Medtronic

InterStim™ systems with SureScan™ MRI technology

Patient safety and technician convenience for MRI scans

Simplified MRI access matters

We continue to advance sacral neuromodulation by offering updated full-body MRI labeling.†

†Under certain conditions; see approved labeling for details. Patients with InterStim™ SureScan™ MRI Leads only.

SureScan™ MRI technology

Please refer to the InterStim™ MRI Guidelines for comprehensive labeling on conducting an MRI scan at medtronic.com/mri. If the patient is found to have a lead fragment left behind from a previous explant, they may be eligible for an MRI if the fragment meets certain conditions as described in the labeling guidelines.

Patients must bring their programmer and communicator to the MRI appointment. Use the applicable My Therapy app to determine MRI eligibility information.

In cases where the implanted system is depleted or at the end of service, the patient may be eligible for a 1.5T head only scan even if they are not carrying a programmer. Please refer to the InterStim™ MRI guidelines for more details.[4]

These instructions[4] apply to:

- Model 97810 InterStim™ Micro neurostimulator with Model 978A1 SureScan™ MRI lead
- Model 3058 InterStim™ II neurostimulator with Model 978B1 SureScan™ MRI lead
- Model 97800 InterStim X ™ neurostimulator with Model 978B1 SureScan™ MRI lead

Note: If the patient has a different model number, please see guidelines at medtronic.com/mri.
If a patient needs to look up their implant model number refer them to Medtronic Patient Registration at 800-551-5544. For requests after hours, contact Medtronic Patient Technical Services at 800-510-6735.

1 BEFORE THE SCAN

Activate MRI Mode

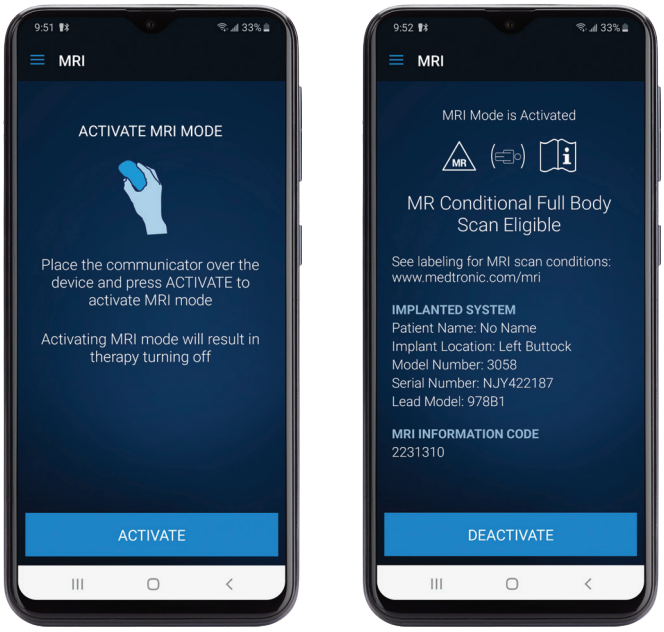
1. On the smart programmer, open the My Therapy App or Micro My Therapy App or InterStim X™ My Therapy App.

   No impedance check is required prior to the MRI scan.

2. Select "Menu" 

   For Model 97810 InterStim™ Micro neurostimulator only, select "Battery" within the menu. Confirm the neurostimulator is charged to a minimum of 30% prior to MRI. Do not proceed if neurostimulator is less than 30% charged.

3. Select “MRI” within the menu
   Note: If MRI is not shown in the menu, refer to InterStim™ MRI Guidelines for eligibility
4. Follow the instructions on the programmer then select “Activate.”
5. The MRI mode activation screen appears. Therapy is off. The text and symbols on screen indicate the system is full-body MRI eligible.



2 MRI SPECIFICATIONS

There are no restrictions on MRI manufacturers

- Approved for the commonly used MRI systems:
  - 3T horizontal closed cylindrical system
  - 1.5T horizontal closed cylindrical system
- MRI magnetic field gradient specifications:
  - Max gradient slew rate ≤ 200 T/m/s per axis
  - Max spatial field gradient: 20 T/m (2000 gauss/cm)
- Scan time limit:

  After 30 minutes of accumulated scan time, allow 5 minutes of cooling.
- Patient body temperature:

  Confirm that the patient’s body temperature is ≤100 °F. Do not use blankets.
- Patient position:

  Position the patient in a prone or supine position in the MRI bore.

SureScan™ MRI technology

3 SCAN PREPARATION

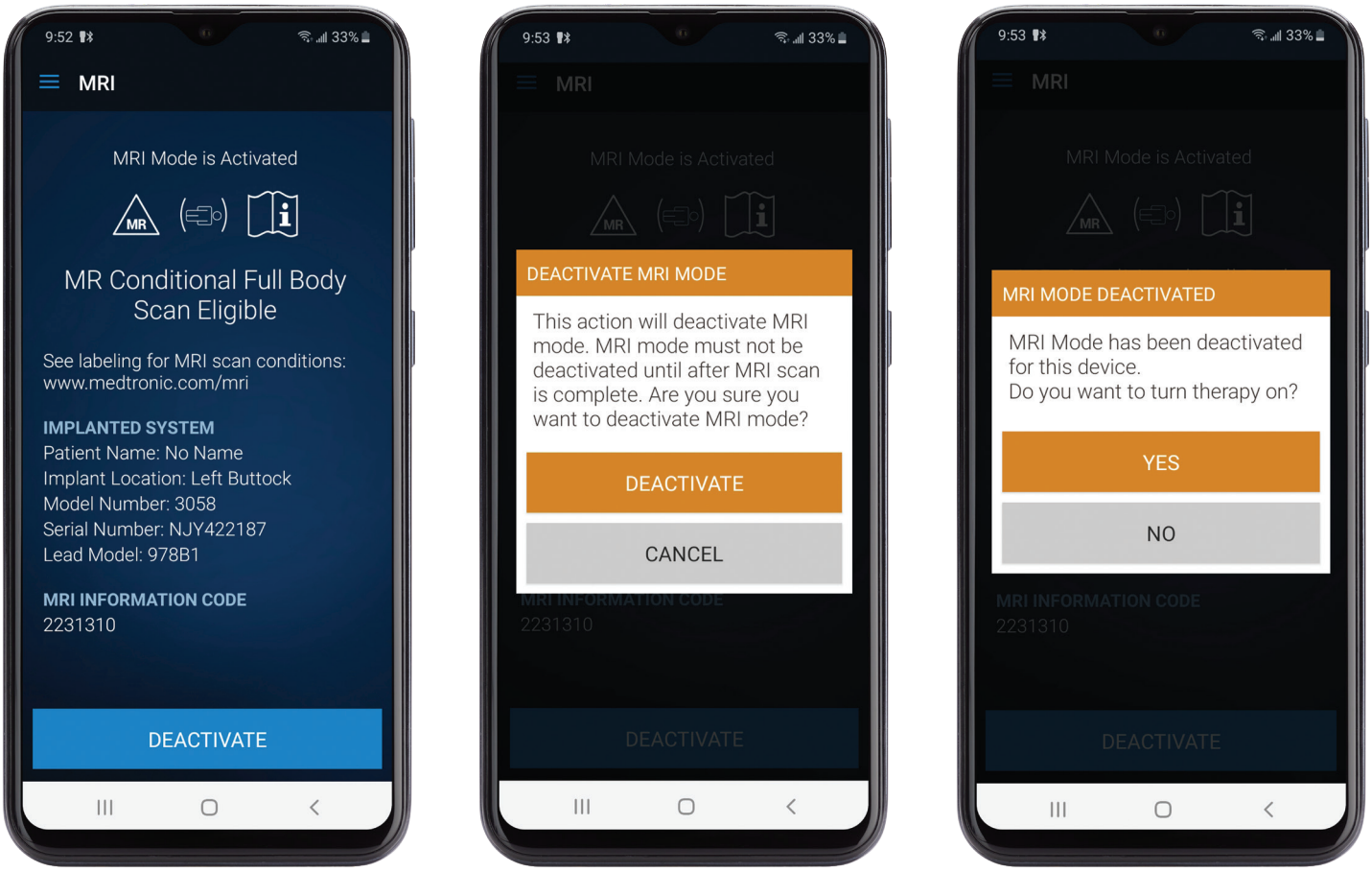
- RF Transmit Coils:
  - whole body integrated transmit coil.
  - detachable transmit/receive head or lower extremity volume coil.
- RF Receive Coils:
  - Unrestricted
- Scanner Operating Modes:
  - Normal Operating Mode
  - First Controlled Operating Mode
- RF Exposure Limits at or Superior to C7 (1.5T and 3T):
  - Up to the First Controlled mode SAR limit (4 W/kg whole body or 3.2 W/kg head)
- RF Exposure Limits Inferior to C7:
  - 1.5T
    - ≤ 4 uT B1+rms using the whole-body RF coil.
    - ≤ 2W/kg whole body SAR if B1+rms is not displayed on the scanner.
    - First Controlled mode SAR limit when using a detachable transmit/receive lower extremity volume coil.
  - 3T
    - ≤ 2 uT B1+rms using the whole-body RF coil.
    - ≤ 1.4 W/kg whole body SAR if B1+rms is not displayed on the scanner.
    - First Controlled mode SAR limit when using a detachable transmit/receive lower extremity volume coil.

Please note: 3T RF whole body transmit coil – MRI systems using two transmit channels may operate in multichannel-2 (MC-2) or circularly polarized (CP) modes. Systems that use more than two transmit channels have not been studied, but such systems could be operated in CP or MC-2 modes, if available.

4 AFTER THE SCAN

Deactivate MRI mode. Turn therapy back on.

Once MRI mode has been deactivated and therapy turned on, the patient's stimulation automatically increases to the previous setting.



The most common adverse events experienced during clinical studies include pain at implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations. Any of these may require additional surgery or cause return of symptoms.

Designed for safety

Patient safety is our top priority.

Full-body†
1.5T|3T
MRI scans

20+
years of MRI research

1.2
million scanning scenarios[1,2]

10
million simulated patient scans[2]

†Under certain conditions; see approved labeling for details. Patients with InterStim™ SureScan™ MRI Leads only.

Simple and convenient

The SureScan™ MRI systems are designed to streamline MRI scans for patients, technicians, and clinic staff.

No impedance checks are required prior to MRI scans.

MRI mode is easy to activate on a smart programmer.[3]

All Medtronic InterStim™ systems with SureScan™ technology have the same MRI conditions.

Dedicated engineers, scientists, and technicians working together at our **MRI Center of Excellence** and **MRI testing lab** developed proprietary SureScan™ MRI technology. This unique design allows patients receiving sacral neuromodulation with the InterStim™ systems to have an MRI scan with confidence.

1. Combination of body model, MRI manufacturer, implant location, lead length, scanner type and stimulator type.
2. Medtronic data on file – result of animal studies combined with lab data, computational modeling and statistical methods.
3. MRI SureScan™ technical manuals on medtronic.com/mri.
4. Medtronic MRI Guidelines for InterStim™ systems, M980291A032 Rev A.

See the device manual for detailed information regarding the instructions for use, implant procedure, indications, contraindications, warnings, precautions, and potential adverse events. For further information, contact your local Medtronic representative or consult the Medtronic website at **medtronic.com.**

Indications for Use:

Sacral Neuromodulation delivered by the InterStim™ system for Urinary Control is indicated for the treatment of urinary retention and the symptoms of overactive bladder, including urinary urge incontinence and significant symptoms of urgency-frequency alone or in combination, in patients who have failed or could not tolerate more conservative treatments.

The following Warning applies only to Sacral Neuromodulation for Urinary Control:

Warning: This therapy is not intended for patients with mechanical obstruction such as benign prostatic hypertrophy, cancer, or urethral stricture.

Sacral Neuromodulation delivered by the InterStim™ system for Bowel Control is indicated for the treatment of chronic fecal incontinence in patients who have failed or are not candidates for more conservative treatments.

Contraindications for Urinary Control and for Bowel Control: Diathermy. Patients who have not demonstrated an appropriate response to test stimulation or are unable to operate the neurostimulator.

Warnings/Precautions/Adverse Events:

For Urinary Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 16; or for patients with neurological disease origins.

For Bowel Control: Safety and effectiveness have not been established for bilateral stimulation; pregnancy, unborn fetus, and delivery; pediatric use under the age of 18; or for patients with progressive, systemic neurological diseases.

For Urinary Control and for Bowel Control: The system may be affected by or adversely affect cardiac devices, electrocautery, defibrillators, ultrasonic equipment, radiation therapy, MRI, theft detectors/ screening devices. Adverse events include pain at the implant sites, new pain, lead migration, infection, technical or device problems, adverse change in bowel or voiding function, and undesirable stimulation or sensations, including jolting or shock sensations. Patients should be assessed preoperatively for the risk of increased bleeding. For full prescribing information, please call Medtronic at 1-800-328-0810 and/ or consult Medtronic's website at www.medtronic.com. Product technical manual must be reviewed prior to use for detailed disclosure.

USA Rx Only. Rev 0517

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