

# MRI Patient Eligibility

This form provides information about the patient's implanted neurostimulator and MRI scan eligibility. It may be provided to the radiologist to support the confirmation of the patient's scan eligibility.

- **Prior to conducting an MRI scan with a Medtronic SureScan® neurostimulator, the radiologist should confirm that the patient's neurostimulator is in MRI Mode** (i.e., stimulation is off). Leaving stimulation on during the scan could increase the potential for uncomfortable, unintended stimulation.
- Refer to [www.medtronic.com/mri](http://www.medtronic.com/mri) for labeling and safety conditions.

## Contact Information

Patient Name:	
Physician Name:	
Physician Phone Number:	
Clinic Name:	
Clinic Address:	

## Eligibility Results

Date/Time Eligibility Determined	Neurostimulator Model #	Neurostimulator Serial #

The eligibility status for this patient is:

<b>MRI-CS FULL-BODY SCAN ELIGIBLE</b>		
<input type="checkbox"/>		<p>Symbols mean that based on the information programmed into the device, this patient has:</p> <ul style="list-style-type: none"> <li>• a SureScan® INS implanted in a tested location.</li> <li>• SureScan leads with lead tips in tested locations.</li> <li>• no extensions or abandoned leads.</li> </ul> <p>System is eligible for a full-body scan under the conditions listed in labeling.</p>
<b>MRI-CS HEAD SCAN ELIGIBLE WITH TRANSMIT/RECEIVE HEAD COIL</b>		
<input type="checkbox"/>		<p>Symbols mean:</p> <ul style="list-style-type: none"> <li>• Medtronic neurostimulation system</li> <li>• Leads are not in the head or neck (i.e., not within the RF head coil)</li> <li>• No abandoned leads</li> </ul> <p>System is eligible for a head scan under the conditions listed in labeling.</p>
<b>The neurostimulation system MRI-CS eligibility cannot be determined.</b>		
<input type="checkbox"/>		<p>Symbols mean that based on the information programmed into the device, the system's MRI eligibility cannot be determined. Review the labeling or contact Medtronic to discuss the MRI safety based on the patient's system configuration.</p>

The radiologist can provide the following information code to Medtronic to obtain additional information about the patient's implanted neurostimulation system.

 Information Code:	
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## Activating MRI Mode with the Medtronic MyStim® Patient Programmer

Prior to the patient's MRI scan appointment, follow these steps to place the implanted neurostimulator in MRI mode using the patient programmer (model 97740 or later).

1. Synchronize the patient programmer and the neurostimulator.
  - a. Hold the patient programmer directly over the neurostimulator with the screen facing outward.
  - b. Press the **Synch** key (Figure 1).
  - c. The **Therapy** screen will appear (Figure 2).

**Note:** If the patient programmer does not synchronize the first time, reposition the programmer over the neurostimulator and try again.

2. Press the up arrow on the **Navigator** key (Figure 1) to move the selection box to the Status row on the **Therapy** screen (Figure 2).
3. Press the left or right arrows on the **Navigator** key to move the selection box until the **MRI Mode Activation** screen appears (Figure 3).
4. Hold the patient programmer directly over the neurostimulator with the screen facing outward and press the **Synch** key. MRI mode is now activated and stimulation is turned off. The **MRI Scan Eligibility** screen will display one of the sets of icons shown on the front of this form, indicating the patient's MRI scan eligibility. **Do not** press any other keys once MRI Mode is activated. The MRI scan eligibility screen will display for 20 minutes, during which time the buttons on the front of the patient programmer are disabled to allow the MRI scan eligibility screen to be photocopied if needed. After 20 minutes, MRI Mode will still be active, but the MRI Scan Eligibility screen will only be viewable if you repeat the same patient programmer steps that were followed to initially activate MRI Mode.

### Notes:

- On the front of this form, check the box to indicate the patient's MRI-CS scan eligibility results.
- If the **MRI Mode** screen displays an information icon (i) and related information code, then write the code on the front of this form.
- Patients who do not have a Medtronic SureScan Neurostimulation system may still be eligible for a head-only scan. Refer to the **MRI Guidelines for Medtronic Neurostimulation Systems for Chronic Pain** to determine if the system is eligible for a head-only scan.

### Inform the patient of the following:

- When MRI Mode is activated, stimulation is turned off. Stimulation must be off during the MRI scan. While stimulation is off, pain symptoms may return.
- After the MRI scan is complete and the patient is outside of the MRI scanner (magnet) room, the patient programmer or clinician programmer can be used to turn stimulation back on (i.e., deactivate MRI Mode).



Figure 1. Patient Programmer

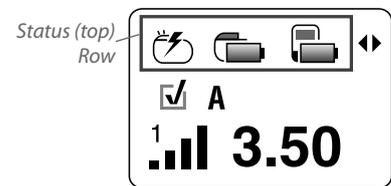


Figure 2. Therapy Screen

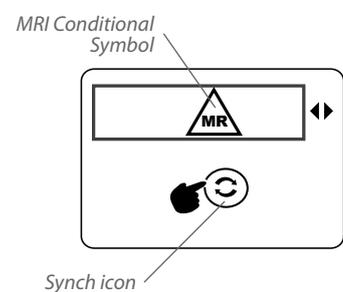


Figure 3. MRI Mode Activation Screen

#### NEUROSTIMULATION SYSTEMS FOR PAIN THERAPY

**Brief Summary:** Product manuals must be reviewed prior to use for detailed disclosure.

**Indication:** Neurostimulation for Spinal Cord Stimulation (SCS) – Medtronic SCS neurostimulation system is indicated for SCS as an aid in the management of chronic, intractable pain of the trunk and/or limbs, peripheral vascular disease, or intractable angina pectoris. Neurostimulation for Peripheral Nerve Stimulation (PNS) using percutaneous leads - A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the posterior trunk. Neurostimulation for Peripheral Nerve Stimulation (PNS) using surgical leads – A Medtronic PNS neurostimulation system is indicated for PNS as an aid in the management of chronic, intractable pain of the trunk and/or limbs.

**Contraindications:** Diathermy - Do not use shortwave diathermy, microwave or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a neurostimulation system. Energy from diathermy can be transferred through the implanted system and cause tissue damage at the locations of the implanted electrodes, resulting in severe injury or death. **Warnings:** Sources of strong electromagnetic interference (e.g., defibrillation, diathermy, electrocautery, MRI, RF ablation, and therapeutic ultrasound) can interact with the neurostimulation system, resulting in serious patient injury or death. These and other sources of EMI can also result in system damage, operational changes to the neurostimulator or unexpected changes in stimulation. Rupture or piercing of the neurostimulator can result in severe burns. An implanted cardiac device (e.g., pacemaker, defibrillator) may damage a neurostimulator, and the electrical pulses from the neurostimulator may result in an inappropriate response of the cardiac device. Patients treated for intractable angina pectoris should be educated on the signs and symptoms of myocardial infarction and should seek medical attention immediately if signs and symptoms develop. **Precautions:** The safety and effectiveness of this therapy has not been established for pediatric use (patients under the age of 18), pregnancy, unborn fetus, or delivery. Patients should be detoxified from narcotics prior to lead placement. Clinicians and patients should follow programming guidelines and precautions provided in product manuals. Patients should avoid activities that may put undue stress on the implanted neurostimulation system components and should avoid manipulating or rubbing the neurostimulation system through the skin. Patients should not scuba dive below 10 meters of water or enter hyperbaric chambers above 2.0 atmosphere absolute (ATA). Electromagnetic interference, postural changes, and other activities may cause shocking or jolting. **Adverse Events:** Adverse events may include: undesirable change in stimulation described by some patients as uncomfortable, jolting or shocking; hematoma, infection, erosion, allergic response, hardware malfunction or migration, pain at implant site, loss of pain relief, surgical risks, seroma.

SCS specific: epidural hemorrhage, paralysis, CSF leakage, and chest wall stimulation. PNS specific: Nerve damage or degeneration.