

# Magnetic resonance imaging interactions with a sacral neuromodulation system

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## Abstract

**Aims:** Sacral neuromodulation (SNM) has successfully treated patients with functional urinary and/or bowel disorders for more than two decades. Historically, patients with the InterStim system (Medtronic) were contraindicated for Magnetic Resonance Imaging (MRI) scans. In 2012, Medtronic obtained Food and Drug Administration (FDA) approval for allowing 1.5 Tesla (T) MRI head scans. In September 2019, the Axonics System (Axonics) received FDA approval for 1.5 T full-body MR Conditional labeling and then 3 T full-body MR Conditional labeling in July 2020. In August 2020, Medtronic received 1.5 and 3 T full-body MR Conditional labeling from the FDA for their new SNM systems (InterStim II and Micro devices with SureScan™ leads). With the advancements in MRI technology and availability of full-body MRI eligible SNM systems, it is important for physicians to better understand MRI safety for these systems.

**Methods:** This paper explains the fundamentals of MRI physics, its interactions with active implantable medical devices (AIMDs), the subsequent potential safety hazards with emphasis on radio frequency (RF)-related safety, and the risks associated with “Off-label” scans, including abandoned and broken leads.

**Results:** MRI guidelines provided by the AIMD device manufacturer should be followed to ensure MRI scan safety and avoid any unnecessary risk to patients.

**Conclusions:** MRI guidelines provided by the device manufacturer are the best resource for guidance for performing safe MRI scanning. Specific conditions should be fully understood and generalizations on MRI safety claims based on partial analysis or case studies should be avoided.

## KEYWORDS

implantable neurostimulator, MRI physics

## 1 | INTRODUCTION

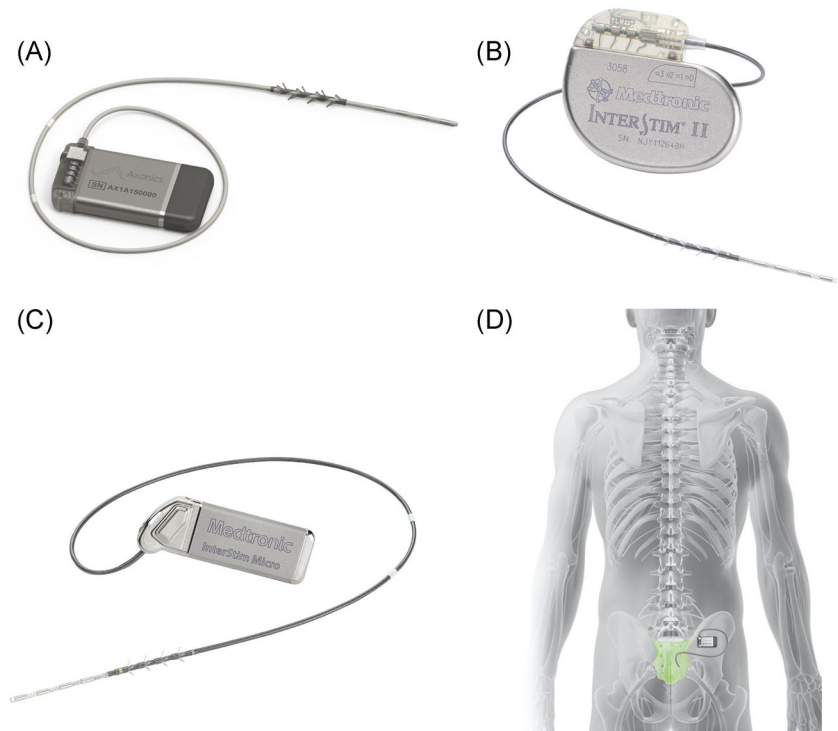
An implantable sacral neuromodulation (SNM) device consists of a pulse generator and lead that delivers electrical stimulation to the target sacral nerve. This

treatment utilizes a neurostimulation device implanted chronically in the body to achieve long-term clinical benefits. There are only two device manufacturers with commercially available SNM systems, shown in Figure 1: (A) the Axonics System, (B) Medtronic's InterStim II

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**FIGURE 1** (A) The Axonics System, (B) Medtronic's InterStim II system, (C) the InterStim Micro system, and (D) typical implant location of the Axonics System. Source: Medtronic and Axonics; with kind permission



system, (C) InterStim Micro system, and (D) a typical implant location of the Axonics System.

Magnetic Resonance Imaging (MRI) is an important diagnostic tool with an estimated 39 million scans performed in the United States in 2018.<sup>1</sup> Before 2012, MRI was contraindicated for SNM systems. With Food and Drug Administration (FDA) approval in 2012, a patient with an SNM device was only allowed head MRI scans at 1.5 T with a head transmit coil. MRI scans of other body parts were restricted, along with other field strength MRI systems. Such restrictions are due to potential hazards from MRI interactions with the implanted SNM device that may lead to patient discomfort, unintended stimulation, tissue injury, and/or device damage. Axonics received FDA approval for its SNM system with 1.5 T full-body MR Conditional labeling in September 2019 and obtained 3 T full-body MR Conditional labeling in July 2020. Following Axonics' approvals, Medtronic received 1.5 and 3 T full-body MR Conditional labeling from the FDA for their new SNM systems (InterStim II and Micro devices with SureScan leads) in August 2020 and updated their labeling again in February 2021.<sup>2</sup>

As defined by the American Society for Testing and Materials (ASTM) standard,<sup>3</sup> a device can be classified as MR Safe, MR Conditional, or MR Unsafe based on its interaction with an MRI scanner. An MR Conditional SNM device means the device can be safely scanned in specific MR environments as determined by extensive testing.

Unlike the field of spinal cord stimulation or cardiac rhythmic management where multiple devices have received full-body MR Conditional approvals since 2011,<sup>4</sup>

physicians in the field of SNM are less familiar with the specifics of full-body MR Conditional labeling. This paper aims to provide an introduction to MRI system physics, offer relevant insights into the MRI interactions of an implanted SNM device, present the potential risks associated with scanning, and discuss key technical parameters and scenarios to optimize the MRI practice.

## 2 | MRI SYSTEM PHYSICS AND INTERACTION WITH AN SNM DEVICE

### 2.1 | MRI system operation

To generate images, MRI relies on the nuclear magnetic properties of the hydrogen nucleus (proton), which is abundant in the human body. Each hydrogen proton behaves like a small magnetic bar and spins around its own axis. When a patient undergoes MRI, the body is exposed to three different electromagnetic fields: the static magnetic field, the gradient fields, and the radio frequency (RF) field.

#### 2.1.1 | Static magnetic field

The static magnetic field ( $B_0$  field), with units of Tesla (T), is a strong magnetic field that is constantly on. Under exposure to the static magnetic field, hydrogen protons inside a body are preferentially aligned along the direction of this magnetic

field. The spinning speed, or precession frequency, of hydrogen protons is proportional to the strength of the static magnetic field, which is about 64 Megahertz (MHz) for 1.5 T and about 128 MHz for 3 T MRI systems.

### 2.1.2 | Gradient fields

On top of the static magnetic field, the gradient fields create slight frequency and phase variations in the spinning of hydrogen protons of the scanned body part. It allows the MRI system to pinpoint and differentiate signals within the targeted body region.

### 2.1.3 | RF field

The RF field ( $B_1^+$ -field) is a pulsed signal that is generated perpendicularly to the static magnetic field. The frequency of RF signal matches the spinning frequency of the hydrogen protons. When a person enters an MR scanner, the hydrogen protons inside the human body align with the static magnetic field. After the hydrogen proton is “excited” by an RF pulse, it tips away from the alignment with the static magnetic field, rotates, and then gradually returns to its initial orientation. This process generates the MR signal picked up by the RF receive (Rx) coil.

## 2.2 | RF power, specific absorption rate (SAR), and $B_1$ +rms (root-mean square)

The predominant factor that determines MRI quality and acquisition speed is the level of RF power used to scan a patient. The higher the RF power, the more signal can be used to generate a higher quality MR image in a shorter scan time. The amount of RF power can be assessed by using either SAR or  $B_1$ +rms:

1. SAR is a measure of RF energy absorbed by the body, in units of Watts per kilogram of body weight (W/kg). SAR is an estimated value depending on the scanned body part.
2.  $B_1$ +rms is a new metric for RF power compared with SAR and is used to describe the average effective strength of the RF field generated by a transmit coil. Units are micro-Tesla ( $\mu$ T).

Because RF power causes heating by depositing energy into the tissue, MRI scanners estimate and restrict SAR in three different operating modes (Normal, First-Level Controlled, and Second-Level Controlled) based on

perceived safety risks to subjects.<sup>5</sup> Additionally, the location of the body scanned has different SAR limits.<sup>5</sup> More restrictive SAR limits may be required for patients with active implantable medical devices (AIMDs) to undergo an MRI scan safely. SAR is a metric that is universally available for all MRI scanners and has been commonly used by MRI technologists. While the International Electrotechnical Commission (IEC) has required that all new MRI systems display  $B_1$ +rms since 2013, it is not a universally available value on MRI scanners.<sup>6</sup> Many MRI technologists are not familiar with managing  $B_1$ +rms.

## 2.3 | Potential adverse events due to MRI exposure

Adverse events, such as device malfunction,<sup>7–10</sup> unintended stimulation,<sup>11</sup> and thermal burns,<sup>8,12,13</sup> have been reported when patients with implanted devices were scanned either “On-label” or “Off-label.” An SNM device may be determined MR Conditional when the risks from MRI exposure have been assessed per testing standards, notably ISO/TS 10974:2018. The international standard ISO/TS 10974:2018 is a consensus of general MRI safety testing procedures for AIMDs, which was developed by a joint working group consisting of a technical committee representing AIMD manufacturers, MRI scanner manufacturers, regulatory agencies, and clinical field experts.

### 2.3.1 | Device malfunction/damage

Device malfunction or damage may be caused by device interactions with each of the output fields ( $B_0$ , gradient, and RF fields) or a combination thereof. Some types of device malfunction reported are device power-on-reset,<sup>14</sup> reed switch activation,<sup>15</sup> loss of communication,<sup>16</sup> and permanent device damage that requires surgical intervention.<sup>10</sup> Device malfunction or damage may lead to loss of therapy and eventually device explant or replacement, adding burden on patients and the healthcare system.

### 2.3.2 | Unintended stimulation

Device interactions with the gradient or RF magnetic fields can induce current flow on the lead. This induced current can be released from the electrode which may stimulate surrounding nervous tissues and cause discomfort or even pain. However, compared with a cardiac device, unintended nerve stimulation is a less serious risk for an SNM device.

### 2.3.3 | Thermal burns

Risk of thermal burns usually refers to RF heating at AIMD electrodes. RF heating at electrodes is a complex problem depending on numerous variables and requires a comprehensive analysis. In an SNM system, the lead length is of the same order of magnitude as the RF field wavelength, and the induced RF current on the lead can be substantial. The induced electrical current on the lead flows from the electrodes to the human body, heating nearby tissue. The degree of RF heating depends on multiple factors, including SAR or B1+rms level, scanner type (1.5 or 3 T), device design, implant location, patient body size, body part under scan, scan parameters, sequence, and so forth. General conclusions about MRI safety cannot be made based on partially known information. The risk of thermal burn is not solely dependent on the lead length and assuming a longer lead would cause more risk or less risk in an MRI environment is incorrect. Several serious patient injuries due to RF-induced heating have been reported with deep brain stimulation devices.<sup>12,13</sup>

RF heating at the generator itself is generally less of an issue compared with RF heating at electrodes. The gradient field could also induce heating on the generator due to eddy currents. However, for SNM devices, the risk of gradient heating on the metallic can is typically lower than RF heating at electrodes.

## 3 | DISCUSSION

The topics discussed in this section aim to provide relevant details on the potential risks associated with 1.5 and 3 T MRI scanning and ultimately provide insights on performing MRI scans effectively and safely in special scenarios.

### 3.1 | MR conditional labeling is MR scanner specific

Each device has its own MRI conditions pertaining to the specific field strength and MRI scanner types. Assuming

a device that is MR Conditional for 1.5 T MRI is also eligible for 3 T MRI, or vice versa, is potentially dangerous. Most implantable devices are indicated for 1.5 and/or 3 T MRI closed bore systems. There are other MRI scanners, such as open bore MRI systems, that use two giant flat magnets and usually operate at static field strengths below 1.0 T. A device that is MR Conditional in a 1.5 or 3 T closed bore scanner does not guarantee MRI safety in a lower field strength open bore MRI system. It is critical to scan patients in the MRI scanners as specified in the manufacturer's MRI guidelines.

### 3.2 | Key RF conditions (SAR and B1+rms) and scan time

MRI offers excellent soft-tissue contrast and does not expose patients to dangerous ionizing radiation. However, MRI acquisitions tend to be slow, limiting patient throughput and potential indications for use, while driving up costs. The speed at which an MRI image can be acquired is directly correlated to the RF power allowed for an MRI scan. The higher the SAR or B1+rms used, the shorter the scan time.

Table 1 lists the key parameters for full-body MRI scans between the Axonics System and the new Medtronic InterStim Micro and InterStim II systems with SureScan leads.<sup>2,17</sup> The SAR and B1+rms limits for the Axonics System are comparable to the Medtronic systems with SureScan leads for both 1.5 and 3 T full-body scans. As discussed previously, both SAR and B1+rms limits are clinically relevant because restrictive RF condition limits may extend scan time and affect image quality. The maximum whole-body (WB) SAR allowed for both the Axonics and Medtronic systems (with SureScan leads) in 1.5 T is 2.0 W/kg, which is the highest WB SAR under the Normal Operating Mode. Both the Medtronic systems with SureScan leads and the Axonics System allow 30 min of continuous scan time, followed by a wait time of 5 min if this limit is reached.

The recent improvements in MRI conditions offer wider flexibility in MRI scanning protocols and improve

**TABLE 1** Some of the key parameters for full-body MRI scans between the Medtronic InterStim systems with SureScan lead<sup>2</sup> and the Axonics System<sup>17</sup>

1.5 T		Scanner strength	3 T	
Axonics	Medtronic	Manufacturers	Axonics	Medtronic
2.0	2.0	<b>SAR limit (W/kg)</b>	1.2	1.4
Not specified	4.0	<b>B1+rms Limit (<math>\mu</math>T)</b>	1.7	2.0
30 min	30 min	<b>Allowed continuous scan time</b>	30 min	30 min
5 min	5 min	<b>Wait time</b>	5 min	5 min

*Note:* The MRI conditions here do not apply to leads left in situ, fracture leads, or any situations outside the MRI guidelines.

Abbreviations: MRI, Magnetic Resonance Imaging; rms, root-mean square; SAR, specific absorption rate.

patient access to MRI, which alleviate burdens in clinical practices.

### 3.3 | Varying conditions among SNM systems affect MRI procedure

It is worthwhile to emphasize that MR Conditional labeling depends on the model of the device and the types of leads used.<sup>2,17</sup> Prior generations of InterStim systems, including various IPGs and leads, are only eligible for head scan or are MRI unsafe. Confirming MRI scanning safety and conditions for a specific implanted device is burdensome to the healthcare system, as it requires the imaging center to know exactly what devices are implanted. Especially for multicomponent systems, most patients do not know these details and are often provided with patient ID cards by the device manufacturers. It is important for patients to bring their ID cards to their MRI appointments. MRI guidelines should be referred for MR conditionality and precautions before conducting MRI examination on a patient with a specific SNM system.<sup>2,17</sup>

The MRI conditions for both Axonics and Medtronic SNM systems are only applied to the fully implanted permanent system. The percutaneous lead and external pulse generator used temporarily in the trial phase are not MR Conditional.

### 3.4 | Approved MRI conditions are dependent on RF coil configurations

Different types of RF coils can be used for scanning the same body part and the use of certain RF Transmit (Tx) coils determines what MRI conditions should be followed. RF whole-body transmit/receive (Tx/Rx) volume coil is built inside 1.5 and 3 T MRI scanners and is capable of scanning the entire body region. Detachable Tx/Rx volume coils dedicated for head, lower or upper extremity scans have smaller sizes and can be placed closely around the body parts to improve image quality. Using detachable Tx/Rx volume coils to avoid RF exposure of the entire body may be important to patients who are less tolerant to thermal stress.

As an example, consider a lower extremity scan, such as a knee scan. If a detachable Tx/Rx knee coil is used, the MRI conditions for the extremity coil must be followed. If a detachable Tx/Rx knee coil is not available, an RF whole-body Tx volume coil can be used for RF transmission. In this case, the MRI conditions for the RF whole-body Tx volume coil must be followed.

### 3.5 | Risk associated with “Off-label” MR scans

There have been reports on “Off-label” MRI scans performed on patients with implanted SNM devices.<sup>10,18–22</sup> These studies present the clinical need for expansion of MRI scanning eligibility of SNM devices. While few serious adverse events were reported in these studies, it is important to note that most of these investigations were performed based on a risk–benefit analysis with MRI expert knowledge, careful selection of scan parameters, and close monitoring of patient status during MRI procedures. Though several MRI-related hazards are considered, most studies focused on particular aspects of MRI safety—for instance, the RF-induced heating complications.<sup>18,23</sup> As these results are based on carefully performed MRI scanning in a small number of patients, one should not advocate “Off-label” MRI scans outside the manufacturers’ recommended MR conditions. Generalized conclusions about MRI safety on “Off-label” MRI scans should be avoided.<sup>24</sup>

The approved MRI conditions for SNM devices are for typical sacral implant locations.<sup>2,17</sup> An SNM device implanted away from the standard implant location (e.g., pudendal) may disqualify its MRI eligibility.

### 3.6 | Risk associated with abandoned leads and broken leads

Patients may decide to have their SNM devices removed when the device is no longer beneficial or for other reasons. Often, the entire SNM system is removed in a regular procedure. However, the lead may break during removal, resulting in an abandoned lead fragment. Investigators at the Cleveland Clinic reported breakage among 7.5% of leads during the timed lead removal procedure at their center from 2002 to 2018.<sup>25</sup> The abandoned lead fragment, though disconnected from the pulse generator, may still have wires within the fragment that can act like an antenna and absorb RF signals during MRI. In cases where all wires are completely removed and only the outer polymer sheath with electrode contacts is left inside the body, the lead fragment is unlikely to induce RF heating risk. Assessing RF heating and other hazards on an abandoned lead fragment could be challenging because of unclear terminal conditions of the broken lead fragment, varying length of the residual lead fragment, and potential migration of the lead fragment inside the body.

A few studies have attempted to measure RF-induced heating in intact leads or lead fragments, both in phantom study and in human model simulation. Depending

on the length of the abandoned lead and terminal conditions, the induced temperature could be lower or greater than the intact system.<sup>26–29</sup> Although some retrospective studies found no safety issues for abandoned pacemaker or implanted cardioverter defibrillator (ICD) leads in patients who have undergone MRI,<sup>30–32</sup> the results could be attributed to many factors, such as blood perfusion around the lead tip, which could be different than the sacral leads that are embedded in various tissues.

The broken lead is another clinically possible situation in which a patient experiences bad electrodes due to wire breakage in a lead.<sup>33,34</sup> The broken wire may enhance RF energy coupling on the lead and increase the possibility of heating damage.<sup>29</sup> An impedance check before MRI examination can confirm the system integrity and verify MR scan eligibility. MR examination eligibility may be disqualified due to the presence of broken, abandoned, or fragmented SNM leads. With the careful risk–benefit analysis by the expert, some “Off-label” MRI scans may be performed with mitigations considered (reduced RF intensity and/or scan time). “Off-label” MRI scan with these compromised lead conditions may lead to adverse effects.

## 4 | CONCLUSIONS

MRI safety of an AIMD is a complex topic and constantly evolving. MRI guidelines provided by the device manufacturer are the best resource for guidance and conditions for performing MRI scanning safely. All conditions and precautions must be fully understood and followed to avoid imposing unnecessary risks and hazards to patients. It is important to understand the specific conditions before arriving to specific conclusions, and generalizations on MRI safety claims based on partial analysis or case studies should be avoided. Any device with new materials, new design, or implanted at new anatomy positions, could result in very different MRI interactions and will need to be evaluated in a systematic manner.

## COMPETING INTEREST

All named authors are employees of Axonics Inc. and members of AAMI Standard Committee of ISO/TS 10974.

## AUTHOR CONTRIBUTIONS

All named authors contributed equally to conception, article drafting, and revisions, as well as read and approved the manuscript for submission.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no data sets were generated or analyzed during the current study.

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