

MRI Patient Guidelines

For patients with the Axonics SNM Systems



For use in Canada



Instruction for Use

Note: This document contains information related to magnetic resonance imaging (MRI) use with the Axonics SNM Systems. 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 Systems.

Table of Contents

GLOSSARY	3
1. WHAT IS MAGNETIC RESONANCE IMAGING (MRI)?	4
2. CAN I HAVE AN MRI?	4
3. MRI SAFETY INFORMATION	5
3.1. MR Conditional Devices	5
3.2. MR Unsafe Devices	6
4. POSSIBLE RISKS OF MRI WITH THE AXONICS SNM SYSTEM	7
4.1. Heating of the Implant	7
4.2. Unintended Stimulation	7
4.3. Magnetic Field Interactions	7
4.4. Device Malfunction or Damage	7
4.5. Image Artifacts	7
5. MRI GUIDELINES	8
5.1. Before Starting an MRI Exam	8
5.2. During the MRI Exam	10
5.3. After the MRI Exam	10

GLOSSARY

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?

Patients with an implanted Axonics Sacral Neuromodulation (SNM) System may have an MRI scan of any body part under certain conditions. Consult with your doctor 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 or 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. MRI SAFETY INFORMATION

The Axonics SNM Systems are **MR Conditional**. This means that patients with the Axonics SNM System can safely have MRI examinations of any body part under certain conditions. The conditions for MRI scans will vary with the type of transmit coil.

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/mri

3.1. MR Conditional Devices

- Axonics R15, Neurostimulator Model 1101 with Tined Lead Model 1201/2201
- Axonics F15, Neurostimulator Model 4101 with Tined Lead Model 1201/2201
- Axonics R20, Neurostimulator Model 5101 with Tined Lead Model 1201/2201

Non-clinical testing has demonstrated that the Axonics SNM System implants, i.e. the Neurostimulator (Models 1101, 4101, and 5101) and Tined Lead (Model 1201/2201), are **MR Conditional**.

3.2. 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 MR scanner 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

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 implant malfunctions or becomes damaged, it may result in nerve damage and other associated problems. 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 or extremity MRI scan.

5. MRI GUIDELINES

The guidelines for MRI exams are based on non-clinical tests conducted on the implantable Axonics SNM Systems. 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 MRI exam (Refer to Section 2).
- Your MRI technologist may also give you MRI Patient Guides and Instructions. Make sure that you fully 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. Do not bring the patient Remote Control into the MR scanner room.
- For MRI using detachable head, upper extremity, or lower extremity RF transmit/receive volume coils, make sure that the Neurostimulator stimulation is turned OFF. Refer to your Remote Control Manual on how to turn the stimulation off.
- For MRI using whole-body RF transmit coil, check the device to confirm it is ready for MRI scan with the following steps:

Note: If you have a patient Remote Control manufactured before May 1, 2020, whole-body MRI readiness check will need to be performed by the doctor or MRI technologist using the Clinician Programmer.

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

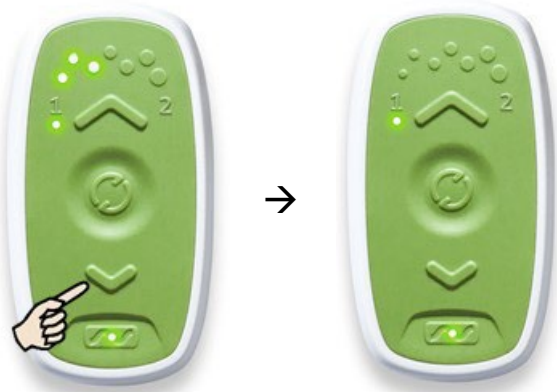
Note: The Stimulation Level lights will show the current stimulation amplitude.



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

Note: The Stimulator Battery Status light should be green to be eligible for whole-body MRI. For Neurostimulator 1101/5101 only, 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.

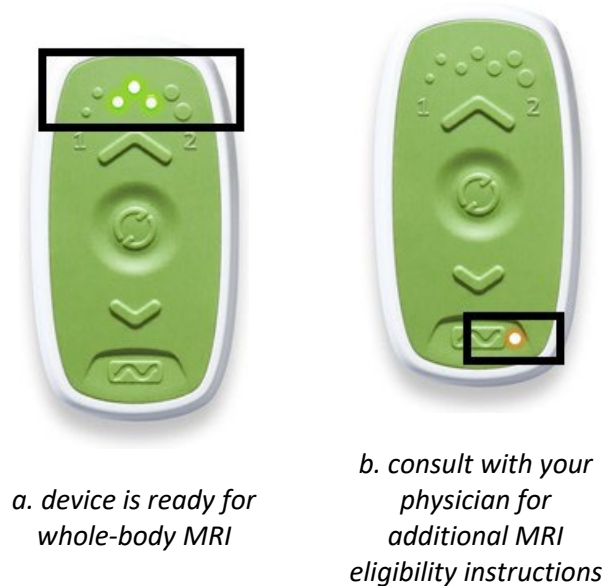
Note: If the red System Error light is on and solid (not flashing), the system needs to be checked prior to an MRI scan.



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 System is ready for whole-body MRI.
- b. If the System Error light is red, consult with your physician for additional MRI eligibility instructions



- Make sure you remove any external metallic objects before entering the MR scanner 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 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.
- 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.

This page intentionally left blank



Axonics, Inc.

Irvine, CA 92618 (USA)

www.axonics.com

Tel. +1-877-9AXONICS (+1-877-929-6642)

Fax +1-949 396-6321

All Rights Reserved. Copyright 2024.

Axonics, Inc.

110-0093-201rA