Axonics
Modulation
Technologies

MRI Guidelines for the

Axonics Sacral Neuromodulation System

Instruction for Use

℞ only

CE
2797

Note: Read this manual in its entirety before performing a Magnetic Resonance Imaging (MRI) scan on patients who are implanted with the Axonics SNM System. This document contains information related to MRI use with the Axonics SNM System. Refer to the Axonics SNM System product manuals for more detailed information about non-MRI aspects of implantation, programming, charging and use of the components of the Axonics SNM System.

Table of Contents

GLOSSARY

B1+rms (root-mean-squared, μT) – the root-mean-squared value of the MRI effective component of the RF magnetic (B1) field or, in other words, the time-averaged RF magnetic field component relevant for creating an MR image that is generated by the MR system during a scan. In 2013, the International Electrotechnical Commission (IEC) mandated that all MR systems manufactured going forward must display B1+rms. Therefore, B1+rms value may only be available on MR scanners acquired after 2013 or an older MR scanner with software updated.

CE 2797 – CE Marking of Conformity

Circularly Polarized (CP)/ Quadrature (QD) Mode – a type of RF coil operation mode, where circularly polarized is also commonly known as quadrature.

Cylindrical MR systems – a type of MR scanner generating horizontal static magnetic B_0 field, also known as closed bore systems.

Hertz (Hz) – a unit of frequency defined as cycles per second. One Megahertz (MHz) is one million cycles per second.

MRI – Magnetic Resonance Imaging.

MRI Transmit/Receive RF Body Coil – a coil used to transmit and to receive RF energy that encompasses the whole body within the MR system bore.

MR Conditional – an item with demonstrated safety in the MR environment within defined conditions. At a minimum, these address the conditions of the static magnetic field, the switched gradient magnetic field and the radio frequency fields. Additional conditions, including specific configurations of the item, may be required.

MR Unsafe – an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment

Radio Frequency (RF) – high frequency electrical fields whose frequencies are in the range of 10,000 Hz and above. The RF used in the 1.5T MRI Scanner is about 64 MHz. The RF used in the 3T MRI Scanner is about 128 MHz.

Sacral Neuromodulation (SNM) – a type of electrical stimulation therapy that uses mild electrical pulses to stimulate the sacral nerve located in the pelvic region.

Specific Absorption Rate (SAR) – RF power absorbed per unit of mass (W/kg).

Tesla (T) – the unit of measure of magnetic field strength. One T is equal to 10,000 Gauss.

W/kg – Watts per kilogram, a measure of the power that is absorbed per kilogram of tissue.

1. MR CONDITIONAL DEVICE

MR Conditional

The Axonics Sacral Neuromodulation (SNM) System is, per the definition in ASTM F2503-13, an **MR Conditional** device. In-vitro tests and simulations have shown that patients implanted with the Axonics SNM System may be safely exposed to MRI environments that follow the MRI guidelines described in this document. The conditions for MRI scans of the head in patients with the Axonics SNM System are different than those for the full body.

Always obtain the latest MRI guidelines. It is important to read this full document prior to conducting or recommending an MRI examination on a patient with the Axonics SNM System. Refer to the contact information on the last page of these MRI guidelines, or go to www.axonicsmodulation.com/MRI

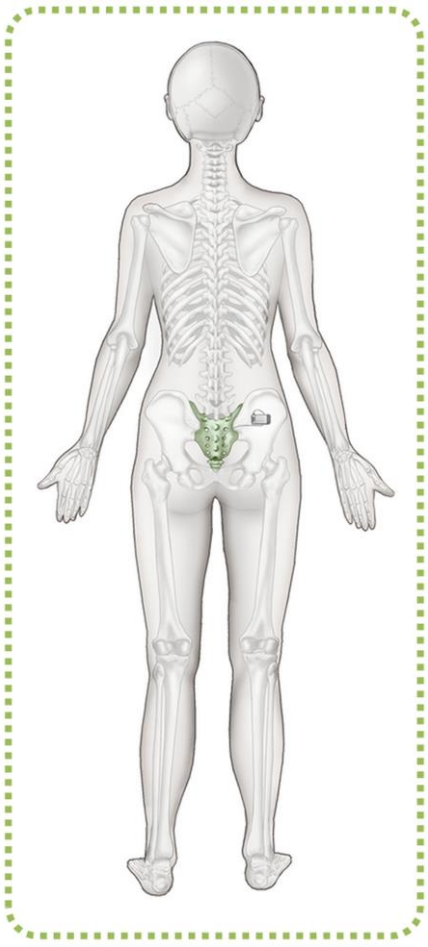
The MR Conditional requirements presented here may impact MR image quality. Other implanted devices or the health state of the patient may impose additional restrictions.

Note: The external components of Axonics SNM System are MR Unsafe, including the Clinician Programmer, Remote Control, Charger and Dock, and External Trial System (External Pulse Generator and percutaneous leads and cables). These devices must **NOT** be brought into the magnet room.

Note: The guidelines in this document are approved only in geographies where CE marking and approval are recognized.

1.1. For 1.5T and 3T Full Body MRI Examinations

A patient implanted with the Axonics SNM system may be safely scanned anywhere in the body at 1.5T or 3T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.

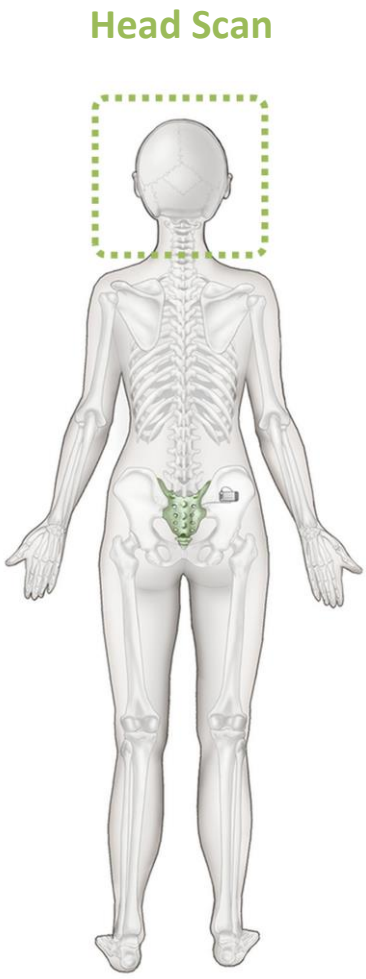


Parameter	Condition
MR Conditional	Yes
Eligible Axonics Devices	Neurostimulator (1101) Tined Lead (1201/2201)
Device Configuration	Stimulation OFF
Static Magnet Strength	1.5T and 3T
Type of Nuclei	Hydrogen/Proton Only
Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Gradient	2500 Gauss/cm (25 T/m)
Maximum Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole Body
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Scan Duration	Maximum 30 minutes of continuous scan time is allowed per session
Scan Regions	Whole Body
For 1.5T Scanner * ***follow either Maximum Whole Body SAR or B1+rms**	
Maximum Whole Body SAR	0.85 W/kg
Maximum B1+rms	3.0 µT
For 3T Scanner * ***follow either Maximum Whole Body SAR or B1+rms**	
Maximum Whole Body SAR	0.6 W/kg
Maximum B1+rms	1.0 µT

Note: Specific Axonics SNM system programming settings are required for safe MRI scanning. Please use Appendix A: Worksheet for Full Body MRI Scan and follow Section 4.1 for 1.5T and 3T full body MRI scanning.

1.2. For 1.5T and 3T Head MRI Examinations

A patient implanted with the Axonics SNM system may be safely scanned at the head with 1.5T or 3T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.



Parameter	Condition
MR Conditional	Yes
Eligible Axonics Devices	Neurostimulator (1101) Tined Lead (1201/2201)
Device Configuration	Stimulation OFF
Static Magnet Strength	1.5T and 3T
Type of Nuclei	Hydrogen/Proton Only
Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Gradient	2500 Gauss/cm (25 T/m)
Maximum Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Head
RF Receive Coil Type	Head
Operating Mode	Normal Operating Mode
Maximum Head SAR	3.2 W/kg
Scan Duration	There is no limit on scan duration
Scan Regions	Head Only

Note: Specific Axonics SNM system programming settings are required for safe MRI scanning. Please follow Section 4.2 for 1.5T and 3T head MRI scanning.

2. WARNINGS

Read and fully understand the guidelines before conducting an MRI scan – Do not conduct an MRI examination on a patient implanted with the Axonics SNM system until you read and fully understand all the information in these MRI guidelines. Failure to follow all warnings and guidelines related to MRI scan could result in serious and permanent injury.

Apply the required B1+rms or SAR limit in the Normal Operating Mode only – Do not conduct MRI scans in the First and Second Level Controlled Operating Modes as it may increase the risk of unintended stimulation and excessive heating.

Assess the neurostimulator implant location for Full Body MRI scan – Figure 1 shows the typical implant location and lead pathway inside a body. Neurostimulator pocket and lead insertion point could be ipsilaterally or contralaterally located. Neurostimulator should be implanted in either the left or right upper buttock area of a patient for considering full body MRI scan eligibility. Full Body MRI scans on a patient with a neurostimulator implanted in locations other than the posterior hip / upper buttock area are untested and may cause unintended stimulation, device damage, or excessive heating, which could result in pain or injury to the tissues surrounding the implants.

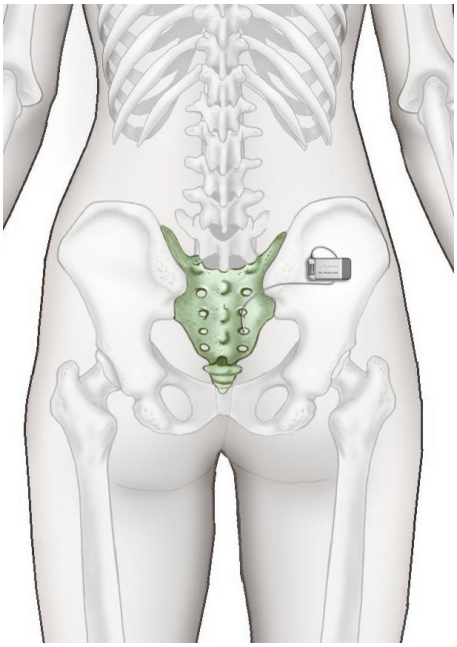


Figure 1: Axonics SNM System implant location eligible for full body MRI

Avoid exposure to unapproved MRI parameters – Non-clinical testing has shown that exposure of the Axonics SNM System to MRI at a B1+rms or SAR level more intense than those described in Section 1 of this manual could induce significant heating at the lead electrodes, device malfunction, and/or rectification. Excessive heating could result in injury or other damage to the sacral nerve and/or tissue surrounding the lead electrodes.

Avoid MR scan of off-label use of Axonics device – MRI safety has only been evaluated on the Axonics SNM System for sacral neuromodulation. Performing MRI on an Axonics SNM System that stimulates nerves other than the sacral nerve may cause serious and permanent injury.

Ensure appropriate supervision - A responsible individual with expert knowledge about MRI, such as an experienced MR technologist, MRI radiologist or MRI physicist, must ensure all procedures in these MRI guidelines are followed and that the MRI scan parameters comply with the recommended settings.

3. POTENTIAL RISKS OF MRI WITH THE AXONICS SNM SYSTEM

Some of the potential risks of performing MRI on a patient with an implanted Axonics SNM System include:

- Heating effects around the Axonics SNM System, especially the lead electrodes, from RF energy
- Unintended stimulation due to current induced through the SNM lead wire by the time-varying magnetic gradient field and/or RF field
- Static magnetic field interactions including magnetic force and torque
- Device malfunction or rectification due to current induced through the SNM lead wire by the time-varying magnetic gradient field and/or RF field
- Image artifacts

3.1. Heating Effects

MRI-related heating is primarily influenced by location of the patient in the MR system, implant (both neurostimulator and lead) location inside the body, lead trajectory, and integrity of the lead and neurostimulator. If the specified MRI conditions are not observed, heating at a lead electrode can be higher than the established safety threshold. This may lead to burn injury or other damage to the sacral nerve and/or surrounding structures, which may be associated with pain and discomfort.

3.2. Unintended Stimulation

Non-clinical testing suggests that gradient or RF induced current is small. If the MRI scan is performed under the conditions specified in Section 1, unintended stimulation to the surrounding tissue is unlikely. Risk of tissue damage due to current induced by the gradient or RF field is very low. If a patient suspects any unintended stimulation while in MRI, he/she should inform the MRI technician immediately and then contact their physician.

3.3. Interactions with the Static Magnetic Field

The Axonics SNM System may experience magnetic field interactions with the MRI system due to small amounts of material in the Neurostimulator being sensitive to magnetic fields. This may cause the Neurostimulator to shift or move slightly within the implant pocket and may place mechanical stress on tissues and the lead. Patients may feel a slight tugging sensation at the site of the Neurostimulator. If the patient experiences significant discomfort, he/she should inform the MRI technician immediately.

3.4. Device Malfunction or Damage

Device malfunction or damage is unlikely if MRI scans are performed following the guidelines described in this document. If device malfunction or damage were to occur, it could cause discomfort, unintended stimulation, painful stimulation, or direct current stimulation, which may result in nerve damage and other associated problems. If a patient suspects a malfunction, he/she should be instructed to exit the magnet room and use the patient Remote Control or Clinician programmer to stop the stimulation. The patient should then contact their physician for further evaluation.

3.5. Image Artifacts

There is minimal image artifact when the device is out of the field of view. Image artifacts can result from the presence of the device within the field of view. Careful choice of MRI sequence parameters and location of the imaging plane may minimize MR image artifacts.

Please note that the extent of image artifacts is dependent on multiple factors and the MRI technician is encouraged to use scan parameters that minimize the image artifacts. General principles for minimizing image artifacts may include:

- Using imaging sequences with stronger gradients for both slice and read encoding directions.
- Using higher bandwidth for both RF pulse and data sampling.
- Choosing an orientation for the read-out axis that minimizes the appearance of in-plane distortion.
- Using a shorter echo time for gradient echo sequences, whenever possible.
- Be aware that the actual imaging slice shape can be curved in space due to static magnetic field disturbances from the neurostimulator.

3.6. Other Precautions

3.6.1 Safety has not been assessed in patients with other implanted devices in addition to the Axonics SNM System.

3.6.2 MRI safety has not been evaluated under the following conditions: a broken lead, an intact tined lead without a neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, or a neurostimulator with open or low impedances (indicating a short circuit) on any electrodes.

3.6.3 Transverse Field MR systems have not been evaluated for scanning patients with the Axonics SNM System.

3.6.4 External components of the Axonics SNM System are MR **UNSAFE**. They should **NOT** be brought into the magnet room. Refer to MR Unsafe Device (Section 3.7) for details.

3.6.5 No testing at magnetic field strengths other than 1.5T and 3T have been performed to evaluate MRI safety of the device.

3.7. MR Unsafe Devices

The external components of Axonics SNM System are MR **UNSAFE**, including the Clinician Programmer, Remote Control, Charger and Dock, and External Trial System (External Pulse Generator and percutaneous leads and cables) (Figure 2). These devices must **NOT** be brought into the magnet room.

Clinician Programmer

Remote Control

Charger and Dock

External Pulse Generator, percutaneous leads and cables

Figure 2*:* MR **UNSAFE** Axonics Devices

4. MRI GUIDELINES

Recommendations for MRI scanning with the Axonics SNM System are based on phantom tests, numerical simulations, and the recommended implant configurations of the standard Axonics SNM Neurostimulator (Model 1101) and Tined Lead (Model 1201/2201).

4.1. Before Starting a Full Body Examination

4.1.1 Determine if the patient has other active medical device implants. Consult with the appropriate device manufacturers for MRI eligibility of those devices.

4.1.2 Verify the Axonics model number of the SNM Neurostimulator and Tined Lead.

4.1.3 Begin filling out **Appendix A: Worksheet for Full Body MRI Scan**:

4.1.3.1 Record basic information prior to MRI scan in **Table 1**.

4.1.3.2 Determine if the patient is eligible for full body MRI by completing **Table 2** and answering all questions listed.

4.1.3.3 Use the Axonics Clinician Programmer to communicate with the patient's neurostimulator and perform an impedance measurement. Press the "Ω" button on the Patient Device screen of the Clinician Programmer (indicated by an index finger in Figure 3) to determine the integrity of the patient's neurostimulator. For detailed instructions on the use of the Axonics' Clinician Programmer, refer to Axonics' Clinician Programmer Manual.

- If open or short circuits are detected, the "Ω" symbol next to that electrode will be red (highlighted with red circles in Figure 3), indicating that the integrity of the patient's SNM system is compromised. This patient is **NOT** eligible for MRI full body scan.
- If the Clinician Programmer cannot communicate with the device, MRI scan eligibility cannot be determined. This patient is **NOT** eligible for MRI full body scan.
- If no open or short circuits are detected, continue to the next step

4.1.3.4 Complete the "Before MRI scanning" column of **Table 3** using the information on the Patient Device screen. Record "Device ID", "Remote Control ID", "Patient ID", "Configuration", and other stimulation parameters and settings (highlighted in two black rectangles in Figure 3).

4.1.4 Turn the Axonics SNM Neurostimulator stimulation OFF with the patient Remote Control or Clinician Programmer.

4.1.5 Make sure the settings and parameters of the MRI system meet the conditions for full body scanning in Section 1.1.

Warning: Apply the required B1+rms or SAR limit in the Normal Operating Mode. Do **NOT** conduct MRI scanning in the First and Second Level Controlled Operating Modes, as this may increase the risk of unintended stimulation and excessive heating.

Figure 3: Patient Device information on the Clinician Programmer

4.2. Before Starting a Head Examination

4.2.1 Determine if the patient has other active medical device implants. Consult with the appropriate device manufacturers for MRI eligibility of those devices.

4.2.2 Verify the Axonics model number of the SNM Neurostimulator and Tined Lead.

4.2.3 Turn the Axonics SNM Neurostimulator stimulation OFF with the patient Remote Control or Clinician Programmer.

4.2.4 Make sure the settings and parameters of the MRI system used meet the conditions for head scanning in section 1.2.

4.3. During the Examination

4.3.1 Monitor the patient both visually and audibly. During the MRI examination, the patient may feel slight tugging and/or vibration of the neurostimulator. Discontinue the MRI examination immediately if the patient experiences significant discomfort or reports any problems.

4.4. After the Examination

4.4.1 Verify that the patient has not experienced any adverse effects as a result of the MRI. Contact Axonics Modulation Technologies Inc. if the patient has experienced any adverse effects.

4.4.2 Turn the Axonics SNM Neurostimulator stimulation back ON with the patient Remote Control or the Clinician Programmer.

4.4.2.1 For full body examinations, record the device settings in the "After MRI Scanning" column of **Table 3** in Appendix A. Make sure the patient's device has the same settings as prior to the MRI examination.

4.4.3 Verify that the patient has the same stimulation sensation as prior to the MRI scan. If a patient suspects any unexpected change in stimulation after an MRI, he/she should contact their physician and should turn the stimulation OFF if uncomfortable.

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Appendix A: Worksheet for Full Body MRI Scan

This form provides information about the patient's implanted SNM system and MRI scan eligibility. It should be completed by the implanting physician or a trained MRI technician to support the confirmation of full body MRI scan eligibility.

- Refer to www.axonicsmodulation.com/MRI for labeling and safety conditions

Table 1: Basic Information

Patient Name	
Physician Name	
Office Address	
Phone	
Date	

Table 2: Determination of Full Body MRI Eligibility (ALL QUESTIONS MUST BE ANSWERED)

	Questions	MRI Full Body Eligible	Not MRI Full Body Eligible
1.	Is the distal (deepest) end of lead implanted near one of the sacral nerves (S2, S3 or S4)?	Yes	No
2.	Is the Neurostimulator implanted in the posterior hip / upper buttock area? Verify by checking patient's records, asking the patient where on their body they charge the Neurostimulator, by X-ray, or palpation.	Yes	No
3.	Can the Clinician Programmer communicate with the Neurostimulator and verify the integrity of the Neurostimulator-lead system? On the "Patient Device" screen of the Clinician Programmer, all of the electrode impedances ("Ω" symbol) next to the electrodes shall appear normal (not red). Refer to 4.1.4 of this document or Axonics' Clinician Programmer manual for the operation of the Clinician Programmer.	Yes	No
4.	Did you confirm that the patient **DOES NOT HAVE** an abandoned lead (a broken lead or an intact lead that is not connected to Axonics Neurostimulator), a partially implanted lead, or a malfunctioning Neurostimulator in his/her body?	Yes	No
5.	Did you confirm that the patient **DOES NOT HAVE** an implanted device/part other than the Axonics SNM implant system?	Yes	No (contact the appropriate device manufacturers for MRI eligibility of those systems)
	Is the patient full body MRI eligible? (see next page)	Yes	No

- **If the answers to all 5 questions are Yes, the patient is eligible for MRI full body scan.**
- **If the answers to questions 1-4 are Yes, and No for question 5, please perform MRI with extra caution following the instructions below:**
    1. Prior to MRI scanning, determine whether the patient has multiple active medical device implants (such as stents, hip implants, deep brain stimulation systems, implantable cardiac defibrillators, and others). If the devices other than Axonics SNM Implant System are also MR Conditional, and there is at least 20 mm of separation from each other, the most restrictive MRI exposure requirements must be used. If you are unclear what implants are present or have concern about the separation among different implanted devices, X-ray imaging should be used. Consult with the appropriate device manufacturers with questions regarding those systems.
    2. If a patient has two Axonics SNM Systems implanted for bilateral sacral neuromodulation therapy and if the two systems have at least 20 mm of separation from each other, the patient is eligible for MRI full body scanning. If you have concerns about the separation of these two systems, X-ray imaging should be used.
- **If any of the answers to questions 1-4 are No, the patient is NOT eligible for MRI full body scan.**

Table 3: Device Information Before and After MRI Scanning

Items	Before MRI Scanning	After MRI Scanning
Device ID		
Remote Control ID		
Patient ID		
Configuration		
Baseline Amplitude		
Amplitude Range		
Frequency		
Pulse Width		
Cycling		
Ramp		

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