Medtronic

Easy choice

InterStim™ SureScan™

SureScan™ technology helps ensure patient safety and technician convenience for MRI scans

Expanded eligibility

Proprietary SureScan™ technology allows patients with InterStim™ SureScan™ systems to get full-body* 1.5-and 3-T MRI scans, so you can **bring life-changing results[1,2,3] to an even wider range of people.**

*Under certain conditions; see approved labeling for details.

Designed for safety

Patient safety is our top priority. Backed by rigorous testing and quality standards, Medtronic SureScan™ MRI systems feature some of the most comprehensive MRI labelling on the market. SureScan™ technology helps ensure patient safety and technician convenience for MRI scans.

* Under certain conditions; see approved labeling for details.

Full-body*

1.5-T & 3-T

MRI Scans

21

years

of full-body MRI research

1.2

million[4,5,6]

scanning scenarios

10

million[5,6]

simulated patient scans

Improved workflow

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

No impedance check prior to scanning, which is designed to reduce repeat visits and to help patients save time.[7]

MRI mode can be easily activated on a smart programmer.[7]

All Medtronic InterStim™ MRI 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™ technology. This unique design allows patients receiving sacral neuromodulation (SNM) therapy to have an MRI scan with confidence.

MRI checklist[7]

1 Eligibility identification checklist - 1 step

Smart programmer with the icon MRI

Ask the patient to tap ≡ in the corner of the patient therapy app Home screen.

☐ Select MRI eligibility icon and from the MRI Eligibility screen, ask the patient to place the communicator over the device and tap **ACTIVATE** to activate MRI mode (following the indication on the screen).

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

2 MRI system checklist-There are no restrictions on MRI manufacturers - 7 steps

1. Check the Neurostimulator and lead model numbers on the smart programmer:

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

2. Check the Battery status (Model 97810 InterStim™ Micro neurostimulator only):

- ☐ Confirm the neurostimulator is charged to a minimum of 30% before scanning. **Do not proceed if the neurostimulator is not sufficiently charged.**

3. Check the MRI system types:

- ☐ 3-T horizontal cylindrical system
- ☐ 1.5-T horizontal cylindrical system

4. Check the MRI field specifications:

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

5. Check 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.

6. Check patient body temperature:

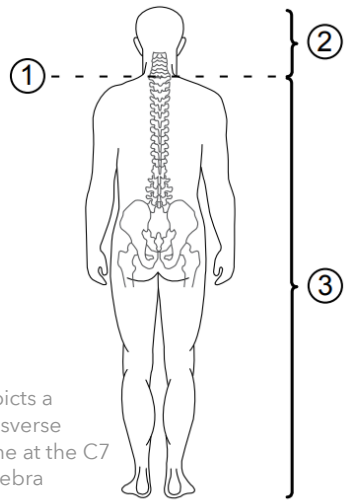
- ☐ Confirm that the patient's body temperature is ≤38 °C (100 °F). Do not use blankets.

7. Check patient position:

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

MRI checklist[7]

❸ Scan preparation checklist - 1 step



① Depicts a transverse plane at the C7 vertebra

1. Check the Scan Region and the RF exposure level:

☐ At or superior to the C7 vertebra (2):

Check the RF coil:

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

☐ Inferior to the C7 vertebra (3):

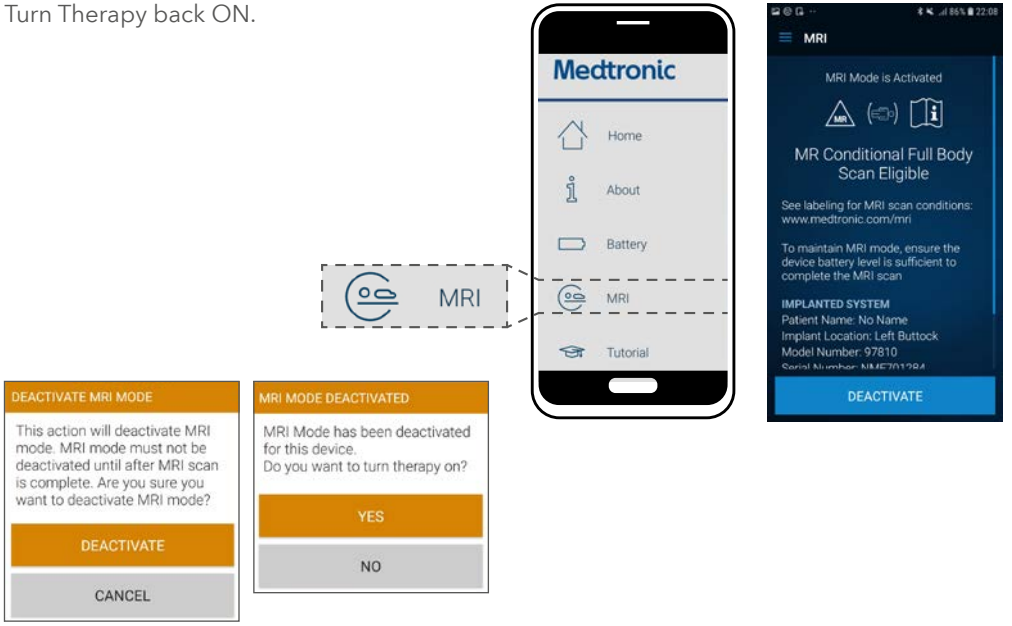
Check the RF coil:

- ☐ RF Whole Body Transmit Coil (Integrated Transmit Coil) with Receive coil: any type.
  RF exposure level:
  - ☐ 3-T Machines: B1+rms ≤ 2.0 µT Values before scanning; For MRI scanners that do not report B1+rms, limit SAR to ≤ 1.4 W/kg.
  - ☐ 1.5-T Machines: 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.
  RF exposure level with both 3-T & 1.5-T Machines:
  - ☐ Normal Operating Mode
  - ☐ First Level Controlled Operating Mode

Please note: 3-T 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.

❹ After the scan checklist - 2 steps

Turn Therapy back ON.



1. 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.

2. Verify that the patient has not experienced adverse effects as a result of the MRI.
Contact Medtronic to report any adverse effects.

Please Note: Instruct the patient to see the implanting physician or managing physician if any of the following instances are 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.

References

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. Van Kerrebroeck P, et al. Results of sacral neuromodulation therapy for urinary voiding dysfunction:outcomes of a prospective, worldwide clinical study. J Urol. 2007; 178:2029-2034
4. Combination of body model, MRI manufacturer, implant location, lead length, & scan type.
5. Medtronic data on file NDHF1567-186848 version 2.0 -result of animal studies combined with lab data, computational modeling and statistical methods
6. Medtronic data on file NDHF1559-186167 version 4.0 -result of animal studies combined with lab data, computational modeling and statistical methods.
7. MRI SureScan® technical manuals on www.Medtronic.com/manuals

Brief Statement

See the device manual for detailed information regarding the instructions for use, indications, contraindications, warnings, precautions, and potential adverse events. If using an MRI SureScan® device, see the MRI SureScan® technical manual before performing an MRI. For further information, contact your local Medtronic representative and/or consult the Medtronic website at medtronic.eu.

For applicable products, consult instructions for use on www.medtronic.com/manuals. Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.

Medtronic

Europe
Medtronic International Trading Sàrl.
Route du Molliau 31
Case postale
CH-1131 Tolochenaz
www.medtronic.eu
Tel: +41 (0)21 802 70 00
Fax: +41 (0)21 802 79 00

United Kingdom/Ireland
Medtronic Limited
Building 9
Croxley Park
Hatters Lane
Watford
Herts WD18 8WW
www.medtronic.co.uk
Tel: +44 (0)1923 212213
Fax: +44 (0)1923 241004

medtronic.eu