MRI Guidelines

Axonics Sacral Neuromodulation System

For use in Europe

MR

Instruction for Use

℞ only

CE 2797

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

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 2013, the International Electrotechnical Commission (IEC) mandated 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.

CE 2797 – CE Marking of Conformity

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.

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

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) – RF 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 F2503-20, 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 described in this document.

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/hcp/mri

The MR Conditional requirements presented here may impact MR image quality. Other implanted devices or the health state of the patient may impose additional restrictions.

The conditions for MRI scans of the head of patients with the Axonics SNM System are different than those for the full body.

Note: The guidelines in this document are approved only in geographies where CE marking and approval are recognized.

1.1. MR Conditional Devices

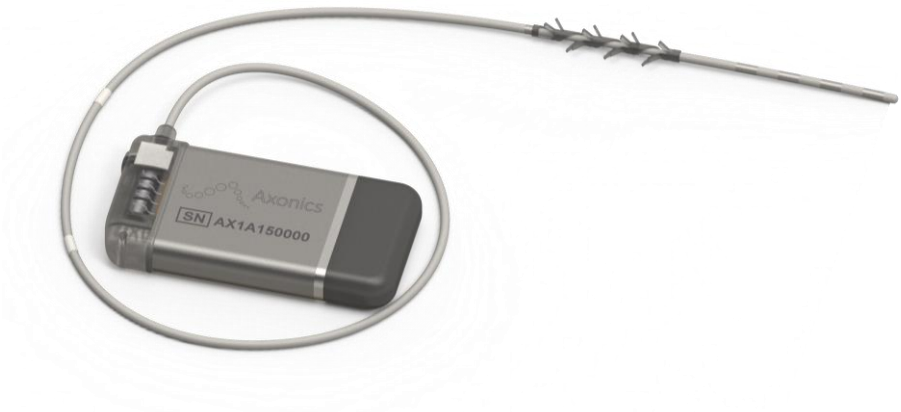
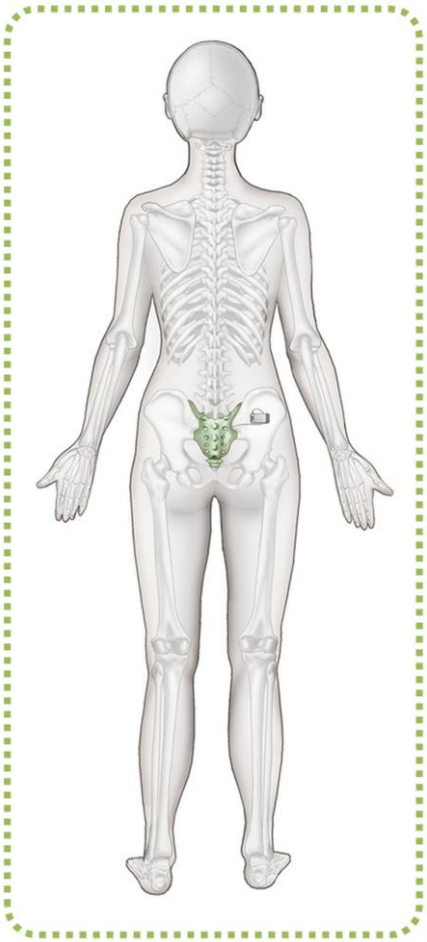


Figure 1: **MR CONDITIONAL** Axonics Devices

Non-clinical testing has demonstrated that the Axonics SNM System implant, i.e. the Neurostimulator (Model 1101) and Tined Lead (Model 1201/2201), is **MR Conditional**. A patient with this device can be safely scanned in an MR system meeting the following conditions:

1.1.1. For 1.5T and 3T Whole Body MRI Examinations

A patient implanted with the Axonics SNM system may be safely scanned anywhere in the body at 1.5T or 3T MRI under the following conditions. Failure to follow these conditions may result in injury to the patient.

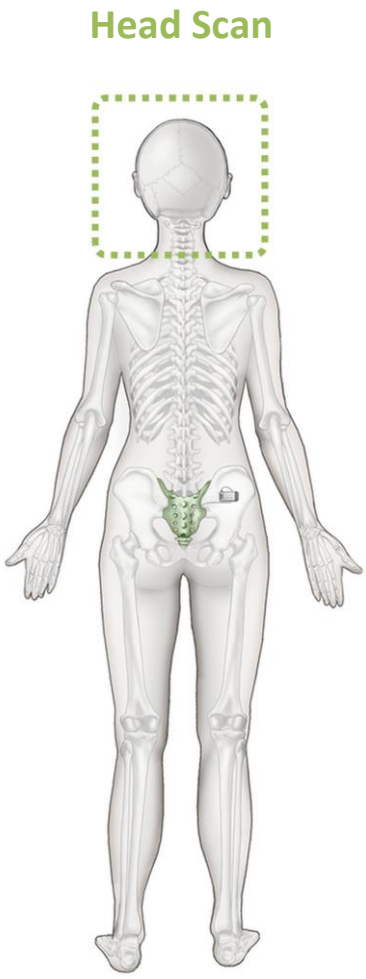


Parameter	Condition
MR Conditional	Yes
Eligible Axonics Devices	Neurostimulator (1101) Tined Lead (1201/2201)
Device Configuration	Device must pass MR readiness check (see section 4.1) and Stimulation OFF
Static Magnet Strength	1.5T and 3T
Type of Nuclei	Hydrogen/Proton Only
Scanner Type	Cylindrical
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 Transmit Coil Type	Whole Body
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode
Scan Duration	Maximum 30 minutes of continuous scan time is allowed per session
Scan Regions	Any landmark is acceptable
For 1.5T Scanner * ***follow either Maximum Whole Body SAR or B1+rms**	
Maximum Whole Body SAR	0.85 W/kg
Maximum B1+rms	3.0 µT
For 3T Scanner * ***follow either Maximum Whole Body SAR or B1+rms**	
Maximum Whole Body SAR	0.6 W/kg
Maximum B1+rms	1.0 µT

Note: Specific Axonics SNM system programming settings are required for safe MRI scanning. Please use Appendix A: Worksheet for MRI Whole Body Scan Eligibility and follow Section 4.1 for 1.5T and 3T full body MRI scanning.

1.1.2. For 1.5T and 3T 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.



Parameter	Condition
MR Conditional	Yes
Eligible Axonics Devices	Neurostimulator (1101) Tined Lead (1201/2201)
Device Configuration	Stimulation OFF
Static Magnet Strength	1.5T and 3T
Type of Nuclei	Hydrogen/Proton Only
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 Transmit Coil Type	Head
RF Receive Coil Type	Head
Operating Mode	Normal Operating Mode
Maximum Head SAR	3.2 W/kg
Scan Duration	There is no limit on scan duration
Scan Regions	Head Only

Note: Specific Axonics SNM system programming settings are required for safe MRI scanning. Please follow Section 4.2 for 1.5T and 3T head MRI scanning.

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** (Figure 2). 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 2*:* **MR UNSAFE** Axonics Devices

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 B1+rms or 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. This MRI Guideline document applies to hydrogen/proton imaging/spectroscopy only.

Assess the neurostimulator implant location prior to MRI Whole Body scan – Figure 1 shows the typical implant location and lead pathway inside a body. Neurostimulator pocket and lead insertion point could be ipsilaterally or contralaterally located. Neurostimulator should be implanted in either the left or right upper buttock area of a patient for MRI Whole Body scan eligibility. 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.

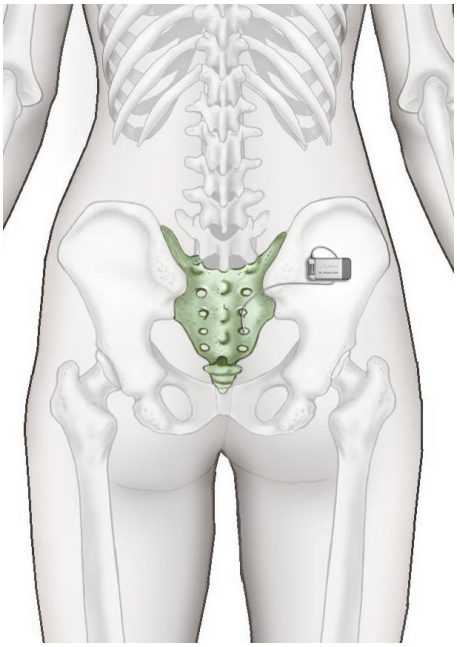


Figure 3: Axonics SNM System implant location eligible for full body MRI

Avoid exposure to unapproved MRI conditions – Non-clinical testing has shown that exposure of the Axonics SNM System to MRI at a B1+rms or SAR level above 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 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 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 time-varying magnetic gradient field and/or RF field
- Static magnetic field interactions including magnetic force and torque
- Device malfunction or rectification due to current induced through the SNM lead wire by the time-varying magnetic gradient field and/or RF field

3.1. Heating Effects

MRI-related heating is primarily influenced by location of the patient in the MR system, implant (both neurostimulator and lead) location inside the body, lead trajectory, and integrity of the lead and neurostimulator. If the specified MRI conditions are not met, heating at a lead electrode can 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 or RF induced current is small. If the 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 gradient or RF field is very low. It might be possible for a sensitive patient to experience mild stimulation during the scan. 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. Interactions with the Static Magnetic Field

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.

3.4. 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 magnet room. The patient should then immediately contact their physician for further evaluation.

3.5. Image 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 MRI sequence parameters and location of the imaging plane may minimize MR image artifacts.

No artifacts or distortion of the brain imaging should be seen when imaging with an RF head coil.

Please note that the extent of image artifacts 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.

3.6. 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: a broken lead, an intact tined lead without a neurostimulator, a partially implanted lead, a malfunctioning neurostimulator, or a neurostimulator with open or low impedances (indicating a short circuit) on any electrodes.

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 magnet room. Refer to MR Unsafe Device (Section 1.2) 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 device.

4. MRI GUIDELINES

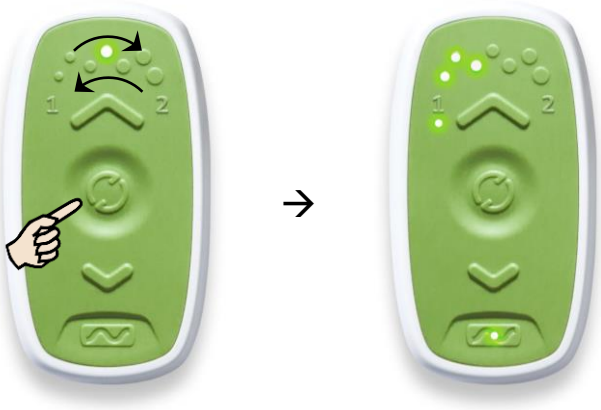
Recommendations for MRI scanning with the Axonics SNM System are based on phantom tests, numerical simulations, and the recommended implant configurations of the standard Axonics SNM Neurostimulator (Model 1101) and Tined Lead (Model 1201/2201). The guidelines below assume that no other implant devices 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 a Whole Body Examination

- Confirm whole-body MRI eligibility by using Appendix A: Worksheet for MRI Whole Body Scan Eligibility.
- Using the patient Remote Control, check the device for whole-body MRI readiness by following the steps below:

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

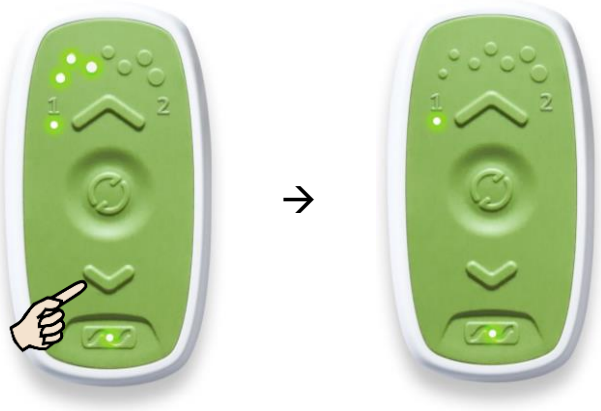
Note: The Stimulation Level lights will show the current stimulation amplitude.



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

Note: 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. 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 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 whole-body MRI

b. device is not ready whole-body for MRI

- Make sure the settings and parameters of the MRI system meet the conditions for whole-body scanning listed in Section 1.1.1.

Warning: Apply the required B1+rms or SAR limit in the Normal Operating Mode. Do **NOT** conduct MRI scanning in the First and Second Level Controlled Operating Modes, as this may increase the risk of unintended stimulation and excessive heating.

4.2. Before Starting a Head Examination

4.2.1 Determine if the patient has other medical device implants. Consult with the appropriate device manufacturers for MRI eligibility of those devices.

4.2.2 Turn the Axonics SNM Neurostimulator stimulation OFF with the patient Remote Control.

4.2.3 Make sure the settings and parameters of the MRI system meet the conditions for head scanning listed in Section 1.1.2.

4.3. During the Examination

4.3.1 Monitor the patient both visually and audibly. Discontinue the MRI examination immediately if the patient reports any problems.

4.3.2 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 Examination

4.4.1 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.

4.4.2 Turn the Axonics SNM 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 Whole Body Scan Eligibility

This form provides information about the patient's implanted SNM system and MRI scan eligibility. 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	MRI Whole Body Eligible	Not MRI Whole Body 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.	Did you confirm that the patient does not have an abandoned lead (a broken lead or an intact lead that is not connected to Axonics Neurostimulator), a partially implanted lead, or a malfunctioning Neurostimulator in his/her body?	☐ Yes	☐ No
4.	Is the device ready for whole-body MRI? Verify by checking "MRI Readiness" with the patient Remote Control. Follow the steps in Section 4.1.	☐ Yes	☐ No
5.	Did you confirm that the patient **DOES NOT HAVE** an implanted device/part other than the Axonics SNM implant system?	☐ Yes	☐ No (contact the appropriate device manufacturers for MRI eligibility of those systems)
	Is the patient whole body MRI eligible? (see next page)	☐ Yes	☐ No

- **If the answers to all 5 questions are Yes, the patient is eligible for MRI whole body scan.**
- **If any of the answers to questions 1-4 are No, the patient is NOT eligible for MRI whole body scan.**
- **If the answers to questions 1-4 are Yes, and No for question 5, please perform MRI with extra caution following the instructions below:**

1. Prior to MRI scanning, 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 compatible, and all parts are at least 20mm 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 the two systems have at least 20 mm away from each other, the patient is eligible for MRI whole body scan. 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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