

Medtronic

MRI guidelines for Medtronic deep	37601
brain stimulation systems	37602
	37603
	37612
	B35200
	B35300

(1) See "Scheduling an MRI" for guidance on patient appointments. (2) Review the entire manual before conducting an MRI.

Instructions for use

! USA Rx only

Explanation of symbols



Magnetic Resonance (MR) Conditional



Magnetic Resonance (MR) Unsafe

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Table of contents

Introduction 7

- Neurostimulator model numbers 7
- Scheduling an MRI 7
- Obtain the latest MRI guidelines labeling 8

MRI and Medtronic DBS Therapy 9

- DBS systems 9
- Contraindication 9
- Warnings 10
- Precautions 11
- External control devices (programmers) 11
- Patient ID card 12
- Patients with more than one DBS system 13
- MRI workflow and MRI mode 14
- Image artifacts and distortion 14

DBS physicians — Determine scan eligibility 15

- MRI Eligibility factors 15
- Use the MRI Eligibility worksheet or the MRI workflow 16
- Completing the MRI Eligibility Worksheet 16
- Completing the MRI Eligibility Report 19
- Patient preparation — Therapy settings for an MRI scan appointment 20

Lead-only DBS systems 21

- DBS physicians – Assessing a Lead-only system 21
- MRI clinicians – Confirming a Lead-only system 21

MRI clinicians — Eligibility confirmation 22

- Confirm the device information and MRI scan eligibility 22
- Review the MRI Eligibility Report 22

Full-body eligible MRI scan conditions 25

- Full-body eligible – 1.5-T and 3-T MRI equipment and scan requirements 25
- Full-body eligible – Preparing the patient before the MRI scan 28
- Full-body eligible – Pre-MRI scan operations and considerations 29
- Full-body eligible – During the MRI scan 29
- Full-body eligible – Post-MRI scan 30

Head-only eligible MRI scan conditions 31

- Head-only eligible – MRI equipment and scan requirements 31
- Head-only eligible – Preparing the patient before the MRI scan 32
- Head-only eligible – Pre-MRI scan operations and considerations 33
- Head-only eligible – During the MRI scan 33
- Head-only eligible – Post-MRI scan 33

Appendix A: X-ray images to assist in identifying a pocket adaptor 35

Introduction

Read this manual before conducting a 1.5-Tesla (T) or 3-T magnetic resonance imaging (MRI) scan of a patient with complete deep brain stimulation (DBS) systems that use the implanted Medtronic DBS neurostimulator model numbers listed, or with any Medtronic DBS lead-only system. These instructions do not apply to other implantable products, or other devices, products, or items.

Note: Not all Medtronic DBS neurostimulator models are listed in this manual, because MRI scanning conditions vary for older models. Please refer to the MRI Guidelines that list the applicable model of implanted neurostimulator.

Contact a Medtronic representative if you have any questions about the information in this or related MRI Guidelines manuals.

Neurostimulator model numbers



The neurostimulator model numbers listed are MR Conditional.

Do not use model numbers alone to determine which MRI scan conditions to use in these MRI guidelines. MRI scan eligibility depends on a combination of eligibility factors pertaining to a DBS system.

These MRI guidelines apply to the following implanted Medtronic DBS neurostimulator model numbers using 1.5-T MRI equipment:

37601 37602 37603 37612 B35200 B35300

Note: If the Model B35200 or B35300 neurostimulator is eligible, certain 3-T MRI scans may be performed using these guidelines.

Follow these MRI guidelines and conditions for approved indications to determine whether and how to perform an MRI scan safely on a patient with a DBS neurostimulator model listed or a Medtronic DBS lead-only system.

Scheduling an MRI


This section is for MRI scan scheduling purposes only. Identify the implanted DBS neurostimulator models to see the possible MRI equipment and scan locations. In some instances, no MRI scan may be recommended after eligibility has been determined.

Neurostimulator model	MRI equipment	Possible scan locations
B35200, B35300	1.5-T or 3-T	Head, torso, extremities
37601, 37603, 37612	1.5-T	Head, torso, extremities
37602	1.5-T	Head
Lead-only systems	1.5-T or 3-T	Head, torso, extremities

Before the MRI appointment, remind patients to take the following steps:

- Consult with the physician who manages their DBS system.
- Bring the patient control device and patient ID cards to the MRI appointment.
- Recharge a rechargeable neurostimulator before the MRI appointment.
- Inform the MRI clinician that they have an implanted device.
- Program therapy to the original settings after the MRI examination.

If two models are implanted, always use the most restrictive MRI settings. Determine scan-type eligibility and review scan conditions before an MRI scan.

 **Warning:** Do not conduct an MRI scan 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.

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines and MRI Eligibility Report. Go to www.medtronic.com/mri and search by the DBS neurostimulator model number.

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 on the same day of the patient's MRI scan appointment.

MRI and Medtronic DBS Therapy

DBS systems

These MRI guidelines apply to two types of Medtronic DBS systems (Figure 1): implanted neurostimulation systems and lead-only systems.

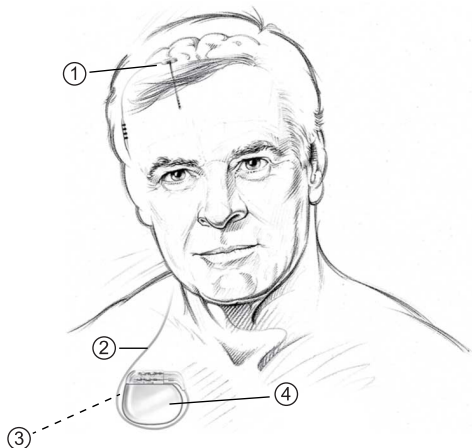


Figure 1. Medtronic DBS System components.

- | | |
|----------------------------|---|
| ① Lead and burr hole cover | ③ Pocket adaptor (not present in all implanted systems) |
| ② Extension | ④ Neurostimulator |

Lead-only systems include only a fully implanted lead (ie, internalized, under the skin) with a burr hole cover and a lead cap.

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:

- 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.

No claims of safety are made for MRI scans involving modified Medtronic DBS systems or components (eg, custom devices to mitigate allergies) or for non-Medtronic components or accessories.

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). Use the most restrictive MRI exposure requirements of the medical devices implanted. 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.

Abandoned Systems and Electromagnetic Interference (EMI) considerations - If any DBS system components (neurostimulator, lead, extension, or a fragment of a lead or extension) 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 abandoned systems (ie, abandoned components no longer providing therapy) cannot be determined for MRI scanning purposes.

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.

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 guideline are followed and that the MRI scan parameters, especially RF specific absorption rate (SAR), B1+rms, and gradient parameters, comply with the recommended settings. The responsible individual must verify that parameters entered into the MRI system meet the guidelines in this manual.

Heating – The MRI RF field induces currents 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, which could result in coma, paralysis, or death.

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 are MR **Unsafe**:

- Patient control devices (for example, patient programmer, patient handset, or communicator)
- Recharger
- External neurostimulator
- Clinician programmer and communicator

Magnetic field interactions - The magnetic material in 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 with recent implant incisions should be monitored for any surgical wound discomfort during an MRI scan.

Induced stimulation - The gradient magnetic and RF fields produced by an MRI scanner induce currents onto implanted lead systems 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 (ie, abandoned system).

External control devices (programmers)

For Medtronic DBS systems, an external control device (ie, clinician programmers and some patient control devices) can be used to confirm the neurostimulator model number, check impedance, turn off therapy or change programming settings, or set up MRI mode prior to an MRI scan. All patient programmers can be used to match the therapy settings indicated on the MRI Eligibility Report prior to an MRI scan.

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

Note: Refer to the DBS clinician application programming guide (eg, Model A610) or patient user guide (eg, Model A620) for instructions on using the MRI workflow, creating a software-generated MRI Eligibility Report, and activating MRI mode.

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.

Patient ID card

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

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

Patients with more than one DBS system

Some patients may have two DBS systems (Figure 2) or a combination of complete DBS systems and lead-only systems. A neurostimulator may be connected to either one or two extensions and leads.

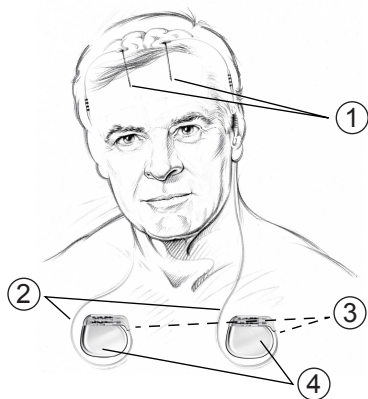


Figure 2. A patient with two DBS systems.

- | | |
|------------------------------|---|
| ① Leads and burr hole covers | ③ Pocket adaptor (not present in all implanted systems) |
| ② Extensions | ④ Neurostimulators |

Regardless of the implanted system configuration, each DBS system must be separately evaluated for MRI scan-type eligibility:

- If two DBS systems are implanted, always use the most restrictive settings. For example, if one DBS system is full-body scan eligible and the other DBS system is head-only scan eligible, the head-only eligible MRI scan conditions should be used.
- Determine the scan-type eligibility for each device prior to an MRI scan.
- Therapy settings must be programmed (or MRI mode activated) for each neurostimulator prior to the MRI scan.
- If a two-lead capable neurostimulator only has one lead implanted, the extra extension should be capped or a connector plug should be used. Otherwise the DBS system is not considered complete for MRI scanning purposes.
- In some instances, no MRI scan may be recommended after scan eligibility has been determined.

MRI workflow and MRI mode

MRI scan eligibility can be established at the time of the scan appointment using an MRI eligibility workflow in Model A610 clinician or A620 patient software applications.

- An impedance check can indicate if there are open or short circuits to investigate.
- Scan-type eligibility will be checked and identified.
- Eligible therapy settings for the scan will be identified.

Note: The MRI workflow on A610 clinician and A620 patient software applications may replace the MRI Eligibility worksheet and the MRI Eligibility Report. However, communication between the DBS physician and the MRI facility is always recommended prior to an MRI scan.

- MRI mode must be used for MRI scans if the patient has a B35200 Percept™ PC or B35300 Percept RC neurostimulator.

When MRI mode is activated, it puts Model B35200 or B35300 neurostimulators into an appropriate state for MRI scans based on the scan-type eligibility determined in the MRI workflow. A patient programmer can also be used to activate MRI mode for a Model B35200 or B35300 neurostimulator at the MRI facility. Activating MRI mode at the MRI facility minimizes the time that therapy settings might either be off or in a group that might not be optimal for patient therapy.

Note: Do not exit MRI mode until after the MRI examination is complete.

Refer to the Model A610 programming guide or Model A620 patient user guide for instructions on using the MRI eligibility workflow, viewing a software-generated MRI Eligibility Report, and entering or exiting MRI mode.

Image artifacts and distortion

Significant image distortion can result from the presence of the neurostimulator within the field of view. Image artifacts and distortion resulting from the presence of the neurostimulator, leads, extensions, 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.

DBS physicians — Determine scan eligibility

The DBS physician or qualified staff member familiar with DBS neurostimulation systems should assess and record a patient's MRI scan-type eligibility and provide the MRI Eligibility Report to the patient's MRI facility prior to the scheduled MRI scan.

Determine the scan eligibility to find the correct MRI scan conditions to follow in this manual. The conditions include instructions, scanning parameters, and therapy settings to safely perform an MRI scan on a patient with a complete DBS system with the listed neurostimulator model number or with a DBS lead-only system.

MRI Eligibility factors

MRI scan-type eligibility depends on a combination of factors pertaining to the patient's implanted DBS system (Table 1):

- Neurostimulator model
- The presence of an implanted pocket adaptor
- System integrity (no open or short circuits)
- Lead-only status (ie, fully implanted leads must use a lead cap)
- Abandoned components (ie, a neurostimulator, lead, extension, or a fragment of a lead or extension) must be outside of the RF transmit coils used for the scan.
- Neurostimulator implant location

Table 1. Factors affecting MRI eligibility.

Full-body scan eligibility factors:

Neurostimulator model	37601 Activa™ PC, 37603 Activa SC, 37612 Activa RC, B35200 Percept™ PC, B35300 Percept RC
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Note: Neurostimulators that are not full-body eligible may still be head-only eligible.

Pocket adaptor	No pocket adaptors are permitted
System integrity	No open or short circuits
Lead-only systems	Fully-implanted leads must use a lead cap
Abandoned components	No abandoned components are permitted (Burr hole covers are acceptable)
Neurostimulator implant location	Pectoral or abdominal

Note: Lead model and neurostimulator location affect the B1+rms for full-body scans.

Head-only scan eligibility factors:

Neurostimulator model	37602 Activa SC
Pocket adaptor	Yes (affects eligibility for any neurostimulator model)

Table 1. Factors affecting MRI eligibility. (continued)

System integrity	No open or short circuits
Abandoned components	No abandoned components are within the head transmit/receive coil. (Burr hole covers are acceptable)
Neurostimulator implant location	No restrictions

Note: Refer to the Model A610 programming guide or Model A620 patient user guide for instructions on using the MRI eligibility workflow, viewing a software-generated MRI Eligibility Report, and entering or exiting MRI mode.

Use the MRI Eligibility worksheet or the MRI workflow

Clinicians familiar with DBS systems should assess patients and identify MRI scan eligibility either by completing the MRI Eligibility worksheet or using the MRI workflow.

Note: MRI scan eligibility can be identified using the MRI eligibility workflow (eg, on Model A610 clinician and A620 patient software applications) and may replace the worksheet and the MRI Eligibility Report. However, communication between the DBS physician and the MRI facility is always recommended prior to an MRI scan.

Completing the MRI Eligibility Worksheet

Complete an MRI Eligibility worksheet (page 2 of the MRI Eligibility Report) or MRI workflow for each DBS system.

Lead-only systems

If the patient has a lead-only system, do not use the MRI Eligibility worksheet. Refer to "Lead-only DBS systems" on page 21 to complete the MRI Eligibility Report.


Step 1: Is it possible to have an MRI scan?

This step rules out factors that would prevent a patient from having any MRI scan.

1. Are there abandoned DBS components implanted such as a complete DBS system that is non-functioning, or a system that was partially explanted but components remain in the patient?
 - a. Review the patient record.
 - b. If there are no abandoned DBS components within the RF transmit coil to be used for the MRI scan, check the box.

Note: An x-ray or review of the patient record may help confirm that there are no additional DBS components implanted in the patient other than the DBS system being assessed for scan eligibility.


2. Interrogate the neurostimulator with a clinician programmer.
3. Note the DBS lead and neurostimulator models, serial number, and implant location, and complete the DBS system information section of the MRI Eligibility Report.

 **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. Measure unipolar (monopolar) impedance between each electrode and the neurostimulator case, and bipolar impedance between all electrode pairs.

The impedance test results that should be investigated vary by lead model:

<input type="checkbox"/> 3387, 3389, 3391 leads	Unipolar	Investigate: > 2000 ohms or < 250 ohms
	Bipolar	Investigate: > 4000 ohms or < 250 ohms
<input type="checkbox"/> B33005, B33015 leads	Unipolar	Investigate: > 8000 ohms or < 350 ohms
	Bipolar	Investigate: > 10000 ohms or < 350 ohms

 **Caution:** If a possible short or open circuit is detected, 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.

5. If the DBS system is functioning properly and no open or short circuits are detected, check the box.
6. If both boxes in step 1 are checked, continue to step 2 of the worksheet.
7. If an open or short circuit is verified, the system is compromised. If the system is compromised, MRI scan type eligibility cannot be determined, and the safety of an MRI scan cannot be evaluated.

 **Warning:** 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.

Notes:

- If a programmer cannot communicate with the device or if the device has reached its end of service, then MRI scan eligibility cannot be determined.
- If you cannot resolve an impedance issue or if you are unsure of system integrity after testing connections, contact Medtronic Technical Services.

8. If shown on the software app, record the information code on the report, which can be used to troubleshoot scan eligibility by Medtronic.


Step 2: Is the MRI scan limited to only a head scan?

This step is used to rule out the factors preventing a patient from having an MRI scan using full-body eligible settings.

1. Is the implanted neurostimulator model listed in this section of the worksheet? If so, check the box.

Note: If the model is not listed, only head scan-type eligibility may apply, or the model may be in a different MRI Guidelines manual.

2. Does the patient record, programmer, or x-rays indicate that the patient has pocket adaptors? If there are no pocket adaptors, check the box. See "Appendix A: X-ray images to assist in identifying a pocket adaptor" on page 35 to assist in identifying a pocket adaptor.

 **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.

3. Confirm that the neurostimulator is located either in the chest (eg, pectoral region) or the abdomen. If so, check the box.
4. If all three boxes in step 2 are checked, continue to step 3 on the worksheet.
If any of the boxes are not checked, the DBS system is MR Conditional Head Scan eligible.
5. Choose the appropriate therapy setting, based on the implanted neurostimulator model.

The MRI Eligibility worksheet is complete for determining Head-only eligibility.


6. If Head-only eligibility is determined, transcribe the eligibility and therapy settings to the Eligibility determination section and complete the MRI Eligibility Report.

Step 3: Confirm full-body scan eligibility

This step confirms that the factors permitting a patient to have an MRI scan using the full-body eligible settings and conditions have been met.

1. Confirm that steps 1 and 2 were completed correctly and all boxes are checked.
2. If the implanted neurostimulator model is listed, choose the desired therapy settings and list the group name or letter.

The decision to turn off a patient's implanted neurostimulator for an MRI scan should be carefully considered based on the patient's underlying medical condition.

 **Warning:** Abruptly ending stimulation for any reason will probably cause a return of disease symptoms. In some cases, symptoms may return with an

intensity greater than those experienced prior to system implant (rebound effect). This can, in rare cases, become a medical emergency.

Note: Full-body scan eligibility includes the head, torso, and extremity scan locations.

The MRI Eligibility worksheet is complete for confirming full-body scan eligibility for this implanted neurostimulator.

3. Transcribe the scan eligibility and therapy settings to the Eligibility determination section and complete the MRI Eligibility Report.

Completing the MRI Eligibility Report

It is critical that the MRI facility receives the MRI scan eligibility information to schedule the MRI scan appointment. The MRI Eligibility Report, provided in the device package or available at www.medtronic.com/mri, can be used to record and send this information.

Notes:

- The MRI Eligibility Report can be generated using the MRI workflow (eg, on Model A610 clinician and A620 patient software applications) and may replace the paper MRI Eligibility Report. However, communication between the DBS physician and the MRI facility is always recommended prior to an MRI scan.
- Complete a separate MRI Eligibility Report for each DBS system.

Patient and DBS system information

Complete the patient information section of the MRI Eligibility Report.

1. Enter the patient's name (and date of birth) for identification purposes.
2. In the DBS physician information field, enter appropriate contact information such as physician name or contact for MRI questions and a phone number.
3. If this is a lead-only system, check the box. Refer to "Lead-only DBS systems" for more information.
4. Use the programmer to confirm the DBS lead and neurostimulator models, serial number, and neurostimulator implant location. The clinician or patient programmer, patient records, patient ID cards, or x-ray imaging can be used to confirm DBS system information.

Eligibility determination

Note: MRI scan-type eligibility determines which set of instructions must be used for the MRI equipment setup, therapy settings, and conditions for the MRI scan.

1. The MRI Eligibility worksheet, programmers, and Table 1 on page 15 may be used to verify the information about scan-type eligibility entered here.

Note: 3-T full-body MRI scanning can be used only with the Model B35200 or B35300 neurostimulator and lead-only systems.

2. When eligibility cannot be determined, the report can still be used to create a record of the reasons why the patient was not eligible for an MRI scan.

3. If available, record the information code, which can be used to troubleshoot scan eligibility by Medtronic.

Physician signature and report date

While a physician signature may not always be mandatory to retain the report as a record in a patient chart, the report date provides critical information to the MRI facility.

1. Record the report date. The older the report, the greater the chance that the following changes could have occurred:
 - a. The patient had a physical trauma or revision surgery that may have changed the scan eligibility.
 - b. The patient's device was turned back on, settings were changed, or it sustained damage, which may affect patient safety during a scan.
2. Send the completed MRI Eligibility Report to the MRI facility before the patient receives the scheduled MRI scan.

Note: Advise patients with implanted neurostimulators to bring all their patient ID cards and a patient control device to the MRI appointment.

Patient preparation — Therapy settings for an MRI scan appointment

Note: Refer to the appropriate programming guide or patient user guide for instructions on changing therapy settings and activating MRI mode.

1. Interrogate the neurostimulator with a clinician programmer.
2. Consider programming and naming a bipolar group for MRI that can provide movement or other symptom control. Using a bipolar group allows therapy to be on during an MRI scan.
 - Bipolar group – stimulation programs where at least one electrode is positive, one electrode is negative, and the case is off.
 - Unipolar group – stimulation programs where at least one electrode is negative and the case is positive.
3. If the DBS system is to be set up for an MRI scan now, program the neurostimulator to the recommended therapy settings, or activate MRI mode as listed on the MRI Eligibility Report.
4. Inform the patient if therapy settings cannot be changed until after the MRI scan.

Note: If the patient will be activating MRI mode with the patient programmer, ensure that the patient or a caregiver understands how to activate and exit MRI mode.

Lead-only DBS systems

Lead-only systems are fully implanted leads (ie, internalized and capped) that have no other implanted, connected components other than a lead cap and burr hole cover to maintain lead position. Lead-only systems may be full-body eligible for 1.5-T and 3-T MRI scans.

Note: If the lead is partially implanted, or other components such as an extension or a non-functioning neurostimulator are attached, the DBS system eligibility cannot be determined for MRI scanning purposes.

DBS physicians – Assessing a Lead-only system

△ **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.

1. Confirm full-body MRI scan eligibility:

Full-body scan eligibility factors:

Lead-only systems	Fully-implanted leads must use a lead cap
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Note: Lead model and neurostimulator location affect the B1+rms limits for full-body scans.

Abandoned components	No abandoned components are permitted (Burr hole covers are acceptable)
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2. Complete the MRI Eligibility Report.
3. In the DBS system information section, check the boxes for the Lead model and Lead-only system.
4. In the eligibility determination section, check the boxes for MR Conditional Full Body scan eligible and Lead-only system.
5. Ensure that the leads are capped and fully internalized before an MRI scan is conducted. For instructions on capping the lead, refer to the appropriate lead implant manual.

MRI clinicians – Confirming a Lead-only system

If a lead-only system has been identified by the DBS physician, follow the instructions for eligibility confirmation in the next section.

MRI clinicians — Eligibility confirmation

Only qualified MRI clinicians (ie, the attending MR radiologist, MR medical director, or designated MR personnel following criteria predetermined by the medical director to make decisions about a patient with any implant) should use these procedures to make decisions about an MRI scan of a DBS patient.

Notes:

- The instructions and conditions to safely perform an MRI scan may significantly extend the duration of the MRI appointment.
- In some instances, no MRI scan may be recommended.
- If two neurostimulators are implanted, review all reports and use the most restrictive settings. Assess other implanted medical devices before conducting an MRI scan.

Confirm the device information and MRI scan eligibility

Before performing an MRI scan on a patient with a Medtronic DBS System, you should receive and review a completed MRI Eligibility Report from the clinician managing the patient's DBS system for each implanted neurostimulator.

Note: MRI scan eligibility can be identified using the MRI eligibility workflow (eg, on Model A610 clinician and A620 patient software applications) and may replace the worksheet and the MRI Eligibility Report. However, communication between the DBS physician and the MRI facility is always recommended prior to an MRI scan.

Review the MRI Eligibility Report

Review the MRI Eligibility Report information to confirm that the patient's MRI scan eligibility and therapy settings are shown, and whether the DBS system has been programmed for the MRI scan (eg, MRI mode). A physician signature may or may not be present in accordance with MRI facility or institutional guidelines. If any required information is missing, contact the DBS physician prior to the MRI scan.

Patient and DBS system information

1. Confirm the patient's name (and date of birth).
2. Review the report date. The older the report, the greater the chance that changes to the DBS system may have occurred.
3. Ask the patient if any of the following changes to the DBS system have occurred since the MRI Eligibility Report was generated:
 - a. Has the patient had a fall, physical trauma, or revision surgery, which may have changed the MRI scan eligibility?
 - b. Was the DBS system turned back on, the settings changed, or was MRI mode disabled, which may affect patient safety during an MRI scan?

If an event or therapy change is suspected, contact the DBS physician before proceeding with the MRI scan.

4. Confirm that the clinician has identified whether the patient has an implanted DBS neurostimulator and/or a lead-only system.
5. If the patient has a lead-only system, skip to step 9.

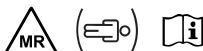
Note: Impedance measurements are not required for lead-only systems.

6. Confirm that the neurostimulator and lead models listed on the report are correct by reviewing the programmer screen, serial number, patient ID card, or implant location, etc.

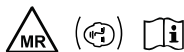
Note: If the patient has more than one neurostimulator implanted, all models should have MRI Eligibility Reports. If all models are not recorded, contact the DBS physician before proceeding with the MRI scan.

Eligibility determination – Review Scan-type eligibility

Scan-type eligibility sections in this manual show the MR Conditional scan conditions and safety information:



Full-body scan eligibility allows therapy to continue when using bipolar stimulation and includes the head, torso, and extremity scan locations using an RF Whole Body Transmit Coil, a Detachable Head Transmit/Receive Volume Coil, or a Detachable Lower Extremity Transmit/Receive Volume Coil.



Head scan eligibility is limited to head scans using only a Detachable Head Transmit/Receive Volume Coil and requires that stimulation be turned off.



MRI scan-type eligibility cannot be determined means that the DBS system does not meet one or more criteria for the other two scan eligibility conditions and MRI eligibility cannot be determined for MRI scanning purposes.

Confirm therapy settings

Note: If the patient only has a lead-only system, therapy settings do not apply.


Therapy settings and the group name or letter, as applicable, should be on the report.

7. Confirm that the patient's neurostimulator is programmed to the correct therapy settings listed in the MRI Eligibility Report.
8. If necessary, the patient or clinician can program the neurostimulator to the recommended therapy settings or activate MRI mode to match what is listed on the MRI Eligibility Report.

Therapy settings and the group name or letter, as applicable, are on the report.

Note: The decision to turn off a patient's implanted neurostimulator for an MRI scan should be carefully considered based on the patient's underlying medical condition.

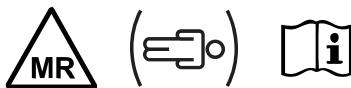
Consultation with the appropriate medical professional (prescribing or implanting clinicians) is recommended.

 **Warning:** Abruptly ending stimulation for any reason will probably cause a return of disease symptoms. In some cases, symptoms may return with an intensity greater than those experienced prior to system implant (rebound effect). This can, in rare cases, become a medical emergency.

Note: If the patient is not sure how to change settings or how to go into MRI mode, contact the DBS physician or Medtronic Technical Services.

9. Go to the appropriate scan-type eligibility section of the MRI guidelines for information about MRI equipment, settings, and scan conditions.

Full-body eligible MRI scan conditions



MR Conditional Full Body Scan Eligible

Before proceeding with this full-body eligible section, confirm that the information in "MRI clinicians — Eligibility confirmation" has been followed and full-body scan eligibility has been correctly identified on the MRI Eligibility Report.

Notes:

- 3-T MRI scanning can be used only with the B35200 or B35300 neurostimulator and lead-only systems.
- Full-body MRI scan eligibility includes the head, torso, and extremity scan locations.

Full-body eligible – 1.5-T and 3-T MRI equipment and scan requirements

Starting with Table 2 for 1.5-T MRI equipment, or Table 3 for 3-T MRI equipment, use the check boxes to keep track of the appropriate MRI equipment, settings, and scan conditions.


 **Warning:** Scans must be conducted using the stated MRI equipment and scan requirements. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.

Table 2. 1.5-T Full-body eligible – MRI equipment and scan requirements

MRI scanner manufacturers	<input type="checkbox"/> There are no restrictions on MRI manufacturers.
1.5-T MRI system type	<input type="checkbox"/> 1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
Maximum spatial field gradient	<input type="checkbox"/> 1.5-T: 19 T/m (1900 gauss/cm)
RF coils [Select one:]	<input type="checkbox"/> RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type <input type="checkbox"/> Detachable Head Transmit/Receive Volume Coil <input type="checkbox"/> Detachable Lower Extremity Transmit/Receive Volume Coil
Note: RF Whole Body Transmit Coil – 1.5-T MRI systems should only be operated in Circularly Polarized (CP) configuration.	
1.5-T RF power [Select the B1+rms limit by neurostimulator location and lead models:]	Chest implant location <input type="checkbox"/> For any DBS lead models: $B1+rms \leq 2.0 \mu T$ Abdomen implant location <input type="checkbox"/> For Model B33005/B33015 leads: $B1+rms \leq 1.7 \mu T$ <input type="checkbox"/> For Model 3387/3389/3391 leads: $B1+rms \leq 2.0 \mu T$
Notes: <ul style="list-style-type: none"> The B1+rms limit shown is the value before scanning. For 1.5-T MRI scanners that do not report B1+rms, limit SAR to ≤ 0.1 W/kg. Detachable Lower Extremity Transmit/Receive Volume Coil: No B1+rms limit. 	
Operating mode	<input type="checkbox"/> 1.5-T: Normal Operating mode
Maximum gradient slew rate specification	<input type="checkbox"/> 200 T/m/s or less per axis
Active scan time limits	<input type="checkbox"/> MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (every 90-minute window should include a total of 60 minutes of wait time).
Landmark restrictions	<input type="checkbox"/> None. All anatomical locations can be scanned.

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

MRI scanner manufacturers	<input type="checkbox"/> There are no restrictions on MRI manufacturers.
3-T MRI system type	<input type="checkbox"/> For Model B35200 or B35300 and all DBS lead-only systems: 3-T horizontal cylindrical system for hydrogen imaging, approximately 128 MHz
Maximum spatial field gradient	<input type="checkbox"/> 3-T: 20 T/m (2000 gauss/cm)
RF coils [Select one:]	<input type="checkbox"/> RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type <input type="checkbox"/> Detachable Head Transmit/Receive Volume Coil <input type="checkbox"/> Detachable Lower Extremity Transmit/Receive Volume Coil
Note: RF Whole Body Transmit Coil – 3-T MRI systems using two transmit channels (or fewer) may operate in Multichannel-2 (MC-2) or CP configurations. Systems that use more than two transmit channels have not been studied, but such systems could be operated in CP or MC-2 configurations, if available.	
3-T RF power [Select the B1+rms limit by lead models:]	<input type="checkbox"/> For Model B33005/B33015 leads: $B1+rms \leq 2.0 \mu T$ <input type="checkbox"/> For Model 3387/3389/3391 leads: $B1+rms \leq 2.5 \mu T$
Notes: <ul style="list-style-type: none"> The B1+rms limit shown is the value before scanning. For 3-T MRI scanners that do not report B1+rms, limit SAR to ≤ 1.0 W/kg. Detachable Lower Extremity Transmit/Receive Volume Coil: No B1+rms limit. 	
Operating mode	<input type="checkbox"/> 3-T: Normal mode or First Level Controlled mode
Maximum gradient slew rate specification	<input type="checkbox"/> 200 T/m/s or less per axis
Active scan time limits	<input type="checkbox"/> MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (every 90-minute window should include a total of 60 minutes of wait time).
Landmark restrictions	<input type="checkbox"/> None. All anatomical locations can be scanned.

Full-body eligible – Preparing the patient before the MRI scan

Warnings:

- Do not perform an MRI scan if the patient's body temperature is above 38 °C (100 °F). Do not cover the patient with blankets or heated blankets. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which may cause tissue damage.
- Do not position patients in positions other than prone or supine, such as on their side within the MRI bore. Scanning patients in positions other than prone or supine is untested and may cause excessive tissue heating during an MRI scan.

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

Abandoned systems or components	<input type="checkbox"/> Do not conduct a full-body MRI scan on a patient with an abandoned system. Abandoned systems are non-functioning neurostimulation systems or components (eg, neurostimulator, lead, extension, or lead-extension fragment) that no longer provide therapy to the patient. Note: An MRI report indicating full-body eligibility confirms that the DBS physician has checked for abandoned systems.
Therapy settings <i>[Adjust each neurostimulator]</i>	<input type="checkbox"/> Confirm that therapy settings have been appropriately adjusted for each neurostimulator per the MRI Eligibility Report prior to the MRI scan. Refer to the MRI Eligibility Report for more information. If uncertain if therapy settings have been appropriately adjusted, ask the patient to confirm that therapy has been adjusted by using the patient control device, or consult the DBS physician. Note: If the patient only has a lead-only system, therapy settings do not apply.
Check core body temperature	<input type="checkbox"/> Confirm that the patient does not have a fever. Do not use blankets.
Patient position	<input type="checkbox"/> Position the patient in a prone or supine position in the MRI bore.
Patient weight, minimum	<input type="checkbox"/> No restrictions
Sedation	<input type="checkbox"/> No restrictions
Patient communication with operator during scan	<input type="checkbox"/> Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the scan.

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

Notes:

- If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.
- Inform the patient of all the risks of undergoing an MRI examination as stated in this full-body eligible section.

Full-body eligible – Pre-MRI scan operations and considerations

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

Enter patient weight	<input type="checkbox"/> 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.
Verify all parameters	<input type="checkbox"/> Verify that all proposed MRI scan parameters comply with the MRI settings 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 scan.
Consider image artifacts and distortion	<input type="checkbox"/> 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.

Full-body eligible – During the MRI scan


-  **Warning:** Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.

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

Keep track of active scan time	<input type="checkbox"/> Keep track that the active scan time is a total of 30 minutes within a 90-minute window.
Patient comfort	<input type="checkbox"/> The patient may feel heating at the neurostimulator site during the MRI scan. If the heating causes patient discomfort, stop the MRI scan immediately.
Neurostimulator tugging, vibration	<input type="checkbox"/> 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.

Full-body eligible – Post-MRI scan

Table 7. Full-body eligible – Post MRI scan

Patient feedback	<input type="checkbox"/> Verify that the patient has not experienced adverse effects as a result of the MRI scan. Contact Medtronic to report any adverse effects.
Return to original therapy settings	<input type="checkbox"/> When the scan is complete, instruct the patient to see the DBS physician to return therapy to the original settings. Or, if the patient has brought a patient programmer to the MRI appointment, instruct the patient (outside of the scanner room) to exit MRI mode, turn therapy on, or return therapy to the original settings. Note: If the programmer 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 follow up with the DBS physician. Contact Medtronic to report the POR event.

Head-only eligible MRI scan conditions



MR Conditional Head Scan Eligible with a Head Transmit/Receive Coil

Before proceeding with this head-only eligible section, confirm that the information in "MRI clinicians — Eligibility confirmation" has been followed and that head-only scan eligibility has been correctly identified on the MRI Eligibility Report.

A patient who is "MR Conditional head scan eligible with head transmit/receive coil" can have 1.5-T MRI scans of the head using a Detachable Head Transmit/Receive Volume Coil in addition to the other specific conditions in this head-only eligible section.

Head-only eligible – MRI equipment and scan requirements

Starting with Table 8, use the check boxes to keep track of the appropriate MRI equipment, settings, and scan conditions.

Warning: Scans must be conducted using the stated MRI equipment and scan requirements. Failure to follow all warnings and guidelines related to MRI can result in serious and permanent injury including coma, paralysis, or death.

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

MRI scanner manufacturers	<input type="checkbox"/> There are no restrictions on MRI manufacturers.
MRI system type	<input type="checkbox"/> 1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
Maximum spatial field gradient	<input type="checkbox"/> 19 T/m (1900 gauss/cm)
RF coils	<input type="checkbox"/> Detachable Head Transmit/Receive Volume Coil
RF power	<input type="checkbox"/> Head SAR: Use MRI scan parameters that limit the head SAR to 0.1 W/kg or less.
Operating mode	<input type="checkbox"/> Normal Operating mode
Maximum gradient slew rate specification	<input type="checkbox"/> 200 T/m/s or less per axis
Active scan time limits	<input type="checkbox"/> No restrictions.
Landmark restrictions	<input type="checkbox"/> Head only (isocenter location).

Head-only eligible – Preparing the patient before the MRI scan

Table 9. Head-only eligible – Preparing the patient before the MRI scan

Abandoned systems or components	<input type="checkbox"/> Confirm that no abandoned systems are inside the transmit/receive head coil. Abandoned systems are non-functioning neurostimulation systems or components (eg, neurostimulator, lead, extension, or a lead or extension fragment) that no longer provide therapy to the patient. The presence of an abandoned component can be confirmed with x-ray imaging, referring to the patient records, or by consulting with the DBS physician.
Therapy settings <i>[Adjust each neurostimulator]</i>	<input type="checkbox"/> Confirm that therapy settings have been appropriately adjusted for each neurostimulator per the MRI Eligibility Report prior to the MRI scan. Refer to the MRI Eligibility Report for more information. If uncertain if therapy settings have been appropriately adjusted, ask the patient to confirm that therapy has been adjusted by using the patient control device, or consult the DBS physician.
Check core body temperature	<input type="checkbox"/> No restrictions
Patient position	<input type="checkbox"/> No restrictions, but the MRI landmark must be the head only.
Patient weight, minimum	<input type="checkbox"/> No restrictions
Sedation	<input type="checkbox"/> No restrictions
Patient communication with operator during scan	<input type="checkbox"/> Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the scan.

Notes:

- Inform the patient of all the risks of undergoing an MRI scan as stated in this head-only eligible section.
- Monitor the patient during the MRI scan. Instruct the patient to immediately inform the MRI operator if any discomfort, unexpected stimulation, shocking, or heating occurs during the scan.

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

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

Enter patient weight	<input type="checkbox"/> Enter the correct patient weight into the MRI console to ensure that the head SAR is estimated correctly.
Verify all parameters	<input type="checkbox"/> Verify that all proposed MRI scan parameters comply with the MRI scanning conditions in this head-only eligible section. If these conditions cannot be met, do not proceed with the MRI scan.
Consider image artifacts and distortion	<input type="checkbox"/> 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.

Head-only eligible – During the MRI scan


 **Warning:** Discontinue the MRI immediately if the patient becomes unresponsive to questions or experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.

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

Keep track of active scan time	<input type="checkbox"/> No restrictions.
Patient comfort	<input type="checkbox"/> The patient may feel heating at the neurostimulator site during the MRI scan. If the heating causes patient discomfort, stop the MRI scan immediately.
Neurostimulator tugging, vibration	<input type="checkbox"/> 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	<input type="checkbox"/> Verify that the patient has not experienced adverse effects as a result of the MRI scan. Contact Medtronic to report any adverse effects.
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Table 12. Head-only eligible – Post MRI scan (continued)

Turn therapy back on and return to original therapy settings

- ☐ When the scan is complete, instruct the patient to see the DBS physician to return therapy to the original settings.

Or, if the patient has brought a patient programmer to the MRI appointment, instruct the patient (outside of the scanner room) to exit MRI mode, turn therapy on, or return therapy to the original settings.

Note: If the programmer 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 follow up with the DBS physician. Contact Medtronic to report the POR event.

Appendix A: X-ray images to assist in identifying a pocket adaptor

This appendix provides examples of x-ray images to assist in identifying whether a pocket adaptor has been implanted with a neurostimulation system. A pocket adaptor 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 MRI scan, but may be eligible for a head scan.

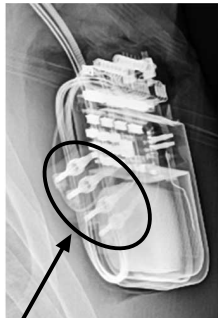
Clinicians should look for the pocket adaptor connector ports and extension connector pins in the x-ray image. Figures 3 and 4 depict one neurostimulator model among several possible neurostimulator models that can be implanted with a pocket adaptor.

- Figure 3: 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 4: The left image is a neurostimulator without a pocket adaptor implanted and the right image is a neurostimulator implanted with two 1x4 pocket adaptors.

Neurostimulator **without**
a pocket adaptor



Neurostimulator **with**
a 2x4 pocket adaptor



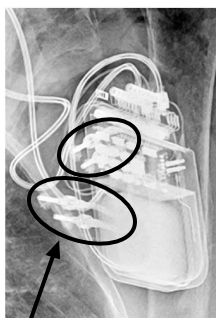
Extension connector pins (4) and
pocket adaptor connector ports (4)

Figure 3. Model 37601 Activa PC Neurostimulator implanted without a pocket adaptor (left) and the same 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 4. Model 37601 Activa PC Neurostimulator implanted without a pocket adaptor (left) and the same neurostimulator implanted with two 1x4 pocket adaptors (right).

Appendix B: 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 integrated into the scanner) or an extremity coil (for example, a head transmit/receive coil).

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