

MRI Patient Guidelines

For patients with the Axonics SNM system

! USA R_x only



Note: 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.

MRI – Magnetic Resonance Imaging.

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1. WHAT IS MAGNETIC RESONANCE IMAGING (MRI)?

Magnetic resonance imaging (MRI) is a technique that is used for creating pictures of the internal structures of the body. Unlike an x-ray exam, it does not use radiation. Instead, it uses a large magnet, radio waves, and a computer to create pictures of body structures and organs.

2. CAN I HAVE AN MRI?

Patients with an implanted Axonics Sacral Neuromodulation (SNM) System may have a head or body MRI scan under certain conditions. Consult with your doctor to determine if you are eligible for MRI examination.

You are required to discuss with your doctor if you have any other device(s) implanted. Possible implanted devices include:

- Pacemaker or implantable cardioverter-defibrillator (ICD)
- Some aneurysm clips
- Cochlear implants
- Orthopedic prostheses (e.g. hip implant)
- Other neurostimulators
- Stents
- Metal plates, pins, or screws
- Dental implants

An MRI requires the patient to lie still during the exam. You should inform the MRI technologist before the MRI procedure:

- If you are pregnant or suspect you are pregnant
- If you are breast feeding at the time of the scheduled procedure
- If you are having a fever

3. MRI SAFETY INFORMATION

The Axonics SNM System is an **MR Conditional** device. This means that patients with the Axonics SNM System can safely have MRI examinations of the head or body under certain conditions. The conditions for MRI scans of the head are different than those for the full body.

Always obtain the latest MRI guidelines. Refer to the contact information on the last page of this manual, or go to www.axonics.com/patients/resources-patients/resources

3.1. MR Conditional Devices

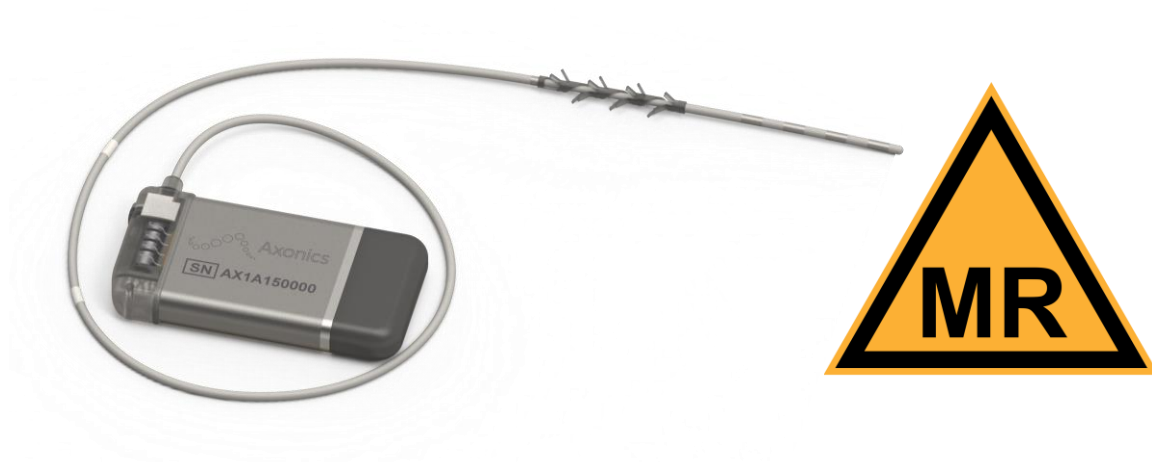


Figure 1: **MR CONDITIONAL** Axonics Devices

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:

3.1.1. For 1.5T Full Body MRI Examinations

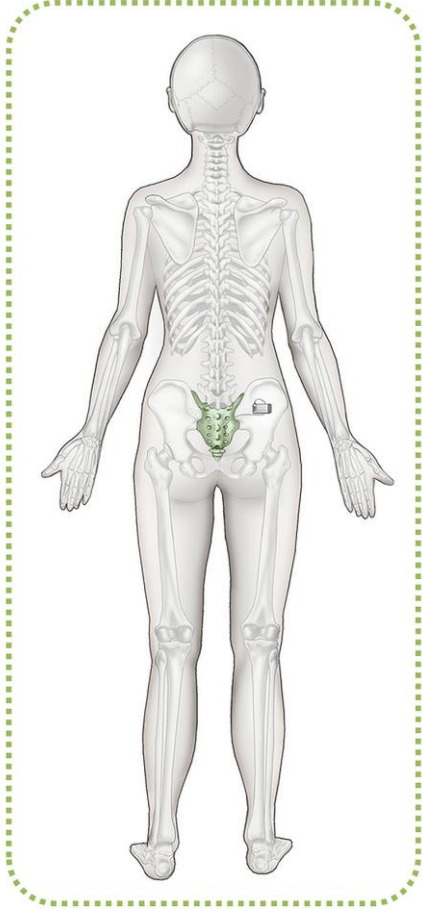
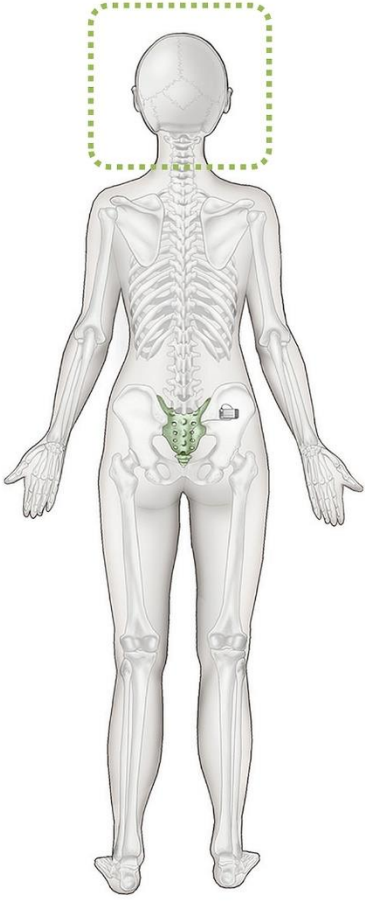
- Static magnetic field of 1.5T
- Maximum spatial field gradient of 2,500 gauss/cm (25 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)
- Maximum MR system reported, head average SAR of 3.2 W/kg (Normal Operating Mode)
- Any landmark 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

3.1.2. 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="380 537 626 573">Full Body Scan</p> 	<p data-bbox="1032 537 1211 573">Head Scan</p> 

Please consult with your Healthcare Provider (HCP) and the MRI technologist to make sure that the specific conditions above are met before MRI examination.

3.2. MR Unsafe Devices

The external components of the 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** (Figure 1). These devices must **NOT** be brought into the magnet room.



Figure 2: **MR Unsafe** Axonics Devices

4. POSSIBLE RISKS OF MRI WITH THE AXONICS SNM SYSTEM

Non-clinical testing has shown that patients with the Axonics SNM System can safely have MRI when the conditions for safe MRI described in this document are followed. However, there may be some risks of performing MRI when you have an implanted SNM System. Possible risks include:

- Heating of the implant
- Unintended stimulation
- Image distortion and artifacts
- Magnetic field interactions
- Device malfunction or damage

4.1. Heating of the Implant

MRI may cause the implant to become hot. However, if the conditions for safe MRI are followed, this heating is minimal. If the specific MRI conditions are not followed, heating of the implant could damage the sacral nerve and/or surrounding structures. If the site of your implant feels hot during MRI, inform the MRI technologist immediately and then contact your doctor.

4.2. Unintended Stimulation

MRI may cause unintended stimulation from the implant. This unintended stimulation may be uncomfortable (e.g. tingling, shocking, or jolting). However, if the conditions for safe MRI are followed, such stimulations may not happen. If you feel any stimulations during MRI, inform the MRI technologist immediately and then contact your doctor.

4.3. Image Distortion and Artifacts

Some level of image distortion and artifacts can result from an MRI scan at the site of the device. The MRI technologist will select MRI settings that minimize these effects. However, there should be minimal image distortion when taking MR images of areas away from the device. No image distortion or artifacts should be seen from an MRI head scan.

4.4. Magnetic Field Interactions

The magnets used in MRI may cause the Neurostimulator to shift or move slightly within the implant pocket. This may cause stress to tissues and/or the lead. As a result, you may feel a slight tugging sensation at the site of your implant. If you feel uncomfortable while in the MRI, inform the MRI technologist immediately.

4.5. Device Malfunction or Damage

Tests in various MRI systems were conducted. These tests did not cause any damage to, or malfunction of, the implant. If the implant malfunctions or becomes damaged, it may result in nerve damage and other associated problems. If you feel any stimulation or discomfort during MRI, inform the MRI technologist immediately and then contact your doctor.

5. MRI GUIDELINES

The guidelines for MRI head and body scans are based on non-clinical tests conducted on the implantable Axonics SNM System. Precautions are to be taken before, during, and after MRI scan. Talk to your MRI technologist or your doctor should you have any questions or concerns.

5.1. Before Starting MRI Scan

- Consult your doctor and MRI technologist to determine if you are eligible for MRI head or body scan:
- Inform your doctor and MRI technologist if you have multiple Axonics SNM devices or any other medical device(s) implanted, such as a pacemaker, drug pump, hip prosthesis, stent, etc.
- Inform your doctor and MRI technologist if you think you have any the following conditions with your device: a broken lead, lead disconnection from the neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, a neurostimulator implanted at an area other than posterior hip or upper buttock, or a neurostimulator with open or low impedances (indicating a short circuit) on any electrodes. Do not perform MRI body scan if any of these conditions apply.
- Bring the most up-to-date patient ID card to all MRI appointments.
- Your MRI technologist may also give you MRI Patient Guides and Instructions. Make sure that you fully comply with those. Discuss with your MRI technologist or your doctor if you have any concerns.
- **Make sure that the Neurostimulator stimulation is turned OFF.** Refer to your Remote Control Manual on how to turn your stimulation off. Alternatively, your doctor or company representative can also turn your stimulation off using the Clinician Programmer.
- Make sure you remove any external metallic objects before entering the MRI room.
- Do not carry any external devices associated with the Axonics SNM system, such as the Remote Control, Charger and Dock etc., into the MR Scanner room.

5.2. During MRI Scan

- You may feel slight tugging, vibration, warming, and/or tapping in the area where the Neurostimulator is located during the MRI scan. If those feelings cause discomfort, you should let the MRI technologist know immediately.
- If you are not feeling well for any other reasons prior to or at the time of MRI scanning, please inform your MRI technologist.

5.3. After MRI Scan

- If you had an MRI head scan, turn the stimulation back on with the Remote Control. Refer to your Remote Control Manual on how to turn your stimulation back on.
- If you had an MRI body scan, your doctor or company representative can also turn the stimulation back on using the Clinician Programmer. They will make sure that the stimulation settings used prior to MRI scan are restored in your device.
- If you feel any changes in stimulation after an MRI, you should contact your doctor and turn the stimulation off if uncomfortable.

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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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