MRI Guidelines

Axonics Sacral Neuromodulation Systems

For use in the United States

MR

Instruction for Use

! USA ℞ only

Note: Read this manual in its entirety before performing an MRI scan on patients who are implanted with the Axonics SNM System. 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 Zones –zones of an MR site that denote areas with various levels of magnetic field exposure, as defined by the American College of Radiology.

B1+rms (root-mean-squared, μT) – the root-mean-squared value of the MRI effective component of the RF magnetic (B1) field or, in other words, the time-averaged RF magnetic field component relevant for creating an MR image that is generated by the MR system during a scan. In 2010, the International Electrotechnical Commission (IEC) recommended that all MR systems manufactured going forward must display B1+rms. Therefore, B1+rms value may only be available on MR scanners acquired after 2013 or an older MR scanner with software updated.

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.

Detachable Extremity RF Transmit/Receive Volume Coil – a coil used to transmit/receive RF energy for upper and lower extremities.

Detachable Head RF Transmit/Receive Volume Coil – a coil used to transmit/receive RF energy at the head region.

Hertz (Hz) – a unit of frequency defined as cycles per second. One Megahertz (MHz) is one million cycles per second.

MRI – Magnetic Resonance Imaging.

Multichannel-2 (MC-2) mode – an RF transmit mode typically used for high field MR scanners (3T or higher) to improve b1+ field homogeneity.

Radio Frequency (RF) – high frequency electromagnetic fields whose frequencies are in the range of 10,000 Hz and above. The RF used in the 1.5T MR scanner is ~ 64 MHz. The RF used in the 3T MR scanner is ~128MHz.

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.

Whole-Body RF Transmit Coil – a coil used to transmit and to receive RF energy that encompasses the entire body region within the MR scanner bore.

W/kg – Watts per kilogram, a measure of the RF power that is absorbed per kilogram of tissue.

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1. MRI SAFETY INFORMATION

The Axonics Sacral Neuromodulation (SNM) Systems are, per the definition in ASTM F2503-20, **MR Conditional**. In-vitro tests and simulations have shown that patients with the Axonics SNM System may be safely exposed to MRI environments that follow the guidelines described in this document.

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

Other implanted devices or the health state of the patient may require additional restrictions on MRI conditions.

1.1. 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:

1.1.1 For MRI Examinations Using a Whole-Body RF Transmit Coil

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

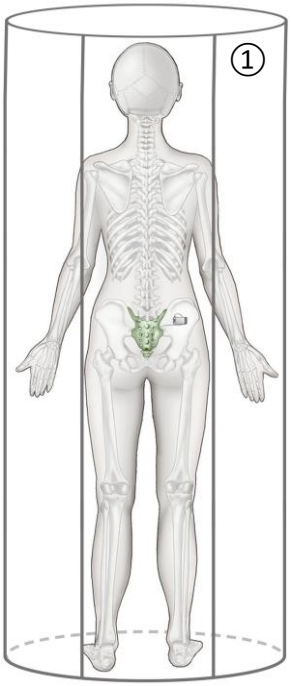


Figure 1-1: MRI scan using ① whole-body RF transmit coil. Any body part may be scanned, and any RF receive coil may be used with a whole-body RF transmit coil.

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 4.1), 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.	

Note: Specific Axonics SNM System programming settings are required for safe whole-body MRI scanning. Please use Appendix A: Worksheet for MRI Scan Eligibility Using Whole-Body RF Transmit Coil and follow Section 4.1 Before Starting MRI Using a Whole-Body RF Transmit Coil.

1.1.2 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 extremity at 1.5T or 3T MRI using a detachable head, upper extremity, or lower extremity RF transmit/receive volume coil under the following conditions. Failure to follow these conditions may result in injury to the patient.

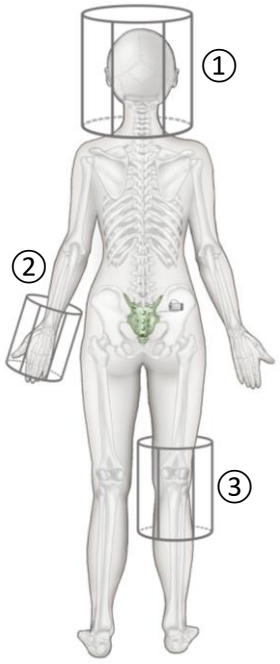


Figure 1-2: MRI scan* using detachable ① head, ② upper extremity, or ③ lower extremity RF transmit/ receive volume coil.

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 1-2 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.

Note: Please follow Section 4.2 Before Starting MRI Using a Detachable Head, Upper Extremity, or Lower Extremity RF Transmit/Receive Volume Coil.

1.2. MR Unsafe Devices

The external components of 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**. 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 Dock (Model 1401)

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

Figure 1-3: **MR Unsafe** Axonics Devices

2. WARNINGS

When a Whole-Body RF Transmit Coil is used for MRI examinations, apply the required B1+rms or the SAR limits in the Normal Operating Mode only – Do not conduct MRI scans in the First or the Second Level Controlled Operating Mode as it may increase the risk of unintended stimulation and excessive heating for whole-body scans. This MRI Guideline document applies to hydrogen/proton imaging/spectroscopy only.

When a detachable Head or Extremity RF Transmit/Receive Volume Coil is used for MRI examinations – Do not conduct MRI scans in the Second Level Controlled Operating Mode as it may increase the risk of unintended stimulation and excessive heating.

Read and fully understand the guidelines before conducting an MRI scan – Do not conduct an MRI examination on a patient with implanted Axonics device until you have read and fully understand all the information in this Guideline. Failure to follow all warnings and guidelines related to MRI scanning could result in serious and permanent injury.

Assess neurostimulator implant location prior to an MRI scan using a Whole-Body RF Transmit Coil – Figure 2-1 shows the typical implant location and lead pathway inside a body. The neurostimulator pocket and lead insertion point could be ipsilaterally or contralaterally located. The neurostimulator should be implanted in either the left or right upper buttock area of a patient for MRI scan eligibility using a Whole-Body RF Transmit Coil. MRI Whole-Body scans on a patient with a neurostimulator implanted in locations other than the posterior hip / upper buttock area are untested and may cause unintended stimulation, device damage, or excessive heating, which could result in pain or injury to the tissues surrounding the implants.

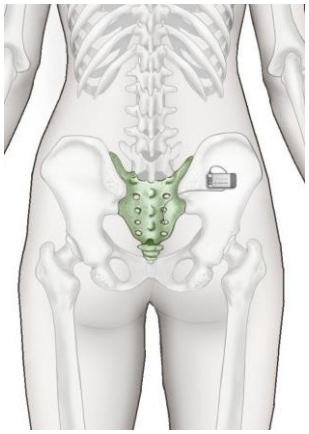


Figure 2-1: Axonics SNM System implant location eligible for MRI scan with Whole-Body RF transmit coil (Neurostimulator 1101 is shown as an example)

Avoid exposure to unapproved MRI conditions – Non-clinical testing has shown that exposure of the Axonics SNM System to MRI at a SAR or B1+rms level above the limits stated in Section 1 of this manual could induce significant heating at the lead electrodes, device malfunction, and/or unintended stimulation. Excessive heating could result in injury or other damage to the sacral nerve and/or tissue surrounding the lead electrodes.

Avoid off-label MR scanning 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 required procedures and conditions in this guideline are followed.

3. POTENTIAL RISKS OF MRI WITH THE AXONICS SNM SYSTEM

The potential risks of performing MRI on a patient with an implanted Axonics SNM System that were considered in testing and analysis by the manufacturer include:

- Heating effects around the Axonics SNM System, especially the lead electrodes, from radio-frequency (RF) energy
- Unintended stimulation due to current induced through the SNM lead wire by the switched gradient magnetic field and/or RF field
- Image distortion and artifacts
- Magnetic field interactions including magnetic force and torque
- Device malfunction or rectification due to current induced through the SNM lead wire by the switched gradient magnetic field and/or RF field

3.1. Heating Effects

MRI-related heating is primarily influenced by location of the patient in the MR scanner, implant (both neurostimulator and lead) location inside the body, lead trajectory, and integrity of the lead and neurostimulator. If the specific MRI conditions are not met, heating at a lead electrode could be higher than the established safety threshold. This may lead to burn injury or other damage to the sacral nerve and/or surrounding structures, which may be associated with pain and discomfort.

3.2. Unintended Stimulation

Non-clinical testing suggests that gradient induced or RF induced current is small. If MRI scan is performed under the conditions specified in Section 1, unintended stimulation to the surrounding tissue is unlikely. Risk of tissue damage due to current induced by the switched gradient magnetic field or RF field is very low. It might be possible for a sensitive patient to experience mild stimulation during the scan. If a patient experiences any uncomfortable stimulation while in MRI, he/she should inform the MRI technologist immediately and then contact their physician.

3.3. Image Distortion and Artifacts

There is minimal image distortion when the device is out of the field of view. Significant image distortion can result from the presence of the device within the field of view. Careful choice of pulse sequence parameters and location of the imaging plane may minimize MR image artifacts.

Please note that the extent of image artifact is dependent on multiple factors and the MRI technologist is encouraged to use scan parameters that minimize the image artifacts. General principles for minimizing image distortion may include:

- Avoid using the body receive coil if possible. Use a local receive-only coil instead.
- Use imaging sequences with stronger gradients for both slice and read encoding directions. Use higher bandwidth for both radio-frequency pulse and data sampling.
- Choose an orientation for the read-out axis that minimizes the appearance of in-plane distortion.
- Use a shorter echo time for gradient echo technique, whenever possible.

- Be aware that the actual imaging slice shape can be curved in space due to field disturbances from the neurostimulator.
- Identify the location of the implant in the patient, and when possible, orient all imaging slices away from the implanted neurostimulator.

3.4. Interactions with the Static Magnetic Field (B0)

The Axonics SNM System may experience magnetic field interactions from the MR scanner 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/or may place mechanical stress on tissues and/or the lead. Patients may feel a slight tugging sensation at the site of the Neurostimulator.

3.5. Device Malfunction or Damage

Device malfunction or damage is highly unlikely if MRI scans are performed following the guidelines described in this document. If device malfunction or damage were to occur, it could cause discomfort, unintended stimulation, painful stimulation, or direct current stimulation which may result in nerve damage and other associated problems. If a patient suspects a malfunction, he/she should be instructed to exit the MR scanner room (ACR Zone IV). The patient should then immediately contact their physician for further evaluation.

3.6. Other Precautions

3.6.1 For patients with other implanted devices in addition to the Axonics SNM System, consult the appropriate device manufacturers for MRI eligibility of those devices.

3.6.2 MRI safety has not been evaluated under the following conditions: an intact tined lead without a neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, or a neurostimulator with low impedances on any electrodes. If a patient has an abandoned lead fragment, the patient is eligible for only 1.5T MRI scanning under the MRI conditions stated in Sections 1.1.1 and 1.1.2.

3.6.3 Transverse Field MR Systems (Open MR scanners) have not been evaluated for scanning patients with the Axonics SNM System.

3.6.4 External components of the Axonics SNM System were not evaluated for MRI safety and therefore are considered **MR Unsafe**. They should **NOT** be brought into the MR Scanner room (ACR Zone IV). Refer to Section 1.2 MR Unsafe Devices for details.

3.6.5 No testing at magnetic field strengths other than 1.5T and 3T have been performed to evaluate MRI safety of the devices.

4. MRI GUIDELINES

Recommendations for MRI scanning with the Axonics SNM System are based on phantom tests, numerical simulations, and the recommended implant configurations of the Axonics Neurostimulator and Tined Lead. The guidelines below assume that no other implant devices are implanted in the patient's body. Refer to Appendix A of this document if a patient has multiple implanted devices.

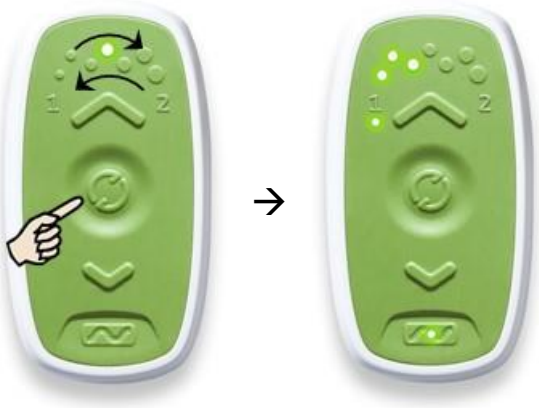
4.1. Before Starting MRI Using a Whole-Body RF Transmit Coil

- Confirm whole-body MRI eligibility by using Appendix A: Worksheet for MRI Scan Eligibility Using Whole-Body RF Transmit Coil.
- Using the patient Remote Control, check the device for MRI readiness by following the steps below (do not bring the patient Remote Control into the MR scanner room):

  Note: If a patient does not have their patient Remote Control at the appointment or has a patient Remote Control manufactured before May 1st, 2020, the Clinician Programmer must be used instead. Refer to Clinician Programmer manual for detailed instructions.

4.1.1. Push "Connect" on the patient Remote Control to connect to Neurostimulator.

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



4.1.2. 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. 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.

4.1.3. 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, see additional MRI eligibility instructions (Appendix A).

a. device is ready for whole-body MRI

b. see additional MRI eligibility instructions

- Make sure the settings and parameters of the MR scanner used meet all the conditions for Whole-Body RF transmit coil scanning listed in Section 1.1.1.

Warning: Do **NOT** conduct MRI scans using a Whole-Body RF transmit coil in the First or the Second Level Controlled Operating Modes for either SAR or gradients, as this may increase the risk of unintended stimulation and excessive heating.

4.2. Before Starting MRI Using a Detachable Head, Upper Extremity, or Lower Extremity RF Transmit/Receive Volume Coil

- Determine if the patient has other medical device implants. Consult with the appropriate device manufacturers for MRI eligibility of those devices.
- Turn the Axonics SNM Neurostimulator stimulation off with the patient Remote Control. Do not bring the patient Remote Control into the MR scanner room.
- Make sure the settings and parameters of the MR scanner meet all the conditions for head, upper extremity, or lower extremity scanning listed in Section 1.1.2.
- It is critical to ensure that the detachable head, upper extremity, or lower extremity RF transmit/receive volume coil is properly plugged in and selected for exclusive use by the MR scanner.

4.3. During the MRI Scan

- Monitor the patient both visually and audibly. Discontinue the MRI examination immediately if the patient reports any problems.
- During the MRI scan, the patient may feel slight tugging and/or vibration of the neurostimulator. If the tugging or vibration causes the patient significant discomfort, stop the MRI scan.

4.4. After the MRI Scan

- Verify that the patient has not experienced any adverse effects as a result of the MRI. Contact Axonics, Inc. if the patient has experienced any adverse effects.
- Turn the Axonics Neurostimulator stimulation back on with the patient Remote Control. 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.

Appendix A: Worksheet for MRI Scan Eligibility Using Whole-Body RF Transmit Coil

This form provides information about the patient's implanted SNM system and MRI scan eligibility using a whole-body RF transmit coil. It should be completed by the implanting physician or a trained radiologist to support the confirmation of whole-body MRI scan eligibility.

- Refer to www.axonics.com/hcp/mri for labeling and safety conditions.

Table 1: Basic Information

Patient Name	
Physician Name	
Office Address	
Phone	
Date	

Table 2: Patient Implant Configuration Information (ALL QUESTIONS MUST BE ANSWERED)

	Questions	Whole-Body MRI Eligible	Not Whole-Body MRI Eligible
1.	Is the device implanted to provide sacral neuromodulation therapy?	☐ Yes	☐ No
2.	Is the Neurostimulator implanted in the posterior hip / upper buttock area? Verify by checking patient's records, asking the patient where on their body they charge the Neurostimulator, by X-ray, or palpation.	☐ Yes	☐ No
3.	Can you verify whole-body MRI eligibility with MRI readiness check? See Section 4.1.	☐ Yes	☐ No (see additional MRI eligibility instructions)
4.	Did you confirm that the patient does not have an implanted device/part other than the Axonics SNM System?	☐ Yes	☐ No (contact the appropriate device manufacturers for MRI eligibility of those systems)
	Is this patient whole-body MRI eligible? (see next page)	☐ Yes	☐ No

- If the answers to all 4 questions are “Yes”, the patient is eligible for whole-body MRI. Follow the MRI conditions stated in Section 1.1.1.
- If the answer to either question 1 or 2 are “No”, the patient is NOT eligible for whole-body MRI.
- If the answer to question 3 is “No”, additional MRI eligibility instructions are provided here:

  Whole-body MRI scan is eligible for some specific cases, including if the patient has a high impedance reading or an abandoned lead fragment (in the case that the lead cannot be removed entirely, an abandoned lead fragment may be left in the body).

  1. For a patient with Neurostimulator 1101, if high impedance (open) is reported, please follow the MRI conditions below:

     - For a whole-body scan, use 1.5T only with B1+rms ≤ 2.8 μT; if B1+rms is not reported, then limit wbSAR ≤ 1.0 W/kg.
     - Maximum of 30 min of continuous scan time is allowed, followed by a wait time of 5 min if this limit is reached.
     - Follow all other MRI conditions stated in Section 1.1.1.

  2. If the patient has an abandoned lead fragment, please follow the MRI conditions below:

     - For MRI scans using 1.5T RF Whole-body coil at Normal Operating Mode of whole-body SAR ≤ 2 W/kg.
     - Maximum of 30 min of continuous scan time is allowed, followed by a wait time of 5 min if this limit is reached.
     - Follow all other MRI conditions stated in Section 1.1.1.

  3. For other cases (e.g., an intact lead that is not connected to Axonics Neurostimulator, a partially implanted lead, or a malfunctioning Neurostimulator), the patient is NOT eligible for whole-body MRI.

- If the answer to question 4 is “No”, please perform MRI with extra caution following the instructions below:

  1. Prior to MRI scan, determine whether the patient has multiple implants (such as stents, hip implants, deep brain stimulation systems, implantable cardiac defibrillators, or other implants). If the devices other than Axonics SNM Implant System are also MRI conditional, and all parts are at least 20 mm away from the Axonics Implant System and each other, the most restrictive MRI exposure requirements must be used for each condition. If you are unclear what implants are present or have concern about the separation among different implanted devices, X-ray imaging should be used to confirm they are at least 20 mm apart. Consult with the appropriate device manufacturers with questions regarding those implants.

  2. If a patient has two Axonics SNM Systems implanted for bilateral sacral neuromodulation therapy and if all parts of the two systems are at least 20 mm away from each other, the patient is eligible for MRI Whole-Body scans. If you have concerns about the separation of these two systems, X-ray imaging should be used to confirm the separation.

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