



Medtronic

MRI GUIDELINES

for Medtronic Deep Brain Stimulation Systems

To the physician

!USA Rx only



Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.



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Refer to the indications sheet for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, resterilization, and component disposal.

Refer to System Eligibility, Battery Longevity, Specifications reference manual for neurostimulator selection, battery longevity calculations and specific neurostimulator specifications.

MRI and Medtronic DBS Therapy

Introduction

It is important to read this manual in its entirety before conducting a magnetic resonance imaging (MRI) examination on a patient with any implanted Medtronic Deep Brain Stimulation (DBS) System component. Contact Medtronic if you have any questions.

Due to the number and variability of parameters that affect MRI compatibility, the safety of patients or continued functioning of Medtronic DBS Systems exposed to MRI cannot be absolutely ensured. MRI systems generate powerful electromagnetic fields that can produce a number of interactions with implanted components of the Medtronic DBS Neurostimulation System. Some of these interactions, especially heating, are potentially hazardous and can lead to serious injury or death. However, with appropriate control measures, particularly with respect to the selection of MRI parameters and RF coils, it is generally possible to safely perform an MRI head scan on a Medtronic DBS patient. In addition, Medtronic DBS System components can affect the MRI image, potentially impacting the diagnostic use of this modality. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions.

Contraindication

Implantation of a Medtronic DBS System is contraindicated for patients who will be exposed to 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. Performing MRI with this equipment can cause tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death.

Warnings

- Do not conduct an MRI examination on a patient with any implanted Medtronic DBS System component until you read and fully understand all the information in this manual. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.
- In-vitro testing has shown that exposure of the Medtronic DBS System to MRI at parameters other than those described in this guideline can induce significant heating at the lead electrodes or at breaks in the lead. Excessive heating may occur even if the lead and/or extension are the only part of the Medtronic DBS System that is implanted. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.

- MRI examinations of patients with an implanted Medtronic DBS System should only be done if absolutely needed and then only if these guidelines are followed. MRI should not be considered for Medtronic DBS patients if other potentially safer diagnostic methods such as CT, x-ray, ultrasound, or other methods will provide adequate diagnostic information.
- A responsible individual with expert knowledge about MRI, such as an MRI radiologist or MRI physicist, must assure all procedures in this guideline are followed and that the MRI scan parameters, especially RF specific absorption rate (SAR) and gradient dB/dt parameters, comply with the recommended settings, both for the prescan (tuning) and during the actual MRI examination. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this manual.
- Do not conduct an MRI examination if the patient has any other implants or limiting factors that would prohibit or contraindicate an MRI examination.

Precautions

- The neurostimulator, especially those without filtered feedthroughs such as the Itrel II Model 7424, may be reset or potentially damaged when subjected to an MRI examination. If reset, the neurostimulator must be reprogrammed. If damaged, the neurostimulator must be replaced.
- MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted Medtronic DBS System components, especially near the neurostimulator. If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator and lead(s) to obtain an image, or use alternate imaging techniques. Do not remove the neurostimulator and leave the lead system implanted as this can result in higher than expected lead heating.
- Carefully weigh any decision to perform MRI examinations on patients who require the neurostimulator to control tremor. Image quality during MRI examinations may be reduced, because the tremor may return when the neurostimulator is turned 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 professional (prescribing or implanting clinicians) is recommended.
- If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
- Monitor the patient during the MRI examination. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination. Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.

- 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 DBS System components implanted in their body to notify all medical personnel that they have an implanted DBS System.

Note: The MRI guidelines provided here may significantly extend the MRI examination time or prevent some types of MRI examinations from being conducted on Medtronic DBS patients.

General information on MRI

An MRI system produces three types of electromagnetic fields that may interact with implanted neurostimulation systems. All three of these fields are necessary to produce an MRI image. Each of these fields can also produce specific but different types of interactions with implanted neurostimulator systems. These fields include the following:

- **Static magnetic field**—This is a steady state nonvarying magnetic field that is normally always on, even when no scan is underway. In a 1.5-Tesla MRI system, the static magnetic field is approximately 30,000 times greater than the magnetic field of the earth.
- **Gradient magnetic fields**—This is a low-frequency pulsed magnetic field that is only present during a scan. The gradient magnetic field can induce voltages onto the lead system that may result in unintended stimulation or functional interactions with the neurostimulator.
- **RF field**—This is a pulsed radio-frequency (RF) field that is only present during a scan. It can be produced by a variety of transmission RF coils such as a whole body transmit coil or an extremity coil such as a transmit-receive head coil. Only a transmit-receive head coil should be used as the other RF coils can expose more of the lead system to RF energy, thereby increasing the risk of excessive heating and thermal lesions possibly resulting in coma, paralysis, or death.

MRI interactions with implanted Medtronic DBS Systems

MRI/neurostimulation system interactions are various, and the risk to the patient can range from minimal to severe. These interactions include the following:

- **Heating**—The MRI RF field induces voltages onto the lead system that can produce significant heating effects at the lead-electrode-tissue interface or at the location of any breaks in the neurostimulator lead system. Component heating from the MRI RF field is the most serious risk from MRI exposure. Failure to follow these MRI recommendations can result in thermal lesions possibly resulting in coma, paralysis, or death.

- **Magnetic field interactions**— Magnetic field interactions such as force and torque effects are produced by the static magnetic field. Any magnetic material will be attracted to the static magnetic field of the MRI. The force and torque effects may produce movement of the neurostimulator that can be uncomfortable to the patient, open a recent incision, or both. Medtronic DBS System components are designed with minimal magnetic materials.
- **Induced stimulation**— Gradient magnetic fields may induce voltages onto the lead system that may cause unintended stimulation. The voltage of the induced stimulation pulses is proportional to the time rate of change (dB/dt) of the gradient pulses, the effective loop area created by the neurostimulator lead system, and the location of the lead system with respect to the gradient coils of the MRI.
- **Effects on neurostimulator function**—The static, gradient, and RF fields of the MRI may affect the neurostimulator operation and programming. The static magnetic field may cause the neurostimulator to turn on or off if the neurostimulator uses a magnetically controlled switch that allows the patient to control stimulation by the application of a handheld magnet. Additionally, the MRI RF, static, and gradient fields may temporarily affect or disable other functions, such as telemetry or stimulation pulses. Parameters will need to be reprogrammed if the MRI causes a POR (power-on-reset) of the neurostimulator. Programmed parameters are retained for Activa PC Model 37601, Activa RC Model 37612, Activa SC Model 37602, and Activa SC Model 37603 Neurostimulators.
- **Image artifacts and distortion**— The neurostimulation system components, particularly the neurostimulator, can cause significant imaging artifacts and/or distortion of the MRI image, particularly if the neurostimulator components contain magnetic material. The neurostimulator can cause the MRI image to be completely blocked from view (ie, signal loss or signal “void”) or severely distorted within several inches of the neurostimulator.

MRI procedure

Scope

These MRI/neurostimulator exposure guidelines apply to Medtronic DBS Systems that use the following neurostimulators:

- Itrel II Model 7424
- Soletra Model 7426
- Kinetra Model 7428
- Activa PC Model 37601
- Activa RC Model 37612
- Activa SC Model 37602
- Activa SC Model 37603

Supervision

A responsible individual such as an MRI radiologist or MRI physicist must assure these procedures are followed. If the MRI is operated by an MRI technician, it is strongly recommended the responsible individual verifies that the MRI recommendations are followed.

Preparation

Do the following prior to performing an MRI examination on a Medtronic DBS patient.

1. Inform the patient of the risks of undergoing an MRI.
2. Check if the patient has any other implants or conditions that would prohibit or contraindicate an MRI examination. Do not conduct an MRI examination if any are found.
3. Verify that all proposed MRI examination parameters comply with the “MRI operation settings” on page 9. If not, the parameters must be modified to meet these requirements. If this cannot be done, do not perform an MRI.
4. If the patient has implanted lead(s) but does not have an implanted neurostimulator, perform the following steps:
 - a. Wrap the external portion of the lead(s)/percutaneous extension(s) with insulating material.
 - b. Keep the external portion of the lead(s)/percutaneous extension(s) out of contact with the patient.
 - c. Keep the external lead(s)/percutaneous extension(s) straight, with no loops, and running down the center of the head coil.
5. If the patient has an implanted neurostimulator, perform the following steps:
 - a. Review the neurostimulator with a clinician programmer and print out a copy of the programmed parameters for reference.
 - b. Test for possible open and short circuits by measuring electrode impedance on all electrodes and the case (see Table 1). If an open or short circuit is suspected, repeat electrode impedance measurements using a higher test voltage. If an open or short circuit is suspected at the higher test voltage, do not perform an MRI.

Table 1. Measurement values (taken with case electrode) indicating possible open circuits

Neurostimulator	Impedance
Itrel II Model 7424	>2000 Ω
Solettra Model 7426	>2000 Ω
Kinetra Model 7428	>2000 Ω
Activa PC Model 37601	>2000 Ω
Activa RC Model 37612	>2000 Ω

Table 1. Measurement values (taken with case electrode) indicating possible open circuits (continued)

Neurostimulator	Impedance
Activa SC Model 37602	>2000 Ω
Activa SC Model 37603	>2000 Ω

Note: For all devices, any measurement with a value of less than 250 Ω typically indicates a possible short circuit.

 **Warning:** An MRI procedure should not be performed in a patient with a Medtronic DBS System that has a broken lead wire because higher than normal heating may occur at the break or the lead electrodes, which can cause thermal lesions. These lesions may result in coma, paralysis, or death.

- c. If the Medtronic DBS System is functioning properly and no open or short circuits are found, program the neurostimulator to the settings provided in Table 2.

Table 2. Recommended neurostimulator settings (for all programs) for MRI

Parameters	Settings
Stimulation output	Turn neurostimulator off for: Itrel II, Soletra, Kinetra, Activa PC, Activa RC, and Activa SC
Stimulation mode	Bipolar (Soletra and Itrel II only)
Amplitude	0 volts (Soletra and Itrel II only)
Magnetic (reed) switch	Disabled (Kinetra only)
Day cycling	Disabled (Kinetra only)
Other parameters	Do not change

 **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.

MRI operation settings

Prior to the MRI examination, a responsible individual such as an MRI radiologist or MRI physicist must assure the examination will be conducted according to the following MRI requirements. If standard MRI pulse sequences will be used, they must meet these requirements. If they do not, the pulse parameters must be adjusted so that they comply with these requirements:

 **Warning:** In-vitro testing has shown that exposure of the Medtronic DBS System to MRI under conditions other than described in this guideline can induce excessive heating at the lead electrodes or at breaks in the lead to cause lesions. These lesions may result in coma, paralysis, or death.

- Use only a 1.5-Tesla horizontal bore MRI (do not use open-sided or other field-strength MRI systems).
- Use only a transmit-receive head coil.

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- Enter the correct patient weight into the MRI console to ensure the head SAR is estimated correctly.
- Use MRI examination parameters that limit the displayed average head SAR to 1/10(0.1)W/kg or less for all RF pulse sequences unless the applied SAR is known. If known, an applied SAR up to 1/10(0.1)W/kg may be used.

 **Warnings:**

- Ensure the SAR value is the value for head SAR. Some MRI systems may only display SAR, whole body SAR, or local body SAR. Make sure the value being limited is for head SAR. Excessive heating may occur if the wrong SAR value is used.
- If MRI parameters must be manually adjusted after the initial automatic MRI prescan, do not make any adjustments that will increase the SAR value. Some MRI machines may not automatically update the displayed SAR value if manual adjustments are made. This may lead to higher than expected temperature increases in the Medtronic DBS System, particularly at the lead electrodes.
- Limit the gradient dB/dt field to 20 Tesla per second or less.

Note: The recommendations provided are based on in-vitro testing and should result in a safe MRI examination of a patient with an implanted Medtronic DBS System. However, due to the many variables that affect safety, Medtronic cannot absolutely ensure safety or that the neurostimulator will not be damaged.

Prior to the MRI examination

Prior to the scan examination, the responsible individual must verify the MRI examination parameters comply with these guidelines.

- Patients with implanted Medtronic DBS Systems should be informed of the risks of undergoing an MRI.

- If possible, do not use sedation so the patient can inform the MRI operator of any heating, discomfort, or other problems.
- Instruct the patient to immediately inform the MRI operator if any discomfort, stimulation, shocking, or heating occurs during the examination.

During the MRI examination

- Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient is unable to respond to questions or reports any problems.
- Conduct the examination using only the MRI pulse sequence that the MRI radiologist or physicist has confirmed meets the MRI requirements above.

Post-MRI examination review

- Verify that the patient has not experienced adverse effects as a result of the MRI.
- Verify that the neurostimulator is functional.
- Reprogram the neurostimulator to pre-MRI settings.

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