissue include titanium, polyurethane, silicone, and nylon. 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 1 of the parts of the brain stimulation system.

Benefits and limitations for Reclaim DBS Therapy for OCD

Reclaim DBS Therapy for OCD may help you manage your symptoms, but **it is not a cure**. Significant OCD symptoms are likely to persist following Reclaim DBS Therapy. When you turn on the brain stimulation system, it will deliver stimulation that may decrease some or all of your symptoms. The stimulation may also make it easier for you to engage in cognitive behavior therapy (CBT), which may also help control your symptoms. Your symptoms will probably return when the system is turned off. In some cases, symptoms may return with an intensity greater than was experienced prior to the system implant (See “Rebound Effect” on page 41).

You will continue to require medications to control your OCD.

What to Expect From Your Implant Procedure

Provided below is general information about how the Reclaim DBS System will be implanted. Your doctor can provide you with more specific information about your implant procedure.

Before Surgery

The evening before surgery, you may be instructed to stop taking all or some of your medications. You will be admitted to the hospital either the night before or the morning of your surgery. You may have all or part of your head shaved prior to surgery to help prevent infection.

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. Pictures of your brain will be taken using MRI (magnetic resonance imaging) and/or CAT (computer-aided tomography) scans. This will allow your surgeon to determine the area in your brain where the leads will be placed.
3. You will then go to the operating room where a small hole will be drilled in your skull for each lead. You will receive local anesthesia before this procedure. This hole is needed to place the lead in your brain. Later in the surgery, your surgeon will cover this hole and secure the lead in place with a separate component called a hole cap (Figure 2.4).
4. Your surgeon may test stimulate areas of your brain to check changes in mood or anxiety levels (ie, OCD symptoms). You

will be awake, but lightly sedated. This is so you can help determine, along with your doctor, when your symptoms are best controlled. Your doctor may ask you questions about your mood.

5. When the best target in the brain is located, the lead is then passed into the brain. The lead's position is then held in place with a hole cap in the hole in your skull.
6. The metal frame is then removed from your head. If you do not have the extension and the neurostimulator implanted right away, you will typically be allowed to go home in approximately 24 to 48 hours. Your doctor will decide the length of your hospital stay.
7. 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.

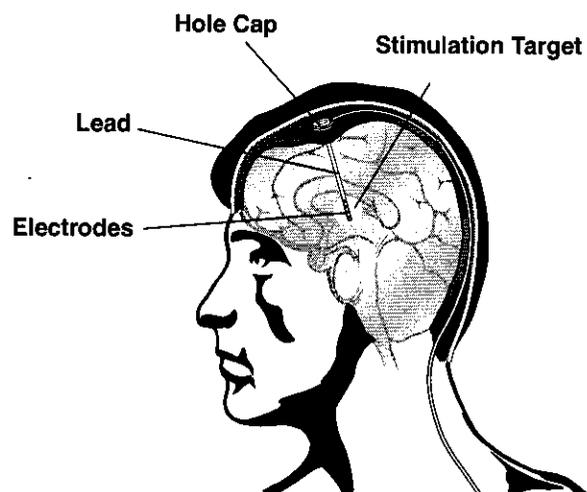


Figure 2.4 The location of the lead in your brain.

After Surgery

Healing stage

Your doctor will decide when to turn on your neurostimulator. It may be turned on immediately or after healing is complete (about 4 weeks).

First programming

Your doctor (or nurse) will use a computer called a clinician programmer to turn on your neurostimulator. This programming session sets the stimulation to best control your symptoms and may take several hours. You may have to return to the clinic a few times to have the stimulation adjusted in order to achieve the best symptom control for you, especially during the first few months after implant.

Changes in Therapy

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

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

Your clinician may correct these changes by programming the brain stimulation system again. However, surgery may be required to reposition or replace the lead, replace the system, or remove the system. You may also ask your doctor to turn off your neurostimulation system.

Your condition may improve, may worsen, or may remain unchanged with stimulation.

General Warnings

Also refer to “When the Device Should Not be Used (Contraindications)” on page 25 and “About Electromagnetic Interference (EMI)” on page 67 for more safety information.

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 (eg, aspirin, coumadin)], inform your doctor. These medications increase the risk of bleeding during surgery.

Side Effects During Programming or Test Stimulation – During test stimulation or a programming session, some side effects may occur, including:

- facial flushing or facial muscle contractions

- increased heart rate
- hyperactivity or euphoria (hypomania)
- increased disease symptoms

Your doctor will select different stimulation settings until these side effects decrease. Because these side effects may not appear immediately, you may be asked to remain in the clinic for at least 30 minutes after your programming or test stimulation is complete.

General Precautions

Component Failures – The brain stimulation 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 or worsen 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.

Long-Term Safety and Effectiveness – The long-term safety and effectiveness of brain stimulation therapy for obsessive compulsive disorder has not been established.

Multiple Implants – The long-term safety associated with leads left in place without use, replacement of leads, multiple implants into the target structure, and lead explant is unknown.

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.

Rebound Effect – If your brain stimulation system ceases to function for any reason (eg, battery depletion or exposure to EMI sources that will shut off the system), your symptoms will probably return. In some cases, symptoms may return with an intensity greater than was experienced prior to the system implant (rebound effect). If this occurs, contact your physician immediately so the status of your system can be assessed and your condition can be closely monitored.

Use in Specific Populations – The safety and probable benefit of this therapy is not known for:

- Patients with Tourette’s syndrome
- Patients with OCD with a primary subclassification of hoarding

- Patients whose diagnosis of OCD is documented to be less than 5 years duration
- Patients whose YBOCS score is less than 30
- Patients who have not completed a minimum of 3 adequate trials of first and/or second line medications with augmentation
- Patients who have not attempted to complete an adequate trial of cognitive behavior therapy (CBT)
- Patients with a previous surgical ablation procedure (e.g., capsulotomy)
- Patients who are pregnant
- Patients under the age of 18 years
- Patients with dementia
- Patients with coagulopathies or who are on anticoagulant therapy
- Patients without comorbid depression and anxiety
- Patients with neurological disorders

- Patients with other serious medical illness including cardiovascular disease, renal or hepatic failure, and diabetes mellitus

Use in Patients with Comorbid Psychiatric Disorders – There are potential risks with implanting the brain stimulation system in OCD patients who have comorbid psychiatric disorders that include:

- bipolar disorder
- body dysmorphic disorder
- expanded personality impulse-control disorders or paraphilias
- psychotic disorder
- severe personality disorders
- substance abuse
- the inability to control suicidal impulses or a history of suicidal attempts

The brain stimulation system may aggravate the symptoms of comorbid psychiatric disorders.

Electromagnetic Interference (EMI)

Electromagnetic Interference is a field of energy (electrical, magnetic, or both) made by equipment found in the home, work, medical or public environments that is strong enough to interfere with your neurostimulator.

Electromagnetic Interference could cause:

- **Serious Injury or Death**, resulting from heating of the implanted system components, which can damage surrounding tissue. See “When the Device Should Not be Used (Contraindications)” on page 25 and “About Electromagnetic Interference (EMI)” on page 67.
- **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 OFF¹, 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 “shocking” or “jolting.”

If you think that equipment is interfering with your neurostimulator function, you should do the following:

1. Move away from the equipment or object.

¹ With all neurostimulators referenced in this manual, unexpected On/Off switching of the devices may occur when they are exposed to magnets and strong electromagnetic fields. With the Kinetra Model 7428, however, your physician may choose to disable the magnet control circuit to avoid unexpected switching. If the magnet control circuit is disabled, you may receive a therapy controller to turn your therapy On or Off.

2. If possible, turn off the equipment or object causing interference.
3. If necessary, use the control magnet or therapy controller to return your neurostimulator to the desired on or off state.
4. Inform the equipment owner/operator of what happened.

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

Refer to “Electromagnetic Interference” on page 67, for information on sources of Electromagnetic Interference and their effect on you and your brain stimulation system.

Living with Your Reclaim DBS Therapy: What You Should Know

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

- **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 at 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 this manual along with you. There may be situations where you need their assistance.
- Go to all follow-up appointments. This will ensure that you get the best care.
- When the neurostimulator is turned off, your symptoms will probably return. Some symptoms return quickly. Other symptoms may take longer to return.

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 side effects such as inappropriate euphoria or disinhibition.
- You experience any unusual symptoms that you think may be caused by electromagnetic interference (e.g., theft detectors).
- You lose your control magnet or therapy controller.

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 will feel some discomfort from the incision sites. You will feel some discomfort or pain at the neurostimulator sites 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 like 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 brain stimulation system parts.

3 OPERATING INFORMATION

Control Devices

Your neurostimulator can be turned on or off using either a control magnet or a therapy controller. Your physician will determine which control device is appropriate for your needs. You will receive a booklet that tells you how to care for your control device.

For Soletra Neurostimulator

The control devices for the Soletra Model 7426 Neurostimulator are the Model 7452 Control Magnet and the Access Review Model 7438 Therapy Controller.

For Kinetra Neurostimulator

The control devices for the Kinetra Model 7428 Neurostimulator are the Model 7452 Control Magnet and the Access Model 7436 Therapy Controller.

Using Your Therapy Controller

If you have a therapy controller², refer to the user manual supplied with the controller for specific applications and procedures.

Using Your Control Magnet

A control magnet² is used to turn your neurostimulator on and off. When the therapy is turned on, you may experience a change in your OCD symptoms. Depending on your individual circumstance, you may have a sensory experience (tingling, smell, or taste), feel a slight muscle contraction, or experience no change at all.

There may be a slight possibility of a “jolting” or “shocking” sensation when the therapy is turned on.

². With all neurostimulators referenced in this manual, unexpected On/Off switching of the devices may occur when they are exposed to magnets and strong electromagnetic fields. With the Kinetra Model 7428, however, your physician may choose to disable the magnet control circuit to avoid unexpected switching. If the magnet control circuit is disabled, you may receive a therapy controller to turn your therapy On or Off.

Turning Your Neurostimulator On or Off with Your Magnet

To start (and stop) therapy, you will place your control magnet over your neurostimulator for 1 to 2 seconds (Figure 3.2). Your doctor or nurse will show you how to position the magnet over your neurostimulator. Use the control magnet as explained to you by your doctor or nurse. Instructions are also given on the next few pages.

Before using your control magnet, read the entire procedure below and examine figures 3.1-3.4 on the following pages.

Note: Family members or caregivers should be able to turn the neurostimulator on and off using the magnet.

1. Grasp the magnet with the flat end away from you using either your right or left hand (Figure 3.1).

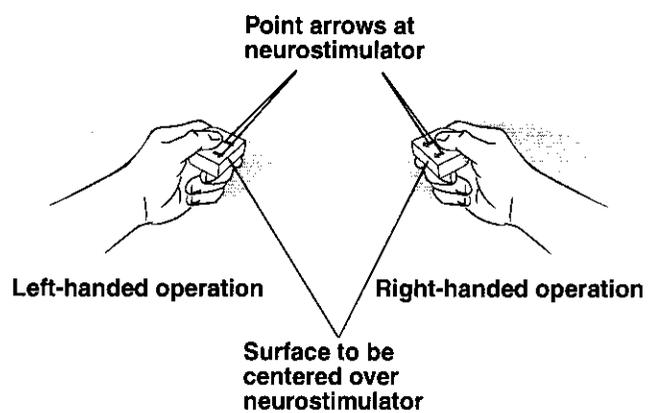


Figure 3.1 Grasp magnet with flat end away from you.

2. Press the flat end of the magnet directly over the length of your neurostimulator (Figure 3.2). Position the magnet so that the arrows are toward your body (Figure 3.3).

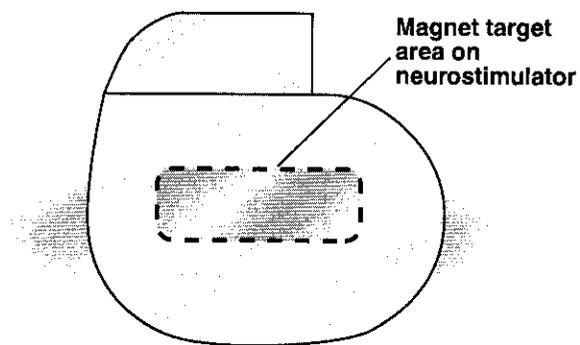


Figure 3.2 Magnet centered over neurostimulator.

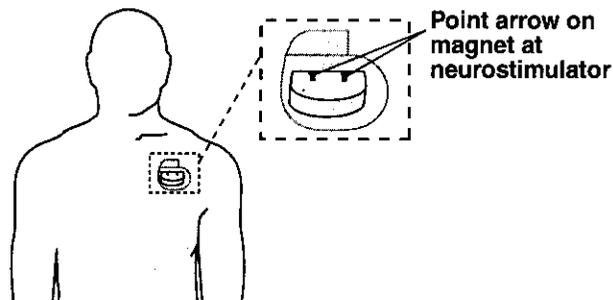
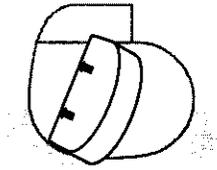


Figure 3.3 Position magnet over neurostimulator and hold in position for 1 to 2 seconds.

3. Hold the magnet steady in place for 1 to 2 seconds and then remove it. Nothing happens if you hold the magnet in place longer because the magnet turns your neurostimulator on or off only as you move it away from your body.

Note: If you have trouble turning your neurostimulator on or off, try changing the position of the magnet. Picture your neurostimulator as the face of a clock. Then place the magnet in the one o'clock position as shown in Figure 3.4. If the one o'clock position does not work try the four o'clock position.

One o'clock position



Four o'clock position

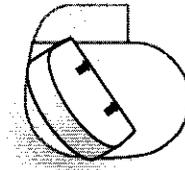


Figure 3.4 You may need to position the magnet at the one o'clock or four o'clock position.

If you have tried repositioning the magnet, but your symptoms do not decrease at the time they normally do, contact your doctor.

Carrying Your Magnet

Your control magnet is a very strong magnet.

Cautions:

- When carrying your control magnet in a pocket or purse, make sure the magnet is on the other side of your body from where the neurostimulator is placed. The control magnet may come close enough to the neurostimulator to turn your therapy on and off when you don't expect it.
- Keep your control magnet away from children.

Storing Your Magnet

The magnetic field of the control magnet can affect other items such as watches, credit cards, and computer disks. These items can be easily protected by keeping the control magnet away from them, as described below:

Keep more than 2 inches away. Store the control magnet more than 2 inches away from a wristwatch, pocket watch, and clock. The control magnet can stop them from working.

Keep more than 6 inches away. The magnetic field of the control magnet may damage the information on some magnetic items. To prevent damage, keep the magnet more than 6 inches away from the following items:

- Items with a magnetic strip such as bank cards and credit cards.
- Magnetic media such as video and audio cassette tapes and computer disks.
- Home electric items such as personal computers, VCRs, televisions, or cameras.

Expected Battery Life

When you visit the clinic or doctor, the energy level of the battery in your neurostimulator will be checked. The length of time the battery will last depends on your programmed settings and the amount of time you use your neurostimulator.

Based on the initial clinical data your battery should last 6 months to 16 months. However, your battery may last longer depending on the neurostimulator setting used. Your doctor can give you an estimate based on your therapy settings.

As the energy in the battery is reduced, the neurostimulator will eventually stop functioning and therapy will not be effective and will not resume until the battery is replaced. This is normal. If you feel this kind of change, ask your doctor to check the battery. No surgery is required for your doctor to check your battery.

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 typically done

using a local anesthetic. It does not require the use of a head frame. As with the initial implant, replacement of your neurostimulator will lead to surgical risks, including pain or discomfort at the surgical site, risk of infection, and internal or external bleeding or hemorrhage at or near the implant location.

Choosing to Turn Off or Explant the Reclaim DBS System

If you and your doctor decide that the neurostimulation system does not provide the therapy you need, it may be turned off or explanted. If it is turned off, it will remain implanted without stimulation. If it is explanted, you will require surgery.

Instructions on Disposing of Your Device

If your implanted system is ever explanted, your physician will dispose of your device for you.

The neurostimulator must be removed before a body is cremated. The cremation process can cause the battery to explode.

Your Patient Identification Card

A patient identification card (Figure 3.5) identifies you as having an implanted medical device. This card also provides basic information about your neurostimulator and lists your doctor's name and telephone number. The information is important for others to know, should you need to bypass a security system, or in case of a medical emergency. Keep this card with you at all times.

You will receive a temporary card during your hospital stay. Several weeks after your surgery you will receive a plastic-coated card.

	
Medical Device Temporary Identification	
<i>The bearer of this card has an implanted medical device prescribed by his or her doctor.</i>	
Patient's Name _____	
Address _____	
City _____	State or Country _____
Phone () _____	
<i>In case of an emergency, please notify:</i>	
Physician _____	
Phone () _____	
Model Number _____	
Serial Number _____	
Implant Date _____	
<small>Medtronic Neurological, Minneapolis MN 55421 Telephone: (763) 514-5000 U.S. Toll-Free: (800) 510-6735 Internet: www.medtronic.com</small>	
<small>UC20000991 EN / 182403-001</small>	

Figure 3.5 Patient Identification Card.

If you change your address or doctor's information, contact Medtronic. Include the current information and indicate the changes. You may either call 1-800-510-6735 with the information or send the information to:

Medtronic Neuromodulation
Device Registration
P.O. Box 59262
710 Medtronic Parkway
Minneapolis, MN 55459-9896

4 TROUBLESHOOTING

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

What should I do if I have trouble turning on my Reclaim DBS Therapy or if I can't tell if it's turned on?

Your doctor can advise you as to how long it takes to feel the effects of the therapy. This time can be different from patient to patient. It also depends upon your medical condition.

If you have a control magnet, be sure to hold it directly over the neurostimulator when attempting to turn on the therapy. Also, try rotating the magnet to the one o'clock or four o'clock position (refer to Figure 3.1 on page 54).

If you have a therapy controller, use it to check the neurostimulator on or off status (refer to the user manual supplied with your therapy controller for specific instructions).

If for some reason you cannot turn on your therapy, call your doctor.

What should I do if I think that my neurostimulator has turned off accidentally?

Turn your neurostimulator back on using your control magnet or therapy controller. If this is happening often, review the section “About Electromagnetic Interference (EMI)” on page 67 and try to identify the source of the problem.

5 ELECTROMAGNETIC INTERFERENCE³

About Electromagnetic Interference (EMI)

Electromagnetic interference is a field (electrical, magnetic, or a combination of both) that is generated by various equipment found in medical, work, and home environments. This equipment can create enough interference to do the following;

- Turn your neurostimulator off or on
- Cause stimulation that can result in an uncomfortable sensation

³ With all neurostimulators referenced in this manual, unexpected On/Off switching of the devices may occur when they are exposed to magnets and strong electromagnetic fields. With the Kinetra Model 7428, however, your physician may choose to disable the magnet control circuit to avoid unexpected switching. If the magnet control circuit is disabled, you may receive a therapy controller to turn your therapy On or Off.

- Reset your neurostimulator to factory settings, which will require reprogramming by your doctor

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

Specific warnings regarding possible effects from EMI are provided in the section “Electromagnetic Interference (EMI)” on page 44.

Even when the therapy is turned off, interference can affect the lead(s). If you suspect EMI, move away from the source of the EMI. If possible, turn off the suspected source of EMI. Then use your control magnet or therapy controller to turn your therapy on or off.

Theft Detectors and Security Gates

Caution: 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 (Figure 5.1).
 - a. If two security gates are present, walk through the middle, keeping as far away as possible from each gate.
 - b. If one gate is present, walk as far away as possible from it.

Note: Some theft detectors may not be visible.

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

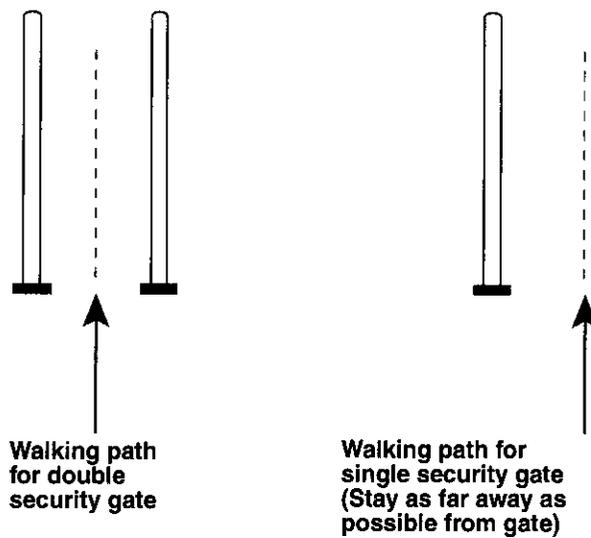


Figure 5.1 Walking through security gates.

4. 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.

Interference Likely – Home and Work Environment

Avoid the following equipment or environments. EMI from the following may affect or damage the neurostimulator.

- Antenna of a citizen band or ham radio
- Electric arc or resistance welding equipment
- Electric induction heaters used in industry to bend plastic
- Electric steel furnaces, for example, the blast furnaces found in steel mills, not the furnaces found in your home
- Power lines
- Television and radio transmitting towers
- Electric substations and power generators

- Therapeutic magnets, if placed close to neurostimulator

Possible Interference – Home and Work Environment

Some household items have small, strong magnets. You can use these items if you keep a distance that is expected for normal use of the item. Some examples are described below. If you notice that your therapy is affected by being too near to an item, move away from it. If EMI has started or stopped your therapy, use the control magnet or therapy controller to return your therapy to its original state.

- You can open and shut a **refrigerator or freezer door**. However, do not lean against the magnetic strip inside a refrigerator or freezer door.
- You can listen with a **standard, cordless or cellular telephone handset**, but do not pass or lay the **earpiece** over the neurostimulator because you may turn it on or off.

- You can be near **stereo speakers** and **radios for the home or the car**. However, do not lift or carry them so that they are close to or touching the part of your body where the neurostimulator is located.
- You can use a **sewing machine** or **salon hair dryer**. However, keep your neurostimulator away from the motors (such as when leaning over these items).
- You can use an **induction range (or smooth top range)**. Keep your neurostimulator away from the burners.
- You can use **power tools** when the motor is kept away from the neurostimulator. Do not lean against the tool. Use caution when using power tools that may be unsafe if your symptoms would return.

Safe from Interference – Home and Work Environment

The following items should not interfere with your neurostimulator when they are properly installed and in good working order:

- Microwave ovens

- Appliances like washing machines, dryers, electric stoves, toasters, blenders, electric can openers, and food processors
- Electric blankets and heating pads
- Hand-held items like hair dryers, shavers, remote controls, and pagers
- Home security systems
- Personal computers, electric typewriters, copiers, and fax machines
- Televisions, AM and FM radios, and stereos
- Vacuum cleaners and electric brooms

Medical and Dental Environments

Tell medical and dental personnel that you have a neurostimulation system that works similar to a pacemaker. (Both systems create amounts of electricity.)

Most routine diagnostic procedures, such as **fluoroscopy** and **x-ray**, do not affect the system. And, some 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; or
- Affect your brain stimulation system, for example, turning your neurostimulator on or off; or
- Cause harm to you, for example, heating a system component enough that it can cause tissue damage.

Interference Likely – Medical and Dental Environment

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

Avoid the following procedures:

- **Diathermy** (deep heat treatment)
- **MRI** (magnetic resonance imaging)
- **TMS** (transcranial magnetic stimulation)

Note: Additional safety information about diathermy, MRI, and TMS is located in the front of this manual. Refer to “When the

Device Should Not be Used
(Contraindications)” on page 25.

If any of the procedures listed below are required, please inform your treating doctor that you have an implanted neurostimulator. Your doctor should contact Medtronic at 1-800-510-6735 for more information:

- **Somatic psychiatric therapies.** The safety of somatic psychiatric therapies using equipment that generates electromagnetic interference (eg, vagus nerve stimulation) has not been established.
- **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.)
- **Radiation therapy** (often used in cancer treatment). This may be done if the focus

of the therapy is away from the neurostimulator.

Possible Interference – Medical and Dental Environment

The following procedures can be done when the therapy is turned off and when the medical equipment is not directly over your neurostimulator. If the equipment is placed over your neurostimulator, it may be turned on accidentally, or it can be permanently damaged, which will require surgery.

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

Note: Additional safety information about therapeutic ultrasound is located in the front of this manual. Refer to “When the Device Should Not be Used (Contraindications)” on page 25.

The following procedures and devices require safeguards:

- **Implantable device that senses electrical signals** such as a **pacemaker** or **defibrillator** (medical device placed

inside the body to regulate the heart rate).
Tell the cardiac doctor that you have a neurostimulator.

- **Mammography** (x-ray of breast tissue).
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 – Medical and Dental Environment

The following medical procedures should not affect your therapy:

- **Computerized axial tomography (CT or CAT) scans.** (A special type of x-ray equipment that gives a cross-section view.)
- **Diagnostic ultrasound.** (An imaging technique which 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.

6 COMMON QUESTIONS

About the System and its Components

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.

Turning On and Turning Off Reclaim DBS Therapy

What happens if the neurostimulator stops working?

Your symptoms will probably return and may be worse than prior to the beginning of stimulation therapy. 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 Kinetra neurostimulator can change stimulation settings by using a therapy controller. If you have an implanted Kinetra neurostimulator, consult with your doctor to determine if you can increase or decrease the strength of stimulation.

Everyday Use of Your Therapy

Will I be able to resume my normal daily activities?

For the first few weeks after surgery, you should avoid strenuous activity, 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 Reclaim 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.

7 QUICK LOOK-UP TABLE FOR INTERFERENCE FROM EQUIPMENT

Equipment in your daily environment could affect your system. Ways to minimize or prevent interference from happening, is discussed in the chapter “Troubleshooting” beginning on page 65. To help you quickly locate information about an item, use this table to find the page number containing details.

Table 7.1 Quick Look-up Table for Interference from Equipment¹

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Airport security gates		✓		68
Arc welding equipment			✓	71
Blenders	✓			74
CAT (or CT) scan	✓			79
Cautery			✓	76
Cellular phones		✓		72
Computers, personal	✓			74
Copiers	✓			74
Defibrillation, external			✓	76
Defibrillation, implantable		✓		77
Dental drills		✓		77

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Dental ultrasonic probes		✓		77
Diagnostic ultrasonic	✓			79
Diathermy treatment			✓	75, 25
Dryers (clothes)	✓			74
Electric blankets	✓			74
Electric brooms	✓			74
Electric can openers	✓			74
Electric power generators			✓	71
Electric stoves	✓			74
Electric substations			✓	71
Electric typewriters	✓			74
Electrocautery			✓	76

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
FAX machines	✓			74
Fluoroscopy	✓			74
Food processors	✓			74
Freezer door		✓		72
Hair dryers, salon		✓		73
Hair dryers, hand-held	✓			74
Ham radio antenna			✓	71
Heating pads	✓			74
Home security system	✓			74
Induction furnace			✓	71
Induction heaters for industry			✓	71
Libraries, theft detectors		✓		68
Lithotripsy			✓	76

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Magnets, therapeutic			✓	72
Magnetic Resonance Imaging			✓	26, 75
Mammography		✓		78
Microwave ovens	✓			73
MRI			✓	26, 75
Pacemaker		✓		77
Pagers	✓			74
Personal computers	✓			74
Power generators, electric			✓	71
Power lines			✓	71
Power tools		✓		73
Psychotherapeutic procedures			✓	76

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Radiation therapy			✓	76
Radio, AM and FM	✓			74
Radio antenna, Ham			✓	71
Radio transmission towers			✓	71
Radio with large speakers		✓		73
Range, induction		✓		73
Refrigerator door		✓		72
Remote controls	✓			74
Security gates at airports and other public places		✓		68
Security systems for the home	✓			74
Sewing machine		✓		73

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Shavers	✓			74
Smooth top oven ranges		✓		73
Steel furnaces			✓	71
Stereos	✓			74
Stereo speakers		✓		73
Stores, theft detectors		✓		68
Stove, electric	✓			74
Surgery that uses cautery			✓	76
Telephone handset, standard		✓		72
Telephones, cellular		✓		72
Television	✓			74
Television towers for transmitting			✓	71

Table 7.1 Quick Look-up Table for Interference from Equipment¹ (continued)

Item or Procedure	Safe from Interference	Possible Interference	Interference Likely	More Information on Page
Theft detectors		✓		68
Toasters	✓			74
Transmission towers for television and radio signals			✓	71
Typewriters	✓			74
Ultrasonic, diagnostic	✓			79
Ultrasonic, therapeutic			✓	25
Vacuum cleaners	✓			74
Washing machines	✓			74
X-ray, CAT scan	✓			79
X-ray, diagnostic	✓			79
X-ray, mammography		✓		78

¹. Assuming equipment is in proper working order.

8 ADDITIONAL INFORMATION

More About Reclaim DBS Therapy

For additional information about Reclaim DBS Therapy, use these resources:

- Medtronic web site: www.medtronic.com
- Contact Medtronic Patient Services
1-800-510-6735
- Contact your doctor

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