MRI Guidelines for the
Axonics Sacral Neuromodulation System

Instruction for Use

Rx only
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.

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GLOSSARY

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.

MRI Transmit/Receive RF Head coil – a coil used to transmit and to receive RF energy that is constrained to the head region.

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) – 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.

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 specified in this document.

Always obtain the latest MRI guidelines. It is important to fully read this 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

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

Note: The guidelines in this document are approved only in Canada and Australia.
1.1. For 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.

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

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 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 patients with an implanted Axonics SNM System include:

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

3.1. Heating Effects

Modeling and simulations show that with the RF transmit head coil, heating of the Axonics SNM System is minimal. If the specific MRI conditions are not met (e.g., RF body coil is used) heating at a lead electrode could damage the sacral nerve and/or surrounding structures. MRI-related heating is primarily influenced by location of the patient in the MR system and by lead configuration and length.

3.2. Unintended Stimulation

Non-clinical testing suggests that gradient or RF induced current is small so that unintended stimulation to the surrounding tissue is unlikely. Risk of tissue damage due to current induced by the gradient or RF field is extremely 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. Static Magnetic Field Interactions

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

Tests in various MRI systems have not shown damage to, or malfunction of, the Axonics SNM System. If device malfunction or damage were to occur, it could cause discomfort, unintended stimulation, difficulty in operation, and other associated problems. If a patient suspects any changes to the device performance after MRI, he/she should be instructed to use the patient Remote Control to stop stimulation and contact their physician for further evaluation.
3.5. Image Artifacts

No artifacts or distortion of the brain imaging should be seen when imaging with a RF Head Coil.

3.6. Other Precautions

- Prior to MRI scanning, determine whether the patient has other medical device implants, such as:
  - deep brain stimulation systems (DBS)
  - vague nerve stimulation systems (VNS)
  - cochlear implants
  - dental implants
  - stents
  - and others

  If the devices other than the Axonics SNM System are also MR Conditional, the most restrictive MRI exposure requirements must be used. If you are unclear what implants are present, X-ray imaging should be used. Consult with the appropriate device manufacturers with questions regarding those systems.

- Do not use the transmit RF body coil for 1.5T or 3T imaging.

- Not all head RF coils are transmit and receive type. The use of RF transmit coil other than the head coil is prohibited.

- Transverse Field MR systems have not been evaluated and should not be used for scanning SNM patients.

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

- No testing at magnetic field strengths other than 1.5T and 3T have been performed to MRI safety of the device.
3.7. MR Unsafe Devices

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

![Clinician Programmer](image1.png)

![Remote Control](image2.png)

![Charger and Dock](image3.png)

![External Trial Stimulator, percutaneous leads and cables](image4.png)

Figure 1. MR UNSAFE Axonics Devices
4. MRI GUIDELINES

Recommendations for head MRI with the Axonics SNM System are based on phantom tests and numerical simulations, and the recommended implant configurations of the standard Axonics SNM Neurostimulator (Model 1101) and 30-cm Tined Lead (Model 1201/2201).

4.1. Before Starting the Head MRI 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. Turn the Axonics SNM Neurostimulator stimulation OFF with the patient Remote Control or Clinician Programmer.

4.1.4. Make sure the settings and parameters of the MRI system used meet the conditions for MRI scanning stated in Section 1.1.

4.2. During the Head MRI Examination

4.2.1. 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.

4.3. After the Head MRI Examination

4.3.1. 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.

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

4.3.3. 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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