MRI Patient Guidelines

For patients with the Axonics SNM Systems

For use in the United States

MR

Instruction for Use

! USA ℞ only

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.

GLOSSARY

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

ACR Zone – zones of an MR site that denote areas with various MR safety levels, as defined by the American College of Radiology

MRI – Magnetic Resonance Imaging.

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

Table of Contents

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 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 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**. Patients with these devices can be safely scanned in an MR system meeting the following conditions:

3.1.1. For MRI Examinations Using a Whole-Body RF Transmit Coil

A patient implanted with the Axonics SNM System may be safely scanned at any body part, including head and extremities, at 1.5T or 3T MRI using a whole-body RF transmit coil under the following conditions. Failure to follow these conditions may result in injury to the patient.

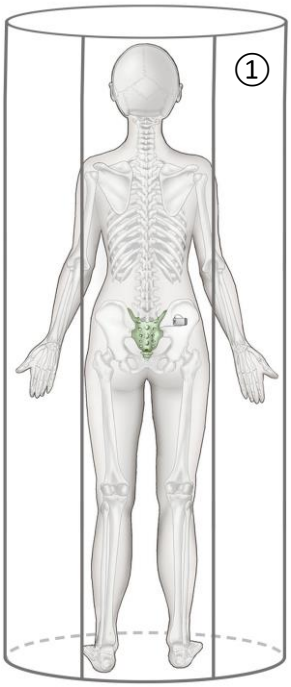

Figure 3-1: MRI scan using ① whole-body RF transmit coil. Any body part may be scanned and any RF receive coil may be used with a whole-body RF transmit coil.

Parameter	Condition	
MR Conditional	Yes	
Eligible Axonics Devices	Neurostimulator (1101, 4101, 5101) Tined Lead (1201/2201)	
Device Configuration	Device must pass MR readiness check (see Section 5.1), Stimulation OFF, and Specified implant locations only	
Static Magnetic Field Strength (B_0)	1.5T and 3T	
Type of Nuclei	Hydrogen/Proton Only	
MR Scanner Type	Cylindrical	
B_0 Field Orientation	Horizontal	
Maximum Spatial Field Gradient	2500 gauss/cm (25 T/m)	
Maximum Slew Rate	200 T/m/s per axis	
RF Transmit Coil Type	Whole-Body	
RF Receive Coil Type	Any type (e.g., surface array coil, head receive only coil, knee receive only coil)	
Operating Mode	Normal Operating Mode	
RF Conditions	**Neurostimulator 1101, 5101**	**Neurostimulator 4101**
	For 1.5T Scanner: Whole-body SAR ≤ 2 W/kg RF Excitation: Circularly Polarized (CP)	**For 1.5T Scanner**: Whole-body SAR ≤ 2 W/kg RF Excitation: Circularly Polarized (CP)
	For 3T Scanner: B1+rms ≤ 2 µT; for MRI scanners that do not report B1+rms, limit Whole-body SAR ≤ 1.6 W/kg RF Excitation: Circularly Polarized (CP) or Multichannel-2 (MC-2)	**For 3T Scanner**: B1+rms ≤ 1.7 µT; for MRI scanners that do not report B1+rms, limit Whole-body SAR ≤ 1.2 W/kg RF Excitation: Circularly Polarized (CP) or Multichannel-2 (MC-2)
Scan Duration and Wait Time	Maximum 30 minutes of continuous scan time is allowed, followed by a wait time of 5 minutes if this limit is reached.	
Scan Regions	Any body part is acceptable (e.g., head, extremities, stomach, pelvic region)	
Image Artifact	The presence of the Axonics SNM System may produce an image artifact. Some manipulation of scan parameters may be required to compensate for the artifact.	

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

3.1.2. For MRI Examinations Using a Detachable Head, Upper Extremity, or Lower Extremity RF Transmit/Receive Volume Coil

A patient implanted with the Axonics SNM System may be safely scanned at the head or upper/lower extremity at 1.5T or 3T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.

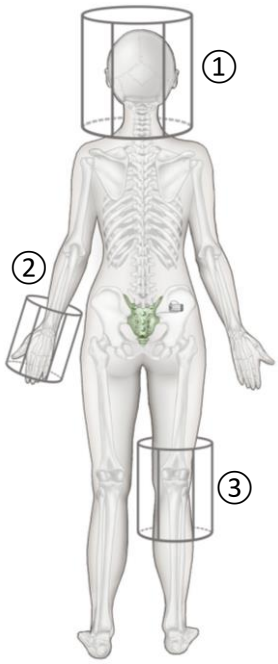

Figure 3-2: MRI scan* using detachable ① head, ② upper extremity, or ③ lower extremity RF transmit/receive volume coil.

Parameter	Condition
MR Conditional	Yes
Eligible Axonics Devices	Neurostimulator (1101, 4101, 5101) Tined Lead (1201/2201)
Device Configuration	Stimulation OFF
Static Magnetic Field Strength (B_0)	1.5T and 3T
Type of Nuclei	Hydrogen/Proton Only
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	2500 gauss/cm (25 T/m)
Maximum Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Coil Type	– Detachable Head RF Transmit/Receive Volume Coil – Detachable Upper Extremity RF Transmit/Receive Volume Coil – Detachable Lower Extremity RF Transmit/Receive Volume Coil
Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode
Scan Duration	There is no limit on scan duration
Scan Regions	Head, Upper or Lower Extremity
Image Artifact	No image artifact should be seen from a head or extremity MRI scan.

*Illustrated in Figure 3-2 are typical use scenarios of detachable RF transmit/receive volume coil. Other scanning scenarios are also permissible according to MR scanner/coil manuals. For example, an MRI scan of the ankle with a detachable lower extremity RF transmit/receive volume coil or an MRI scan of the upper arm with a detachable lower extremity RF transmit/receive volume coil in the superman posture is permissible given the aforementioned scan conditions are met.

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 3-3). These devices must **NOT** be brought into the MR scanner room (ACR Zone IV).

Clinician Programmer (Model 1501/2501)

Remote Control (Model 1301/2301)

Charger and Doc (Model 1401)

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

Figure 3-3: **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 uncomfortable 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 and extremity scans.

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 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 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 fragment, 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 system with open or low impedances (indicating a short circuit) on any electrodes. Consult with your physician for MRI eligibility if any of these conditions apply.
- 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.
- 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 your stimulation off.
- For MRI using whole-body RF transmit coil, check the device to confirm it is ready for MRI body scan with the following steps:

  Note: If you have a patient Remote Control manufactured before May 1st, 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 scan. 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.

a. device is ready for whole-body MRI

b. consult with your physician for additional MRI eligibility instructions

- 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 or 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

- After the MRI 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 feel any changes in stimulation after an MRI, you should contact your doctor and turn the stimulation off, if uncomfortable.

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