

MRI Patient Guidelines

For patients with the Axonics SNM System



For use in Europe



Instruction for Use



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

 **CE Marking of Conformity**

MRI – Magnetic Resonance Imaging.

 **MR Conditional** – an item with demonstrated safety in the MR environment within defined conditions.

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

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

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?

The Axonics Sacral Neuromodulation (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. Consult with your doctor and MRI technologist to determine if you are eligible for MRI examination.

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

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

You are also required to discuss with your doctor and MRI technologist if you have or suspect you have any of the following issues with your implant:

- broken lead
- lead disconnection from the neurostimulator
- malfunctioning neurostimulator
- neurostimulator implanted at an area other than posterior hip or upper buttock
- irregular stimulation

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. MR CONDITIONAL DEVICE



MR Conditional

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 body under certain conditions. The conditions for MRI scanning of the head are different than those for the whole body.

Consult with your MRI technologist prior to the MRI exam. They will make sure the specific conditions for either head or body MRI scanning are met. Make sure to read the entire document and follow the procedures in Section 5.

Always obtain the latest MRI guidelines. Refer to the contact information on the last page of these MRI guidelines, or go to www.axonics.com/patients/mri

Note: The external components of the Axonics SNM System are **MR UNSAFE**, including the Clinician Programmer, Remote Control, 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 geographies where CE marking and approval are recognized.

4. POSSIBLE RISKS OF MRI WITH THE AXONICS SNM SYSTEM

Patients with the Axonics SNM System can safely have an MRI exam when the conditions for safe MRI specified in this document are followed. However, there may be some risks from having an MRI exam with the implanted SNM System. Possible risks include:

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

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 should not happen. If you feel any stimulation during MRI, inform the MRI technologist immediately and then contact your doctor.

4.3. Magnetic Field Interactions

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

4.4. Device Malfunction or Damage

Device malfunction or damage refers to changes in stimulation, difficulty in operation, and other device-related problems that occur after the MRI scan. If the conditions for safe MRI are followed, device malfunction or damage should not happen. If you feel any changes to the device performance after MRI, inform the MRI technologist immediately and then contact your doctor.

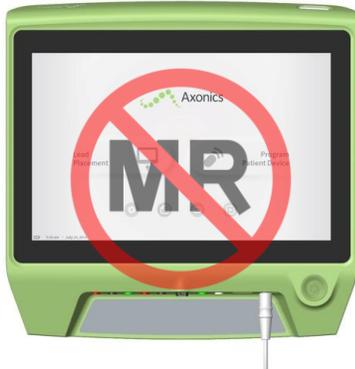
4.5. Image Artifacts

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

4.6. MR UNSAFE DEVICES

The external components of the Axonics SNM System are **MR UNSAFE**, including the Clinician Programmer, Remote Control, Charger and Dock, and External Trial System (External Trial Stimulator and percutaneous leads and cables) (Figure 1). These devices must **NOT** be brought into the magnet room.

**Clinician Programmer
(Model 1501/2501)**



**Remote Control
(Model 1301/2301)**



**Charger and Dock
(Model 1401)**



**External Pulse Generator (Model 1601),
percutaneous leads and cable
(Model 1901, 9009, 9014)**



Figure 1. **MR UNSAFE** Axonics Devices

5. MRI GUIDELINES

The guidelines for head and whole body MRI exams are specific for the implantable Axonics SNM System. Precautions are to be taken before, during, and after the MRI exam. Talk to your MRI technologist or your doctor should you have any questions or concerns.

5.1. Before Starting an MRI Exam

- Consult your doctor and MRI technologist to determine if you are eligible for a head or whole-body MRI exam (Refer to Section 2):
- 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 your neurostimulator and/or lead have any issues. Do not have a body MRI exam if there are issues with your implant.
- Inform your MRI technologist if you are pregnant, suspect you are pregnant, breastfeeding, or having a fever.
- Your MRI technologist may also give you additional MRI Patient Guides and Instructions. Make sure that you fully understand and comply with those instructions. Discuss with your MRI technologist or your doctor if you have any concerns.
- Bring the most up-to-date patient ID card to all MRI appointments.
- Bring your patient Remote Control to all MRI appointments.
- For MRI head scans, make sure that the Neurostimulator stimulation is turned OFF. Refer to your Remote Control Manual on how to turn the stimulation off.
- For MRI body scans, check the device to confirm it is ready for MRI body scan with the following steps:

5.1.1. Push “Connect” on the patient Remote Control to connect to Neurostimulator.

Note: The Stimulation Level lights will show the current stimulation amplitude.



5.1.2. Turn stimulation OFF by pressing and releasing the down arrow until all Stimulation Level lights are off.

Note: Check that the Stimulator Battery Status light is green prior to the MRI scan. If the Stimulator Battery Status light is flashing orange or is solid orange, charge the Neurostimulator so the battery light is green prior to the MRI scan. Refer to the Charging System manual for charging instructions.

Note: If the red System Error light is on and solid (not flashing), the system needs to be checked prior to an MRI scan.



5.1.3. To check MRI readiness, press and hold the down arrow for 5 seconds.

Note: The Active Program lights will flash back and forth, indicating MRI readiness check is in progress. It is normal for a sensitive patient to experience mild stimulation during the check. Once the check is complete, the patient Remote Control will vibrate.

- a. If Stimulation Level lights #3, 4, and 5 are ON, the SNM device is ready for whole-body MRI.
- b. If the System Error light is red, the SNM device is NOT eligible for whole-body MRI.



a. device is ready for MRI



b. device is not ready for MRI

- Make sure you remove any external metallic objects before entering the magnet room.
- Do not carry any external devices associated with the Axonics SNM system, such as the Remote Control, Charger and Dock, etc. into the magnet room.

5.2. During the MRI Exam

- You may feel slight tugging, vibration, warming, and/or tapping in the area where the Neurostimulator is located during the MRI exam. If those feelings cause discomfort, you should let the MRI technologist know immediately. See Section 4 for more details on the risks of MRI with the Axonics SNM System.
- If you are not feeling well for any other reasons prior to or at the time of the MRI exam, please inform your MRI technologist.

5.3. After the MRI Exam

- Turn the stimulation back on with the Remote Control. Refer to your Remote Control Manual on how to turn the stimulation back on.
- 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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