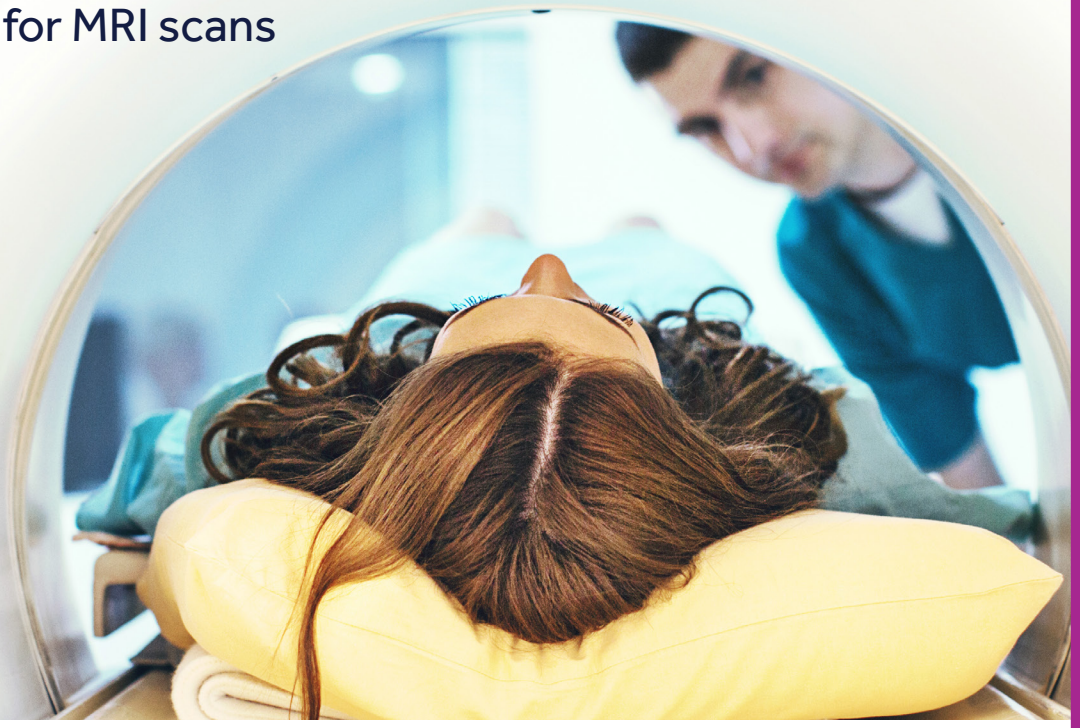
INTERSTIM™ SYSTEMS WITH SURESCAN™ MRI TECHNOLOGY

Ensures patient safety and technician convenience for MRI scans



THERAPY WITHOUT LIMITS

Proprietary SureScan™ MRI technology expands eligibility and allows patients with either InterStim™ system to get full-body* 1.5 and 3T MRI scans, so you can **bring life-changing relief[1,2] to even more people.**

*Under certain conditions; see approved labeling for details.

Medtronic

SURESCAN™ MRI TECHNOLOGY

Please refer to the InterStim™ MRI Guidelines for comprehensive labeling on conducting an MRI scan at www.medtronic.com/mri.

Patients must bring their programmer and communicator to the MRI appointment. Consult the My Therapy or Micro My Therapy app for MRI eligibility information.

These instructions apply to:

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

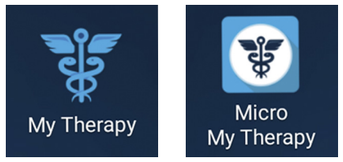
Note: if the patient has a different model number, please see guidelines at www.medtronic.com/mri

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

☐ **On the smart programmer, open the My Therapy App or Micro My Therapy App.**



☐ **Select "Menu"** 

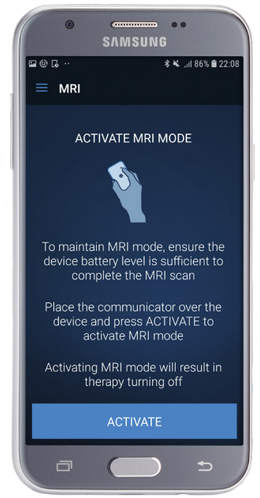
- For model 97810 InterStim™ Micro neurostimulator only select "Battery" within the menu. Confirm the neurostimulator is charged to a minimum of 30% prior to MRI. Do not proceed if neurostimulator is less than 30% charged.

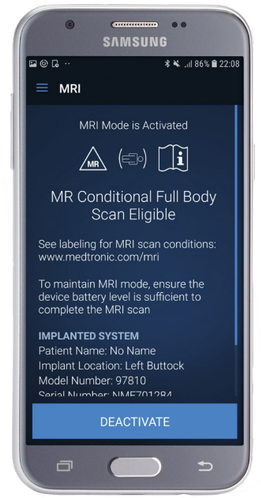
☐ **Select "MRI" within the menu**

Note: If you do not have "MRI" in your menu, please visit www.medtronic/mri for MRI eligibility.

☐ **Follow the instructions on the programmer then select "Activate".**

☐ **The MRI mode activation screen appears. Therapy is off. The text and symbols on screen indicate the device is full-body MRI eligible.**





2 MRI SPECIFICATIONS

There are no restrictions on MRI manufacturers

Approved for both MRI systems:

- 3T horizontal closed cylindrical system
- 1.5T horizontal closed cylindrical system

MRI field specifications:

- Max Gradient Slew Rate ≤ 200 T/m/s per axis
- Max Spatial Field Gradient: 20 T/m (2000 gauss/cm)

Scan Time limit:

- Do not exceed a total of 30 minutes of active scan time within a 90-minute window.

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

If you are scanning at or superior to the C7 vertebra, check the RF coil:

- RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type.
  RF exposure level with both 3T & 1.5T Machines:
  - Normal Operating Mode
  - First Level Controlled Operating Mode
- Detachable Head Transmit/ Receive Volume Coil.
  RF exposure level with both 3T & 1.5T Machines:
  - Normal Operating Mode
  - First Level Controlled Operating Mode

If you are scanning inferior to the C7 vertebra, check the RF coil:

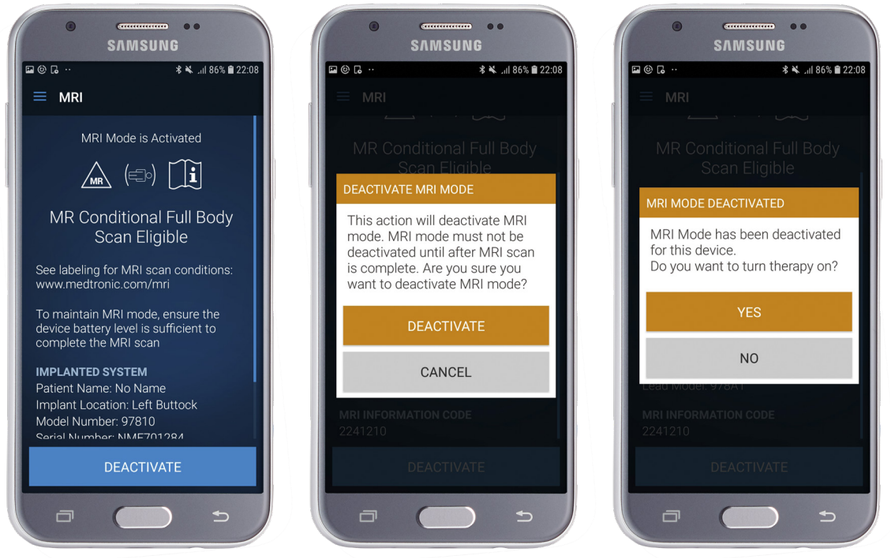
- RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type.
  RF exposure level:
  - 3T Machines: B1+rms ≤ 1.3 μTValues before scanning; For MRI scanners that do not report B1+rms, limit SAR to ≤ 0.5 W/kg.
  - 1.5T Machines: B1+rms ≤ 3.0 μTValues before scanning; For MRI scanners that do not report B1+rms, limit SAR to ≤ 0.5 W/kg.
- Detachable Lower Extremity Transmit/ Receive Volume Coil
  RF exposure level with both 3T & 1.5T Machines:
  - Normal Operating Mode
  - First Level Controlled Operating Mode

Please note: 3T RF Whole Body Transmit Coil -MRI systems using two transmit channels (or fewer) 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 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.

*Under certain conditions; see approved labeling for details.

Full-body*
1.5T | 3T
MRI Scans

19 years
of MRI research

1.2 million
scanning scenarios[3,4]

10 million
simulated patient scans[4]

SIMPLE AND CONVENIENT

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

- No impedance checks required prior to MRI scans
- MRI mode is easy to activate on a smart programmer.[5]
- 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. Siegel, S., Noblett, K., MangelJ, et al. " Five Year Follow-up Results of a Prospective, Multicenter Study in Overactive Bladder Subjects Treated with Sacral Neuromodulation." J Urol.2018;199(1), 229 –236.
2. Hull T, Giese C, Wexner SD, et al. Long-term durability of sacral nerve stimulation therapy for chronic fecal incontinence. Dis Colon Rectum. 2013;56(2):234-245
3. Combination of body model, MRI manufacturer, implant location, lead length, & scan type.
4. Medtronic data on file -result of animal studies combined with lab data, computational modeling and statistical methods.
5. MRI SureScan™ technical manuals on www.Medtronic.com/mri

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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