Medtronic

MRI Guidelines for InterStim™ systems

97810
97800
3058 3023

Sacral Neuromodulation Therapy

(1) To schedule MRI, see "Schedule MRI" section for guidance. (2) To conduct MRI, review entire manual and see "ELIGIBILITY IDENTIFICATION" section before scanning.

Instructions for use

! USA Rx only

Explanation of symbols

CE 0123 Conformité Européenne (European Conformity).


Manufacturer

Authorized Representative in the European Community


Importer

For USA audiences only


BLUETOOTH®

Magnetic Resonance (MR) Conditional

Magnetic Resonance (MR) Unsafe

Table of contents

Introduction to MRI and InterStim™ systems for sacral neuromodulation therapy

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 InterStim system. These instructions apply ONLY to Medtronic InterStim implanted systems; they do not apply to other implantable products, or other devices, products, or items. No claims of safety are made for MRI scans involving modified Medtronic InterStim system components (except where referenced in this manual) or for non Medtronic components or accessories.

Contact Medtronic at the appropriate address or phone number listed at the back of this manual if you have questions.

Schedule MRI

To schedule an MRI for a patient with a fully implanted Medtronic InterStim system:

- Identify the model numbers for the implanted Medtronic neurostimulator and the lead.
- For MRI scheduling purposes only, see Table 1 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 ID card, or check with the clinician, or contact Medtronic support.
- If the lead model number is not known, the patient should only be scheduled for the most conservative scan available with the identified neurostimulator model number.

Prior to the MRI appointment, remind patients to do the following:

- Consult with the clinician who manages their InterStim system.
- Bring their patient control device and patient ID card to the MRI appointment.
- Recharge a rechargeable neurostimulator before the MRI appointment.
- Inform the MRI clinician that they have an implanted device.

NOTE: A neurostimulator at End-of-Service (EOS) requires MRI eligibility confirmation from the clinician who manages the patient's neurostimulation system. See "Appendix E: MRI Scan-Type Eligibility Form" for an example of the form required before head-only scanning of Model 97800, Model 3058, and eligible Model 3023 neurostimulators at End-of-Service.

Neurostimulator and lead model numbers

MR Conditional: Non-clinical testing has demonstrated that Medtronic InterStim systems have been found to be MR Conditional. Follow these MRI guidelines for approved indications to determine whether and how to perform an MRI scan safely on a patient with a fully implanted Medtronic InterStim system for sacral neuromodulation therapy.

These MRI guidelines apply to the neurostimulator model numbers listed in Table 1, when implanted as a system including a neurostimulator and lead (and an extension if applicable).

IMPORTANT: Review the entire manual, then see the "ELIGIBILITY IDENTIFICATION" section and use the checklist that starts on page 13 to determine the patient's MRI scan-type eligibility and the appropriate scan conditions to use for the patient's implanted InterStim system.

Table 1. InterStim systems – implanted neurostimulator and lead model numbers associated with these MRI guidelines

Neurostimulator	Lead	MRI scanner
Model 97810 InterStim Micro SureScan™ MRI rechargeable neurostimulator	Model 978A1 SureScan lead	If eligible, 3-Tesla (T) and 1.5-T MR Conditional **Check "ELIGIBILITY IDENTIFICATION" on page 13 before scanning.** Ask the patient to recharge the neurostimulator before the MRI appointment.
Model 97800 InterStim X OR Model 3058 InterStim II neurostimulator *[Type of lead:]*	Model 978B1 SureScan lead	If eligible, 3-T and 1.5-T MR Conditional **Check "ELIGIBILITY IDENTIFICATION" on page 13 before scanning.**
	No need to determine the InterStim lead model for this scenario[a].	If eligible, 1.5-T MR Conditional Head Scan Eligible with Detachable Head Transmit/Receive Volume Coil **Check "ELIGIBILITY IDENTIFICATION" on page 13 before scanning.**
Model 3023 InterStim neurostimulator	No need to determine the InterStim lead model for this scenario[a].	If eligible, 1.5-T MR Conditional Head Scan Eligible with Detachable Head Transmit/Receive Volume Coil only **Check "ELIGIBILITY IDENTIFICATION" on page 13 before scanning.** **No MRI scans for serial numbers:** ▪ Less than NBV132955H ▪ Between NBV133037H and NBV133063H ▪ Between NBV628045S and NBV628263S **Note:** If a programmer is used to check the neurostimulator serial number, the letter suffix (H or S) may not be included in the serial number displayed.

Table 1. InterStim systems – implanted neurostimulator and lead model numbers associated with these MRI guidelines (continued)

Neurostimulator	Lead	MRI scanner
Model 7427T InterStim Twin neurostimulator	**No MRI scans**	**No MRI scans**

Non Medtronic components or accessories are not supported by these MRI guidelines.

[a] When implanted per approved indications, InterStim system components are outside of the head coil.

Patient ID card

Ask the patient to provide the most up-to-date patient ID card at the MRI appointment. MRI personnel can use the patient ID card to identify Medtronic as the manufacturer of the patient's neurostimulation system.

Obtain the latest MRI guidelines labeling

Always obtain the latest MRI guidelines. See the contact information at the back of this manual, or go to www.medtronic.com/mri and enter the neurostimulator model number.

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

External control device

For Medtronic InterStim neurostimulation systems, external control devices (that is, a patient control device, handset with clinician or patient therapy app, or a clinician programmer) are used to determine MRI scan-type eligibility and prepare the system for MRI scan.

IMPORTANT: Ensure the patient brought a patient control device to the MRI appointment. Unless the neurostimulator is at End-of-Service (EOS), a patient control device is necessary to determine eligibility for MRI following the "ELIGIBILITY IDENTIFICATION" section. See "Appendix E: MRI Scan-Type Eligibility Form" for an example of the form required before head-only scanning of eligible neurostimulators at End-of-Service.

Eligible Model 3023 neurostimulator only: if the patient uses a control magnet to turn the neurostimulator on or off, a clinician must first disable the magnet switch in the neurostimulator using the Model 8840 Clinician Programmer.

Patient control device identification and operation – For identification and operation of the patient control devices used for InterStim systems, go to "ELIGIBILITY IDENTIFICATION" on page 13 and use the identification checklist in that section. If the patient control device cannot communicate with the implanted neurostimulation system, 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 or see "Appendix C: X-ray identification – InterStim systems"

in this manual for additional guidance. 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.

Note: In this manual, illustrations of the patient control device (handset) hardware are representative. Actual handset hardware may differ.

Image artifacts and distortion (for full-body eligible scans only)

Significant image distortion can result from the presence of the neurostimulator when in the field of view. Image artifacts and distortion resulting from the presence of the neurostimulator and the leads when in 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.

General information on MRI procedures and neurostimulation system interactions

MRI systems generate electromagnetic fields that may interact with implanted components of the neurostimulation system. Some of these interactions, especially heating, are potentially hazardous and can lead to serious or permanent patient injury. The following information describes the potential interactions and control measures that should be taken to minimize the risks from these interactions.

Information for prescribers

Risks associated with implanted neurostimulation systems in the MRI environment

Exposing a patient with an implanted neurostimulation system or component to MRI settings other than those listed in this manual may potentially injure the patient or damage the neurostimulator. The known potential risks for implanted neurostimulation systems in the MRI environment are as follows:

- **Heating –** RF induced currents may cause lead electrode heating resulting in tissue damage. In addition, the time varying magnetic field gradient may result in heating of the neurostimulator.

  Note: This applies even if only a lead or extension is implanted. Factors that increase the risks of heating and tissue damage include, but are not limited to, the following:

  - Values that exceed the B1+rms or SAR limits specified in these MRI guidelines
  - Exceeding the continuous scan time limit or not allowing for sufficient wait time as specified in these MRI guidelines

- **Induced stimulation –** The gradient magnetic and RF fields produced by an MRI scanner induce energies onto an implanted lead system that may potentially cause unintended stimulation to the patient such as a tingling, shocking, or jolting sensation.

- **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, or the neurostimulator may move within the implant pocket and align itself with the magnetic field, which may cause patient discomfort. Patients being scanned with recent implant incisions should be monitored for any surgical wound discomfort.
- **Device damage –** The static magnetic field, pulsed gradient magnetic field, or the pulsed RF field generated by MRI may permanently damage the neurostimulator, requiring explant 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. Reprogramming with the clinician programmer after the MRI scan may also be needed if the MRI scan resets the parameters to power-on-reset (POR) settings.

Warnings

MRI during therapy evaluation (temporary evaluation) — Ensure all therapy evaluation (temporary evaluation) components are explanted if an MRI scan is required. Physicians should not prescribe MRI for patients undergoing therapy evaluation or who have any neurostimulation system components that are not fully implanted. MRI has not been evaluated with therapy evaluation components. The external neurostimulator is unsafe in the MR environment.

Limitations for scanning patients with fully implanted neurostimulation systems:

- Prior to an MRI scan, determine whether the patient has multiple active medical device implants (such as deep brain stimulation systems, implantable cardiac defibrillators, and others). The most restrictive MRI exposure requirements must be used if the patient has multiple active 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.
- If the system is removed, ensure all portions of the neurostimulation system are removed prior to an MRI scan. Even partial systems can have MRI interactions such as RF heating. Excessive heating can cause tissue damage and result in serious or permanent patient injury. See “Appendix D: MRI eligibility of lead fragments”, for guidance in determining MRI eligibility for patients with lead fragments.

See specific procedural warnings and conditions throughout these MRI guidelines. Failure to follow all warnings and conditions may result in patient discomfort, device damage, or serious or permanent patient injury due to excessive heating or other risks associated with implanted neurostimulation systems in the MR environment.

Precautions

External devices are MR Unsafe in the scanner (magnet) room — Do not allow the following Medtronic external devices into the MRI scanner (magnet) room. These devices are MR Unsafe:

- Patient control devices (for example, patient programmer, patient handset, or communicator)
- Control magnet for Model 3023 neurostimulator
- Recharger
- External neurostimulator
- Clinician programmer

ELIGIBILITY IDENTIFICATION

Do not proceed with the instructions for MRI if the patient does not have a patient control device for their InterStim system. A patient control device is necessary for the MRI clinician (eg, MRI technologists and radiographers) to determine eligibility for MRI.

Identify the patient's MRI scan-type eligibility

Use the eligibility identification checklist in this section to determine the patient's MRI scan-type eligibility and the appropriate MRI equipment, scan requirements, and RF field requirements to use for the patient's implanted Medtronic InterStim system.

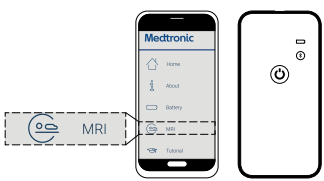
The MRI scan-type eligibility depends on a combination of factors pertaining to the patient's implanted neurostimulation system.

NOTE: A neurostimulator at End-of-Service (EOS) requires MRI eligibility confirmation from the clinician who manages the patient's neurostimulation system. See "Appendix E: MRI Scan-Type Eligibility Form" for an example of the form required before head-only scanning of Model 97800, Model 3058, and eligible Model 3023 neurostimulators at End-of-Service.

Eligibility identification checklist

1. What type of patient control device did the patient bring to the MRI appointment? Select one of the following five options (including two options for patient control device A).

☐ **Patient control device A with MRI**



HH90 Handset (left) and TM90 Communicator (right)

- Ask the patient to tap ☰ in the corner of the patient therapy app Home screen.
- Select **MRI** and activate MRI mode. (See Appendix A "Part 1. Patient Control Device A with MRI icon: Activating MRI Mode " on page 30 for guidance.)
- Using the information on the screen, proceed to step 2 on page 15.
- If no MRI icon is shown on patient control device A, proceed to the next section in this checklist "Patient control device A without MRI icon".

☐	**Patient control device A without MRI icon**  **HH90 Handset (left) and TM90 Communicator (right)**	▪ Ask the patient to tap ☰ in the corner of the patient therapy app Home screen. If no MRI icon is shown on patient control device A, go to "Head-only eligible – Handset identification" on page 23 to determine MRI eligibility.
☐	**Patient control device B**  **Model 3037 Patient Programmer**	▪ Go to "Head-only eligible – Handset identification" on page 23 to determine MRI eligibility.
☐	**Neurostimulator is at End-of-Service (No patient control device)**	If the patient's neurostimulator is at End-of-Service (EOS): ▪ Confirm the patient brought a completed form indicating the neurostimulator is at EOS and is considered off. A patient control device is not required to prepare the system for MRI. See "Appendix E: MRI Scan-Type Eligibility Form" for an example of the form required. ▪ Go to "Head-only eligible – Handset identification" on page 23 to determine MRI eligibility.
☐	**No patient control device**	If the patient did not bring a patient control device: ▪ **STOP.** If the patient has an active InterStim system, a patient control device is required to prepare the system for MRI. The MRI appointment may need to be rescheduled for the patient to return with a patient control device, or contact the clinician managing the implanted InterStim system.

2. Determine which of the following four options including images and text appear on patient control device A with MRI icon, and follow the instructions provided:

☐ **MRI Mode is Activated**

MR Conditional Full Body Scan Eligible

Go to "Full-body eligible MRI scan conditions" on page 17.

☐ **MRI Mode is Activated**

MR Conditional Head Scan Eligible with Transmit/Receive Head Coil

Go to "Head-only eligible MRI scan conditions" on page 23.

☐ **MRI Mode is Activated**

MRI eligibility cannot be determined

STOP. Contact the clinician managing the patient's implanted InterStim system before conducting an MRI scan. At the end of the MRI appointment, instruct the patient to deactivate MRI mode.

☐ **Not Ready for MRI Scan**

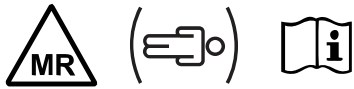
Not Eligible

STOP. No MRI scans. Contact the clinician managing the patient's implanted InterStim system.

Notes:

- The “consult instructions for use” symbol (📖) when shown with MRI scan eligibility means “consult the MRI guidelines for this neurostimulation system.”
- For interpretation of the information code on the MRI Mode screen of the patient control device, call Medtronic support.
- Do not deactivate, or exit, MRI mode or turn therapy 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 via the "ELIGIBILITY IDENTIFICATION" section (starts on page 13) that the patient's implanted system is MR Conditional full-body scan eligible.

A patient with a fully implanted InterStim system that is identified as "MR Conditional Full Body Scan Eligible" can have 3-T and 1.5-T scans of any part of the anatomy when all the specific conditions in this full-body eligible section are met.

Full-body eligible – MRI equipment and scan requirements

Starting with Table 2 on page 18, use the check boxes to keep track of the patient's model numbers and appropriate MRI equipment.

⚠ **Warning:** Scans must be conducted using the MRI equipment, scan and RF field requirements, and other conditions stated in this MRI guidelines manual. Failure to follow all the conditions within this full-body section may result in patient discomfort, device damage, or serious or permanent patient injury due to excessive heating or other risks associated with implanted neurostimulation systems in the MRI environment.

General MRI conditions:

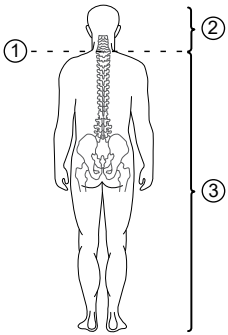
- Identify scan-type eligibility using the patient control device. Do not proceed unless you can determine full-body eligibility.
- Activate MRI mode using the patient control device.
- If the patient has a rechargeable neurostimulator, ensure the neurostimulator is sufficiently charged.

Table 2. Model 97810, Model 97800, and Model 3058 full-body eligible conditions – 3-T and 1.5-T MRI equipment and scan requirements

There are no restrictions on MRI manufacturers.		
Confirm the neurostimulator and lead model numbers on the patient control device. *[Select one:]*	☐	Model 97810 neurostimulator with Model 978A1 lead
	☐	Model 97800 neurostimulator with Model 978B1 lead
	☐	Model 3058 neurostimulator with Model 978B1 lead
Confirm battery status (Model 97810 neurostimulator only).	☐	Confirm with the patient that the neurostimulator is charged to a minimum of 30% before scanning. Do not proceed if the neurostimulator is not sufficiently charged.
Confirm scan-type eligibility and that MRI mode is activated on the patient control device.	☐	Placing the device in MRI mode turns therapy off. The text and all of the symbols below denote full-body MRI scan eligibility and indicate that the implanted system is in MRI mode.  **MR Conditional Full Body Scan Eligible**
MRI system types *[Select one:]*	☐	3-T horizontal cylindrical system for hydrogen imaging, approximately 128 MHz
	☐	1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
Maximum gradient slew rate specification	☐	≤ 200 T/m/s per axis
Maximum spatial field gradient	☐	20 T/m (2000 gauss/cm)
Scan time limit	☐	Maximum 30 minutes of continuous scan time is allowed, followed by a wait time of 5 minutes if this limit is reached.

Proceed to MRI scan regions and RF field requirements in Table 3 for 3-T on page 19 or Table 4 for 1.5-T on page 20.

Table 3. Full-body eligible 3-T MRI scan regions and RF field requirements



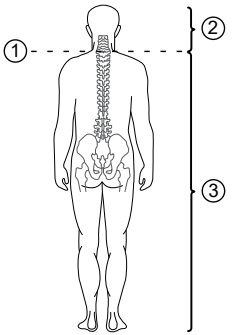
① Depicts a transverse plane at the C7 vertebra.

Scan region	3-T RF coil	3-T RF exposure level
② At or superior to the C7 vertebra *[Select one:]*	☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type	**3-T:** Normal Operating Mode or First Level Controlled Operating Mode
	☐ Detachable Head Transmit/ Receive Volume Coil	**3-T:** Normal Operating Mode or First Level Controlled Operating Mode
③ Inferior to the C7 vertebra *[Select one:]*	☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type	**3-T:** B1+rms ≤ 2.0 µT Values before scanning; for MRI scanners that do not report B1+rms, limit SAR to ≤ 1.4 W/kg.
	☐ Detachable Lower Extremity Transmit/Receive Volume Coil	**3-T:** Normal Operating Mode or First Level Controlled Operating Mode

Note:

- **RF Whole Body Transmit Coil** - 3-T MRI systems using two transmit channels may operate in Multichannel-2 (MC-2) or Circularly Polarized (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. Full-body eligible 1.5-T MRI scan regions and RF field requirements



① Depicts a transverse plane at the C7 vertebra.

Scan region	1.5-T RF coil	1.5-T RF exposure level
② At or superior to the C7 vertebra *[Select one:]*	☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type	**1.5-T:** Normal Operating Mode or First Level Controlled Operating Mode
	☐ Detachable Head Transmit/ Receive Volume Coil	**1.5-T:** Normal Operating Mode or First Level Controlled Operating Mode
③ Inferior to the C7 vertebra *[Select one:]*	☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type	**1.5-T:** B1+rms ≤ 4.0 μT Values before scanning; for MRI scanners that do not report B1+rms, limit SAR to ≤ 2.0 W/kg.
	☐ Detachable Lower Extremity Transmit/Receive Volume Coil	**1.5-T:** Normal Operating Mode or First Level Controlled Operating Mode

Note: RF Whole Body Transmit Coil - 1.5-T MRI systems should only be operated in CP configuration.

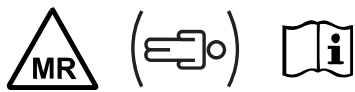
Proceed to "Full-body eligible – Preparing the patient before the MRI scan" on page 21.

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

⚠ **Warnings:**

- Do not perform an MRI scan if the patient's body temperature is above 38°C (100°F). Do not cover the patient with blankets or heated blankets. Elevated body temperature in conjunction with tissue heating caused by an MRI scan increases the risk of excessive tissue heating, which may cause tissue damage.
- Do not position patients in positions other than prone or supine, such as on their side within the MRI bore. Scanning patients in positions other than prone or supine is untested and may cause excessive tissue heating during an MRI scan.
- Keep track of continuous scan time and wait time. A maximum of 30 minutes of continuous scan time is allowed, followed by a wait time of 5 minutes if this limit is reached. Exceeding the continuous scan time limit or not allowing for sufficient wait time increases the risk of tissue heating.

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

Ensure that MRI mode is activated.	☐ The text and all of the symbols below denote full-body MRI scan eligibility and indicate that the implanted system is in MRI mode.  **MR Conditional Full Body Scan Eligible**
Check core body temperature.	☐ Confirm that the patient's body temperature is ≤38 °C (100 °F). Do not use blankets.
Patient position	☐ Position the patient in a prone or supine position in the MRI bore.

Notes:

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

After confirming the previous conditions, proceed to "Full-body eligible – During the MRI scan" on page 22 to perform the scan.

Full-body eligible – During the MRI scan

- Keep track of continuous scan time and wait time. A maximum of 30 minutes of continuous scan time is allowed, followed by a wait time of 5 minutes if this limit is reached.
- Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination.
- Discontinue the MRI immediately if the patient experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.

After the scan has been completed, proceed with "Full-body eligible – Post-MRI scan" on page 22.

Full-body eligible – Post-MRI scan

△ **Cautions:**

- MRI may affect the operation of the neurostimulator. MRI may also reset the parameters to power-on-reset (POR) settings, requiring reprogramming with the clinician app. If the patient control device cannot synchronize with the neurostimulator, or cannot turn therapy back on, or displays a screen with the letters “POR” on it, instruct the patient to see the clinician managing the patient’s neurostimulation system.
- Failure to return to normal therapy settings after the MRI scan may result in a return of symptoms.

Table 6. Full-body eligible – Post MRI scan

Turn therapy back on	☐ After the scan has been completed, instruct the patient (outside of the scanner room) to turn the therapy back on. From the **MRI Eligibility** screen, ask the patient to place the communicator over the device and tap **DEACTIVATE** when prompted to deactivate MRI mode, then tap **YES** to return to previous therapy settings.

Notes:

- Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
- Instruct the patient to see the implanting physician or managing physician if any of the following instances is applicable:
  - the patient has any questions about neurostimulator function
  - assistance is required to return program parameters to pre-MRI scan settings
  - the patient control device displays a power-on-reset (POR) screen

Head-only eligible MRI scan conditions

MR Conditional Head Scan Eligible with Transmit/Receive Head Coil

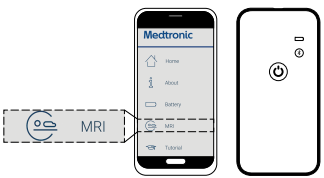
Before proceeding with this head-only eligible section, confirm via the "Head-only eligible – Handset identification" section that a head-only scan is appropriate.

A patient with a fully implanted InterStim system identified as head-only eligible can have 1.5-T MRI scans of the head only using a Detachable Head Transmit/Receive Volume Coil in addition to the other specific conditions in this head-only eligible section.

Head-only eligible – Handset identification

1. What type of patient control device did the patient bring to the MRI appointment?

☐ **Patient control device A with MRI**



HH90 Handset (left) and TM90 Communicator (right)

- The text and all of the symbols below denote head-only MRI scan eligibility and indicate that the implanted system is in MRI mode.

MR Conditional Head Scan Eligible with Transmit/Receive Head Coil

- Proceed with head-only eligible Table 7 for Model 97800 and Model 3058 on page 26 or Table 8 for Model 3023 on page 27.

☐ **Patient control device A without MRI icon**

HH90 Handset (left) and TM90 Communicator (right)

- Confirm eligible neurostimulator model number on patient control device screen. See Appendix A "Part 2. Patient Control Device A without MRI icon: Stopping Therapy" on page 32 for guidance.
- Turn therapy off before scanning.
- Proceed with head-only eligible Table 7 for Model 3058 on page 26 or Table 8 for Model 3023 on page 27.

☐	**Patient control device B**  **Model 3037 Patient Programmer**	▪ Confirm eligible neurostimulator model number on patient control device screen. See "Appendix B: Patient Control Device B Instructions" on page 34 for guidance. ▪ Turn therapy off before scanning. ▪ Proceed with head-only eligible Table 7 for Model 3058 on page 26 or Table 8 for Model 3023 on page 27.
☐	**Neurostimulator is at End-of-Service (No patient control device)**	▪ Confirm the patient brought a completed form indicating the neurostimulator is at End-of-Service (EOS) and is considered off. A patient control device is not required to prepare the system for MRI. See "Appendix E: MRI Scan-Type Eligibility Form" for an example of the form required. ▪ Confirm eligible neurostimulator model number. ▪ Proceed with head-only eligible Table 7 for Model 97800 and Model 3058 on page 26 or Table 8 for Model 3023 on page 27.

Head-only eligible – MRI equipment and scan requirements

⚠ **Warning:** Scans must be conducted using the MRI equipment, scan and RF field requirements, and other conditions stated in the head-only section of this MRI guidelines manual. Other conditions and parts of the body have not been tested. Failure to follow all the conditions within this head-only section may result in patient discomfort, device damage, or serious or permanent patient injury due to excessive heating or other risks associated with implanted neurostimulation systems in the MRI environment.

General MRI conditions

- Identify scan-type eligibility using the patient control device. Do not proceed unless you can determine eligibility.
- Activate MRI mode using patient control device A with MRI. If using patient control device A without MRI icon or patient control device B, turn therapy off.

△ **Cautions:**

Model 3023 neurostimulator only: Do not conduct an MRI scan if the serial number is ineligible for MRI. To avoid increased risk of neurostimulator damage, patients with the following serial numbers should not have MRI scans:

- Less than NBV132955H
- Between NBV133037H and NBV133063H
- Between NBV628045S and NBV628263S

Model 3023 neurostimulator only: Do not conduct an MRI scan if the patient can use a control magnet to turn the neurostimulator on or off, unless a clinician has first disabled the magnet switch in the neurostimulator using the Model 8840 Clinician Programmer. Failure to disable the magnet switch could result in uncomfortable, unintended stimulation during the MRI examination.

Model 3023 neurostimulator only: Control magnet function after MRI – Do not conduct an MRI scan if the patient can only use a control magnet to turn the neurostimulator on or off. An MRI scan may permanently damage the magnet switch in the neurostimulator. If the magnet switch in the neurostimulator is damaged, the patient will require a patient control device to turn the neurostimulator on or off.

Table 7. Model 97800 and Model 3058 head-only eligible conditions – 1.5-T MRI equipment and scan requirements

There are no restrictions on MRI manufacturers, and no scan time limit restrictions.	
Confirm the neurostimulator model number on the patient control device or on the completed form if the neurostimulator is at End-of-Service. *[Select one:]*	☐ Model 97800 neurostimulator ☐ Model 3058 neurostimulator
Confirm that MRI mode is activated or therapy is off. *[Select one:]*	☐ **Patient control device A with MRI**: Placing the device in MRI mode turns therapy off. The text and all of the symbols below denote head-only MRI scan eligibility and indicate that the implanted system is in MRI mode.  **MR Conditional Head Scan Eligible with Transmit/Receive Head Coil** ☐ **Patient control device A without MRI icon or patient control device B**: Confirm therapy is off. Refer to the instructions in Appendix A Part 2 page 32 or Appendix B page 34, if needed. ☐ **Completed form indicating the neurostimulator is at End-of-Service (EOS) and is considered off.**
MRI system type	☐ 1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
Maximum gradient slew rate specification	☐ ≤ 200 T/m/s per axis
Maximum spatial field gradient	☐ 20 T/m (2000 gauss/cm)
RF coil type	☐ Detachable Head Transmit/Receive Volume Coil
RF exposure level	☐ Normal Operating Mode
Note: When implanted per approved indications, InterStim system components are outside of the head coil.	

After confirming the MRI equipment and scan requirements, proceed to "Head-only eligible – Preparing the patient before the MRI scan" on page 28.

If the patient has a Model 3023 neurostimulator, see Table 8 on page 27.

Table 8. Model 3023 head-only eligible conditions – 1.5-T MRI equipment and scan requirements

There are no restrictions on MRI manufacturers, and no scan time limit restrictions.	
Confirm the neurostimulator model number on the patient control device or on the completed form if the neurostimulator is at End-of-Service.	☐ Check ineligible serial numbers for the Model 3023 neurostimulator in Table 1 on page 8.
Confirm patient cannot use a control magnet.	☐ Do not conduct an MRI scan if the patient can use a control magnet to turn the neurostimulator on or off, unless a clinician has first disabled the magnet switch in the neurostimulator.
Confirm that MRI mode is activated or therapy is off. *[Select one:]*	☐ **Patient control device A with MRI**: Placing the device in MRI mode turns therapy off. The text and all of the symbols below denote head-only MRI scan eligibility and indicate that the implanted system is in MRI mode.  **MR Conditional Head Scan Eligible with Transmit/ Receive Head Coil**
	☐ **Patient control device A without MRI icon or patient control device B**: Confirm therapy is off. Refer to the instructions in Appendix A Part 2 page 32 or Appendix B page 34, if needed.
	☐ **Completed form indicating the neurostimulator is at End-of-Service (EOS) and is considered off.**
MRI system type	☐ 1.5-T horizontal cylindrical system for hydrogen imaging, approximately 64 MHz
Maximum gradient slew rate specification	☐ ≤ 200 T/m/s per axis
Maximum spatial field gradient	☐ 20 T/m (2000 gauss/cm)

Table 8. Model 3023 head-only eligible conditions – 1.5-T MRI equipment and scan requirements (continued)

RF coil type	☐ Detachable Head Transmit/Receive Volume Coil
RF exposure level	☐ Normal Operating Mode
Note: When implanted per approved indications, InterStim system components are outside of the head coil.	

After confirming the MRI equipment and scan requirements, proceed to "Head-only eligible – Preparing the patient before the MRI scan" on page 28.

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

- Ensure that MRI mode is activated or therapy is off.
- If possible, do not sedate the patient so that the patient can provide feedback during the examination.
- Inform the patient of all the risks of undergoing an MRI examination as stated in this section.
- Monitor the patient during the MRI examination.

Head-only eligible – During the MRI scan

- Monitor the patient both visually and audibly. Verify that the patient is feeling normal and is responsive between each individual scan sequence of the MRI examination.
- Discontinue the MRI immediately if the patient experiences any heating, pain, shocking sensations, uncomfortable stimulation, or unusual sensations.

Head-only eligible – Post-MRI scan

△ **Cautions:**

- MRI may affect the operation of the neurostimulator. MRI may also reset the parameters to power-on-reset (POR) settings, requiring reprogramming with the clinician app or a clinician programmer. If the patient control device cannot synchronize with the neurostimulator, or cannot turn therapy back on, or displays a screen with the letters “POR” on it, then instruct the patient to see the clinician managing the patient’s neurostimulation system.
- Failure to return to normal therapy settings after the MRI scan may result in a return of symptoms.

Table 9. Head-only eligible – Post MRI scan

Turn therapy back on. *[Select one:]*	After the scan has been completed, instruct the patient (outside of the scanner room) to turn the therapy back on using patient control device A or B. ☐ **For patient control device A with MRI:** From the **MRI Eligibility** screen, ask the patient to place the communicator over the device and tap **DEACTIVATE** when prompted to deactivate MRI mode, then tap **YES** to return to previous therapy settings. ☐ **For patient control device A without MRI icon:** Ask the patient to turn therapy on. **1.** Place the communicator over the implanted neurostimulator site. **2.** On the patient therapy app Home screen, swipe the On/Off Switch from Off to On. ☐ **For patient control device B:** Ask the patient to press the Sync key. Then the patient can use normal procedures to turn therapy back on.

Notes:

- Verify that the patient has not experienced adverse effects as a result of the MRI. Contact Medtronic to report any adverse effects.
- Instruct the patient to see the implanting physician or managing physician if:
  - the patient has any questions about neurostimulator function
  - assistance is required to return program parameters to pre-MRI scan settings
  - the patient control device displays a power-on-reset (POR) screen

Appendix A: Patient Control Device A Instructions

HH90 Handset Instructions

Use the following instructions to guide the patient in using patient control device A (HH90 Handset and TM90 Communicator) to prepare the patient's system for the MRI scan.

Part 1. Patient Control Device A with MRI icon: Activating MRI Mode

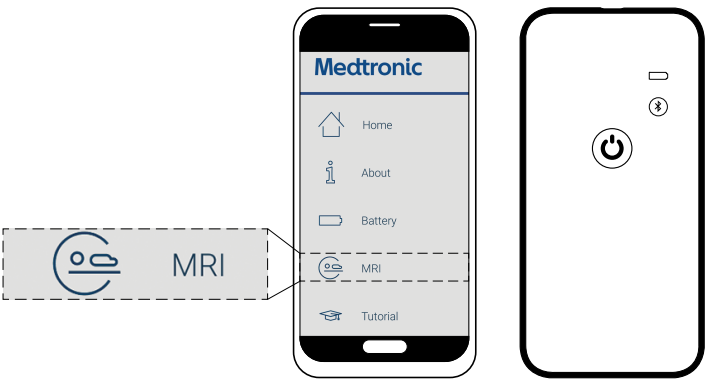


Figure 1. *HH90 Handset (left) and TM90 Communicator (right)*

If **MRI** appears on patient control device A, the handset must be used to place InterStim systems in MRI mode before an MRI scan. Ensure you are outside of the MRI scanner room before proceeding with the following steps. When you use the handset to place InterStim systems in MRI mode, Scan Eligibility icons will appear.

Note: During the MRI scan, keep the InterStim system in MRI mode. Do not deactivate MRI mode. Therapy must remain off.

1. Press on the communicator to turn the communicator on. The communicator will attempt to connect to the handset but cannot do so until the patient therapy app is launched. The blue LED light on the communicator will continuously blink to indicate it is on and in discovery mode.
2. Open the patient therapy app on the handset to initiate the connection process.
3. Once the communicator has successfully connected to the handset, the blue LED light on the communicator will be solid and no longer blinking. Place the communicator over the area where the neurostimulator has been implanted, and tap **FIND DEVICE** on the handset.

Note: If the communicator fails to connect to the neurostimulator, readjust the location of the communicator over the neurostimulator, and tap **RETRY** on the patient control device.

4. Once the communicator has successfully connected to the implanted neurostimulator, you will be taken to the patient therapy app Home screen.
5. Tap ☰ in the corner of the patient therapy app Home screen and select **MRI**.

   Note: If the handset screen says **Not Ready for MRI Scan** and **Not Eligible**, STOP. The neurostimulator is not eligible for MRI scans and MRI mode is not available. Do not scan. Contact clinician.
6. Tap **ACTIVATE** to activate MRI mode. (Activating MRI mode stops therapy.)
7. Determine which message appears on the MRI eligibility screen:
   - MR Conditional Full Body Scan Eligible
   - MR Conditional Head Scan Eligible with Transmit/Receive Head Coil
   - MRI eligibility cannot be determined

   Note: If the handset screen says **MRI eligibility cannot be determined**, STOP. Further assessment by a clinician is required before conducting an MRI scan. Contact clinician before scanning.
8. Return to Step 2 page 15 in the ELIGIBILITY IDENTIFICATION section and follow the instructions for the images and text on patient control device A with **MRI**.

   Note: If the patient has patient control device A without the MRI icon (without **MRI**), proceed to "Part 2. Patient Control Device A without MRI icon: Stopping Therapy" on page 32.

Part 2. Patient Control Device A without MRI icon: Stopping Therapy

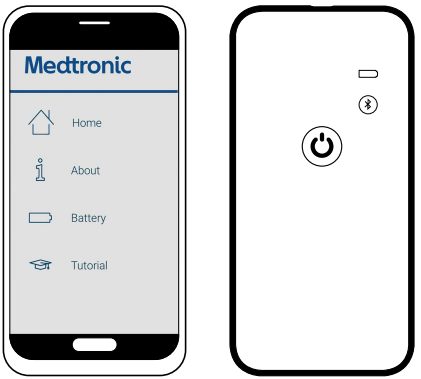


Figure 2. *HH90 Handset (left) and TM90 Communicator (right)*

If the patient has patient control device A without the MRI icon, the handset must be used to stop therapy to prepare the neurostimulator for the MRI scan. Ensure you are outside of the MRI scanner room before proceeding with the following steps.

Note: During the MRI scan, keep the InterStim system off. Therapy must remain off.

1. Press ⏻ on the communicator to turn the communicator on. The communicator will attempt to connect to the handset but cannot do so until the patient therapy app is launched. The blue LED light on the communicator will continuously blink to indicate it is on and in discovery mode.
2. Open the patient therapy app on the handset to initiate the connection process.
3. Once the communicator has successfully connected to the handset, the blue LED light on the communicator will be solid and no longer blinking. Place the communicator over the area where the neurostimulator has been implanted, and tap **FIND DEVICE** on the handset.

   Note: If the communicator fails to connect to the neurostimulator, readjust the location of the communicator over the neurostimulator, and tap **RETRY** on the patient control device.
4. Once the communicator has successfully connected to the implanted neurostimulator, you will be taken to the patient therapy app Home screen where you can turn off therapy (turn off the neurostimulator).

5. **Confirm the neurostimulator model number and serial number.** Use the following steps:
   - Tap ☰ in the corner of the screen on the handset, and select **About** from the list of options.
   - Tap the Device tab for details about the model and serial number

   For a Model 3058 neurostimulator: All serial numbers are MR Conditional Head Scan Eligible with Transmit/Receive Head Coil.

   For a Model 3023 neurostimulator: Check the serial number to confirm that the Model 3023 neurostimulator is MR Conditional Head Scan Eligible with Transmit/ Receive Head Coil.
6. **Turn therapy off.**
   - First, place the communicator over the implanted neurostimulator site.
   - Then on the patient therapy app Home screen, swipe the On/Off Switch from On to Off.
   - You will be asked to confirm that you want to turn off the therapy. Confirm by tapping OK.
7. Proceed with head-only eligible Table 7 for Model 3058 on page 26 or Table 8 for Model 3023 on page 27.

△ **Cautions:**

Model 3023 neurostimulator only: Do not conduct an MRI scan if the serial number is ineligible for MRI. To avoid increased risk of neurostimulator damage, patients with the following serial numbers should not have MRI scans:
- Less than NBV132955H
- Between NBV133037H and NBV133063H
- Between NBV628045S and NBV628263S

Model 3023 neurostimulator only: Do not conduct an MRI scan if the patient can use a control magnet to turn the neurostimulator on or off, unless a clinician has first disabled the magnet switch in the neurostimulator using the Model 8840 Clinician Programmer. Failure to disable the magnet switch could result in uncomfortable, unintended stimulation during the MRI examination.

Model 3023 neurostimulator only: Control magnet function after MRI – Do not conduct an MRI scan if the patient can only use a control magnet to turn the neurostimulator on or off. An MRI scan may permanently damage the magnet switch in the neurostimulator. If the magnet switch in the neurostimulator is damaged, the patient will require a patient control device to turn the neurostimulator on or off.

Appendix B: Patient Control Device B Instructions

Model 3037 Patient Programmer Instructions

Figure 3. *Model 3037 Patient Programmer keys.*

Stopping Therapy for MRI

Use the following instructions to guide the patient in using the patient control device B (InterStim iCon Model 3037 Patient Programmer) to display the screen that will show either the neurostimulator model (IM) or the serial number (IS) and to turn therapy off for the MRI scan:

1. Synchronize the patient control device and neurostimulator. Hold the programmer over the neurostimulator and press the **Sync** key.
2. Using the patient's Model 3037 Patient Programmer, press the Up arrow on the Navigator key.
3. Press the Left arrow on the Navigator key once to select information screens.
4. Press the Down arrow on the Navigator key.
5. Press the Left or Right arrows on the Navigator key to scroll through each information screen to find the model number (Figure 4, left).
   - For a Model 3058 neurostimulator, all serial numbers are MR Conditional Head Scan Eligible with Transmit/Receive Head Coil.
   - For a Model 3023 neurostimulator, check the serial number (IS) by pressing the Left or Right arrows until the IS screen appears (Figure 4, right). Consult Table 1 on page 8 to confirm that the Model 3023 neurostimulator is MR Conditional Head Scan Eligible with Transmit/Receive Head Coil.

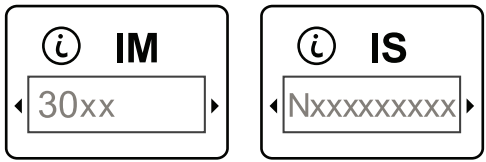


Figure 4. *Neurostimulator model (IM) (left) and serial number (IS) (right) screens.*

6. After confirming whether the neurostimulator is head-scan eligible, hold the programmer over the neurostimulator and press the Neurostimulator off key, (Figure 3).
7. If the neurostimulator is head-scan eligible, proceed with head-only eligible Table 7 for Model 3058 on page 26 or Table 8 for Model 3023 on page 27.

△ **Cautions:**

Model 3023 neurostimulator only: Do not conduct an MRI scan if the serial number is ineligible for MRI. To avoid increased risk of neurostimulator damage, patients with the following serial numbers should not have MRI scans:

- Less than NBV132955H
- Between NBV133037H and NBV133063H
- Between NBV628045S and NBV628263S

Model 3023 neurostimulator only: Do not conduct an MRI scan if the patient can use a control magnet to turn the neurostimulator on or off, unless a clinician has first disabled the magnet switch in the neurostimulator using the Model 8840 Clinician Programmer. Failure to disable the magnet switch could result in uncomfortable, unintended stimulation during the MRI examination.

Model 3023 neurostimulator only: Control magnet function after MRI – Do not conduct an MRI scan if the patient can only use a control magnet to turn the neurostimulator on or off. An MRI scan may permanently damage the magnet switch in the neurostimulator. If the magnet switch in the neurostimulator is damaged, the patient will require a patient control device to turn the neurostimulator on or off.

Appendix C: X-ray identification – InterStim systems

X-ray identification permits the determination of the manufacturer and the InterStim neurostimulator model number using standard X-ray procedures. The Medtronic symbol identifies Medtronic as the manufacturer. To identify the lead, use X-ray imaging and look for a transition of the lead body diameter size near the lead electrodes. In an InterStim SureScan MRI lead, the part of the lead body with braiding has a wider radiographic diameter than the lead body at the lead-electrode (distal) end. See Table 10.

InterStim system X-ray identification

Table 10. Neurostimulator ID code and X-ray identification of the lead

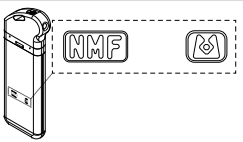
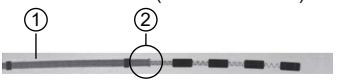
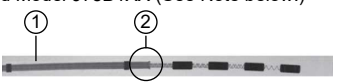
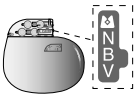
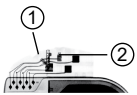
INS radiopaque ID code	X-ray identification of the lead
 ID code NMF – Model 97810 InterStim Micro rechargeable neurostimulator	Full-body MR Conditional with InterStim SureScan MRI lead Model 978A1XX (See Note below.)  ① Lead body with braiding ② Lead body radiographic diameter transition near distal end
 ID code NJY – Model 97800 InterStim X neurostimulator OR Model 3058 InterStim II neurostimulator	Full-body MR Conditional with InterStim SureScan MRI lead Model 978B1XX (See Note below.)  ① Lead body with braiding ② Lead body radiographic diameter transition near distal end
	Head-scan MR Conditional with Detachable Head Transmit/Receive Volume Coil with lead Model 3093  Head-scan MR Conditional with Detachable Head Transmit/Receive Volume Coil with lead Model 3889  ① Lead body without braiding

Table 10. Neurostimulator ID code and X-ray identification of the lead (continued)

INS radiopaque ID code	X-ray identification of the lead
 ID code NBV – Model 3023 InterStim neurostimulator No MRI scans if the Model 3023 serial number is: ▪ Less than NBV132955H ▪ Between NBV133037H and NBV133063H ▪ Between NBV628045S and NBV628263S	If eligible, head-scan MR Conditional with Detachable Head Transmit/Receive Volume Coil with any InterStim lead model
 **1.** ① Neurostimulator Connector Block **2.** ② NFE ID code NFE – Model 7427T InterStim Twin Neurostimulator	Model 7427T is not eligible for MRI scans.

Note: "XX" in 978A1XX and 978B1XX in labeling refers to the lead length. Wherever 978A1 and 978B1 are used, this refers to all lead lengths.

Appendix D: MRI eligibility of lead fragments

Medtronic sacral neurostimulation system MRI eligibility of lead fragments

For clinicians or qualified staff members trained on the use of InterStim systems.

Part 1: Assessing lead fragments from neurostimulation leads for MRI eligibility.

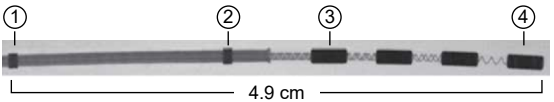


Figure 5. *Example lead x-ray image of InterStim SureScan MRI lead Models 978A1 and 978B1 shown above*

① Proximal radiopaque marker (Marker band B)
② Distal radiopaque marker (Marker band A)
③ Proximal electrode (E3)
④ Distal electrode (E0)

A lead fragment (for example, a partial lead) may remain behind when lead explant is attempted. This lead fragment is usually considered an abandoned component and limits MRI eligibility unless it meets all of the following four criteria:

- ☐ **Lead fragment length ≤ 6.0 cm.** Total length of metallic content must be less than or equal to 6.0 cm. Review an x-ray image to confirm no metallic content is visible proximal to the proximal radiopaque marker (Figure 5-①).
- ☐ **Distance from the lead fragment to other metallic components is ≥ 2.0 cm.** The distance between the lead fragment and any other implanted metallic components including any intact sacral neurostimulation system must be greater than or equal to 2.0 cm. Review an x-ray image or medical records to confirm lead placement location (eg, the new lead is implanted contralateral to the lead fragment location).
- ☐ **Lead fragment location is sacral.** The lead fragment is located in or near the sacral foramen, consistent with a lead tip location used for sacral neuromodulation therapy.

☐ **Lead fragment is eligible.**

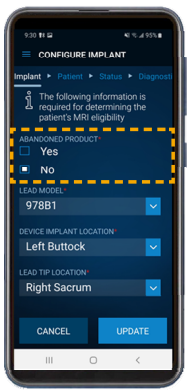
- Eligible Medtronic tined leads are Models 3093, 3889, 978A1, and 978B1. Refer to "Appendix C: X-ray identification – InterStim systems" for x-ray identification of Medtronic tined leads.
- For non Medtronic lead fragments, consult applicable labeling for eligible leads.

If all four criteria are met, MRI programming should be updated because the lead fragment does not need to be considered an abandoned component for MRI eligibility. Proceed to Part 2 or Part 3 as applicable.

Part 2: Updating MRI eligibility for lead fragments using the HH90 Handset and TM90 Communicator

Use this section to update MRI programming parameters using the clinician app on the HH90 Handset, if the lead fragment MRI eligibility has been verified and is not considered an abandoned component.

For patients with a fully intact implanted Medtronic InterStim system, the MRI eligibility condition for abandoned product may be programmed to reflect the MRI eligibility of a lead fragment.



Configure Implant screen in the clinician app on the HH90 Handset

1. Confirm the lead fragment meets the four criteria in Part 1 indicating it does not need to be considered an abandoned component.
2. After connecting to the INS using the clinician app, select the workflow for **CONFIGURE IMPLANT.**
3. On the Configure Implant screen, select **ABANDONED PRODUCT = No.**
4. Confirm the lead model and implant location for the fully intact system.
5. Tap **UPDATE** to save MRI eligibility settings.

Scans may then be conducted following the "ELIGIBILITY IDENTIFICATION" section of these MRI guidelines.

Part 3: Determining MRI scan parameters for patients with a Medtronic lead fragment only

Use this section to provide information required by MRI centers to determine the appropriate MRI scan parameters for patients whose sacral neurostimulation system was explanted and only a Medtronic lead fragment remains.

If the patient no longer has an intact, implanted sacral neurostimulation system, and only has a lead fragment:

1. Confirm that the lead fragment meets the four criteria in Part 1 indicating it does not need to be considered an abandoned component.
2. See "Appendix E: MRI Scan-Type Eligibility Form", Form B, for an example of a patient record that can be provided to the MRI center.

Scans may then be conducted according to the applicable MRI equipment and scan requirements in Table 2, Table 3, and Table 4 of these MRI guidelines.

Appendix E: MRI Scan-Type Eligibility Form

InterStim sacral neurostimulation systems at End-of-Service (EOS) or InterStim lead fragments

- At the time of the MRI appointment, go to www.medtronic.com/mri and enter the neurostimulator model number for the latest MRI guidelines.
- Enter patient information and confirm scan eligibility by completing the appropriate Form A or Form B for the MRI center.

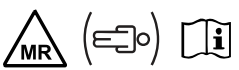
Form A. Patient record for fully implanted InterStim neurostimulation systems at End-of-Service (EOS). Enter information and confirm scan eligibility below.

Model 97800, Model 3058, and eligible Model 3023 neurostimulators only: Confirm that the neurostimulator is depleted or at EOS (considered off) prior to the MRI scan by attempting telemetry with the neurostimulator using another programmer or by consulting patient records.

Patient name:		
Clinician name, office, address, and phone number:		
The abovenamed patient is considered eligible for an MRI scan of the head region only, following all the MRI scan conditions for neurostimulator Model 97800, Model 3058, or eligible Model 3023* only.		
Neurostimulator model number:		Neurostimulator serial number:
☐		MR Conditional Head Scan Eligible with Transmit/Receive Head Coil Follow the "Head-only eligible MRI scan conditions" of the latest MRI guidelines at www.medtronic.com/mri.
☐	**I confirm the neurostimulator for the abovenamed patient is depleted or at End of Service (EOS) - considered off.**	
Clinician signature:		
Form date:		
MRI center: a working patient control device is not required for this patient. If the neurostimulator is depleted or at End-of-Service (EOS), then the neurostimulator is considered off. *Additional eligibility is required for Model 3023 prior to scanning. Consult Table 1 of the latest MRI guidelines.		

Form B. Patient record for InterStim lead fragments. Enter information and confirm scan eligibility below.

InterStim lead fragments: Before filling out this form, confirm that no lead fragments greater than 6 cm remain implanted using the guidance in "Appendix D: MRI eligibility of lead fragments" of the latest MRI guidelines available at www.medtronic.com/mri.

<table>
<tr><td colspan="2">Patient name:</td><td></td></tr>
<tr><td colspan="2" rowspan="4">Clinician name, office, address, and phone number:</td><td></td></tr>
<tr><td></td></tr>
<tr><td></td></tr>
<tr><td></td></tr>
<tr><td colspan="3">The abovenamed patient is considered eligible for an MRI scan of the region indicated because all components of their InterStim system have been explanted and no lead fragments greater than 6 cm remain per an assessment using "Appendix D: MRI eligibility of lead fragments".</td></tr>
<tr><td colspan="2">Neurostimulator model number:</td><td>Neurostimulator serial number:</td></tr>
<tr><td>☐</td><td>  </td><td>MR Conditional Full Body Scan Eligible
Follow the applicable MRI equipment and scan requirements in Table 2, Table 3, and Table 4 of the latest MRI guidelines at www.medtronic.com/mri.</td></tr>
<tr><td>☐</td><td colspan="2">I confirm the neurostimulation system for the abovenamed patient has been explanted, no lead fragments greater than 6 cm remain, and the patient is eligible for the type of MRI scan indicated.</td></tr>
<tr><td colspan="3">Clinician signature:</td></tr>
<tr><td colspan="3">Form date:</td></tr>
</table>

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