

MRI Guidelines for the Axonics Sacral Neuromodulation System

Instruction for Use

! USA Rx only



Note: Read this manual in its entirety before performing an MRI scan on patients who are implanted with the Axonics SNM System. This document contains information related to magnetic resonance imaging (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.

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GLOSSARY



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.

! USA – For USA audiences only.

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

MRI – Magnetic Resonance Imaging.

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 ~ 64 MHz. The RF used in the 3T MRI Scanner is ~128MHz.

Specific Absorption Rate (SAR) – radio frequency 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.

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

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

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

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1. MRI SAFETY INFORMATION



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 with the Axonics SNM System may be safely exposed to MRI environments that follow the guidelines described in this document.

Always obtain the latest MRI guidelines. Refer to the contact information on the last page of this manual, or go to www.axonics.com/hcp/axonics-system/mri-safety-compatibility

The MRI Guidelines provided here may prevent a clear view of body areas that are at close proximity to the implanted components. Other implanted devices or the health state of the patient may require reduction of MR conditions.

1.1. MR Conditional Devices



Figure 1: **MR CONDITIONAL** Axonics Devices

Non-clinical testing has demonstrated that the Axonics SNM System implant, i.e. the Neurostimulator (Model 1101) and Tined Lead (Model 1201/2201), is **MR Conditional**. A patient with this device can be safely scanned in an MR system meeting the following conditions:

1.1.1 For 1.5T Full Body MRI Examinations

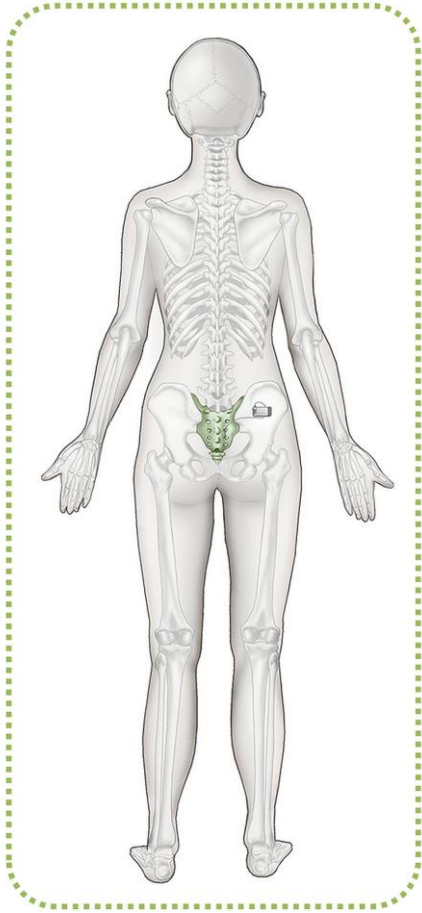
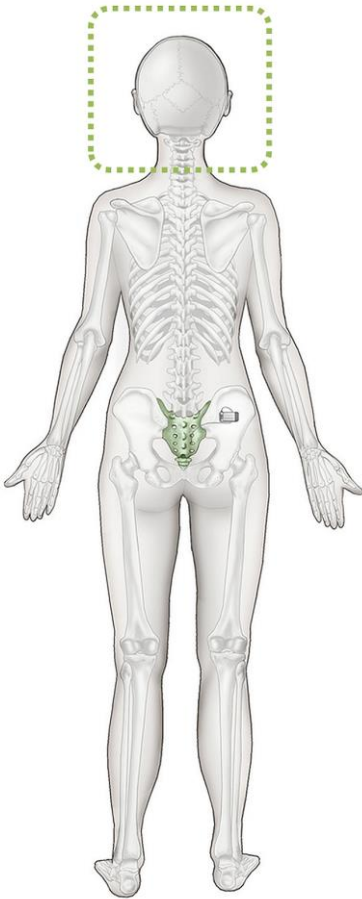
- Static magnetic field of 1.5T
- Maximum spatial field gradient of 2,500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Maximum MR system reported, head average SAR of 3.2 W/kg (Normal Operating Mode)
- Any landmark is acceptable
- B₀ field in horizontal orientation
- Cylindrical scanner type only
- Hydrogen/proton imaging only
- Maximum gradient slew rate per axis of 200 T/m/s
- RF excitation of circularly polarized (CP mode)
- RF transmit coil: full body transmit coil (integrated transmit coil) or detachable head transmit/receive coil
- RF receive coil: any receive only coil
- Maximum 30 minutes of continuous scan time is allowed per session
- Device must be configured into “Stimulation OFF” mode

1.1.2 For 3T Head MRI Examinations

- Static magnetic field of 3T
- Maximum spatial field gradient of 2,500 gauss/cm (25 T/m)
- Maximum MR system reported, head average SAR of 3.2 W/kg (Normal Operating Mode)
- Head scan only
- B₀ field in horizontal orientation
- Cylindrical scanner type only
- Hydrogen/proton imaging only
- Maximum gradient slew rate per axis of 200 T/m/s
- RF excitation of circularly polarized (CP mode)
- RF coil type: detachable RF head transmit/receive coil
- There is no limit on scan duration
- Device must be configured into “Stimulation OFF” mode

In non-clinical testing, the maximum image artifact caused by the device extends approximately 5 mm from the Tined lead (Model 1201/2201) when imaged with spin echo pulse sequence and gradient echo pulse sequence, and up to 96 mm from the boundary of Neurostimulator (Model 1101) when imaged with gradient echo pulse sequence in a 1.5T MRI system.

Allowable scan regions for 1.5T and 3T are different and must be followed strictly for a safe MRI examination.

Allowable scan regions for 1.5T	Allowable scan regions for 3T
<p data-bbox="380 474 626 510">Full Body Scan</p> 	<p data-bbox="1032 474 1211 510">Head Scan</p> 

1.2. MR Unsafe Devices

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



Figure 2: MR Unsafe Axonics Devices

2. WARNINGS

Apply the required 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. This MRI Guideline document applies to hydrogen/proton imaging only.

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

Assess neurostimulator implant location for MRI Full Body scan – Figure 3 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 MRI Full Body scan eligibility. MRI Full Body 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.

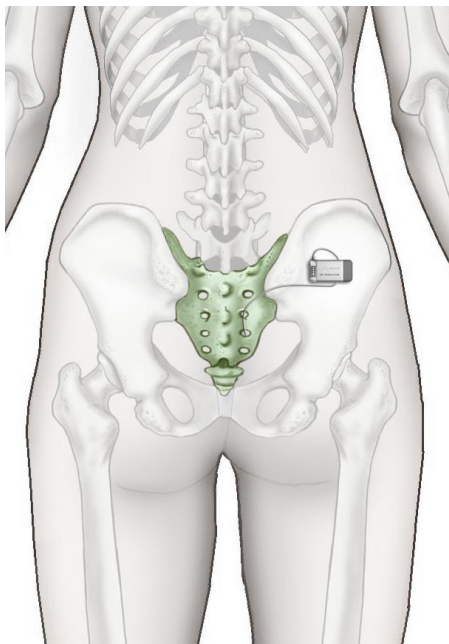


Figure 3: Axonics SNM System implant location eligible for full body MRI

Avoid exposure to unapproved MRI parameters – Non-clinical testing has shown that exposure of the Axonics SNM System to MRI at a 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 this guideline are followed and that the MRI scan parameters comply with the recommended settings.

3. POTENTIAL RISKS OF MRI WITH THE AXONICS SNM SYSTEM

The potential risks of performing MRI on a patient with an implanted Axonics SNM System that were considered in testing and analysis by the manufacturer include:

- Heating effects around the Axonics SNM System, especially the lead electrodes, from radio-frequency (RF) energy
- Unintended stimulation due to current induced through the SNM lead wire by the time-varying magnetic gradient field and/or RF field
- Image distortion and artifacts
- 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

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 specific MRI conditions are not met, heating at a lead electrode could 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 induced or combined field induced current is small. If 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 combined 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. Image Distortion and Artifacts

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

No artifacts or distortion of the brain imaging should be seen when imaging with an RF head coil.

Please note that the extent of image artifact 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 distortion may include:

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients for both slice and read encoding directions. Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of in-plane distortion.
- Use a shorter echo time for gradient echo technique, whenever possible.

- Be aware that the actual imaging slice shape can be curved in space due to field disturbances from the neurostimulator.
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator.

3.4. Interactions with the Static Magnetic Field

The Axonics SNM System may experience magnetic field interactions from 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/or may place mechanical stress on tissues and/or the lead. Patients may feel a slight tugging sensation at the site of the Neurostimulator.

3.5. 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 stimulation. The patient should then contact their physician for further evaluation.

3.6. Other Precautions

- 3.6.1 Safety has not been demonstrated 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 Open MRI scanners have not been evaluated for scanning patients with the Axonics SNM System.
- 3.6.4 External components of the Axonics SNM System were not evaluated for MRI safety and therefore determined to be **MR Unsafe**. They should **NOT** be brought into magnet room. Refer to MR Unsafe Devices (Section 1.2) for details.
- 3.6.5 No testing at magnetic field strengths other than 1.5 T have been performed to evaluate full body MRI safety of the device.

4. MRI GUIDELINES

Recommendations for MRI scan with the Axonics SNM System are based on phantom tests, numerical simulations, and with the recommended implant configurations of the standard Axonics SNM Neurostimulator and Tined Lead. The guidelines below assume that no other implant devices are implanted in the patient's body. Refer to Appendix A of this document for when there is other implant device in the body.

4.1. Before Starting MRI Body Scan

- 4.1.1 Record basic information prior to MRI scan in Table 1 of Appendix A “Worksheet for MRI full body scan eligibility”.
- 4.1.2 Verify Axonics model number of the SNM Neurostimulator and Tined lead.
- 4.1.3 Complete Table 2 of Appendix A to check whether the patient with implant is eligible for full body MRI scan.
- 4.1.4 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 4) 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.
 - 4.1.4.1 If no open or short circuits are detected, the patient is eligible for MRI body scan.
 - 4.1.4.2 If open or short circuits are detected, the “Ω” symbol next to that electrode will be red (highlighted with a red circle in Figure 4), indicating that the integrity of the patient's SNM system is compromised. This patient is **NOT** eligible for MRI full body scan.
 - 4.1.4.3 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.
- 4.1.5 Complete the “Before MRI scan” column of Table 3 in Appendix A 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 4).
- 4.1.6 Turn the Axonics SNM Neurostimulator stimulation off with the patient Remote Control or Clinician Programmer.
- 4.1.7 Make sure the settings and parameters of the MRI system meet the conditions for body scan in Section 1.1.1.

Warning: Do **NOT** conduct MRI scans in the First and Second Level Controlled Operating Modes for either SAR or gradients, as this may increase the risk of unintended stimulation and excessive heating.

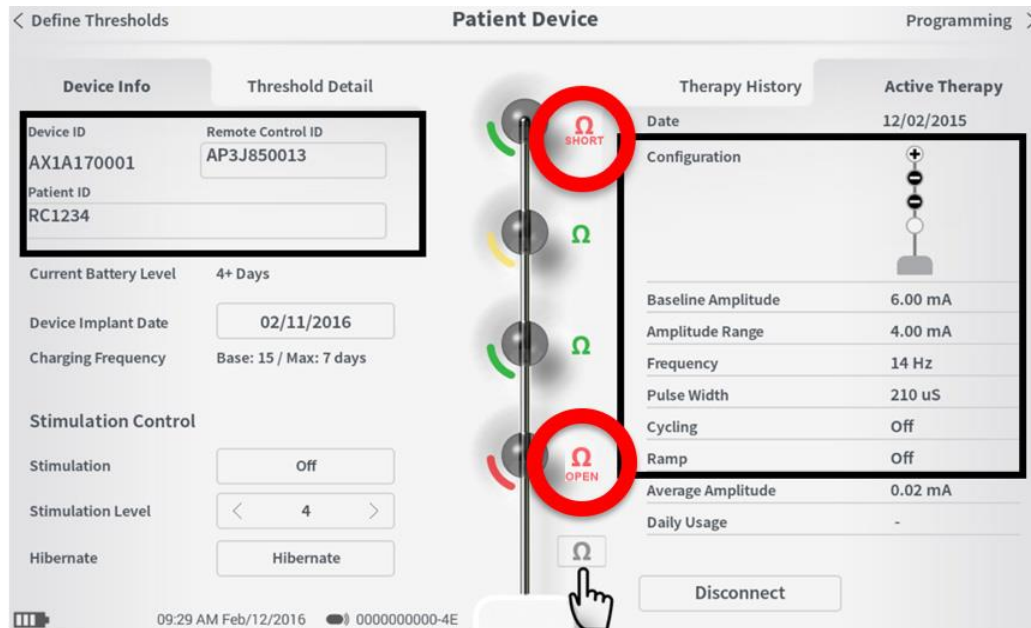


Figure 4: "Patient Device" information on the Clinician Programmer

4.2. Before Starting MRI Head Scan

- 4.2.1 Verify Axonics model number of the SNM Neurostimulator and Tined lead.
- 4.2.2 Turn the Axonics SNM Neurostimulator stimulation off with the patient Remote Control or Clinician Programmer.
- 4.2.3 Make sure the settings and parameters of the MRI system used meet the conditions for head scan in Section 1.1.2.

4.3. During the MRI Scan

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

4.4. After the MRI Scan

- 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. Make sure the patient's device has the same settings as prior to the MRI, and verify the patient has the same 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.
- 4.4.3 Record the device settings in the "After MRI scan" column of Table 3 in Appendix A and make sure all the information listed remains the same as before the MRI scan.

Appendix A: Worksheet for MRI Full Body Scan Eligibility

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 radiologist to support the confirmation of full body MRI scan eligibility.

- Refer to www.axonics.com/hcp/axonics-system/mri-safety-compatibility for labeling and safety conditions

Table 1: Basic Information

Patient Name	
Physician Name	
Office Address	
Phone	
Date	

Table 2: Patient Implant Configuration Information (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 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 malfunctioned 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 this patient full body MRI eligible? (see next page)	Yes or No (Circle one)	

- If the answers to all 5 questions are Yes, the patient is eligible for full body MRI.
- 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 scan, determine whether the patient has multiple 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 MRI compatible, and all parts are at least 20 mm away from the Axonics Implant System and 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 to confirm they are at least 20 mm apart. Consult with the appropriate device manufacturers with questions regarding those implants.
 2. If a patient has two Axonics SNM Systems implanted for bilateral sacral neuromodulation therapy and if all parts of the two systems are at least 20 mm away from each other, the patient is eligible for MRI Full Body scans. If you have concerns about the separation of these two systems, x-ray imaging should be used to confirm the separation.
- If any of the answers to questions 1-4 are No, the patient is NOT eligible for full body MRI.

Table 3: Device Information Before and After MRI Scan

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

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Axonics Modulation Technologies, Inc.
Irvine, CA 92618 (USA)
www.axonics.com
Tel. +1-877-9AXONICS (+1-877-929-6642)
Fax +1-949 396-6321

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