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.

CE 0123 Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Directives.


Manufacturer

Authorized Representative in the European Community


Importer

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.

These instructions apply to Medtronic neurostimulation systems for chronic pain identified by a neurostimulator model number. No claims of safety are made for MRI scans involving modified Medtronic neurostimulation system components or for Medtronic neurostimulation systems that contain components or accessories that have not been tested for safety in an MRI environment.

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 12** 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 Medtronic **implanted** neurostimulator model numbers listed in Table 1.

Table 1. Applicable model numbers of Medtronic implanted neurostimulators for these MRI guidelines

977117	977005	97702	37701	37711	7479	7425 (see the warning)
977118	977006	97712	37702	37712	7479B	
977119	97715	97713	37703	37713	7427	
	97716	97714	37704	37714	7427V	

⚠ **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.

Scheduling MRI

To schedule an MRI for a patient with a fully implanted Medtronic neurostimulation system for chronic pain:

- Identify the model number for the implanted Medtronic neurostimulator.
- For MRI scheduling purposes only, see Table 2 to determine potential MRI scan-type eligibility.
- If the neurostimulator model number is not known, ask the patient to look for the neurostimulator model number on the Medtronic patient identification (ID) card, or check with the clinician, or contact Medtronic support.
- Prior to the MRI appointment, remind patients to do the following:
  - Consult with the clinician who manages their neurostimulation system.
  - Bring their patient control device and all patient ID cards, particularly all cards with "MR" symbols to the MRI appointment.
  - Recharge a rechargeable neurostimulator before the MRI appointment.
  - Inform the MRI clinician that they have an implanted device.

Table 2. Potential MRI scan-type eligibility for Medtronic Neurostimulation systems for chronic pain

Model numbers of implantable neurostimulators		MRI equipment	Potential scan-type eligibility	Notes
977117 977118 977119		1.5-T or 3-T	▪ Full-body ▪ Head-only ▪ No MRI	Scan-type eligibility depends on implanted components and other factors. Go to "START HERE – Eligibility identification" on page 11 to determine eligibility.
97702 97712 97713 97714	97715 97716 977005 977006	1.5-T	▪ Full-body ▪ Head-only ▪ No MRI	Scan-type eligibility depends on implanted components and other factors. Go to "START HERE – Eligibility identification" on page 11 to determine eligibility.
37701 37702 37703 37704 37711 37712	37713 37714 7479 7479B 7427 7427V 7425	1.5-T	▪ Head-only ▪ No MRI	Scan-type eligibility depends on implanted components and other factors. Go to "START HERE – Eligibility identification" on page 11 to determine eligibility. For model 7425, refer also to the warning on page 7.

Patient identification (ID) cards

The patient may have more than one Medtronic patient ID card that displays an "MR" symbol for the implanted neurostimulation system. Advise the patient to bring all patient ID cards to all MRI appointments and to ensure the information on the cards is up to date. MRI personnel can then use the Medtronic patient ID cards 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 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 11 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 battery is depleted or has reached EOS (end of service), then MRI scan-type eligibility 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. Only use the types of RF coils specified in these MRI guidelines.

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 12 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.

Implanted components that are MR Unsafe – No claims of safety are made for MRI scans involving Medtronic neurostimulation systems that contain components or accessories that have not been tested for safety in an MRI environment. MRI scans of such systems may cause heating of the lead electrodes, resulting in tissue damage or serious patient injury.

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 Medtronic sheet denoting the MRI scan-type eligibility for the patient's MRI appointment?

See "Appendix A: Examples of Medtronic MRI scan-type eligibility sheets" on page 35.

☐ **No** Go to the next step (step 2 on page 12).

☐ **Yes**

(1) Confirm the patient's name and date on the Medtronic 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) Does the Medtronic eligibility sheet state: "MR Unsafe"?

☐ If No, proceed to step 7 on page 14.

☐ If Yes, then No MRI. See page 38.

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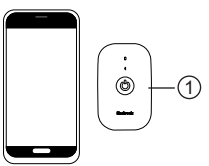
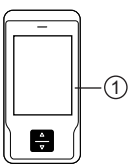
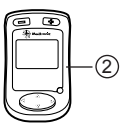
2. **Patient control devices**



Model HH90 (left) and TM91 (right)



Model 97745



Model 97740

① Model number is on the back. ② Model number is on the front.

Did the patient bring one of the patient control devices pictured above to the MRI appointment?

☐ **No** Go to step 4 on page 13.

☐ **Yes** 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 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.
- Go to the next step (step 3 on page 13).

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3. After the MRI Mode screen displays on the patient control device, go to step 7 on page 14.

MR Unsafe possibility: 

Note: If the patient control device displays “MR Unsafe”, stop. The patient is not eligible for any MRI scan. See page 38.

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4. Did the patient bring a Medtronic patient ID card?

☐ **Yes** Go to the next step (step 5 on page 13).

☐ **No** Stop. Contact Medtronic Technical Services for assistance.

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5. Does the Medtronic patient ID card display one of the following neurostimulator model numbers?

97715, 97716, 977005, 977006, 977117, 977118, 977119

☐ **Yes** Go to the next step (step 6 on page 13).

☐ **No** Go to page 28 and start with step 3 in the "Checklist before proceeding with the head-only scan conditions".

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6. Does the Medtronic patient ID card that displays one of the following neurostimulator model numbers indicate MR Conditional or MR Unsafe?

97715, 97716, 977005, 977006, 977117, 977118, 977119

☐ **Yes** ☐ **MR Conditional:** Inform the patient that the MRI scan needs to be rescheduled.

Notes:

- The following neurostimulator models are not eligible for scans of any type unless the patient control device is present:
  97715, 97716, 977005, 977006, 977117, 977118, 977119
- Tell the patient to bring the patient control device to the rescheduled MRI appointment.

OR

☐ **MR Unsafe:** Inform the patient that an MRI examination cannot be performed.

☐ **No** Stop. Contact Medtronic Technical Services for assistance.

7.

MR Conditional Full Body Scan Eligible

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

☐ **No** Go to the next step (step 8 on page 14).

☐ **Yes** (1) Confirm that the neurostimulator model number on the Medtronic eligibility sheet or on the MRI Mode screen of the patient control device matches one of the neurostimulator model numbers in Table 1 on page 7.

(2) If yes, go to "Full-body eligible MRI scan conditions" on page 17.

8.

MR Conditional Head Scan Eligible with Transmit/Receive Head Coil

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

☐ **No** Go to the next step (step 9 on page 15).

☐ **Yes** (1) Confirm that the neurostimulator model number on the Medtronic eligibility sheet or on the MRI Mode screen of the patient control device matches one of the neurostimulator model numbers in Table 1 on page 7.

(2) Go to "Head-only eligible MRI scan conditions" on page 27.

9.

The neurostimulation system MRI scan-type eligibility cannot be determined.

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

Note: "Cannot be determined" means that the patient control device or the Medtronic clinician programmer was not able to determine eligibility. Use the directions in this and the next step to determine the patient's MRI eligibility.

☐ **Yes** Go to the next step (step 10 on page 15).

☐ **No** Stop. These MRI guidelines do not apply. Go to **www.medtronic.com/mri** or call Medtronic Technical Services.

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10. Does the MRI Information Code on the Medtronic eligibility sheet or on the MRI Mode screen of the patient control device begin with a '2'?

☐ If Yes (MRI Information Code begins with a '2'), then No MRI.

Note: If needed, see page 38 for information on locating the MRI Information Code to confirm if it begins with a '2'.

☐ If No (MRI Information Code does not begin with a '2'), the patient may be eligible for a head-only scan:

(1) Confirm that the neurostimulator model number on the Medtronic eligibility sheet or on the MRI Mode screen of the patient control device matches one of the neurostimulator model numbers in Table 1 on page 7.

(2) Then go to page 27 and start with step 2 in the "Checklist before proceeding with the head-only scan conditions".

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.
- 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

MR Conditional Full Body Scan Eligible

Before proceeding with this full-body eligible section, confirm that the "START HERE – Eligibility identification" section (starts on page 11) has been followed and full-body scan eligibility has been determined by either a Medtronic MRI scan-type eligibility sheet or a patient control device.

Notes:

- 3-T MRI scanning can be used only with the 977117, 977118, and 977119 neurostimulators.
- 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

Use the check boxes to keep track of the appropriate MRI equipment, settings, and scan conditions.

- For 1.5-T scan conditions, start with Table 3.
- For 3-T scan conditions, start with Table 4 on page 19.

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

1.5-T MRI system type	☐ 1.5-T horizontal cylindrical system for hydrogen imaging with maximum spatial field gradient of 19 T/m (1900 gauss/cm). ⚠ **Warning**: Only use the type of MRI systems specified in these MRI guidelines. Other MRI systems (such as 0.6-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.

Table 3. 1.5-T Full-body eligible – MRI equipment and scan requirements (continued)

Radio-frequency (RF) frequency	☐ 1.5-T: Approximately 64 MHz. ⚠ **Warning**: Do not conduct MRI scans with nonproton scanning frequencies (such as, 13C, 23Na, or 31P). Frequencies other than 64 MHz for 1.5-T MRI systems have not been tested and could cause device damage and excessive heating, which can result in tissue damage or serious patient injury.
RF coils	☐ Receive-only coil: any type. ⚠ **Warning**: Only use the types of RF transmit coils specified in these MRI guidelines. 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. Types of transmit coils permitted: ☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) ☐ Detachable Head Transmit/Receive Volume Coil ☐ 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.	
Operating mode	☐ 1.5-T: Use **Normal** Operating Mode. ⚠ **Warning**: Do not conduct MRI scans in the following modes: ▪ First Level Controlled Operating Mode ▪ Second Level Controlled Operating Mode (ie, research mode) These modes allow higher levels of RF energy and may cause excessive heating, which can result in tissue damage or serious patient injury.

Table 3. 1.5-T Full-body eligible – MRI equipment and scan requirements (continued)

1.5-T RF power limits	Specific absorption rate (SAR): ☐ 1.5-T: Whole body SAR must be ≤ 2.0 W/kg as reported by the MRI equipment. ☐ 1.5-T: Head SAR must be ≤ 3.2 W/kg as reported by the MRI equipment.
Gradients	☐ Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less. ⚠ **Warning**: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or heating of the neurostimulator.
Active scan time limits	☐ MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (within every 90-minute window, there should be a total of 60 minutes of nonscan time). ⚠ **Warning**: Do not exceed a total of 30 minutes of active scan time within a 90-minute window. Exceeding the active scan time duration increases the risk of tissue heating.
Landmark (isocenter location)	☐ No restrictions. All anatomical locations can be scanned.
	Proceed to Table 5 on page 22.

Table 4. 3-T Full-body eligible – MRI equipment and scan requirements

Neurostimulator model numbers and 3-T scans	☐ Confirm that the patient's implanted neurostimulator is one of the following model numbers: 977117, 977118, or 977119

Table 4. 3-T Full-body eligible – MRI equipment and scan requirements (continued)

3-T MRI system type	☐ 3-T horizontal cylindrical system for hydrogen imaging with maximum spatial field gradient of 20 T/m (2000 gauss/cm). ⚠ **Warning**: Only use the type of MRI systems specified in these MRI guidelines. Other MRI systems (such as 0.6-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	☐ 3-T: Approximately 128 MHz. ⚠ **Warning**: Do not conduct MRI scans with nonproton scanning frequencies (such as, 13C, 23Na, or 31P). Frequencies other than 128 MHz for 3-T MRI systems have not been tested and could cause device damage and excessive heating, which can result in tissue damage or serious patient injury.
RF coils	☐ Receive-only coil: any type. ⚠ **Warning**: Only use the types of RF transmit coils specified in these MRI guidelines. 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. Types of transmit coils permitted: ☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) ☐ Detachable Head Transmit/Receive Volume Coil ☐ 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.

Table 4. 3-T Full-body eligible – MRI equipment and scan requirements (continued)

Operating mode	☐ 3-T: Normal Operating Mode or First Level Controlled Operating Mode ⚠ **Warning**: Do not conduct 3-T MRI scans in Second Level Controlled Operating Mode (ie, research mode) because this mode allows high levels of RF energy and may cause excessive heating, which can result in tissue damage or serious patient injury.
3-T RF power limits	Specific absorption rate (SAR): ☐ 3-T: Whole body SAR must be ≤ 4.0 W/kg as reported by the MRI equipment. ☐ 3-T: Head SAR must be ≤ 3.2 W/kg as reported by the MRI equipment.
Gradients	☐ Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less. ⚠ **Warning**: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or heating of the neurostimulator.
Active scan time limits	☐ MRI scan durations should not exceed a total of 30 minutes of active scan time within a 90-minute window (within every 90-minute window, there should be a total of 60 minutes of nonscan time). ⚠ **Warning**: Do not exceed a total of 30 minutes of active scan time within a 90-minute window. Exceeding the active scan time duration increases the risk of tissue heating.
Landmark (isocenter location)	☐ No restrictions. All anatomical locations can be scanned.
	Proceed to Table 5 on page 22.

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

Table 5. Full-body eligible – Preparing the patient before the MRI scan

MRI mode on, stimulation off	 **MR Conditional Full Body Scan Eligible** ☐ Placing the device in MRI 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 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. **Note:** If the neurostimulator battery is depleted or at EOS, then the neurostimulator is considered 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	☐ No restrictions for adult patients
Sedation	☐ If possible, do not sedate the patient so that the patient can provide feedback of any problems during the examination.

Table 5. 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 6. 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.

Contact Medtronic Technical Services for more information about the expected extent and appearance of MRI image artifacts and distortion for various scan conditions.

Full-body eligible – During the MRI scan

Table 7. Full-body eligible – During the MRI scan

Keep track of active scan time	☐	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, there should be a total of 60 minutes of nonscan time).
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.

Table 7. Full-body eligible – During the MRI scan (continued)

Patient comfort	☐ Heating may be felt at the neurostimulator site during the MRI scan. If the heating causes the patient discomfort, stop the MRI scan immediately. Consider applying an ice pack or cold compress to the location after the scan is stopped.
Neurostimulator tugging, vibration	☐ During the MRI scan, the patient may feel tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient considerable discomfort, stop the MRI scan.
	☐ If the neurostimulator is close to the MRI bore wall, consider using a pillow to keep the neurostimulator away from the bore wall to minimize vibration.

Full-body eligible – Post-MRI scan

Table 8. Full-body eligible – Post-MRI scan

Patient feedback	☐ Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
Turn stimulation back on	☐ 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.
	☐ 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. Use the following notes to guide the patient.

Table 8. Full-body eligible – Post-MRI scan (continued)

Notes:

- The patient control device may need to be re-enabled to make it operable for the patient to turn stimulation back on.

☐ **For patient control device, Medtronic Model HH90 (left) and TM91 (right):**

Tell the patient to press the **Exit MRI Mode** button.

Then the patient can turn on stimulation.

☐ **For patient control device, Medtronic Model 97745:**

Tell the patient to do the following:

1. Press the **Increase/Decrease** key to wake up the patient control device.
2. Press and hold the **Lock** button on the Unlock screen.
3. Press the **Exit MRI Mode** button.

Then the patient can turn on stimulation.

☐ **For patient control device, Medtronic MyStim Model 97740:**

Tell the patient to press the **Sync** key.

Then the patient can turn on stimulation.

- 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 11) has been followed, then proceed to the following checklist.

Checklist before proceeding with the head-only scan conditions

1.

MR Conditional 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 Medtronic MRI scan-type 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 30 and continue from there.

☐ **No** Go to the next step.

2.

The neurostimulation system MRI scan-type eligibility cannot be determined.

Did the instructions for No in **step 10 on page 15 of the identification checklist** direct you to this head-only eligible section because the Medtronic MRI scan-type 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 step 4 on page 28 to confirm that no part of the implanted system will be within the Detachable Head Transmit/Receive Volume Coil.

☐ **No** Contact Medtronic Technical Services.

---

3. Did **step 5 on page 13 of the identification checklist** direct you to this head-only eligible section because the patient brought only the patient ID card and the neurostimulator model number was **not** one of the following?

   97715, 97716, 977005, 977006, 977117, 977118, 977119

   Note: The following neurostimulator models are **not eligible for scans** of any type unless the patient control device is present:

   97715, 97716, 977005, 977006, 977117, 977118, 977119

☐ **Yes** Confirm that the neurostimulator model number on the card is one of the following: 97714, 97713, 97712, 97702, 37714, 37713, 37712, 37711, 37704, 37703, 37702, 37701, 7479, 7479B, 7427, 7427V, 7425.

Then go to step 4 to confirm that no part of the implanted system will be within the Detachable Head Transmit/Receive Volume Coil.

Note: If one of the following neurostimulator model numbers is on the patient ID card, go back to step 6 on page 13 in the identification checklist and follow the instructions for the Yes answer:

97715, 97716, 977005, 977006, 977117, 977118, 977119

☐ **No** Contact Medtronic Technical Services.

---

4. Confirm that no part of the implanted system (ie, neurostimulator, extensions, leads, abandoned leads) is within the Detachable Head Transmit/Receive Volume 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.

---

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. **Note:** If the neurostimulator battery is depleted or at EOS, then the neurostimulator is considered 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 30 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 a Detachable Head Transmit/Receive Volume Coil may be safely performed.

Note: Use the check boxes in the following tables to keep track of the appropriate MRI equipment, settings, and scan conditions.

Head-only eligible – MRI equipment and scan requirements

Table 9. Head-only eligible – MRI equipment and scan requirements

RF coils	☐ Detachable Head Transmit/Receive Volume Coil **only**. **Important:** ☐ The Detachable Head Transmit/Receive Volume 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 (caudal) edge of the head coil, but no part shall be inside the head coil. ☐ Ensure that the RF Whole Body Transmit Coil (Integrated Transmit Coil) is not used. ☐ If you are unsure if your MRI system has Detachable Head Transmit/Receive Volume Coil capability, consult the MRI manufacturer. ⚠ **Warnings**: ▪ An MRI examination of the head only (no other part of the body) can be conducted safely using a Detachable Head Transmit/Receive Volume Coil when all instructions in this head-only eligible section are followed. ▪ Do not place any part of the Detachable Head Transmit/Receive Volume 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.

Table 9. Head-only eligible – MRI equipment and scan requirements (continued)

MRI system type	☐ 1.5-T horizontal cylindrical system for hydrogen imaging with maximum spatial field gradient of 19 T/m (1900 gauss/cm). ⚠ **Warning**: Only use the type of MRI systems specified in these MRI guidelines. Other MRI systems (such as 0.6-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, 13C, 23Na, or 31P). Frequencies other than 64 MHz for 1.5-T MRI systems have not been tested and could cause device damage and excessive heating, which can result in tissue damage or serious patient injury.
Operating mode	☐ Use **Normal** Operating Mode. ⚠ **Warning**: Do not conduct MRI scans in the following modes: ▪ First Level Controlled Operating Mode ▪ Second Level Controlled Operating Mode (ie, research mode) These modes allow higher levels of RF energy and may cause excessive heating, which can result in tissue damage or serious patient injury.
1.5-T RF power limit	Specific absorption rate (SAR): ☐ 1.5-T: Head SAR must be ≤ 3.2 W/kg as reported by the MRI equipment.
Gradients	☐ Gradient systems with a maximum gradient slew rate performance per axis of 200 T/m/s or less. ⚠ **Warning**: Do not use gradient systems producing gradient slew rates greater than 200 T/m/s because they have not been tested and could cause increased risk of induced stimulation (resulting in shocking or jolting sensations, discomfort, or pain for the patient) or heating of the neurostimulator.

Table 9. Head-only eligible – MRI equipment and scan requirements (continued)

Active scan time limits	☐ No restrictions.
Landmark (isocenter location)	☐ Head only. Do not place any part of the Detachable Head Transmit/Receive Volume Coil over any implanted neurostimulation system component.

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

Table 10. Head-only eligible – Preparing the patient before the MRI scan

Confirm that stimulation is turned off	☐ Confirm that the checklist on page 27 (at the beginning of this head-only eligible section) was followed. △ **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. **Note:** If the neurostimulator battery is depleted or at EOS, then the neurostimulator is considered off.
Core body temperature	☐ **Fever** No restrictions. ☐ **Blankets** No restrictions.
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 11. 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 12. 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 13. 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	☐ 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.
	☐ 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. Use the following notes to guide the patient.

Table 13. Head-only eligible – Post-MRI scan (continued)

Notes:

- The patient control device may need to be re-enabled to make it operable for the patient to turn stimulation back on.

☐ **For patient control device, Medtronic Model HH90 (left) and TM91 (right):**

Tell the patient to press the **Exit MRI Mode** button.

Then the patient can turn on stimulation.

☐ **For patient control device, Medtronic Model 97745:**

Tell the patient to do the following:

1. Press the **Increase/Decrease** key to wake up the patient control device.
2. Press and hold the **Lock** button on the Unlock screen.
3. Press the **Exit MRI Mode** button.

Then the patient can turn on stimulation.

☐ **For a Medtronic MyStim patient control device:**

Tell the patient to press the **Sync** ⟲ key.

Then the patient can turn on stimulation.

- 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 Medtronic MRI scan-type eligibility sheets

This appendix shows examples of Medtronic MRI scan-type eligibility sheets produced by Medtronic clinician programmers that are appropriate for the patient's MRI appointment.

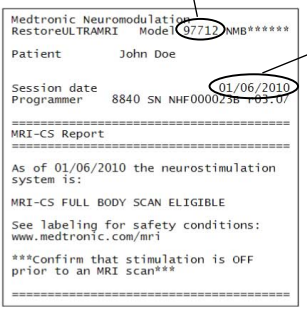
The Medtronic MRI scan-type eligibility sheet shows the scan-type eligibility for the patient’s implanted neurostimulation system for chronic pain after the patient has seen the clinician managing the patient's neurostimulation system.

The following are the three types of Medtronic MRI scan-type eligibility sheets:

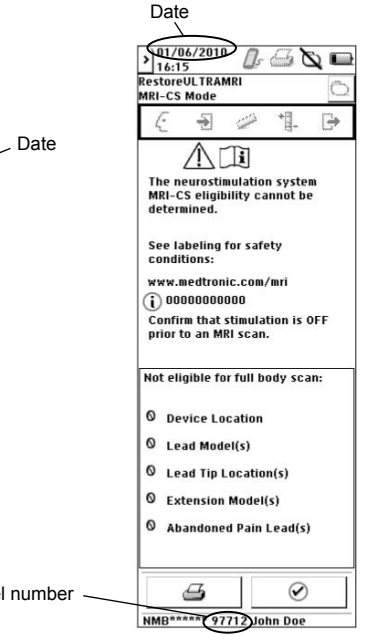
- MRI Report
- MRI-CS Mode screen printout
- MRI Scan-Type Eligibility Form completed by the patient's physician (see "Appendix C: MRI Scan-Type Eligibility Form" on page 40)

Examples of Medtronic MRI reports and screen printouts

See the following two pages for examples of Medtronic MRI scan-type eligibility sheets produced by Medtronic clinician programmers that are appropriate for the patient's MRI appointment.



Example MRI-CS report (text only)



Example MRI-CS Mode screen printout

Neurostimulator model number

Date

MRI Scan-Type Eligibility Report

Tony Martin 123–45–789

97715 NME******

Medtronic Neuromodulation

Session Date:

Dec 22, 2015 4:14 PM

As of Dec 22, 2015

MR Conditional Head Scan Eligible with Transmit/Receive Head Coil

See labeling for MRI scan conditions:
www.medtronic.com/mri

Confirm that stimulation is OFF prior to an MRI scan.

Not eligible for full body scan due to:
Lead Models
Extensions Present

Information Code:12807070000

END OF REPORT

Dec 22, 2015 4:15 PM from Programmer RF2G901G82W

Example MRI Scan-Type Eligibility Report

Appendix B: MRI Information Code

An MRI Information Code (or Information Code, or simply, MRI code) is a string of 11 digits that encodes why an implanted neurostimulation system with a neurostimulator model number beginning with 977 delivers an MRI scan-type eligibility of “head-only” or “cannot be determined” or "MR Unsafe" instead of “full body”. Possible reasons could be the presence of an abandoned lead or a component in the neurostimulation system that disqualifies the implanted system from full-body eligibility or from any MRI exam.

If needed, contact Medtronic for help interpreting the MRI code on the Medtronic eligibility sheet or on the MRI screen of the patient control device.

MRI Information Code and the corresponding MRI eligibility

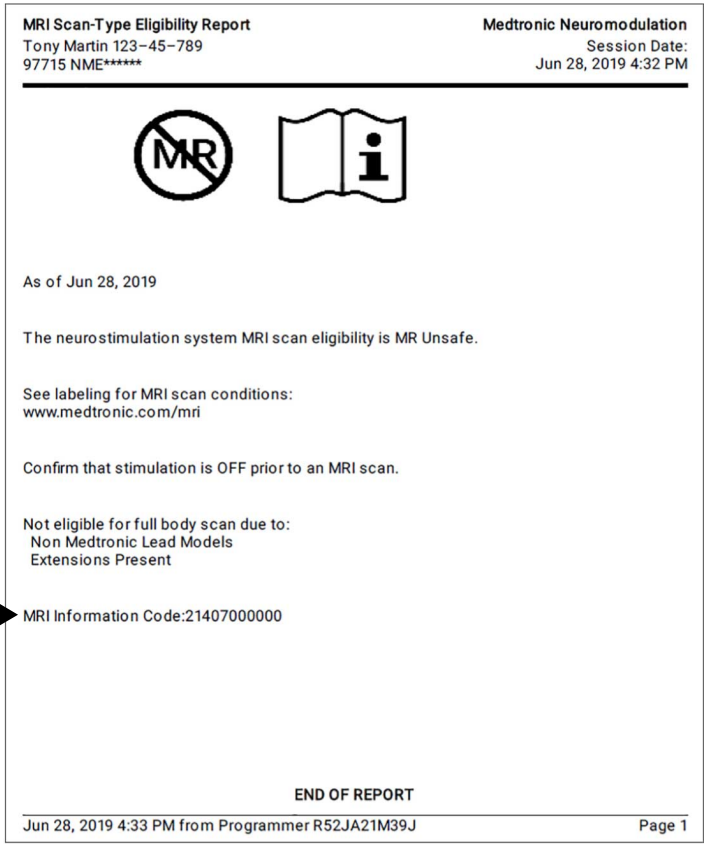
The following table explains the correlation of the MRI Information Code and the corresponding MRI eligibility.

MRI eligibility	MRI Information Code
Full body eligibility	Not applicable - there is no MRI Information Code for full-body eligibility.
Head-only eligibility	Begins with a '1'.
Cannot be determined	Begins with a '0' (zero).
No MRI	Begins with a '2'. '2' denotes that the implanted neurostimulation system contains a component that is designated as MR Unsafe.

The following information points to examples for locating the MRI Information Code to confirm if it begins with a '2':

- The location of the MRI Information Code on the **In MRI Mode** screens of Medtronic patient control devices HH90 (left) and 97745 (right):

- For the location of the MRI Information Code on an MRI Scan-Type Eligibility Report, see page 39.
- For the location of the ⓘ Information Code on an MRI Scan-Type Eligibility Form, see page 40.



MRI Scan-Type Eligibility Report
Tony Martin 123–45–789
97715 NME******

Medtronic Neuromodulation
Session Date:
Jun 28, 2019 4:32 PM

As of Jun 28, 2019

The neurostimulation system MRI scan eligibility is MR Unsafe.

See labeling for MRI scan conditions:
www.medtronic.com/mri

Confirm that stimulation is OFF prior to an MRI scan.

Not eligible for full body scan due to:
Non Medtronic Lead Models
Extensions Present

MRI Information Code:21407000000

END OF REPORT

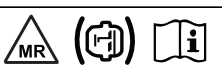
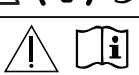
Jun 28, 2019 4:33 PM from Programmer R52JA21M39J

Page 1

Example MRI Scan-Type Eligibility Report with an MRI Information Code that begins with a '2'.

Appendix C: MRI Scan-Type Eligibility Form

Medtronic Neurostimulation System MRI Scan-Type Eligibility

<table>
<tr><td colspan="3">At the time of the MRI appointment:
1. See labeling for MRI scan conditions: www.medtronic.com/mri.
2. Confirm that stimulation is off prior to the MRI scan.</td></tr>
<tr><td colspan="2">Patient name:</td><td></td></tr>
<tr><td colspan="2" rowspan="2">Physician name, office, address, and phone number:</td><td></td></tr>
<tr><td></td></tr>
<tr><td colspan="3">Important: Use any of the following to enter the information and scan eligibility result below: MRI (or MRI-CS) mode on the clinician programmer or patient control device, a Medtronic MRI Scan-Type Eligibility Report, or the patient's medical records.</td></tr>
<tr><td colspan="2">Date:</td><td>Neurostimulator model number:</td><td>Neurostimulator serial number:</td></tr>
<tr><td colspan="2"></td><td></td><td></td></tr>
<tr><td>☐</td><td>  </td><td colspan="2">MR Conditional Full Body Scan Eligible</td></tr>
<tr><td>☐</td><td>  </td><td colspan="2">MR Conditional Head Scan Eligible with Transmit/ Receive Head Coil</td></tr>
<tr><td>☐</td><td>  </td><td colspan="2">The neurostimulation system MRI scan-type eligibility cannot be determined.</td></tr>
<tr><td>☐</td><td>  </td><td colspan="2">The neurostimulation system MRI scan eligibility is MR Unsafe.</td></tr>
<tr><td colspan="2" rowspan="2">ⓘ Information Code:</td><td colspan="2"></td></tr>
<tr><td colspan="2">(not applicable for FULL BODY SCAN ELIGIBLE)</td></tr>
</table>

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2022-04-15
M939858A028 Rev A

M939858A028