Medtronic

Medtronic® DBS™ Therapy

Implanted neurostimulators

Information for prescribers

℞ USA Rx only

CE 0123

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Refer to the Indications sheet for indications and related information.

Refer to the device implant manual for device description, package contents, device specifications, and instructions for use.

Refer to the System Eligibility Battery Longevity reference manual, packaged with the software application card, for neurostimulator selection and battery longevity calculations.

! USA **Refer to the Clinical Summary booklet for information on the clinical study results of the neurostimulation system, individualization of treatment, and use in specific populations.**

IFP booklet and IFP addendum organization

This Information for prescribers (IFP) booklet contains general information that is applicable to Medtronic DBS therapies. Additional information, including indication-specific warnings and precautions, can be found in the individual IFP addendum.

PLEASE REFER TO THE APPROPRIATE INDICATION-SPECIFIC IFP ADDENDUM FOR COMPLETE INFORMATION.

Contraindications

Implantation of a DBS system is contraindicated for:

Diathermy – Patients exposed to diathermy. Do not use shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and can cause tissue damage at the location of the implanted electrodes, resulting in severe injury or death.

Diathermy can also damage the neurostimulation system components, resulting in loss of therapy and requiring additional surgery for system explantation and replacement. Advise your patient to inform all their health care professionals that they should not be exposed to diathermy treatment.

Injury to the patient or damage to the device can occur during diathermy treatment when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on the body - not just at the location of the neurostimulation system.
- diathermy delivers heat or no heat.
- any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

Magnetic Resonance Imaging (MRI) using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area – Some specific types of MRI are contraindicated for patients with any implanted DBS system or system component. Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death can occur if performing 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

Refer to the MRI guidelines manual packaged with this product for comprehensive safety information and instructions.

Unable to operate patient devices – Patients who are unable, or do not have the necessary assistance, to properly operate the DBS therapy patient programmer, magnet, or a charging system (applicable to rechargeable DBS systems only).

Transcranial Magnetic Stimulation (TMS) – Contraindicated for use in patients with an implanted DBS system.

Warnings

Avoid excessive stimulation – There is a potential risk of brain tissue damage from high amplitude and wide pulse width parameter settings. Parameter values exceeding the recommended output settings should only be programmed with due consideration of the charge density warning described in the software programming guide.

The Medtronic DBS System can be programmed to use parameter settings outside the range of those used in the clinical studies. If the programming of stimulation parameters exceeds charge density limits, the following programmer warning appears: **WARNING: CHARGE DENSITY MAY BE HIGH ENOUGH TO CAUSE TISSUE DAMAGE**.

Note: Higher amplitudes and wider pulse widths may indicate a system problem or a less than optimal lead placement.

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

Coagulopathies – Use extreme care with lead implantation in patients with a heightened risk of intracranial hemorrhage. Physicians should consider underlying factors, such as previous neurological injury, or prescribed medications (anticoagulants), that may predispose a patient to the risk of bleeding.

Electromagnetic Interference (EMI) – Electromagnetic interference is a field of energy generated by equipment found in the home, work, medical, or public environments that is strong enough to interfere with neurostimulator function. Neurostimulators include features that provide protection from electromagnetic interference. Most electrical devices and magnets encountered in a normal day are unlikely to affect the operation of a neurostimulator. However, sources of strong electromagnetic interference can result in the following effects:

- **Serious patient injury or death -** it is possible for the extension, lead, or both to “pick up” electromagnetic interference and deliver an excess current causing tissue damage, including brain tissue damage.
- **System damage -** resulting in a loss of or change in symptom control and requiring surgical replacement.
- **Operational changes to the neurostimulator -** causing it to turn on or off or to reset to power-on-reset (POR) settings, resulting in loss of stimulation, return of symptoms, and in the case of a POR, may require reprogramming by a clinician.
- **Unexpected changes in stimulation -** causing a momentary increase in stimulation or intermittent stimulation, which some patients have described as a jolting or shocking sensation.

Refer to "Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 19 for guidelines on medical procedures that generate EMI and the possible adverse effects of EMI on an implanted DBS system.

Interaction with implanted cardiac devices – When a patient's medical condition requires both a neurostimulator and an implanted cardiac device (eg, pacemaker, defibrillator), physicians involved with both devices (eg, neurologist, neurosurgeon, cardiologist, cardiac surgeon) should discuss the possible interactions between the devices before surgery.

Possible effects of implanted device interaction include:

- Defibrillation therapy from an implanted defibrillator may damage the neurostimulator.
- The electrical pulses from the neurostimulation system may interact with the sensing operation from a cardiac device and could result in an inappropriate response of the cardiac device.

To minimize possible interactions:

- implant the devices on opposite sides of the body and follow any additional instructions.
- program the neurostimulator to a bipolar configuration and to a minimum rate of 60 Hz. and program the cardiac device to bipolar sensing.

See also: "Neurostimulator location" on page 10.

Magnetic Resonance Imaging (MRI) – Refer to safety information and instructions in the MRI guidelines manual packaged with this product. Do not conduct an MRI examination on a patient with any implanted DBS system component until you read and fully understand all MRI information in this manual and the safety information and instructions in the MRI guidelines manual packaged with this product.

Placement of lead-extension connector in neck – Do not place the lead-extension connector in the soft tissues of the neck. Placement in this location has been associated with an increased incidence of lead fracture, which would require surgical replacement.

Psychotherapeutic procedures – Safety has not been established for psychotherapeutic procedures using equipment that generates electromagnetic interference (eg, electroconvulsive therapy) in patients who have an implanted DBS system.

Theft detectors and screening devices – Theft detectors found in retail stores, public libraries, etc, and airport/security screening devices may cause the stimulation power source of an implantable neurostimulation system to switch off. It is also possible that sensitive patients, or those with low stimulation thresholds, may experience a momentary increase in their perceived stimulation. For other indications, higher levels of stimulation have been described as uncomfortable ("jolting" or "shocking") by some patients as they pass through these devices. Refer to **"Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 19** for more information.

Precautions

Physician training

Please see the appropriate indication-specific IFP addendum for more information on indication-specific physician training.

Implanting physicians – Implanting physicians should be experienced in DBS procedures and should review the procedures described in the implant manuals before surgery.

Prescribing physicians – Prescribing physicians should be experienced in the diagnosis and treatment of DBS-indicated diseases and should be familiar with using the neurostimulation system.

Medical procedure coordination

Turning the neurostimulator off – The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures should be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professionals (prescribing and implanting clinicians) is recommended.

Storage and sterilization

Component packaging – Do not implant a component if the following circumstances have occurred:

- The storage package has been pierced or altered because component sterility cannot be guaranteed and infection may occur.
- The component shows signs of damage because the component may not function properly.
- The use-by date has expired because component sterility cannot be guaranteed and infection may occur; also, neurostimulator battery longevity may be reduced and may require early replacement.

Sterilization – Medtronic has sterilized the package contents according to the process indicated on the package label before shipment. This device is for single use only and is not intended to be resterilized.

Storage temperature: leads and extensions – Do not store or transport the leads or extensions above 57°C (135°F) or below -34°C (-30°F). Temperatures outside this range can damage components.

Storage temperature: neurostimulators – Do not store or transport the neurostimulator above 52°C (125°F) or below -18°C (0°F). Temperatures outside this range can damage components.

System implant

Compatibility, all components – Follow these guidelines when selecting system components for either initial implant or replacement:

- Medtronic components: For proper therapy, use only Medtronic Neuromodulation components that are compatible or specified in an intended use statement (if present). For each product, refer to the indication insert(s) and shipping label for this information.
- Components are compatible when the following conditions are met:
  - Components have the same indication.
  - For implanted components, the contact spacing and the number of electrode contacts at the connections for the lead and extension/neurostimulator or extension and neurostimulator are the same.
- Non-Medtronic components: No claims of safety or efficacy are made with regard to the compatibility of using non-Medtronic components with Medtronic components. Refer to the non-Medtronic documentation for information.

Components – The use of non-Medtronic components with this system may result in damage to Medtronic components, loss of stimulation, or patient injury.

Explantation and EMI considerations – If any DBS system components (neurostimulator, lead, extension, or lead/extension fragment) remain implanted in the patient's body after a partial system explant, the patient is still susceptible to possible adverse effects from EMI. These effects include induced current and component heating which may result in shocking or jolting the patient and tissue damage resulting in serious injury or death. Advise patients who have any DBS system components implanted in their body to notify all medical personnel that they have an implanted DBS system.

Component failures – The DBS system may unexpectedly cease to function due to certain events. These events, which can include electrical short or open circuits, conductor wire fracture, and insulation breaches, cannot be predicted. The patient's disease symptoms will return if the device ceases to function.

Component handling – Handle the implantable components of this system with extreme care. These components may be damaged by excessive traction or sharp instruments, which may result in intermittent or loss of stimulation, requiring surgical replacement. Refer to the appropriate implant manual for additional instructions.

Extension routing for multiple leads – When multiple leads are implanted, route the lead-extensions so the area between them is minimized (Figure 1). If the lead-extensions are routed in a loop, the loop will increase the potential for electromagnetic interference (EMI).

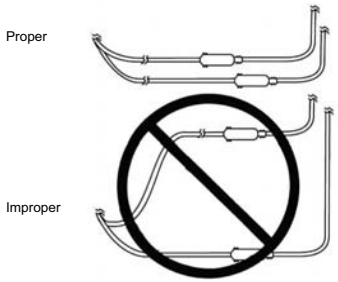


Figure 1. *Routing for multiple lead-extensions.*

Lead materials – The polyurethane tubing of the lead may release neurotoxic or carcinogenic compounds. Data are insufficient to assess the likelihood of these effects occurring in patients who receive the device.

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

Neurostimulator location – Select a location that is:

- a minimum of 20 cm (8 in) away from another neurostimulator to minimize telemetry interference and possible inappropriate therapy.
- on the opposite side of the body from another active implanted device (eg, pacemaker, defibrillator) to minimize possible interaction between the devices.
- away from bony structures (eg, 3 – 4 cm [1.2 – 1.6 in]) to minimize discomfort at the neurostimulator site.
- away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.
- in an area accessible to the patient for proper operation of a patient control device and for proper neurostimulator recharging (rechargeable neurostimulator only).

Neurostimulator location and MRI – If MRI is planned, avoid, if possible, implanting the neurostimulator in the abdomen. This requires the use of a longer length lead/extension system that can increase the heating from MRI induced RF currents, especially at the lead electrodes. Refer to the MRI guidelines manual for comprehensive safety information and instructions.

Device specific considerations

Soletra Model 7426 and Kinetra Model 7428 neurostimulators

Replacement Procedure – Do not replace two Soletra Model 7426 Neurostimulators with one bilateral neurostimulator unless retunneling is performed so both lead-extensions are

on the same side of the body. Otherwise, the “looped” configuration formed by the lead-extensions increases the potential for electromagnetic interference (EMI) effects.

EMI procedures for neurostimulators with magnet switch – See **“Appendix A: Electromagnetic interference (EMI) and mechanical interference” on page 19** for device specific guidelines.

Activa RC Model 37612 neurostimulator

Importance of regular recharging (rechargeable neurostimulator only) – Inform patients and their caregivers of the importance of maintaining a regular schedule of recharging.

Charging system (rechargeable neurostimulator only)

Wound contact – DO NOT use the recharger on an unhealed wound. The recharger, antenna, and belt are not sterile, and contact with the wound may cause an infection.

Low battery charge level – Advise patients to charge the neurostimulator on a regular basis to prevent the battery from becoming discharged. How often the neurostimulator battery needs to be charged depends on the therapeutic parameter settings and battery usage for each individual patient.

- A low battery charge is indicated by the Low Battery screen display on the patient programmer or recharger.
- A discharged battery is indicated by the Low Battery screen and no available therapy.

Furthermore, advise patients that the neurostimulator battery can be recharged when it is in a discharged state. If the battery is not recharged and allowed to remain in a discharged state, the neurostimulator will become overdischarged.

The patient cannot charge an overdischarged neurostimulator. However, the clinician may be able to restore the battery function using the Physician Recharge Mode on the recharger (refer to the troubleshooting section of the software manual).

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

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

Clinician programming

Effects on other medical devices – The DBS system may affect the operation of other implanted devices, such as cardiac pacemakers and implantable defibrillators. Possible effects include sensing problems and inappropriate device responses. If the patient requires

concurrent implantable pacemaker and/or defibrillator therapy, careful programming of each system may be necessary to optimize the patient's benefit from each device.

Parameter adjustment – To prevent possible unpleasant stimulation, decrease the amplitude(s) to 0.0 V before:

- connecting or disconnecting the cable to the screener or external neurostimulator.
- replacing the external neurostimulator or screener batteries.

Programmer interaction with a cochlear implant – When the patient has a cochlear implant, minimize or eliminate the potential for unintended audible clicks during telemetry by keeping the external portion of the cochlear system as far from the programming head as possible or by turning off the cochlear implant during programming.

Programmer interaction with flammable atmospheres – The programmer is not certified for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide. The consequences of using the programmer near flammable atmospheres are unknown.

Programmer interaction with other active implanted devices – When a patient has a neurostimulator and another active implanted device (eg, pacemaker, defibrillator, neurostimulator), the radio-frequency (RF) signal used to program these devices may reset or reprogram the other device. To verify that inadvertent programming did not occur, clinicians familiar with each device should check the programmed parameters of each device before the patient is discharged from the hospital and after each programming session of either device (or as soon as possible after these times).

Also, inform patients to contact their physician immediately if they experience symptoms that could be related to either device or to the medical condition treated by either device.

Screening with external neurostimulators – When screening a patient who has multiple leads implanted, do not operate multiple external neurostimulators simultaneously. The signals from simultaneously operated external neurostimulators can interfere with each other and result in incorrect results.

Telemetry signal disruption from EMI – Do not attempt telemetry near equipment that may generate electromagnetic interference (EMI). If EMI disrupts programming, move the programmer away from the likely source of EMI. Examples of sources of EMI are magnetic resonance imaging (MRI), lithotripsy, computer monitors, cellular telephones, motorized wheelchairs, x-ray equipment, and other monitoring equipment. Interrupting telemetry can result in incorrect or incomplete programming.

Clinician information and general guidance

Patient counseling information

Before surgery, the patient and family should be advised of the known risks of the surgical procedure and the therapy, as well as the potential benefits. After the DBS system is implanted, the patient should also be advised to read the patient manual included in the neurostimulator package.

Physicians should provide patients with information about:

- the components of the neurostimulation system: lead, extension, and neurostimulator.
- instructions for using the neurostimulation system, including the patient programmer and charging system (rechargeable neurostimulators only).
- the indications, contraindications, warnings, and precautions for a neurostimulation system.

Physicians should also instruct patients to:

- always inform any health care personnel that they have an implanted neurostimulation system before any procedure is begun.
- contact their physician if they notice any unusual symptoms or signs.

Patient selection (rechargeable neurostimulator only)

Consultation with the neurologist who will provide follow-up care is recommended prior to selection of a rechargeable neurostimulator.

Compliance with checking the battery status regularly is critical. Medtronic recommends a practice period for the patient and associated caregiver prior to implant, to assess whether the patient will be willing and able to incorporate the required recharging activities into current activities of daily living.

Selection of patients living in assisted care or nursing home facilities is not recommended, as maintenance of therapy maybe relegated to the care staff who may not be adequately trained to assist with recharge activities.

Careful consideration should be exercised when determining if a patient is appropriate for a rechargeable neurostimulator. The following should be considered for the expected duration of the implant period:

- Patient’s ability to use the patient programmer and correctly interpret the icons that appear on the screen.
- Patient's ability to regularly monitor the status of the rechargeable battery and respond appropriately.
- Patient’s ability to accurately locate their implanted neurostimulator, properly position the recharge antenna for sufficient coupling, put on the recharge holster/belt, and monitor progress during the recharge session.
- Patient's ability to perform charging activities for sufficient duration and frequency to maintain therapy and to perform charging activities on an ongoing basis.

Special consideration should be given to:

- Available level of support from a caregiver, to assist the patient with monitoring and recharging activities.
- Expected effect from cessation of therapy, should patient fail to recharge on schedule or when alerted.
- Patient's age, as very young or very old patients may have difficulty performing required monitoring and recharging of the device.

- Patient's mental capacity, as patients with cognitive impairment or those prone to developing dementia would likely have difficulty performing device-related tasks without assistance.
- Patient’s physical ability, as patients with higher degrees of motor impairment might have difficulty with the physical requirements of monitoring and recharging the device.
- Patient’s visual ability, as patients need to be able to read the patient programmer or recharger display screen to assess battery status.
- Patient’s willingness to use the patient programmer alert or a different method that will be effective in reminding the patient to check the battery status on a regular basis.
- Patient’s (and caregiver’s) willingness to continue recharging activities as necessary under all circumstances, (eg, power outages, travel, and hospitalizations), and recognize the critical nature of maintaining a charged battery in the neurostimulator.

Patient information

Programming and patient control devices

Group selection – Patients should select the group recommended by the clinician for the desired therapeutic effect. Use of another group may result in unpleasant stimulation when stimulation is turned on.

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

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

Patient device use – When operating a patient programmer or charging system (rechargeable models only), use special care near flammable or explosive atmospheres. An interaction between the flammable or explosive atmospheres and the battery in the device could occur. The consequences of using a battery-powered device near flammable or explosive atmospheres are unknown.

Patient activities

Patients should avoid activities that may put undue stress on the implanted components of the neurostimulation 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.

Component manipulation by patient – Advise your patient to avoid manipulating the implanted system components (eg, the neurostimulator, the burr hole site). This can result in component damage, lead dislodgement, skin erosion, or stimulation at the implant site.

Manipulation may cause device inversion, making a rechargeable neurostimulator impossible to charge.

Patient activities/environmental precautions – Patients should exercise reasonable caution in avoidance of devices that generate a strong electric or magnetic field. Close proximity to high levels of electromagnetic interference (EMI) may cause a neurostimulator to switch on or off. The system also may unexpectedly cease to function. For these reasons, the patient should be advised about any activities that would be potentially unsafe if their symptoms unexpectedly return. For additional information about devices which generate electromagnetic interference, call Medtronic. Refer to the contacts listed at the end of this manual.

Scuba diving or hyperbaric chambers – Patients 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 neurostimulation system. Before diving or using a hyperbaric chamber, patients should discuss the effects of high pressure with their physician.

Skydiving, skiing, or hiking in the mountains – High altitudes should not affect the neurostimulator, however, the patient should consider the movements involved in any planned activity and take precaution to avoid putting undue stress on the implanted system. Patients should be aware that 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.

Hospital or medical environment

Before undergoing any medical procedure, patients should always inform any health care personnel that they have an implanted neurostimulation system. There is potential for an interaction between the neurostimulation system and equipment used for the procedure—even when both are working properly.

Most routine diagnostic procedures, such as fluoroscopy and x-rays, are not expected to affect system operation. However, because of higher energy levels, sources such as transmitting antennas found on various diagnostic and therapeutic equipment may interfere with the DBS system, see **"Appendix A: Electromagnetic interference (EMI) and mechanical interference" on page 19** for more information on electromagnetic interference.

In order to minimize the effects of EMI for some medical procedures, it is recommended to turn off the neurostimulator during the procedure. The clinician ordering the procedure should contact the implanting clinician or prescribing clinician to determine if it is appropriate to turn off the neurostimulator based on the patient's underlying medical condition.

Implanting or prescribing clinicians should also explain the following information to their patients:

- whether or not it is safe to have their neurostimulator turned off
- what effects patients may experience when their neurostimulator is turned off and turned back on again
- whether or not patients should contact them before turning their neurostimulator off

Effect on electrocardiograms (ECGs) – Ensure the neurostimulator is programmed off prior to initiating an ECG. If the neurostimulator is on during an ECG, the ECG recording may be adversely affected, resulting in inaccurate ECG results. Inaccurate ECG results may lead to inappropriate treatment of the patient.

Home or occupational environment

Medtronic DBS neurostimulators should not be affected by normal operation of electrical equipment such as household appliances, electric machine shop tools, microwave ovens, RF transmitting systems, or microwave frequency transmitting systems. A strong magnetic field (electromagnet or permanent magnet) can switch the neurostimulator output from on to off or off to on, but does not change the programmed parameters.

Advise your patients to avoid or to exercise care when approaching the following:

- Theft detectors
- Airport/security screening devices
- Large stereo speakers with magnets
- Electric arc welding equipment
- Electric steel furnaces
- Electric induction heaters (used in industry to bend plastic)
- Power lines
- Electric substations and power generators

If your patient suspects an electrical device or magnet is interfering with the neurostimulator, advise him/her to move away from it, or turn the device off. Then, the patient can use the patient programmer to set the neurostimulator back to the desired on or off state. When switched on, the neurostimulator will resume stimulation at the previously programmed level.

Radio frequency sources – Analog and digital cellular phones, AM/FM radios, cordless phones, and conventional wired telephones may contain permanent magnets. To prevent undesired turning on or off of the stimulation, these devices should be kept at least 10 cm (4 in) away from the implanted neurostimulator.

Component disposal

When explanting a device (eg, replacement, cessation of therapy, or postmortem), or when disposing of accessories, follow these guidelines:

- If possible, return the explanted device with completed paperwork to Medtronic for analysis and disposal. Refer to the back cover for the mailing addresses.
- To allow for device analysis, do not autoclave the device or expose the device to ultrasonic cleaners.
- Dispose of any unreturned components according to local environmental regulations; in some countries, explanting a battery-powered implantable device is mandatory.
  - Do not incinerate or cremate the neurostimulator because it may explode if subjected to these temperatures.

– Do not reuse any implantable device or implantable accessory after exposure to body tissues or fluids because the functionality of the component cannot be guaranteed.

Appendix A: Electromagnetic interference (EMI) and mechanical interference

Electromagnetic interference (EMI) is a field (electrical, magnetic, or a combination of both) that is generated by various types of equipment or environmental devices found in medical, work, and home environments. These EMI sources may generate enough interference to change the parameters of a neurostimulator, turn a neurostimulator off and on, or cause a neurostimulator to surge, shock, or jolt the patient.

In addition, it is possible for the extension, lead, or both to “pick up” electromagnetic interference and deliver excess voltage, which can in turn deliver an excessive amount of heat to the brain (or other tissues in contact with the lead or extension).

Refer to the sections that follow for guidelines on the interaction of electromagnetic interference and an implanted brain stimulation system.

Types of electromagnetic interference (EMI)

Electromagnetic interference generated by medical equipment and devices found in everyday environments (eg, home, work, or public places) can be categorized into three types of EMI. See Table 1 for a description of these three types of EMI.

Table 1. Types of EMI and examples

EMI type	Example
Conductive current – Conducted current flow is introduced by the EMI source or medical equipment touching the body.	For example, conductive current flow in body tissue that is produced between an electrocautery tool and grounding plate.
Induced/coupled current – Current flow introduced by a magnetic or electrical field, where the energy travels through the air (no physical contact). Induced or coupled current may be generated from other medical equipment or EMI source.	For example, inductive current flow could be induced in an implanted lead system by the strong magnetic field of an MRI scan.
Radiated energy – Electromagnetic (EM) radiation is energy traveling through air, named after the manner it is produced: x-rays-produced by tungsten x-ray tubes, gamma rays-produced by radioactive nuclei, etc.	For example, a high energy x-ray beam directed at the electrical circuitry of the implanted neurostimulator can potentially disrupt the neurostimulator output.

All three types of EMI can occur alone or in combination and may generate enough interference to:

- change/reprogram the neurostimulator parameters.
- turn the neurostimulator on or off.
- cause the neurostimulator to surge or produce a shocking/jolting sensation to the patient.
- induce/conduct excessive current in the lead or extension system causing tissue damage, including brain tissue damage.
- temporarily suppress the neurostimulator output.
- cause damage to the implanted system components.

Reducing the possible effects from EMI

Table 2 provides some general information about how to reduce the effects of possible EMI.

Table 2. Reducing the effects of EMI on implanted brain stimulation systems

EMI type	Suggested guidelines
Conductive current	Conductive current follows the path of least resistance. It will diverge between body tissue and any implanted lead system in this path. Keep the implanted neurostimulator and lead system out of the conductive path in order to reduce possible disruptive EMI effects. For example to minimize EMI effects, keep the electrosurgery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.
Induced/coupled current	The lead system in any implanted system will act as an antenna to electric fields. Any loops formed by the lead system will act as a pickup coil to magnetic fields. The strength of an electric or magnetic field decreases with distance. Increase the distance between an EMI source and the implanted brain stimulation system in order to reduce any possible disruptive EMI effects.
Radiated energy	There is a possibility for high-dose radiation to transiently affect or permanently damage an implanted neurostimulator and lead system. Avoid placing the neurostimulator or lead system directly under the radiating beam.

EMI guidelines for medical procedures

Medtronic neurostimulators are designed to assure immunity from most common sources of electromagnetic interference (EMI). Because many different types of EMI sources exist, it is impossible to specify all interference sources here. The following sections describe the most common sources of EMI along with guidelines on avoiding possible EMI effects.

Turning the neurostimulator off

A few of the following guidelines recommend that you turn the neurostimulator off (using either the patient or clinician programmer). If the neurostimulator is not turned off, it may be possible for some EMI sources to increase the output amplitude of the stimulation. This could result in patient discomfort, overstimulation effects, and tissue damage, including brain tissue. Turning off the neurostimulator reduces this risk of inductive or coupling EMI.

Note: Even when the neurostimulator is turned off and the neurostimulator stops generating stimulation pulses, the lead and extension are still connected to the neurostimulator and this system could act as a conductive pathway to an EMI source.

Caution: The decision to turn off a patient's implanted neurostimulator in order to perform medical diagnostic or therapeutic procedures should be carefully considered based on the patient's underlying medical condition. Consultation with the appropriate medical professionals (prescribing and implanting clinicians) is recommended.

Computed Tomography (CT) scan

Prior to the patient undergoing a CT scan, turn the neurostimulator off. Failure to follow these guidelines may result in an increase in stimulation, risk of tissue damage, and damage to the implanted system.

Diathermy

As detailed in the Contraindications section, injury to the patient or damage to the neurostimulator can occur during diathermy treatment even when:

- the neurostimulation system is turned on or off.
- diathermy is used anywhere on the body - not just at the location of the neurostimulation system.
- diathermy delivers heat or no heat.
- any component of the neurostimulation system (lead, extension, neurostimulator) remains in the body.

Electrocautery

If electrocautery is used near an implantable neurostimulator or touches an implantable neurostimulator, the following effects may occur:

- The insulation on the lead or extension may be damaged, resulting in component failure or induced currents into the patient that may damage tissue or stimulate or shock the patient.
- The neurostimulator may be damaged, output may be temporarily suppressed or increased, or stimulation may stop because parameters were changed to power-on-reset settings (eg, output off, amplitude 0.0 V).

When electrocautery is necessary, following these precautions may reduce EMI effects:

- Before using electrocautery, turn off the neurostimulator.
- Disconnect any cable connecting the lead or extension to a screener or external neurostimulator.
- Use only bipolar cautery.
- If unipolar cautery is necessary:
  - use only a low-voltage mode.
  - use the lowest possible power setting.
  - keep the current path (ground plate) as far from the neurostimulator, extension, and lead as possible.
  - do not use full-length operating room table grounding pads.
  - keep the implanted neurostimulator and lead system out of the conductive path.
  - keep the electrocautery current flow perpendicular to a line drawn between the neurostimulator case and lead electrodes.
- After using electrocautery, confirm that the neurostimulator is functioning as intended.

Refer to Table 3 for recommended neurostimulator settings.

Table 3. DBS system considerations for electrocautery

Soletra	Kinetra	Activa RC	Activa PC
• Set amplitude to 0.0 V • Turn off neurostimulator	• Set amplitude to 0.0 V • Disable magnet switch • Turn off neurostimulator	• Turn off neurostimulator	• Turn off neurostimulator

Laser procedures

Turn off the neurostimulator during laser procedures. Keep the laser directed away from the neurostimulation system. Laser procedures may cause heating, especially at the lead electrode site, resulting in tissue damage.

Magnetic Resonance Imaging (MRI)

Refer to safety information and instructions in the MRI guidelines manual packaged with this product. It is important to read the MRI guidelines manual in its entirety before conducting an MRI examination on a patient with any implanted DBS system component. Contact Medtronic if you have any questions.

Additional EMI source examples

Table 4. Additional possible EMI sources (listed by EMI type)

Procedure/device	Conductive/ Inductive/ Radiation	Guidelines
Bone growth stimulators	Conductive	Safety has not been established for the use of bone growth stimulators on patients with implanted DBS systems. When using either an implantable or external bone growth stimulator, make sure that both the bone stimulator and the implanted DBS system are working as intended.
External defibrillators	Conductive	If a patient requires external defibrillation, the first consideration should be patient survival. Safety for the use of external defibrillatory discharges on patients with implanted neurostimulation systems has not been established. External defibrillation may damage a neurostimulator system or may cause tissue damage, including brain tissue. If external defibrillation is necessary, follow these precautions to minimize the current flowing through the neurostimulator and lead system: ▪ Position defibrillation paddles as far from the neurostimulator as possible. ▪ Position defibrillation paddles perpendicular to the implanted neurostimulator-lead system. ▪ Use the lowest clinically appropriate energy output (joules [watt seconds]). ▪ Confirm neurostimulation system function following any external defibrillation.

Table 4. Additional possible EMI sources (listed by EMI type) (continued)

Procedure/device	Conductive/ Inductive/ Radiation	Guidelines
Radio-frequency or microwave ablation	Conductive	Safety has not been established for radio-frequency (RF) or microwave ablation in patients who have an implanted neurostimulation system. Induced electrical currents may cause heating, especially at the lead-electrode site, resulting in tissue damage, including brain tissue.
Recording procedures	Conductive	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.
Transcutaneous electrical nerve stimulation (TENS)	Conductive	Do not place TENS electrodes so that the TENS current passes over any part of the neurostimulation system. If patients feel that the TENS may be interfering with the implanted neurostimulator, patients should discontinue using the TENS until they talk with their doctor.
Therapeutic magnets	Inductive	Therapeutic magnets (for example, those found in bracelets, back braces, shoe inserts and mattress pads) can cause inadvertent on or off activations of the neurostimulator. Therefore, patients should be advised not to use them.

Table 4. Additional possible EMI sources (listed by EMI type) (continued)

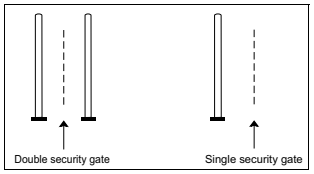
Procedure/device	Conductive/ Inductive/ Radiation	Guidelines
Theft detectors and security screening devices (such as those found in airports, libraries, and some department stores)	Inductive	Advise patients to use care when approaching theft detectors and security screening devices because these devices can turn their neurostimulator on or off. When approaching these devices, patients should do the following: **1.** If security personnel are present, patients should show them their neurostimulator identification card and request a manual search. Security personnel may use a handheld security wand, but patients should ask the security personnel to avoid placing the wand over the neurostimulator. **2.** If patients must pass through the security device, they should approach the center of the device and walk normally. ▪ If two security gates are present, they should walk through the middle, keeping as far away as possible from each gate. ▪ If one gate is present, they should walk as far away as possible from it. **Note:** Some theft detectors may not be visible. **3.** Patients should proceed through the security device. Patients should not touch, lean on or linger near the security device.  If patients suspect that their neurostimulator was turned off, they should make sure someone is able to turn on the system again. (This person could be the patient, if his or her medical condition allows it. It could also be a family member or clinician who has been taught how to use the system.)

Table 4. Additional possible EMI sources (listed by EMI type) (continued)

Procedure/device	Conductive/ Inductive/ Radiation	Guidelines
Home appliances	Conductive and Inductive	Home appliances that are in good working order and properly grounded do not usually produce enough EMI to interfere with neurostimulator operation. However, items with magnets (eg, stereo speakers, refrigerators, freezers, power tools) may cause the neurostimulator to switch on or off.
Occupational environments	Conductive and Inductive	Commercial electrical equipment (arc welders, induction furnaces, resistance welders), communication equipment (microwave transmitters, linear power amplifiers, high-power amateur transmitters), and high voltage power lines may generate enough EMI to interfere with neurostimulator operation if approached too closely.
Radiation therapy	Radiation	High radiation sources, such as cobalt 60 or gamma radiation, should not be directed at the neurostimulator. High radiation exposure may cause heating, especially at the lead-electrode site, resulting in tissue damage or damage to the neurostimulator. If a patient requires radiation therapy in the vicinity of the neurostimulator, placing lead shielding over the device may reduce radiation damage.

Mechanical interference

Mechanical interference can be defined as interference that is caused by pressure waves generated by vibrating transducers used in imaging (ie, diagnostic ultrasound) or surgical procedures such as lithotripsy. The mechanical motion of the actual transducers may also be a source of interference.

Diagnostic ultrasound – Diagnostic ultrasound poses no electrical interference problems for the DBS system, however the transducer should not be placed directly over the implanted neurostimulator.

Lithotripsy – Use of high output ultrasonic devices, such as an electrohydraulic lithotriptor, is not recommended for patients with an implanted DBS system. While there is no danger to the patient, exposure to high output ultrasonic frequencies may result in damage to the neurostimulator circuitry. If lithotripsy must be used, do not focus the beam within 15 cm (6 in) of the neurostimulator.

Contacts:

Asia: Medtronic International Ltd.
Tel. 02891-4068
Fax 02591-0313

Asia: Medtronic Asia Ltd.
Tel. (02)-548-1148
Fax (02)-518-4786

Australia: Medtronic Australasia Pty. Ltd.
Tel. +61-2-9857-9000
Fax +61-2-9878-5100
Toll-free 1-800-668-670

Austria: Medtronic Österreich GmbH
Tel. (01)-240440
Fax (01)-24044-100

Belgium: Medtronic Belgium S.A.
Tel. 02-456-0900
Fax 02-460-2667

Canada: Medtronic of Canada Ltd.
Tel. (1905)-826-6020
Fax (1905)-826-6620

Czech Republic: Medtronic Czechia s.r.o.
Tel. 2-965-795-80
Fax 2-965-795-89

Denmark: Medtronic Danmark A/S
Tel. 45-32-48-18-00
Fax 45-32-48-18-01

Finland: Medtronic Finland Oy/Ltd
Tel. (09)-755-2500
Fax (09)-755-25018

France: Medtronic France S.A.S.
Tel. 01-5538-1700
Fax 01-5538-1800

Germany: Medtronic GmbH,
Tel. (02159)-81490
Fax (02159)-8149100

Greece: Medtronic Hellas S.A.
Tel. 210-67-79-099
Fax 210-67-79-399

Hungary: Medtronic Hungária Kft.
Tel. 1-889-06-00
Fax 1-889-06-99

Ireland: Medtronic Ireland Ltd.
Tel. (01)-890-6522
Fax (01)-890-7220

Italy: Medtronic Italia SpA
Tel. 02-241371
Fax 02-241381

Italy: Medtronic Italia SpA
Tel. 06-328141
Fax 06-3215812

Japan: Medtronic Japan
Tel. 3-6430-2011
Fax 3-6430-7140

Latin America: Medtronic, Inc.
Tel. (1305)-500-9328
Fax (1786)-709-4244

The Netherlands: Medtronic B.V.
Tel. (045)-566-8000
Fax (045)-566-8668

Norway: Medtronic Norge AS
Tel. 67-10-32-00
Fax 67-10-32-10

Poland: Medtronic Poland Sp. z.o.o.,
Tel. (022)-465-69-00
Fax (022)-465-69-17

Portugal: Medtronic Portugal Lda.
Tel. 21-724-5100
Fax 21-724-5199

Russia: Medtronic Russia
Tel. (8495) 580-7377
Fax (8495) 580-7378

Slovakia: Medtronic Slovakia, o.z.
Tel. 0268 206 911
Fax 0268 206 999

Spain: Medtronic Ibérica S.A.
Tel. 91-625-0400
Fax 91-650-7410

Sweden: Medtronic AB
Tel. 08-568-585-00
Fax 08-568-585-01

Switzerland: Medtronic (Schweiz) AG
Tel. 031-868-0100
Fax 031-868-0199

U.K.: Medtronic U.K. Ltd.
Tel. 01923-212213
Fax 01923-241004

USA: Medtronic, Inc.
Tel. (1763)-505-5000
Fax (1763)-505-1000
Toll-free (1800)-328-0810

Medtronic
Alleviating Pain · Restoring Health · Extending Life

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

Medtronic E.C. EC REP
Authorized Representative/
Distributed by
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
Tel. 31-45-566-8000
Fax 31-45-566-8668

Europe/Africa/Middle East
Headquarters

Medtronic International Trading Sàrl
Route du Molliau 31
Case Postale 84
CH-1131 Tolochenaz
Switzerland
Internet: www.medtronic.com
Tel. 41-21-802-7000
Fax 41-21-802-7900

Asia-Pacific
Medtronic International Ltd.
Suite 1602 16/F, Manulife Plaza
The Lee Gardens, 33 Hysan Avenue
Causeway Bay
Hong Kong
Tel. 852-2891-4068
Fax 852-2591-0313

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Contacts for specific countries are listed inside this cover.

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