



Medtronic

MRI guidelines for Medtronic neurostimulation systems for chronic pain

See "START HERE" section before conducting MRI.

Instructions for use

USA

Rx only



Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.



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



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 component of a Medtronic neurostimulation system for chronic pain.

Contact a Medtronic representative if you have any questions about the information in this manual.

Neurostimulator model numbers




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. Always begin with the "START HERE – Eligibility identification" section of this manual and **use the yes/no identification checklist that starts on page 8** to determine the patient's MRI scan-type eligibility and the appropriate scan conditions to use for the patient's implanted Medtronic neurostimulation system for chronic pain.

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 fully implanted Medtronic neurostimulation system for chronic pain with the neurostimulator model number listed herein.

These MRI guidelines apply to the following Medtronic **implanted** neurostimulator model numbers:

| | | | |
|------------------------|-------|-------|-------|
| 97702 | 37701 | 37711 | 7479 |
| 97712 | 37702 | 37712 | 7479B |
| 97713 | 37703 | 37713 | 7427 |
| 97714 | 37704 | 37714 | 7427V |
| 7425 (see the warning) | | | |

 **Warning:** Medtronic recommends physicians not prescribe MRI for a patient who has an implanted Itrel 3 Model 7425 Neurostimulator. The Itrel 3 Neurostimulator is highly susceptible to reset or damage when subjected to an MRI examination. If reset, the neurostimulator must be reprogrammed. If damaged, the neurostimulator must be replaced. The Itrel 3 Neurostimulator has an increased risk of induced electrical current, which may stimulate or shock the patient.

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.

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.

Clinician programmer and patient control device

For Medtronic neurostimulation systems with SureScan MRI Technology, external control devices (ie, a clinician programmer or a patient control device) are used to determine MRI scan-type eligibility and are used to place the neurostimulation system in MRI conditionally safe (MRI-CS) mode (also referred to as "MRI mode"), which turns stimulation off. Inform the patient with a neurostimulation system that stimulation needs to be turned off prior to the MRI scan.

If the patient brought a patient control device to the MRI appointment, go to "START HERE – Eligibility identification" on page 8 and use the identification checklist in that section.

If the clinician programmer or a patient control device cannot communicate with the implanted neurostimulation system or if the neurostimulator has reached EOS (end of service), then MRI conditional safety cannot be confirmed via the external control devices. Researching the implanted neurostimulation system configuration from the patient's medical records is required. Unless the implanted system configuration is known and it is determined to be safe to perform 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.

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



The Medtronic neurostimulation systems with SureScan MRI Technology have been designed to minimize the potential interactions described in this section when the appropriate conditions described in this manual are followed.

Heating – The RF fields generated by an MRI scanner induce RF energy onto an implanted lead system that may cause heating at the lead electrodes or along the lead body. In addition, the gradient magnetic and RF fields may cause heating of the neurostimulator.

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

Factors that increase the risks of heating and patient injury include, but are not limited to, the following:

- High MRI specific absorption rate (SAR) RF power levels
- Low impedance leads or extensions (Medtronic product names or model numbers designated by a “Z,” an “LZ,” or “low impedance”)
- Implanted lead systems with small surface area electrodes
- Short distances between lead electrodes and heat-sensitive tissue

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 the patient could experience as a tingling, shocking, or jolting sensation.

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

Device damage – The voltages induced by the MRI fields may damage the neurostimulator electronics requiring reprogramming, explantation, or replacement.

Device interactions – MRI may affect the operation of the neurostimulator and require reprogramming of the neurostimulator with the clinician programmer after the MRI scan. The MRI may also reset the parameters to power-on-reset (POR) settings, which may also require reprogramming of the neurostimulator after the MRI scan.

START HERE – Eligibility identification

Use the identification checklist to identify the patient's scan eligibility first



Use the yes/no identification checklist that starts on page 8 in this section to determine the patient's MRI scan-type eligibility and the appropriate scan conditions to use for the patient's implanted Medtronic neurostimulation system for chronic pain.

The MRI scan-type eligibility depends on a combination of factors pertaining to the patient's implanted neurostimulation system.

Warnings

Other implanted devices – Prior to an MRI examination, determine whether the patient has multiple medical device implants, either active medical device implants (such as deep-brain 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.

Trial systems (neurostimulation systems that are not fully implanted) – Physicians should not prescribe MRI for patients undergoing trial stimulation or who have any neurostimulation system components that are not fully implanted. Explant all trial stimulation components if an MRI scan is required. MRI has not been tested on trial stimulation components and may cause heating of the lead electrodes, resulting in tissue damage or serious patient injury.

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

Identification checklist

1. Did you receive a sheet denoting the MRI conditionally safe (MRI-CS) scan-type eligibility for the patient's MRI appointment?

See "Appendix A: Examples of MRI-CS eligibility sheets" on page 24.

- ☐ **Yes** (1) Confirm the patient's name and date on the eligibility sheet. The date on the eligibility sheet should be on or near the date of the MRI appointment.
- Note:** 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 (eg, revision surgery of the implanted neurostimulation system) that may have changed the scan eligibility.
 - The patient's stimulation was turned back on.
- (2) Go to step 4 on page 10.
- ☐ **No** Go to the next step.
-

2.

Model number of patient control device
is on the front



Did the patient bring a **Model 977__ series** patient control device to the MRI appointment?

- ☐ **Yes** (1) Ask the patient to navigate to the MRI Mode screen to activate MRI mode.
- **MRI mode:** When MRI mode is activated:
 - The screen on the patient control device displays MRI-CS scan-type eligibility.
 - If the eligibility screen displays, it means stimulation has been turned off.
 - If the patient is unable to navigate to the MRI Mode screen, contact Medtronic Technical Services for assistance.
 - Do not deactivate, or exit, MRI mode or turn stimulation on with the patient control device until after the patient's MRI scan is complete and the patient is outside of the scanner (magnet) room.
- (2) After the MRI Mode screen displays, go to step 4 on page 10.
- ☐ **No** Go to the next step.
-

3. Does the patient have a Medtronic patient ID card with a neurostimulator model number that matches one of the neurostimulator model numbers listed on page 5?

- ☐ **Yes** Go to "Head-only eligible MRI scan conditions" on page 18.

- ☐ **No** The patient's implanted system cannot be determined. Stop. These MRI guidelines do not apply. Go to www.medtronic.com/mri or call Medtronic Technical Services.
-

4.



MRI-CS FULL BODY SCAN ELIGIBLE

Does the MRI-CS eligibility sheet or patient control device denote (with text and/or all of these symbols) full-body scan eligible?

- ☐ **Yes**
- (1) Confirm that the neurostimulator model number on the eligibility sheet or on the MRI Mode screen of the patient control device matches one of the model numbers on page 5.
 - (2) If yes, go to "Full-body eligible MRI scan conditions" on page 12.
- ☐ **No** Go to the next step.
-

5.



**MRI-CS HEAD SCAN ELIGIBLE WITH
TRANSMIT/RECEIVE HEAD COIL**

Does the MRI-CS eligibility sheet or patient control device denote (with text and/or all of these symbols) head-only scan eligible?

- ☐ **Yes**
- (1) Confirm that the neurostimulator model number on the eligibility sheet or on the MRI Mode screen of the patient control device matches one of the model numbers on page 5.
 - (2) Go to "Head-only eligible MRI scan conditions" on page 18.
- ☐ **No** Go to the next step.
-

6.




**The neurostimulation system MRI-CS
eligibility cannot be determined.**

Does the MRI-CS eligibility sheet or patient control device denote (with text and/or all of these symbols) that the MRI scan-type eligibility cannot be determined?

- ☐ **Yes** (1) Confirm that the neurostimulator model number on the eligibility sheet or on the MRI Mode screen of the patient control device matches one of the model numbers on page 5.
- (2) Go to "Head-only eligible MRI scan conditions" on page 18.
- ☐ **No** Stop. These MRI guidelines do not apply. Go to www.medtronic.com/mri or call Medtronic Technical Services.
-

Notes:

- The "consult instructions for use" symbol () when shown with MRI scan eligibility means "consult the MRI guidelines for this neurostimulation system."
- If a patient control device was used to determine eligibility, make a photocopy of the MRI Mode screen (shows the scan-type eligibility) that displayed on the patient control device, if needed.
- For interpretation of the information ⓘ code if given on the eligibility sheet or on the MRI Mode screen of the patient control device, call Medtronic Technical Services.
- Do not deactivate, or exit, MRI mode or turn stimulation on with the patient control device until after the patient's MRI scan is complete and the patient is outside of the scanner (magnet) room.

Full-body eligible MRI scan conditions



MRI-CS FULL BODY SCAN ELIGIBLE

Before proceeding with this full-body eligible section, confirm that the "START HERE – Eligibility identification" section (starts on page 8) has been followed and full-body scan eligibility has been determined by either an MRI-CS eligibility sheet or a patient control device.

A patient who is "MRI-CS 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 1. Full-body eligible – MRI equipment and scan requirements







| | |
|--------------------------------|--|
| MRI system type | 1.5-T horizontal closed bore with maximum spatial gradient 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 tissue damage or serious patient injury. |
| MRI manufacturers | No restrictions. |
| Radio-frequency (RF) frequency | Approximately 64 MHz.  Warning: Do not conduct MRI scans with nonproton scanning frequencies (such as, ¹³ C, ²³ Na, or ³¹ P). Frequencies other than 64 MHz have not been tested and could cause device damage and excessive heating, which can result in tissue damage or serious patient injury. |
| RF coils | Transmit coil: <ul style="list-style-type: none">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 tissue damage or serious patient injury. |
| | Receive-only coil: any type. |

Table 1. Full-body eligible – MRI equipment and scan requirements (continued)

| | |
|-------------------------------|--|
| RF power | <p>Use Normal Operating Mode.</p> <p>Specific absorption rate (SAR):</p> <ul style="list-style-type: none">▪ Whole body SAR: must be ≤ 2.0 W/kg (0.91 W/lb) as reported by the MRI equipment.▪ Head SAR: must be ≤ 3.2 W/kg (1.45 W/lb) as reported by the MRI equipment. <p> Warning: Do not conduct MRI scans in the following modes:</p> <ul style="list-style-type: none">▪ First Level Controlled Operating Mode▪ Second Level Controlled Operating Mode (ie, research mode) <p>These modes allow higher levels of RF energy and may cause excessive heating, which can result in tissue damage or serious patient injury.</p> |
| Gradients | <p>Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less.</p> <p> 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 induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or heating of the neurostimulator.</p> |
| Active scan time limits | <p>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).</p> <p> 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.</p> |
| Landmark (isocenter location) | <p>No restrictions. All anatomical locations can be scanned.</p> |

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

Table 2. Full-body eligible – Preparing the patient before the MRI scan

MRI-CS mode on,
stimulation off



MRI-CS FULL BODY SCAN ELIGIBLE

Placing the device in MRI-CS mode turns stimulation off. The text and/or all of the symbols above denote full-body MRI scan eligibility and indicate that the implanted system is in MRI-CS mode.

Caution: Before conducting the MRI scan, confirm that the patient's implanted neurostimulation system is off. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.

If you are not certain if stimulation is off, ask the patient if it is off.

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

Caution: Do not conduct MRI scans on patients who weigh less than 40 kg (88 lbs). Scans for patients who weigh less than 40 kg (88 lbs) have not been tested and could cause excessive heating, resulting in tissue damage.

Sedation

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

Table 2. Full-body eligible – Preparing the patient before the MRI scan (continued)

| | |
|---|---|
| Patient position within the bore | Position the patient in a prone or supine position in the MRI bore.  Warning: 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. |
| 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. |

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

Table 3. Full-body eligible – Pre-MRI scan operations and considerations


| | |
|-----------------------|---|
| Enter patient weight | 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 tissue damage or serious patient injury. |
| 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. |

Image artifacts and distortion

SureScan leads have demonstrated minimal image distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Image artifacts and distortion resulting from the presence of the device and the leads 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 in-plane 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.



Warnings:

- If the MRI targeted image area is near the neurostimulator, it may be necessary to move the neurostimulator to obtain an image, or use alternate imaging techniques. MRI images may be severely distorted or image target areas can be completely blocked from view near the implanted neurostimulation system components, especially near the neurostimulator.
- If the neurostimulator is removed, remove the entire neurostimulation system. Do not remove the neurostimulator and leave the lead system implanted as this can result in higher than expected lead heating. Excessive heating can result in tissue damage or serious patient injury.

Full-body eligible – During the MRI scan

Table 4. 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 1. |
| Monitor the patient | Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient is unable to respond to questions or reports any problems. |
| 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. |

Table 4. Full-body eligible – During the MRI scan (continued)

| | |
|------------------------------------|--|
| Neurostimulator tugging, vibration | <p>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.</p> <p>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.</p> |
|------------------------------------|--|

Full-body eligible – Post-MRI scan

Table 5. Full-body eligible – Post-MRI scan

| | |
|--------------------------|--|
| Patient feedback | <p>Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.</p> |
| Turn stimulation back on | <p>After the scan has been completed, instruct the patient to see the clinician managing the patient's neurostimulation system to have the stimulation turned back on.</p> <p>Or, if the patient has brought a patient control device to the MRI appointment, instruct the patient (outside of the scanner room) to turn the stimulation back on using the patient control device.</p> <p>Notes:</p> <ul style="list-style-type: none">▪ To take the patient control device out of MRI mode and re-enable it to make it operable, tell the patient to press the Sync  key. Then the patient can turn stimulation on.▪ Turning stimulation on takes the neurostimulator out of MRI mode.▪ If the patient control device cannot synchronize with the neurostimulator, or cannot turn stimulation 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 "START HERE – Eligibility identification" section (starts on page 8) has been followed, then proceed to the following checklist.

Checklist before proceeding with the head-only scan conditions

1.



MRI-CS HEAD SCAN ELIGIBLE WITH TRANSMIT/RECEIVE HEAD COIL

Did the "START HERE – Eligibility identification" section direct you to this head-only eligible section because the MRI-CS eligibility sheet or screen on the patient control device denotes (with text and/or all of these symbols) head-only scan eligible?

- ☐ **Yes** Go to "Head-only eligible – MRI equipment and scan requirements" on page 20 and continue from there.
- ☐ **No** Go to the next step.
-

2. Confirm that no part of the implanted system (ie, neurostimulator, extensions, leads, abandoned leads) is within an RF transmit/receive head coil.

This can be confirmed with x-ray imaging of the neck and head region or referring to the patient records, for example.

- ☐ **Yes** Yes, confirmed. Go to the next step.
- ☐ **No** No, could not confirm. Stop. Contact Medtronic Technical Services.
-

3.



The neurostimulation system MRI-CS eligibility cannot be determined.

Did the "START HERE – Eligibility identification" section direct you to this head-only eligible section because the MRI-CS eligibility sheet or screen on the patient control device denotes (with text and/or all of these symbols) that the MRI scan-type eligibility cannot be determined?

- ☐ **Yes** Go to "Head-only eligible – MRI equipment and scan requirements" on page 20 and continue from there.

☐ **No** Go to the next step.

4. The patient brought only the patient ID card to the MRI appointment, and the neurostimulator model number on the card is listed on page 5.

Confirm that the neurostimulator stimulation parameters are set as follows:

Stimulation: Off

If you are not certain if stimulation is off, ask the patient if it is off.

Other parameters: No change

In addition for the Itrel 3 Model 7425 only:

Magnetic (reed) switch: Disabled

☐ **Yes** Yes, confirmed. Go to "Head-only eligible – MRI equipment and scan requirements" on page 20 and continue from there.

☐ **No** No, could not confirm. Contact Medtronic Technical Services.

If all of the instructions stated in this head-only eligible section are followed, MRI scans of the head only using an RF transmit/receive head coil may be safely performed.

Head-only eligible – MRI equipment and scan requirements

Table 6. Head-only eligible – MRI equipment and scan requirements







| | |
|-------------------|--|
| RF coils | <p>Transmit/receive head coil only.</p> <p>Important:</p> <ul style="list-style-type: none">▪ The RF transmit-receive head coil must not cover any implanted system component. Implanted system components may be located per approved labeling and may be as close as 0 cm to the lower (caudad) edge of the head coil, but no part shall be inside the head coil.▪ Ensure that the RF transmit body coil is not used.▪ If you are unsure if your MRI system has RF transmit/receive head coil capability, consult the MRI manufacturer. <p> Warnings:</p> <ul style="list-style-type: none">▪ 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.▪ Do not place any part of the RF transmit/receive head coil over any implanted neurostimulation system component. If the head coil extends over any part of the patient's neurostimulation system, higher than normal heating may occur at the location of the implanted lead electrodes. In addition, if the patient's neurostimulation system has a broken lead wire and the head coil extends over any part of the patient's neurostimulation system, higher than normal heating may occur at the break or lead electrodes. Excessive heating can cause tissue damage or serious patient injury. |
| MRI system type | <p>1.5-T horizontal closed bore with maximum spatial gradient of 19 T/m (1900 gauss/cm).</p> <p> 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 tissue damage or serious patient injury.</p> |
| MRI manufacturers | No restrictions. |

Table 6. Head-only eligible – MRI equipment and scan requirements (continued)

| | |
|--------------------------------|---|
| Radio-frequency (RF) frequency | <p>Approximately 64 MHz.</p> <p> Warning: Do not conduct MRI scans with nonproton scanning frequencies (such as, ^{13}C, ^{23}Na, or ^{31}P). Frequencies other than 64 MHz have not been tested and could cause device damage and excessive heating, which can result in tissue damage or serious patient injury.</p> |
| RF power | <p>Use Normal Operating Mode.</p> <p>Specific absorption rate (SAR):</p> <ul style="list-style-type: none">▪ Head SAR: must be ≤ 3.2 W/kg (1.45 W/lb) as reported by the MRI equipment. <p> Warning: Do not conduct MRI scans in the following modes:</p> <ul style="list-style-type: none">▪ First Level Controlled Operating Mode▪ Second Level Controlled Operating Mode (ie, research mode) <p>These modes allow higher levels of RF energy and may cause excessive heating, which can result in tissue damage or serious patient injury.</p> |
| Gradients | <p>Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less.</p> <p> 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 induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or heating of the neurostimulator.</p> |
| Active scan time limits | No restrictions. |
| Landmark (isocenter location) | Head only. Do not place any part of the RF transmit/receive head coil over any implanted neurostimulation system component. |

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

Table 7. Head-only eligible – Preparing the patient before the MRI scan

| | |
|---|--|
| Confirm that stimulation is turned off | <p>Confirm that the checklist on page 18 (at the beginning of this head-only eligible section) was followed.</p> <p> Caution: Before conducting the MRI scan, confirm that the patient's implanted neurostimulation system is off. Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.</p> <p>If you are not certain if stimulation is off, ask the patient if it is off.</p> |
| Core body temperature | <p>Fever</p> <p>No restrictions.</p> <p>Blankets</p> <p>No restrictions.</p> |
| Patient weight, minimum | No restrictions. |
| Sedation | 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 8. 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. |


Head-only eligible – During the MRI scan

Table 9. Head-only eligible – During the MRI scan

| | |
|------------------------------------|---|
| Monitor the patient | Monitor the patient both visually and audibly. Check the patient between each imaging sequence. Discontinue the MRI examination immediately if the patient is unable to respond to questions or reports any problems. |
| 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 10. 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 stimulation back on | <p>After the scan has been completed, instruct the patient to see the clinician managing the patient's neurostimulation system to have the stimulation turned back on.</p> <p>Or, if the patient has brought a patient control device to the MRI appointment, instruct the patient (outside of the scanner room) to turn the stimulation back on using the patient control device.</p> <p>Notes:</p> <ul style="list-style-type: none">▪ If MRI mode was activated using the patient control device, tell the patient to press the Sync  key first to re-enable the patient control device. Then the patient can turn stimulation on.▪ Turning stimulation back on takes the neurostimulator out of MRI mode for those neurostimulators with that feature.▪ If the patient control device cannot synchronize with the neurostimulator, or cannot turn stimulation 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 MRI-CS eligibility sheets

This appendix shows examples of MRI conditionally safe (MRI-CS) eligibility sheets produced by Medtronic clinician programmers that are appropriate for the patient's MRI appointment.

The MRI-CS eligibility sheet shows the MRI-CS scan-type eligibility for the patient's implanted neurostimulation system for chronic pain after the patient has seen the clinician managing the patient's neurostimulation system.

The following are the three types of MRI-CS eligibility sheets:

- MRI-CS Report
- MRI-CS Mode screen printout
- MRI-CS Eligibility Form completed by the patient's physician (see "Appendix B: MRI-CS Eligibility Form" on page 27)

Examples of MRI-CS reports and screen printouts

See the next page for examples of MRI conditionally safe (MRI-CS) eligibility sheets produced by Medtronic clinician programmers that are appropriate for the patient's MRI appointment.

Neurostimulator model number

Medtronic Neuromodulation
RestoreULTRAMRI Model 97712 NMB*****

Patient John Doe

Session date 01/06/2010
Programmer 8840 SN NHF0000236 103.07

=====

MRI-CS Report

=====

As of 01/06/2010 the neurostimulation system is:

MRI-CS FULL BODY SCAN ELIGIBLE

See labeling for safety conditions:
www.medtronic.com/mri

Confirm that stimulation is OFF prior to an MRI scan



=====

Example MRI-CS report
(text only)

Date


01/06/2010 16:15

RestoreULTRAMRI
MRI-CS Mode






The neurostimulation system MRI-CS eligibility cannot be determined.



See labeling for safety conditions:
www.medtronic.com/mri

 00000000000

Confirm that stimulation is OFF prior to an MRI scan.

Not eligible for full body scan:

-  Device Location
-  Lead Model(s)
-  Lead Tip Location(s)
-  Extension Model(s)
-  Abandoned Pain Lead(s)

NMB***** 97712 John Doe

Neurostimulator model number

Example MRI-CS Mode screen printout

Appendix B: MRI-CS Eligibility Form





Medtronic Neurostimulation System MRI-CS Scan Eligibility

At the time of the MRI appointment:

1. See labeling for safety conditions: www.medtronic.com/mri.
2. Confirm that stimulation is off prior to the MRI scan.

| | |
|--|--|
| Patient name: | |
| Physician name, office, address, and phone number: | |
| | |
| | |

Important: Use the MRI conditionally safe (MRI-CS) mode on the clinician programmer or patient control device to enter the information and scan eligibility result below.

| | | | |
|---|---|--|--------------------------------|
| Date and time eligibility was determined: | | Neurostimulator model number: | Neurostimulator serial number: |
| | | | |
| <input type="checkbox"/> |  | MRI-CS FULL BODY SCAN ELIGIBLE | |
| <input type="checkbox"/> |  | MRI-CS HEAD SCAN ELIGIBLE WITH TRANSMIT/RECEIVE HEAD COIL | |
| <input type="checkbox"/> |  | The neurostimulation system MRI-CS eligibility cannot be determined. | |
|  Information code: | | | |
| | | (not applicable for MRI-CS FULL BODY SCAN ELIGIBLE) | |

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