

MRI guidelines for Medtronic deep brain stimulation systems

Instructions for use

! USA Rx only

C€0123

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

C€0123

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123).



Manufacturer



Authorized Representative in the European Community



For USA audiences only



Magnetic Resonance (MR) Conditional



Magnetic Resonance (MR) Unsafe

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Introduction

It is important to read the information in 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 a Medtronic representative if you have any questions about the information in this manual.

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines. Refer to the contact information at the back of this manual, or go to www.medtronic.com/mri.

Copies of these MRI guidelines may not be the most up-to-date version if not received directly from the website or in another manner from Medtronic the same day of the patient's MRI appointment.

MRI and Medtronic DBS Therapy



MR Conditional - Non-clinical testing has demonstrated that Medtronic DBS Systems have been found to be MR Conditional. If this patient is implanted with a Medtronic DBS System, MRI examinations of the head only or the entire body may be safely performed depending on the DBS system components implanted.

Medtronic DBS Systems that are eligible for MRI scans of the entire body (ie. full-body eligible) must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- Maximum spatial gradient of 19 T/m (1900 gauss/cm)
- RF transmit/receive body coil (built-in) or RF transmit/receive head coil
- Maximum RF power of 2.0 µT B1+rms (B1+ root mean squared)
- If B1+rms is not available, a maximum RF power of 0.1 W/kg (0.05 W/lb) whole body and head SAR (specific absorption rate). Using a SAR setting may result in a more restrictive MRI scan.
- Gradient slew rate limited to 200 T/m/s

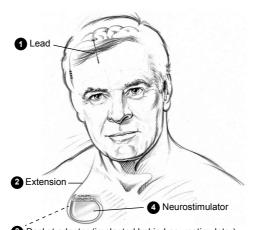
Medtronic DBS Systems that are eligible for MRI scans of the head only must be scanned under the following conditions:

- 1.5-tesla (T) horizontal closed bore
- RF transmit/receive head coil only
- Maximum RF power of 0.1 W/kg (0.05 W/lb) head SAR
- Gradient slew rate limited to 200 T/m/s.

Follow these MRI guidelines and conditions for approved indications to determine whether and how to conduct an MRI scan safely on a patient with a Medtronic DBS system. No claims of safety are made for MRI scans involving modified Medtronic DBS systems or components (eq. custom devices to mitigate allergies) or for non-Medtronic components or accessories.

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.

Neurostimulation systems for DBS



3 Pocket adaptor (implanted behind neurostimulator)

Figure 1. Medtronic DBS System components.

These MRI guidelines apply to two types of Medtronic DBS Systems: implanted neurostimulation systems and lead-only systems. Figure 1 outlines the components used in both system types.

Implanted neurostimulation systems include the following components:

- Lead
- 2. Extension
- 3. Pocket adaptor (not present in all implanted systems)
- Implanted neurostimulator

Lead-only systems include the following component implanted in one of two ways:

- 1. Lead
 - Fully-implanted, also called internalized (under the skin)
 - Partially-implanted, also called externalized (exits the skin)

If the patient has an implanted neurostimulation system, these MRI guidelines apply to the following Medtronic implanted neurostimulator model numbers:

37612 37603 37602 37601 7428 7426



The neurostimulator model numbers listed herein are MR Conditional. Do not use model numbers alone to determine which MRI scan conditions to use in these MRI guidelines. The MRI scan-type eligibility depends on a combination of factors pertaining to a patient's DBS system. Clinicians familiar with neurostimulation systems should assess a patient's MRI scantype eligibility, record MRI scan-type eligibility on a separate MRI eligibility sheet, and provide the MRI eligibility sheet to the patient's MRI facility before the scheduled MRI scan. For more information, refer to "Eligibility identification and patient preparation — for clinicians managing neurostimulation systems" on page 14.

MRI clinicians (ie, radiologists, MRI technologists, and radiographers) should use an MRI eligibility sheet to confirm the patient's MRI scan-type eligibility and refer to the scan conditions provided in this manual that are appropriate for the patient. For more information on confirming a patient's MRI scan-type eligibility, refer to "Eligibility confirmation — for radiologists, MRI technologists, and radiographers" on page 22.

Contraindication

Certain MRI procedures - Use of a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area is contraindicated for patients with the following implanted DBS systems or system components:

- Soletra Model 7426 Neurostimulator
- Kinetra Model 7428 Neurostimulator.
- Activa SC Model 37602 Neurostimulator
- Model 64001 and Model 64002 pocket adaptors implanted with any DBS system

Tissue lesions from component heating, especially at the lead electrodes, resulting in serious and permanent injury including coma, paralysis, or death, can occur if a contraindicated MRI scan is performed on a patient with these DBS systems.

Warnings

Read and fully understand guidelines before conducting MRI scan - 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.

Assess other implanted devices - Prior to an MRI examination, determine whether the patient has multiple medical device implants, either active medical device implants (such as chronic pain stimulation systems, implantable cardiac defibrillators, etc) or passive

medical device implants (such as spinal hardware, stents, etc). The most restrictive MRI exposure requirements must be used of the medical device implants. Contact the appropriate device manufacturers if you have questions. If you are unclear what implants may be present, perform an x-ray to determine implant type and location. Do not conduct an MRI examination if any conditions or implants that would prohibit or contraindicate an MRI are present.

Assess neurostimulator implant location for full-body eligible DBS systems - MRI scans using the full-body eligible MRI scan conditions on patients with a neurostimulator implanted in locations other than the pectoral and abdominal regions are untested and may cause unintended stimulation, device damage, or excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.

Avoid exposure to unapproved MRI parameters - 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 conductor wire (in the lead, extension, or pocket adaptor). 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.

Consider alternative diagnostic methods - 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.

Ensure appropriate supervision - A responsible individual with expert knowledge about MRI, such as an MRI radiologist or MRI physicist, must ensure all procedures in this quideline are followed and that the MRI scan parameters, especially RF specific absorption rate (SAR), B1+rms, and gradient 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 quidelines in this manual.

Precautions

External devices are MR Unsafe in the scanner (magnet) room - Do not allow the following Medtronic external control devices into the MRI scanner (magnet) room. These devices contain ferromagnetic material, which can be affected by the MRI magnet. These devices are MR Unsafe:

- Patient control device
- Recharger
- External neurostimulator
- Clinician programmer

Explantation and Electromagnetic Interference (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 DBS system components implanted in their body to notify all medical personnel that they have an implanted DBS system.

MRI scan-type eligibility for patients with partial system explants (also known as "abandoned systems") varies depending on the type of scan being conducted. Once the patient's MRI scan-type eligibility (ie, full-body or head-only) has been determined, refer to "Full-body eligible - Preparing the patient before the MRI scan" on page 28 or "Head-only eligible - Preparing the patient before the MRI scan" on page 35. depending on the scan type identified.

Patient ID card

Advise the patient to bring the most up-to-date patient ID card to all MRI appointments. MRI personnel can then use the patient ID card to identify Medtronic as the manufacturer of the patient's neurostimulation system and to confirm the model number of the implanted neurostimulator.

Note: Advise patients with multiple implanted neurostimulators to bring all patient ID cards to their MRI appointments.

External control devices

For Medtronic DBS systems, an external control device (ie, a clinician programmer) may be used to confirm the neurostimulator model number, evaluate system integrity, and turn off therapy or change programming settings prior to an MRI scan. A patient control device (eg., a patient programmer) may be used to turn off therapy or change programming settings prior to an MRI scan.

If the clinician programmer cannot communicate with the implanted neurostimulation system or if the neurostimulator has reached EOS (end of service), then MRI eligibility cannot be established. Unless the implanted system configuration is known and it is determined to be safe to conduct an MRI under specific conditions, an MRI scan should not be conducted.

For operation of the clinician programmer, refer to the appropriate clinician programmer software manual for those instructions. For operation of a patient control device, refer to the appropriate patient programmer or therapy controller manual.

General information on MRI procedures and neurostimulation system interactions

Types of electromagnetic fields generated by MRI systems

An MRI system produces 3 types of electromagnetic fields that may interact with implanted device systems. All 3 of these fields are necessary to produce an MRI image. The 3 fields are defined as follows:

Static magnetic field - This is a steady state non-varying magnetic field that is always present around an MRI machine, even when no scan is underway.

Gradient magnetic fields - These low-frequency pulsed magnetic fields are present only during a scan. MRI equipment uses 3 orthogonal gradient magnetic fields to construct the 3-dimensional image.

RF field – This is a pulsed radio-frequency (RF) field that is present only during a scan. The RF field can be produced by a variety of transmission RF coils, such as a whole body transmit coil (that is built into the scanner) or an extremity coil (for example, a transmit/receive head coil).

Potential interactions for implanted neurostimulation systems in the MRI environment

Following the appropriate safety conditions described in this manual will minimize the potential interactions described in this section.

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 - The magnetic material of an implanted system may exert force, vibration, and torque effects due to the static magnetic field and gradient magnetic fields produced by an MRI scanner. Patients may feel a mild tugging or vibration sensation at the site of the device implant. Patients being scanned with recent implant incisions should be monitored for any surgical wound discomfort.

Induced stimulation - The gradient magnetic and RF fields produced by an MRI scanner induce energies onto an implanted lead system that could potentially cause unintended stimulation, which may result in uncomfortable stimulation or unusual sensations

Note: Induced stimulation can occur even if only a lead or extension is implanted.

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, which includes Kinetra Model 7428 and Soletra Model 7426 neurostimulators, 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. If the patient control device displays a screen with the letters "POR" on it, instruct the patient to see the clinician managing the patient's neurostimulation system. Programmed parameters are retained for Activa RC Model 37612. Activa SC Model 37603, Activa SC Model 37602, and Activa PC Model 37601 neurostimulators.

Image artifacts and distortion

DBS leads have demonstrated image distortion for areas surrounding the implanted leads when the device is out of the field of view. Image distortion can also result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device, the leads, and any other DBS system components

within the field of view must be considered when selecting the field of view and imaging parameters. These factors must also be considered when interpreting the MRI images. Careful choice of pulse sequence parameters, location of the angle, and location of the imaging plane may minimize MR image artifacts. However, the reduction in image distortion obtained by adjustment of pulse sequence parameters will usually compromise signal-to-noise ratio.

The following general principles should be followed:

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients for both slice and read encoding directions. Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of inplane distortion.
- Use spin echo or gradient echo MR imaging sequences with a relatively high data sampling bandwidth.
- Use a shorter echo time for gradient echo technique, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to the presence of the field disturbance of the neurostimulator.
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator.

Eligibility identification and patient preparation for clinicians managing neurostimulation systems

Identify the patient's MRI scan-type eligibility

It is recommended that clinicians familiar with neurostimulation systems assess their patients' MRI scan-type eligibility (ie, full-body or head-only) before each patient receives an MRI scan.

Clinicians determining MRI scan-type eligibility must record scan eligibility and system preparation information on a separate MRI eligibility sheet and provide the MRI eligibility sheet to the patient's MRI facility before the scheduled MRI scan. For instructions on completing the MRI eligibility sheet, refer to "Complete the MRI eligibility sheet" on page 15.

MRI scan-type eligibility is based on the following combination of factors pertaining to a patient's DBS system:

- implantable neurostimulator model number
- presence of an implanted pocket adaptor
- lead implant status
- neurostimulation system integrity

DBS systems that are full-body eligible must comply with a specific set of conditions.

DBS systems that are full-body eligible:		
Neurostimulator models	37612 Activa RC, 37603 Activa SC, 37601 Activa PC	
Pocket adaptor	No pocket adaptor can be implanted with the DBS system.	
Lead-only systems	Fully-implanted leads (ie, leads that are internalized and capped)	
System integrity	No open or short circuits	

DBS systems that do not satisfy full-body eligible conditions are considered headonly eligible systems.

DBS systems that are head-only eligible:		
Neurostimulator models	Neurostimulator models 37602 Activa SC, 7428 Kinetra, 7426 Soletra	
Pocket adaptor	Any DBS system that is implanted with a pocket adaptor. ^a	
Lead-only systems	Partially-implanted leads (ie, leads that are externalized)	
System integrity	No open or short circuits	

DBS systems that are head-only eligible:

a The presence of a pocket adaptor means that a full-body eligible neurostimulator (models 37612, 37603, or 37601) is implanted, but the pocket adaptor restricts the MRI scan-type eligibility to headonly.

Complete the MRI eligibility sheet

To confirm MRI scan-type eligibility, it is critical that the MRI facility receives the scan eligibility and system preparation information outlined in steps 1 - 10. Use an MRI eligibility sheet, such as the one provided in the device package or on www.medtronic.com/mri. to record this information.

An MRI eligibility sheet containing the information outlined in steps 1 - 10 must be completed for each patient and sent to the patient's MRI facility before the scheduled MRI scan.

Use the following to identify Medtronic DBS System components:

- clinician programmer by interrogating the neurostimulator(s) and reviewing model number information
- patient medical records
- Medtronic patient identification (ID) card(s)
- x-ray imaging

Record information for each step by checking at least one box in each section of the MRI eligibility sheet.

1. Demographics — Section 1 of the MRI eligibility sheet

- Record the date that eligibility is determined. The further the date eligibility is determined is from the MRI appointment, the greater the chance that the following could occur:
 - The patient had an event (eq. physical trauma or revision surgery of the implanted neurostimulation system) that may have changed the scan eligibility.
 - The patient's device was turned back on, changed in settings, or sustained damage, which may affect patient safety during a scan.
- Record the patient's name and date of birth.
- Record your name and your office phone number.

2. DBS system types — Section 2 of the MRI eligibility sheet

- a. Identify the patient's DBS system type (ie, implanted neurostimulation system and/or lead-only system). For more information on the DBS system types described in this manual, refer to Figure 1 under "Neurostimulation systems for DBS" on page 8.
- b. Identify all of the patient's DBS system types by checking the associated box.
- 3. Implanted neurostimulator model(s) Section 3 of the MRI eligibility sheet

- a. If the patient does not have an implanted neurostimulation system, check the box that indicates that this section is not applicable.
- b. If the patient has an implanted neurostimulation system:
 - (1) Identify the implanted neurostimulator model number(s).
 - (2) Check the box associated with the neurostimulator model number(s) and brand name(s). If the patient has more than one neurostimulator implanted, record all neurostimulator models.
- Warning: Confirm the implanted neurostimulator model number(s) and record the model number(s) on the MRI eligibility sheet. Misidentification of neurostimulator model number(s) may result in exposure to MRI parameters not approved for the DBS system, which can induce significant heating. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.

4. Pocket adaptor(s) — Section 4 of the MRI eligibility sheet

- a. If the patient does not have an implanted neurostimulation system, check the box that indicates that this section is not applicable.
- b. If the patient has an implanted neurostimulation system:
 - (1) Determine whether a pocket adaptor has been implanted using patient records or by performing a lateral x-ray. For examples of x-ray images of neurostimulation systems with pocket adaptors, refer to "Appendix A: Examples of x-ray images to assist in identifying a pocket adaptor" on page 39.

Note: Identification of specific pocket adaptor models is not necessary. The presence of any pocket adaptor indicates that a patient is not eligible for a full-body scan, but may be eligible for a head scan.

- (2) Check the box associated with the patient's pocket adaptor status.
- ⚠ Warning: Confirm if any pocket adaptors are implanted with the neurostimulation system and, if present, record that a pocket adaptor is implanted on the MRI eligibility sheet. Failure to identify the presence of a pocket adaptor may result in exposure to MRI parameters not approved for the DBS system, which can induce significant heating. Excessive heating can result in serious and permanent injury including coma, paralysis, or death.

5. Lead-only system(s) — Section 5 of the MRI eligibility sheet

- a. If the patient does not have a lead-only system, check the box that indicates that this section is not applicable.
- b. If the patient has a lead-only system:

- (1) Identify whether the lead is partially implanted (externalized) or fully implanted (internalized).
- (2) Check the box associated with the type of lead-only system.

6. MRI scan-type eligibility - Section 6 of the MRI eligibility sheet

a. Identify what type of MRI scan the patient is eligible to receive (ie, full-body or head-only).

Note: If more than one DBS system has been implanted. MRI scan eligibility should be based on the most restrictive DBS system components (ie. if a patient has both a full-body eligible system and a head-only eligible system, the patient should receive only a head scan).

- (1) To determine MRI scan-type eligibility for implanted neurostimulation systems, compare answers from step 3 and step 4 to the information provided in "Identify the patient's MRI scan-type eligibility" on page 14 of this manual
- (2) To determine MRI scan-type eligibility for lead-only systems, compare the answer from step 5 to the information provided in "Identify the patient's MRI scan-type eligibility" on page 14 of this manual.
- b. Check the box associated with the patient's MRI scan-type eligibility.

7. System integrity — Section 7 of the MRI eligibility sheet

- a. If the patient does not have an implanted neurostimulation system, check the box that indicates that this section is not applicable.
- b. If the patient has an implanted neurostimulation system:
 - (1) Perform impedance measurements to determine the integrity of the patient's DBS system (ie. whether open or short circuits are detected). For instructions on performing impedance measurements, refer to step 1 under "Prepare the patient for an MRI scan" on page 19.
 - (2) If no open or short circuits are detected, check the box that indicates that system integrity has been verified.
 - (3) If an open or short circuit is verified, check the box that indicates that the system is compromised. If the system is compromised, an MRI scan should not be performed.

Note: If the clinician programmer cannot communicate with the device or if the device has reached its end of service, MRI scan eligibility cannot be determined and an MRI scan should not be performed.

8. MR Conditional neurostimulator settings — Section 8 of the MRI eligibility sheet

- a. If the patient does not have an implanted neurostimulation system, check the box that indicates that this section is not applicable.
- b. If the patient has an implanted neurostimulation system:
 - (1) Identify the recommended MR Conditional parameter settings for each neurostimulator model. For information on recommended parameter settings, refer to Table 2 under "Prepare the patient for an MRI scan" on page 20.
 - (2) Check the box(es) associated with recommended MR Conditional parameter settings for the neurostimulator(s). If more than one neurostimulator has been implanted, record recommended parameter settings for both neurostimulator models.
 - (3) Determine when to program the neurostimulator(s) to recommended MR Conditional parameter settings before the MRI scan, either prior to the MRI appointment or at the MRI appointment.
 - (4) Check the box that indicates when to program the patient's neurostimulator(s) to recommended MR Conditional parameter settings. If the decision is to program the neurostimulator(s) prior to the MRI appointment, program the neurostimulator(s) now.

9. Lead-only system preparation — Section 9 of the MRI eligibility sheet

- a. If the patient does not have a lead-only system, check the box that indicates that this section is not applicable.
- b. If the patient has a lead-only system:
 - (1) Prepare the lead(s) for the MRI scan. For instructions on preparing the lead for an MRI scan, refer to step 3 under "Prepare the patient for an MRI scan" on page 20.
 - (2) If the patient has a fully-implanted lead, check the box that indicates that the fully-implanted lead(s) has been capped and internalized.
 - (3) If the patient has a partially-implanted lead, check the box that indicates that the partially-implanted lead(s) has been insulated, and the externalized portion of the lead is out-of-contact with the patient, is straight with no loops, and is centered in the head coil.
- 10. Sign and date the MRI eligibility sheet to acknowledge that MRI scan-type eligibility was assessed and that DBS system preparation occurred.
- 11. Send the completed MRI eligibility sheet to the MRI facility before the patient receives the scheduled MRI scan.

Note: Advise patients with implanted neurostimulator(s) to bring their patient ID card(s) and patient control device to their MRI appointment.

Prepare the patient for an MRI scan

Note: For operation of the clinician programmer, refer to the appropriate clinician programmer software manual for instructions.

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

- 1. Perform impedance measurements on any implanted neurostimulation systems to verify system integrity. If the patient has a lead-only system, refer to step 3 to prepare the lead for the MRI scan.
 - a. Review the neurostimulator with a clinician programmer and print out a copy of the programmed parameters for reference.
 - b. Test for possible open circuits by measuring electrode impedance between all electrodes and the case (unipolar measurements). For information on impedance values indicating a possible open circuit, refer to Table 1.
 - c. Test for possible short circuits by measuring electrode impedance between all electrode pairs (bipolar measurements). For information on impedance values indicating a possible short circuit, refer to Table 1.

Table 1. Impedance values indicating a possible open or short circuit

Impedance measurement	Circuit status	Impedance value
Unipolar	Possible open circuit	> 2000 ohms
Bipolar	Possible short circuit	< 250 ohms

△ Caution: DO NOT rely solely on the results of impedance testing for troubleshooting. Accuracy of the data generated during impedance tests can fluctuate based on the neurostimulator that is being tested and on the programmed therapy settings.

Note: If you cannot determine system integrity using impedance measurements or other methods, contact Medtronic Technical Services.

Marning: An MRI procedure should not be performed on a patient with a Medtronic DBS System that has a broken conductor wire (in the lead, extension. or pocket adaptor) 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.

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.

2. If the patient has an implanted neurostimulator, program the neurostimulator to the recommended MR Conditional parameter settings (refer to Table 2).

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

System type	Settings	
37612, 37603, 37601	Unipolar configuration ^a — Turn therapy off.	
(no pocket adaptor implanted)	Bipolar configuration $^{\rm b}$ — Keep therapy on or turn therapy off.	
37612, 37603, 37601	Turn therapy off.	
(with pocket adaptor implanted)		
37602	Turn therapy off.	
7428	Turn therapy off.	
	Disable magnetic (reed) switch.	
	Disable day cycling.	
7426	Turn therapy off.	
	Set to bipolar configuration.	
	Set amplitude to 0 volts.	

a At least one electrode is negative and the case is positive, the other electrodes can be either negative or 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.
- 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
- 3. If the patient has a lead-only system, prepare the lead before conducting the MRI scan

For fully-implanted leads (full-body eligible):

a. Cap and internalize the lead(s). For instructions on capping the lead, refer to the appropriate lead implant manual.

△ Caution: For lead-only systems, ensure that the lead is capped before it is internalized if an MRI scan will be performed after surgery. Failure to cap the lead may result in unintended stimulation during an MRI scan.

b At least one electrode is positive, one electrode is negative, and the case is off.

For partially-implanted leads (head-only eligibile):

- a. Wrap the external portion of the lead(s)/percutaneous extension(s) with thermally and electrically insulating material.
- Keep the external portion of the lead(s)/percutaneous extension(s) out of contact with the patient.
- Keep the external lead(s)/percutaneous extension(s) straight, with no loops, and running down the center of the head coil.

Eligibility confirmation — for radiologists, MRI technologists, and radiographers

Confirm device information and scan eligibility with the MRI eligibility sheet

These MRI guidelines are for Medtronic DBS Systems only. For more information on the Medtronic DBS Systems described in this manual, refer to "Neurostimulation systems for DBS" on page 8.

Before performing an MRI scan on a patient with a Medtronic DBS System, you should receive and review a completed MRI eligibility sheet from the clinician managing the patient's neurostimulation system or from a referring clinician.

Reviewing the MRI eligibility sheet

Follow steps 1 - 11 below to review the MRI eligibility sheet and confirm that the clinician has completed the steps necessary to determine the patient's MRI scan-type eligibility and prepared the patient's DBS system for the MRI scan.

Confirm that at least one box is checked for each numbered section of the MRI eligibility sheet. If information is missing from any section, contact the patient's clinician before proceeding with the MRI scan.

1. Demographics — Section 1 of the MRI eligibility sheet

- a. Review the date that eligibility was determined. The further the date on the eligibility sheet is from the patient's MRI appointment, the greater the chance that the following occurred:
 - The patient had an event (eq. physical trauma or revision surgery of the implanted neurostimulation system) that may have changed the scan eligibility.
 - The patient's device was turned back on, changed in settings, or sustained damage, which may affect patient safety during a scan.
- b. Ask the patient if any falls, physical trauma, revision surgery, or therapy changes have occurred since the date recorded on the MRI eligibility sheet. If an event or therapy change occurred, contact the patient's clinician before proceeding with the MRI scan.
- c. Confirm the patient's name and date of birth using patient medical records, the patient's Medtronic ID card(s), and other identification information.
- d. Confirm that the DBS clinician's name and phone number have been completed.

2. DBS system types — Section 2 of the MRI eligibility sheet

Confirm that the clinician has identified whether the patient has an implanted neurostimulation system and/or lead-only system. For more information on the **DBS system types** described in this manual, refer to Figure 1 under "Neurostimulation systems for DBS" on page 8.

3. Implanted neurostimulator model(s) — Section 3 of the MRI eligibility sheet

a. If the patient has an implanted neurostimulation system, confirm that the clinician has identified the implanted neurostimulator model number(s).

Note: If the patient has more than one neurostimulator implanted, all models should be recorded on the eligibility sheet. If all models are not recorded, contact the patient's managing clinician before proceeding with the MRI scan.

b. Proceed to the next step if the clinician indicated that this section of the MRI eligibility sheet is not applicable because the patient does not have an implanted neurostimulation system.

4. Pocket adaptor(s) — Section 4 of the MRI eligibility sheet

- a. If the patient has an implanted neurostimulation system, confirm that the clinician has identified whether a pocket adaptor is implanted with the neurostimulator(s).
- b. Proceed to the next step if the clinician indicated that this section of the MRI eligibility sheet is not applicable because the patient does not have an implanted neurostimulation system.

5. Lead-only system(s) — Section 5 of the MRI eligibility sheet

- a. If the patient has a lead-only system, confirm that the clinician has identified whether the lead is partially implanted or fully implanted.
- b. Proceed to the next step if the clinician indicated that this section of the MRI eliqibility sheet is not applicable because the patient does not have a lead-only system.

6. MRI scan-type eligibility — Section 6 of the MRI eligibility sheet

Confirm that the clinician identified whether the patient is eligible for a full-body scan or a head-only scan.

System integrity — Section 7 of the MRI eligibility sheet

- a. If the patient has an implanted neurostimulation system, confirm that the clinician has indicated that system integrity has been verified (ie, no open or short circuits detected in the patient's system).
- Marning: An MRI procedure should not be performed on a patient with a Medtronic DBS System that has a broken conductor wire (in the lead, extension. or pocket adaptor) 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.

Note: Impedance measurements are not required for lead-only systems.

b. Proceed to the next step if the clinician indicated that this section of the MRI eligibility sheet is not applicable because the patient does not have an implanted neurostimulation system.

8. MR Conditional neurostimulator settings — Section 8 of the MRI eligibility sheet

- a. If the patient has an implanted neurostimulation system:
 - (1) Ensure that section 3 and section 4 have been completed on the MRI eligibility sheet.
 - (2) Confirm that the clinician identified the recommended MR Conditional neurostimulator parameter settings for the neurostimulator(s).
 - (3) Confirm that the clinician indicated whether the patient's neurostimulator(s) has been programmed to recommended settings prior to the MRI appointment or should be programmed at the MRI appointment. If the patient's neurostimulator(s) needs to be programmed at the MRI appointment, have the patient or clinician program the neurostimulator(s) now according to the recommended settings. See step 2 on page 19 in the "Prepare the patient for an MRI scan" section.
 - (4) If the patient's neurostimulator(s) has been programmed prior to the MRI appointment, ask the patient if therapy settings have changed. If the patient has changed therapy settings, contact the patient's clinician or Medtronic Technical Services.
- Proceed to the next step if the clinician indicated that this section of the MRI. eligibility sheet is not applicable because the patient does not have an implanted neurostimulation system.

9. Lead-only system preparation — Section 9 of the MRI eligibility sheet

- a. If the patient has a lead-only system:
 - (1) Ensure that section 5 has been completed on the MRI eligibility sheet.
 - (2) If the patient has a fully-implanted lead, confirm that the clinician indicated that the fully-implanted lead(s) has been capped and internalized.
 - (3) If the patient has a partially-implanted lead, confirm that the clinician indicated that the partially-implanted lead(s) has been insulated, and the externalized portion of the lead is out-of-contact with the patient, is straight with no loops, and is centered in the head coil.
- b. Proceed to the next step if the clinician indicated that this section of the MRI eliqibility sheet is not applicable because the patient does not have a lead-only system.
- 10. Confirm that the clinician signed and dated the MRI eligibility sheet.

11. Complete the radiology section of the MRI eligibility sheet to confirm that MRI scantype eligibility and DBS system preparation information have been reviewed and accepted by a member of the radiology staff.

Note: Assess other implanted medical devices before conducting an MRI scan. For information on how other implanted devices may affect MRI scan eligibility, refer to "Warnings" on page 9.

12. Refer to the appropriate section in this manual for MRI scan conditions and safety information related to the patient's MRI scan-type eligibility.

If full-body eligible, refer to "Full-body eligible MRI scan conditions" on page 26. If head-only eligible, refer to "Head-only eligible MRI scan conditions" on page 33.

Full-body eligible MRI scan conditions

Before proceeding with this full-body eligible section, confirm that the "Eligibility confirmation — for radiologists, MRI technologists, and radiographers" section (starts on page 22) has been followed and that full-body scan eligibility has been correctly identified on the MRI eligibility sheet.

A patient who is full-body scan eligible can have any part of the anatomy scanned when the specific conditions in this full-body eligible section are met.

Full-body eligible - MRI equipment and scan requirements

Table 3. Full-body eligible – MRI equipment and scan requirements

Radio-frequency (RF) coils	Transmit coil: body transmit/receive (built-in), quadrature only. head transmit/receive, quadrature only.	
	Warning: Do not use RF transmit coils other than a body transmit/receive (built-in) quadrature coil or a head transmit/receive quadrature coil. Other transmit/receive coils (eg, linear coils) have not been tested and could cause excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.	
	Receive-only coil: any type.	
MRI system type	1.5-T horizontal closed bore with maximum spatial gradien of 19 T/m (1900 gauss/cm).	
	⚠ Warning: Only use 1.5-T horizontal closed bore MRI systems. Other MRI systems (such as 0.6-T or 3.0-T, and open bore machines) have not been tested and could cause device damage and excessive heating, which can result in serious and permanent injury including coma, paralysis or death.	
MRI manufacturers	No restrictions.	
RF frequency	Approximately 64 MHz.	
	Warning: Do not conduct MRI scans with nonproton scanning frequencies (such as, 13C, 23Na, or 31P). Frequencies other than 64 MHz have not been tested and could cause device damage and excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.	

RF power

B1+rms (B1+ root mean squared):

 B1+rms must be ≤ 2.0 µT as reported by the MRI equipment.

If a B1+rms setting is not available on the MRI equipment, a SAR setting may be used. Using a SAR setting may result in a more restrictive MRI scan.

SAR (specific absorption rate):

 Use MRI examination parameters that limit the displayed average whole body and head SAR to 0.1 W/kg (0.05 W/lb) or less for all RF pulse sequences unless the applied SAR is known. If known, an applied SAR up to 0.1 W/kg (0.05 W/lb) may be used.

To determine whether patient weight will affect the RF power setting, refer to "Full-body eligible – Pre-MRI scan operations" and considerations" on page 30.

⚠ Warnings:

- If using B1+rms, do not exceed 2.0 µT. If B1+rms is not available and SAR must be used, do not exceed an average whole body and head SAR of 0.1 W/kg (0.05 W/lb). Exceeding these power limits may cause excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.
- 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

Operating mode

Use Normal Operating Mode.

Warning: Do not conduct MRI scans in the following modes:

- First Level Controlled Operating Mode
- Second Level Controlled Operating Mode (ie, research) mode)

These modes allow higher gradient levels, which could cause increased risk of unintended stimulation or heating of the neurostimulator.

Table 3. Full-body eligible – MRI equipment and scan requirements (continued)

Gradients	Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less.
	Warning: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of unintended stimulation or heating of the neurostimulator.
Active scan time limits	MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (within every 90-minute window should be a total of 60 minutes of nonscan time).
	⚠ Warning: Do not exceed a total of 30 minutes of active scan time within a 90-minute window. Exceeding the active scan time duration increases the risk of tissue heating.
Landmark (isocenter location)	No restrictions. All anatomical locations can be scanned.

Full-body eligible – Preparing the patient before the MRI scan Table 4. Full-body eligible – Preparing the patient before the MRI scan		
Abandoned systems	Do not conduct a full-body MRI scan on a patient with an abandoned system. Abandoned systems are complete neurostimulation systems or partially-explanted systems (eg, neurostimulator, lead, extension, or lead-extension fragment) that no longer provide therapy to the patient.	
	The presence of an abandoned system can be confirmed with x-ray imaging, referring to the patient records, or consulting with the clinician managing the patient's neurostimulation system.	
	For more information on the effects of MRI on abandoned systems, refer to "Precautions" on page 10.	

Table 4. Full-body eligible – Preparing the patient before the MRI scan (continued)

Neurostimulation system (ie, therapy) settings

Confirm that therapy settings have been appropriately adjusted prior to the MRI scan. Refer to the MRI eligibility sheet for more information.



△ Caution: If therapy should be turned off prior to the MRI scan, confirm that therapy is off before conducting the MRI scan. Leaving therapy on during the scan could increase the potential for uncomfortable, unintended stimulation.

If you are not certain if therapy settings have been appropriately adjusted, ask the patient to confirm that therapy has been adjusted using the patient control device or consult the clinician managing that patient's neurostimulation system. To review MR Conditional therapy settings, refer to Table 2 on page 20.

Core body temperature

Fever



⚠ Warning: Do not perform an MRI scan if the patient's body temperature is above 38 °C (100 °F). Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which could cause tissue damage.

No blankets



⚠ Warning: Do not cover the patient with blankets or heated blankets. Blankets raise the patient's body temperature and increase the risk of tissue heating. which could cause tissue damage.

Patient weight, minimum

No restrictions

Sedation

No restrictions



Caution: If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination

Patient position within the bore

Position the patient in a prone or supine position in the MRI hore



Marning: Do not position the patient in other positions, eg, on his or her side (called the lateral decubitus position) within the MRI bore. Scanning patients in positions other than prone or supine is untested and could cause excessive tissue heating during an MRI scan

Table 4. Full-body eligible – Preparing the patient before the MRI scan (continued)

Inform the patient of risks	Inform the patient of all the risks of undergoing an MRI examination as stated in this full-body eligible section.
Patient communication with operator during scan	Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the examination

with operator during sca	an any discomfort, unexpected stimulation, shocking, or heating occurs during the examination.
, ,	 Pre-MRI scan operations and considerations y eligible – Pre-MRI scan operations and considerations
Enter patient weight	If a B1+rms setting is used for the MRI scan, patient weight will not affect the setting. Ensure that the B1+rms value is $\leq 2.0 \ \mu T$.
	If a SAR setting is used for the MRI scan, enter the correct patient weight into the MRI console to ensure that the SAR is estimated correctly.
	Warning: Ensure the patient weight is entered correctly to avoid the risk that the MRI scan is performed at an RF power level too high for the patient. An inappropriately high RF power level may cause excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.
Verify all parameters	Verify that all proposed MRI examination parameters comply with the MRI exposure requirements in this full-body eligible section. If not, the parameters must be modified to meet these requirements. If the parameters cannot be modified, do not perform an MRI.

Table 5. Full-body eligible – Pre-MRI scan operations and considerations (continued)

Consider	image	artifacts
and disto	rtion	

Image artifacts and distortion resulting from the presence of the device, the leads, and any other DBS system components within the field of view must be considered when selecting the field of view and imaging parameters. Careful choice of pulse sequence parameters, location of the angle, and location of the imaging plane may minimize MR image artifacts. For more information on minimizing artifacts and distortion caused by DBS systems, refer to "Image artifacts and distortion" on page 12.



Caution: 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.

Full-body eligible - During the MRI scan

Table 6. Full-body eligible – During the MRI scan

Keep track of active scan time	Keep track that the active scan time is within a 90-minute window. See "Active scan time limits" in Table 3.	
Monitor the patient	Caution: 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.	
Patient comfort	Heating may be felt at the neurostimulator site during the MRI scan. If the heating causes the patient discomfort, stop the MRI scan immediately. Consider applying an ice pack or cold compress to the location after the scan is stopped.	
Neurostimulator tugging, vibration	During the MRI scan, the patient may feel tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient considerable discomfort, stop the MRI scan.	
	If the neurostimulator is close to the MRI bore wall, consider using a pillow to keep the neurostimulator away from the bore wall to minimize vibration.	

Full-body eligible - Post-MRI scan

Table 7. Full-body eligible - Post-MRI scan

Patient feedback	Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
Turn therapy back on or return therapy to original parameter settings	After the scan has been completed, instruct the patient to see the clinician managing the patient's neurostimulation system to have the therapy turned back on or program therapy to the original settings.
	Or, if the patient has brought a patient control device to the MRI appointment, instruct the patient (outside of the scanner room) to turn therapy back on or program therapy to the original settings using the patient control device.
	Notes:

- - To turn on or adjust therapy, tell the patient to hold the patient control device over the neurostimulator and press the **Check** key. Then the patient can turn on or adjust therapy.
 - If the patient control device cannot synchronize with the neurostimulator, or cannot turn therapy back on, or displays a screen with the letters "POR" on it, instruct the patient to see the clinician managing the patient's neurostimulation system. Contact Medtronic to report the POR event.

Head-only eligible MRI scan conditions

Before proceeding with this head-only eligible section, confirm that the "Eligibility confirmation — for radiologists, MRI technologists, and radiographers" section (starts on page 22) has been followed and that head-only scan eligibility has been correctly identified on the MRI eligibility sheet.

Head-only eligible - MRI equipment and scan requirements

Table 8. Head-only eligible – MRI equipment and scan requirements

Radio-frequency (RF) coils	Transmit/receive head coil only. Important: Do not use an RF transmit body coil, a receive-only head coil, or a head transmit coil that extends over the chest area. If you are unsure if your MRI system has RF transmit/receive head coil capability, consult the MRI manufacturer.
	 Warnings: An MRI examination of the head only (no other part of the body) can be conducted safely using an RF transmit/ receive head coil when all instructions in this head-only eligible section are followed. If the patient's neurostimulation system has a broken conductor wire (in the lead, extension, or pocket adaptor), higher than normal heating may occur at the break or lead electrodes. Excessive heating can cause serious and permanent injury including coma, paralysis, or death.
MRI system type	1.5-T horizontal closed bore
	Warning: Only use 1.5-T horizontal closed bore MRI systems. Other MRI systems (such as 0.6-T or 3.0-T, and open bore machines) have not been tested and could cause device damage and excessive heating, which can result in serious and permanent injury including coma, paralysis or death.
MRI manufacturers	No restrictions.

eligible – MRI equipment and scan requirements (continued)
Approximately 64 MHz.
⚠ Warning: Do not conduct MRI scans with nonproton scanning frequencies (such as, 13C, 23Na, or 31P). Frequencies other than 64 MHz have not been tested and could cause device damage and excessive heating, which can result in serious and permanent injury including coma, paralysis, or death.
Use MRI examination parameters that limit the displayed average head SAR (specific absorption rate) to 0.1 W/kg (0.05 W/lb) or less for all RF pulse sequences unless the applied SAR is known. If known, an applied SAR up to 0.1 W/kg (0.05 W/lb) may be used.
 ✓ Warnings: 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. ■ 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.
Use Normal Operating Mode.
Warning: Do not conduct MRI scans in the following modes: First Level Controlled Operating Mode Second Level Controlled Operating Mode (ie, research mode)

These modes allow higher gradient levels, which could cause increased risk of unintended stimulation or

heating of the neurostimulator.

Table 8. Head-only eligible – MRI equipment and scan requirements (continued)

·	3 (
Gradients	Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less.
	⚠ Warning: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of unintended stimulation or heating of the neurostimulator.
Active scan time limits	No restrictions.
Landmark (isocenter location)	Head only.

Head-only eligible – Preparing the patient before the MRI scan Table 9. Head-only eligible – Preparing the patient before the MRI scan	
Abandoned systems	Confirm that no abandoned systems are within 0 cm of the transmit/receive head coil. Abandoned systems are complete neurostimulation systems or partially-explanted systems (eg, neurostimulator, lead, extension, or lead-extension fragment) that no longer provide therapy to the patient.
	The presence of an abandoned system can be confirmed with x-ray imaging, referring to the patient records, or consulting with the clinician managing the patient's neurostimulation system.
	For more information on the effects of MRI on abandoned systems, refer to "Precautions" on page 10.
Neurostimulation system (ie, therapy) settings	Confirm that therapy settings have been appropriately adjusted prior to the MRI scan. Refer to the MRI eligibility sheet for more information.
	△ Caution: If therapy should be turned off prior to the MRI

scan, confirm that therapy is off before conducting the MRI scan. Leaving therapy on during the scan could increase the potential for uncomfortable, unintended stimulation.

If you are not certain if therapy settings have been appropriately adjusted, ask the patient to confirm that therapy has been adjusted using the patient control device or consult the clinician managing that patient's neurostimulation system. To review MR Conditional therapy settings, refer to Table 2 on page 20.

Table 9. Head-only eligible - Preparing the patient before the MRI scan (continued)

Core body temperature	Fever
	No restrictions.
	Blankets
	No restrictions.
Patient weight, minimum	No restrictions.
Sedation	No restrictions.
	△ Caution: If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
Inform the patient of risks	Inform the patient of all the risks of undergoing an MRI examination as stated in this head-only eligible section.
Patient communication with operator during scan	Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the examination.

Head-only eligible - Pre-MRI scan operations and considerations

Table 10. Head-only eligible - Pre-MRI scan operations and considerations

Enter patient weight	Enter the correct patient weight into the MRI console to ensure that the head SAR is estimated correctly.
Verify all parameters	Verify that all proposed MRI examination parameters comply with the MRI exposure requirements in this head-only eligible section. If not, the parameters must be modified to meet these requirements. If the parameters cannot be modified, do not perform an MRI.

Table 10. Head-only eligible – Pre-MRI scan operations and considerations (continued)

Consider	image	artifacts
and disto	rtion	

Image artifacts and distortion resulting from the presence of the device, the leads, and any other DBS system components within the field of view must be considered when selecting the field of view and imaging parameters. Careful choice of pulse sequence parameters, location of the angle, and location of the imaging plane may minimize MR image artifacts. For more information on minimizing artifacts and distortion caused by DBS systems, refer to "Image artifacts and distortion" on page 12.



Caution: 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.

Head-only eligible - During the MRI scan

Table 11. Head-only eligible – During the MRI scan

Monitor the patient	Caution: 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.
Patient comfort	Heating may be felt at the neurostimulator site during the MRI scan. If the heating causes the patient discomfort, stop the MRI scan immediately. Consider applying an ice pack or cold compress to the location after the scan is stopped.
Neurostimulator tugging, vibration	During the MRI scan, the patient may feel tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient considerable discomfort, stop the MRI scan.

Head-only eligible - Post-MRI scan

Table 12. Head-only eligible - Post-MRI scan

Patient feedback	Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
Turn therapy back on and return therapy to original parameter settings	After the scan has been completed, instruct the patient to see the clinician managing the patient's neurostimulation system to have the therapy turned back on and program therapy to the original settings. Or, if the patient has brought a patient control device to the MRI appointment, instruct the patient (outside of the scanner room) to turn therapy back on and program therapy to the original settings using the patient control device. Notes: To turn on or adjust therapy, tell the patient to hold the patient control device over the neurostimulator and press the Check we key or the Neurostimulator on key, depending on which key is on the patient control device. If the patient control device cannot synchronize with the neurostimulator, or cannot turn therapy back on, or displays a screen with the letters "POR" on it, instruct the patient to see the clinician managing the patient's neurostimulation system. Contact Medtronic to report the POR event.

Appendix A: Examples of x-ray images to assist in identifying a pocket adaptor

This appendix shows examples of x-ray images to assist in identifying whether a pocket adaptor has been implanted with a neurostimulation system. A pocket adaptor is a system component that may be used to connect an implanted neurostimulator to an extension.

Identification of specific pocket adaptor models is not necessary. The presence of any pocket adaptor indicates that a patient is not eligible for a full-body scan, but may be eligible for a head scan.

Example x-ray images

The examples provided in Figure 2 and Figure 3 depict one neurostimulator model among several possible neurostimulator models that may be implanted with a pocket adaptor.

- Figure 2 on page 40 shows two images: the left image is a neurostimulator without a pocket adaptor implanted and the right image is a neurostimulator implanted with a 2x4 pocket adaptor.
- Figure 3 on page 41 shows two images: the left image is a neurostimulator without a pocket adaptor implanted and the right image is a neurostimulator implanted with two 1x4 pocket adaptors.

Clinicians seeking to identify whether a pocket adaptor has been implanted with a neurostimulation system via x-ray should observe the pocket adaptor connector ports and extension connector pins in the x-ray image.

Neurostimulator without pocket adaptor



Neurostimulator with 2x4 pocket adaptor



Extension connector pins (4) and pocket adaptor connector ports (4)

Figure 2. Model 37601 Activa PC Neurostimulator implanted without a pocket adaptor (left) and a Model 37601 Activa PC Neurostimulator implanted with a 2x4 pocket adaptor (right).

Neurostimulator without a pocket adaptor



Neurostimulator with two 1x4 pocket adaptors



Extension connector pins (2) and pocket adaptor connector ports (2) for each 1x4 pocket adaptor

Figure 3. Model 37601 Activa PC Neurostimulator implanted without a pocket adaptor (left) and a Model 37601 Activa PC Neurostimulator implanted with two 1x4 pocket adaptors (right).

Contacts:

Asia.

Medtronic International Ltd.

Tel 02919-1300

Fax 02891-6830

Medtronic Asia Ltd.

Tel. (02)-548-1148

Fax (02)-518-4786

Australia:

Medtronic Australasia Ptv. Ltd.

97 Waterloo Road

North Rvde, NSW 2113

Australia

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. (1-905)-460-3800

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 Ov/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

Tel. 06-328141

Fax 06-3215812

Japan:

Medtronic Japan

Tel. 03-6430-2016

Fax 03-6430-7110

Latin America:

Medtronic, Inc.

Tel. (1305)-500-9328

Fax (1786)-709-4244

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

The Netherlands:

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

Turkey:

Medtronic Turkey Tel. +90 216 636 1000 Fax +90 216 636 1008

U.K.:

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

USA:

Medtronic, Inc. Tel. (1-763)-505-5000 Fax (1-763)-505-1000 Toll-free: (1-800)-328-0810



Manufacturer

Medtronic, Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604, USA

www.medtronic.com Tel. +1-763-505-5000

Fax +1-763-505-1000

Authorized Representative in the European Community

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

EC REP

Medtronic International Trading Sarl Route du Molliau 31, Case Postale 84 CH - 1131 Tolochenaz, Switzerland www.medtronic.eu

Tel. +41-21-802-7000 Fax +41-21-802-7900

Asia-Pacific

Medtronic International Ltd. Suite 1106-11, 11/F, Tower 1, The Gateway, 25 Canton Road, Tsimshatsui, Kowloon, Hong Kong

Tel. +852-2919-1300 Fax +852-2891-6830



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