Standard Operating Procedure for MRI Scanning Patients with a Sacral Nerve Stimulator

Background

A sacral nerve stimulator (SNS) is an active implanted medical device which aims to improve bladder or bowel function in patients with urinary retention, overactive bladder symptoms and/or chronic faecal incontinence [1]. This urinary/ bowel control is achieved via the transmission of electrical signals to the sacral nerves [2]. The most commonly implanted SNS systems are the Medtronic Interstim II and Interstim X. Components of these systems are described below and illustrated in *Figure 1*.

The rechargeable Interstim Micro systems are also available. However, the Interstim Micro will very rarely be implanted in GG&C as the Interstim X has a similar lifetime and does not need to be charged regularly.

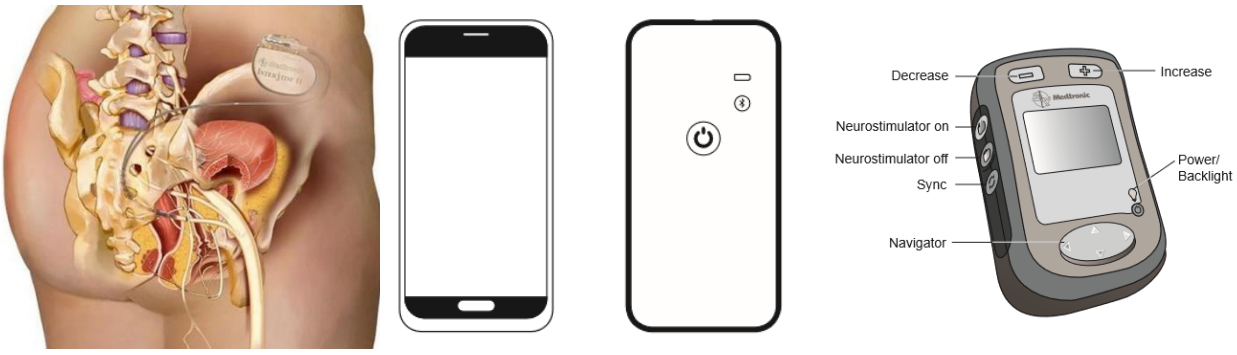


Figure 1: Interstim system components. Left: Example schematic of implanted SNS illustrating its location within the body. Centre: HH90 Handset and TM90 Communicator. Right: InterStim iCon Model 3037 Patient Programmer.

There are generally 3 components to an SNS system:

- **Lead** – this is a single fine wire with four separate electrode contacts that can each be stimulated individually or in various combinations to tailor the neuromodulation therapy to the individual's needs.
- **Pulse generator** – this is the small battery that drives the system. The Interstim II generally needs replaced every 6-7 years. The Interstim X has a predicted lifetime of 12-15 years and the Interstim Micro has a similar lifetime to the Interstim X.
- **Programmer** – this is the small remote control that allows the patient to adjust the SNS device themselves and for them to turn it off and on. These are **MR Unsafe** and must not be taken into the MR Environment. Instructions on how to operate each type of programmer are provided in the latest manufacturer guidelines.

On Receipt of Referral

- The referrer must state in the clinical indications that the patient has a Sacral Nerve Stimulator within the clinical safety questions.
- Core MRI Radiographers should be consulted regarding the organisation, booking and scanning of these patients. The patient should be put 'on hold' on the CRIS system until the following steps have been followed.
- The make and model of the implanted generator and lead must be identified to allow the MR safety status of the combined system to be determined. Ideally, the referrer will have provided the make and model of the generator and lead in the MRI referral. However, if this is not the case, identification of the generator and lead can be obtained through various other approaches:
    - Clinical Portal
    - GG&C SNS device specialists may be able to advise:
        - Urology service based at QEUH
        - Bowel service based at GRI
    - The patient may be aware of the make and model of the pulse generator and lead or be able to provide details of the implanting clinician or hospital
    - If required, it may be possible to determine the make and model from previous x-rays. Some manufacturers provide guidance on how to identify the pulse generator and lead model from an x-ray within their MRI Guidelines (e.g. the appendix of the latest InterStim MRI Guidelines)
    - If the make and model still cannot be found and there are no previous x-rays then a new pelvic x-ray would be recommended
- Once the make and model of the generator and lead has been identified, the current MR safety guidance from the manufacturer should be checked. The following links will direct you to MRI safety documentation from the main SNS manufacturers:
    - Medtronic (e.g. Interstim): www.medtronic.com/mri
    - Axonics https://www.axonics.com/hcp/resources/resource-library
    - Finetech-Brindley Bladder System (Vocare) Sacral Anterior Root Stimulator https://finetech-medical.co.uk/support/
- MR Conditional systems may include restrictions on which coils can be used (e.g. a Transmit/Receive head coil only) or which body regions can be scanned. The stimulator must either be placed in MRI mode or the stimulation turned off (depending on the device conditions) before the MRI and restored to the pre-scan settings after the scan. More detail on this topic is included in Appendix A.
- If a patient with a fully implanted Interstim SNS has a depleted battery or the device has reached the End of Service (EOS) then contact MRI Physics for advice. Some models are still able to undergo an MRI scan of the head using a Transmit/Receive head coil (i.e. follow the "head-only eligible MRI scan conditions") but otherwise it may require an off-label risk assessment to proceed. Medtronic guidance on this topic can be found within their MRI Guidelines (e.g. the appendix of the latest InterStim MRI Guidelines)
- It is recommended to check previous imaging for patients but this is especially important if the patient has had their SNS replaced as there are often abandoned leads/electrodes which

require additional consideration. Abandoned leads were previously considered off-label but the guidance has been updated and, provided certain criteria are met, these are considered MR Conditional. Contact MRI Physics for advice.

- If the MR Conditions cannot all be met, please see Appendix B
- If you are unsure of the MRI safety status of an SNS device or require help meeting the conditions, please contact a member of the MRI Physics team.
- Please be aware that some devices may be subject to scanning time or SAR/B1+rms restrictions and the imaging protocol may need to be adjusted to accommodate this. An MR Clinical Scientist can provide details and, where required, attend the scan to ensure these limits are met.

Booking Guidance

- Patients should only be booked within Core hours (Monday to Friday, 9am to 5pm).
- We recommend calling the patient before their appointment to ask them whether they have a device programmer that they are able to place in the appropriate mode and to ensure they know to bring the programmer with them to their MRI appointment.
- If they do not have a device programmer or do not know how to use this, then a device specialist can be asked to attend before and after the scan, to set the device to MRI mode, and reset it back after the MRI.
- The rechargeable Interstim Micro also needs to be fully charged prior to the MRI scan so the patient will need to be asked to charge it in advance and bring the charger to the appointment.
- When vetting the patient, sites should consider if additional time may be required to be added to the normal slot length or if the patient should be instructed to arrive earlier for their appointment. How much additional time required will depend on the level of experience with these devices and the MR Conditions.
- A Radiographer or MR Clinical Scientist dealing with this case should ensure that an implant alarm has been generated on the CRIS system.
- For patients undergoing their MRI under general anesthesia (GA), the Consultant Anaesthetist in charge of the list should be informed via email about the implant and the potential risks. Any queries they have should be discussed with the Lead Radiographer/Clinical Scientist and/or Radiologist in advance of the patient booking being confirmed.

Day of the scan - Preparation

- The MRI Conditions for the device should be located, scrutinised and be referenced throughout the examination.
- The MRI Conditions must be followed, regardless of the site of interest being local or remote from the implant.
- The patient must still undergo standard MRI safety screening.
- Obtain the height and weight of the patient before preparing the patient.

- The patient should be advised that they should press the staff call button should they experience any discomfort or unusual sensations at any time during the examination.
- The external programmer is MRI UNSAFE. It must never enter the MRI scan room.
- Do not conduct the MR scan if the SNS has not been placed in MRI mode (or stimulation turned off for Interstim II with an older programmer) – see appendix A for how to put devices into MRI Mode or turn off stimulation
- For scans outside the MR Conditions, this can only proceed following an off-label benefit vs risk assessment and clinical justification, see appendix B for more guidance.
- For any emergency during the scan follow standard procedures.

Post-scan

- The patient's programmer should be used to set the SNS back to the pre-MRI settings. If there is any issue with the SNS device they should contact their implant clinician as soon as possible.

Special Notes

- Patients who attend for MRI appointments who, when screened, are found to have a sacral nerve stimulator may not be able to be scanned on the day. In these instances, explanation should be given to the patient and they will be rebooked when the appropriate checks have taken place.

References

[1] A. Fry, N. Kotnis, R. Edward and P. J. Wright, "Off-label magnetic resonance imaging of an InterStim II sacral nerve stimulator device.," BJR Case Report, no. 4, 2017.
[2] "Sacral Nerve Stimulation," NHS North Bristol , [Online]. Available: https://www.nbt.nhs.uk/sites/default/files/attachments/Sacral%20Nerve%20Stimulation_NBT002656_0.pdf. [Accessed 09 May 2019].
[3] M. Elkelini and M. Hassouna, "Safety of MRI at 1.5Tesla in Patients with Implanted Sacral Nerve Neurostimulator," European Urology, vol. 50, no. 2, pp. 311-316, 2006.
[4] Chermansky et al, "Magnetic Resonance Imaging Following InterStim: An Institutional Experience with Imagiing Safety and Patient Satisfaction," Neurourology and Urodynamics , vol. 30, pp. 1486-1488, 2011.
[5] Thornton et al, "Technical Challenges and Safety of Magnetic Resonance Imaging with in situ neuromodulation from spine to brain," European Joournal of Paediatric Neurology , vol. 21, pp. 232-241, 2017.
[6] F. H. Hetzer, "Fifteen years of sacral nerve stimulation: from an open procedure to a minimally invasive technique.," Colorectal Disease, vol. 13, pp. 1-4, 2011.

Appendix A – Further details on the SNS programmer

There are two programmers for the Medtronic Interstim systems, the HH90 Handset and TM90 Communicator (labelled Device A in the MRI Guidelines) and the InterStim iCon Model 3037 Patient Programmer (labelled Device B in the MRI Guidelines). Please follow the guidance in Appendix A and B of the latest Interstim MRI Guidelines for instructions for placing the SNS system into MRI mode or switching off the stimulation.

- The Interstim X and Micro systems can only be connected to the HH90 Handset and TM90 Communicator whereas the older Interstim II device can be connected to either programmer.
- Only the HH90 Handset and TM90 Communicator has an option to place the device into MRI mode.
- However, not all HH90 Handset and TM90 Communicators display the MRI mode option. If MRI mode is not an option the Interstim MRI Guidelines state that it is "head-only eligible".
- Likewise, the Interstim MRI Guidelines state that if a patient has the iCon Model 3037 Patient Programmer then it states they are "head-only eligible". However, following discussions with Medtronic representatives, we have clarified that if a patient has an Interstim II with a full-body eligible lead then turning off the therapy on any programmer model has the same effect as it would placing it into MRI mode. The Interstim X and Micro are the only 2 batteries that carry out additional checks when going into MRI mode. Therefore, if the implanted Interstim II battery and lead combination is full body eligible then the patient is full-body eligible irrespective of which programmer model they have.

Confirming MRI mode/stimulation switched off on the iCon 3037 programmer

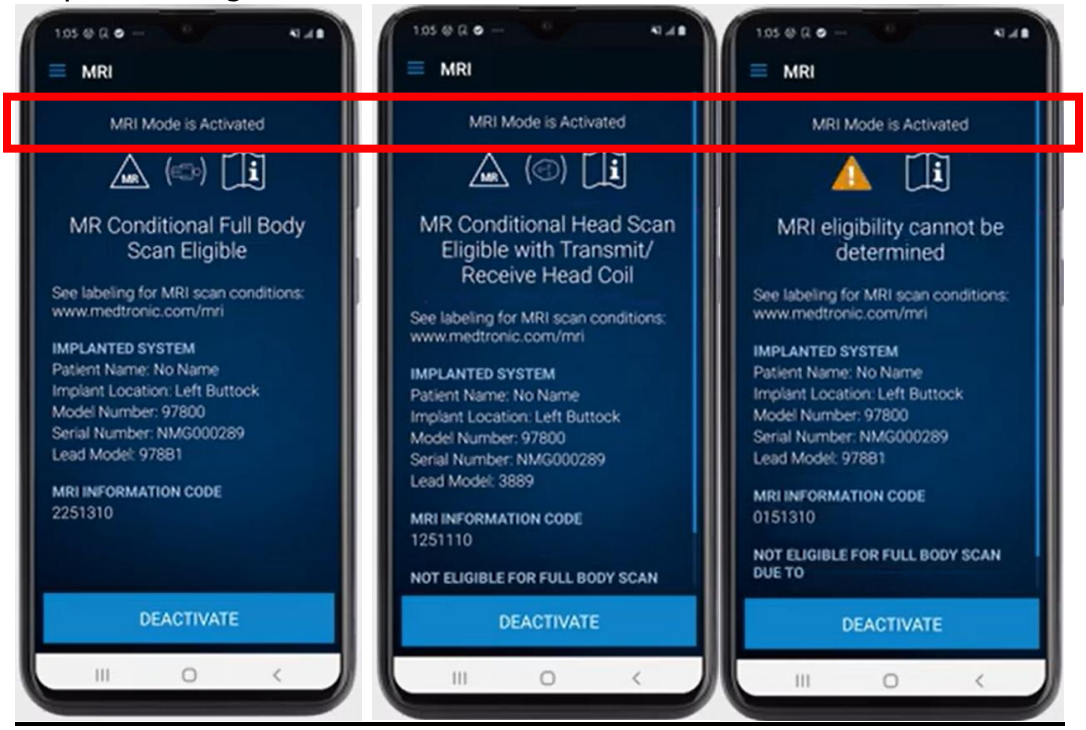
The iCon 3037 programmer sometimes causes confusion so the images below show what to look for on the programmer to confirm the stimulation is turned on (left image, lightning bolt present on device background) or off (right image, no lightning bolt present on device background).

Confirming MRI mode/stimulation switched off on the HH90 Handset and TM90 Communicator

This YouTube video provides clear instructions for patients preparing for an MRI scan: **https://youtu.be/OmNHW9ZG7pY?si=HaFb4v0sUesLGbyx**

In short, to place the device into MRI mode:

1. turn on the handset and communicator
2. open up the My Therapy app on the handset
3. place the communicator over the SNS implant with the blue side against the skin
4. press 'Find Device' on the handset, this may take multiple attempts with repositioning the communicator directly over the device
5. Press the menu icon (3 lines at the upper left corner of the handset) and select MRI mode in the pop up menu. If there is no 'MRI mode' option in the menu, turn the therapy off from the home screen and follow the MR Conditions provided by MR Physics.
6. Press 'Activate' to activate MRI mode, this will also turn the therapy off
7. Check the MR Eligibility (Full Body Scan Eligible, Head only Eligible with T/R Head Coil, or MRI eligibility cannot be determined, see Figures below) and follow the guidance displayed and the MR Conditions provided by MR Physics. If there is a discrepancy, contact MR Physics.
8. Confirm the screen displays 'MRI Mode is Activated' at the top of the handset display as per the images below



Appendix B – Off-label guidance

The following examples should be considered off-label:

- the make and model of both generator and lead could not be identified
- the MR Conditions cannot be met

If considering scanning off-label, please review the potential risks copied below from the 2021 Interstim MRI Guidelines:

"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."

For patients with head only eligible systems, it is common to receive requests for MR spine scans. There is strong evidence that this can be performed safely with additional precautions in place. An off-label risk assessment is required and an informed consent form has been prepared

and reviewed by the 'Clear To All' team if the benefit is deemed to outweigh the risk (**MR-GGC-TEMP-007**).