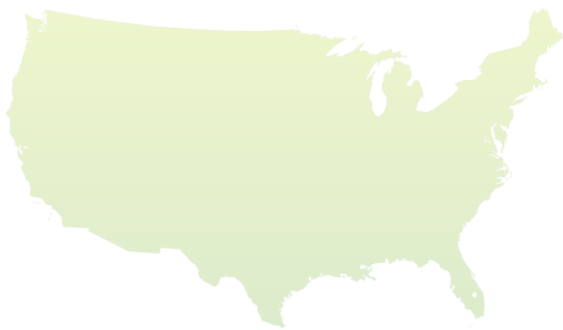


MRI Guidelines

Axonics Sacral Neuromodulation System

For use in the United States



Instruction for Use

! USA R_x 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 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.

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.

Specific Absorption Rate (SAR) – radio frequency power absorbed per unit of mass (W/kg).

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

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 entire body region within the MR scanner bore.

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 ~ 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.

Tesla (T) – the unit of measure of magnetic field strength. One T is equal to 10,000 gauss.

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1. MRI SAFETY INFORMATION

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 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 a reduction of the MR Conditions.

1.1. MR Conditional Devices

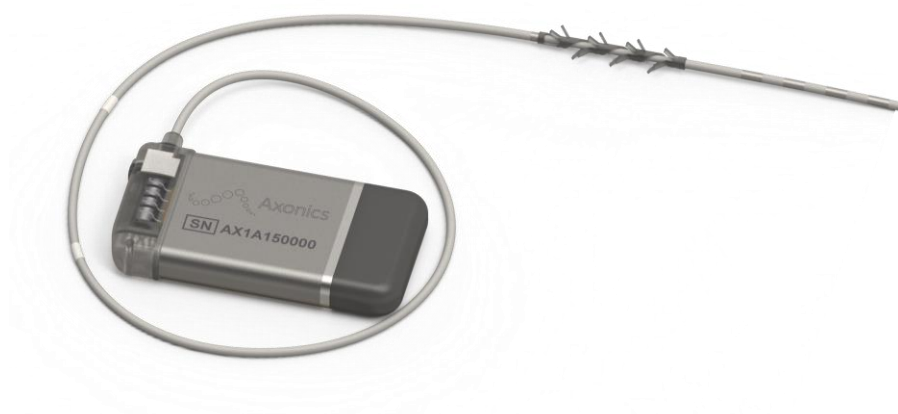
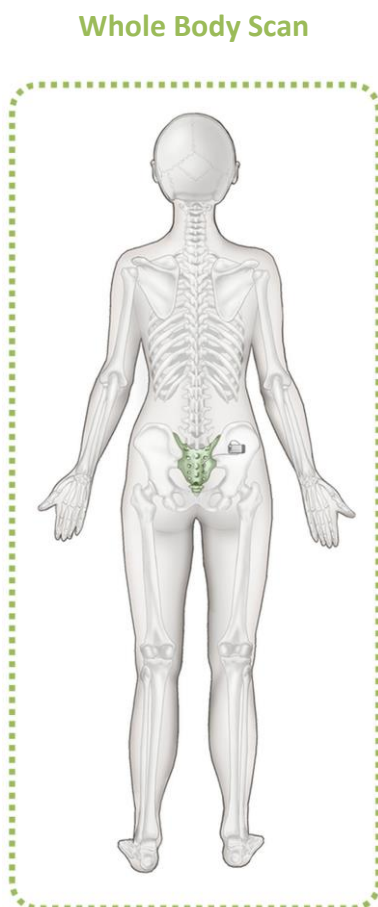


Figure 1: **MR CONDITIONAL** Axonics Devices

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 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.

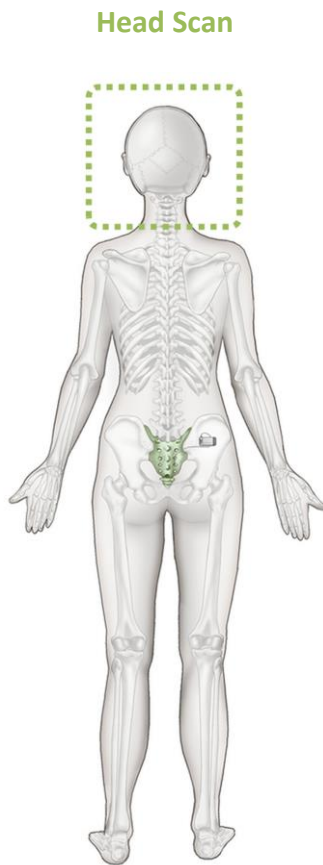


| Parameter | Condition |
|--|--|
| MR Conditional | Yes |
| Eligible Axonics Devices | Neurostimulator (1101) Tined Lead (1201/2201) |
| Device Configuration | Device must pass MR readiness check (see Section 4.1), Stimulation OFF, and Specified implant locations only |
| Static Magnet Strength (B ₀) | 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 Transmit Coil Type | Whole Body |
| RF Receive Coil Type | Any |
| Operating Mode | Normal Operating Mode |
| RF Conditions | For 1.5T Scanner: Whole Body SAR ≤ 2 W/kg For 3T Scanner: B _{1+rms} ≤ 1.7 μT; for MRI scanners that do not report B _{1+rms} , limit Whole Body SAR ≤ 1.2 W/kg |
| 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 landmark is acceptable |
| 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 Whole Body Scan Eligibility and follow Section 4.1 Before Starting MRI Whole Body Scan.

1.1.2 For Head MRI Examinations

A patient implanted with the Axonics SNM system may be safely scanned at the head 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 | Stimulation OFF |
| Static Magnet 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 Transmit/Receive Coil ONLY |
| Operating Mode | Normal Operating Mode |
| RF Conditions | Head SAR ≤ 3.2 W/kg |
| Scan Duration | There is no limit on scan duration |
| Scan Regions | Head Only |
| Image Artifact | No image artifact should be seen from a head MRI scan. |

Note: Please follow Section 4.2 Before Starting MRI Head Scan.

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 2: **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 Modes 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 Transmit/Receive Coil is used for MRI examinations – Do not conduct MRI scans in the First Level Controlled Operating Mode or 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 MRI Whole Body scan – Figure 3 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 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.

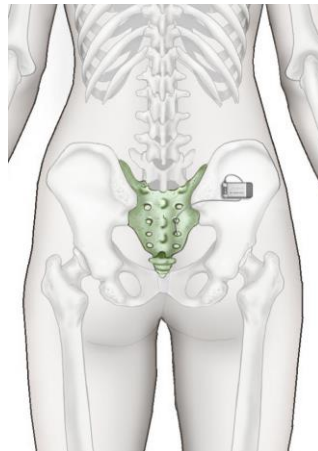


Figure 3: Axonics SNM System implant location eligible for whole body MRI

Avoid exposure to unapproved MRI conditions – Non-clinical testing has shown that exposure of the Axonics SNM System to MRI at a SAR level above Section 1 of this manual limits 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.

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 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: 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 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 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 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 Whole Body Scan

- 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 (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 1, 2020, the Clinician Programmer must be used instead. Refer to Appendix B: Clinician Programmer, Whole Body MRI Readiness Check for instructions on how to use the Clinician Programmer.

- 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 for whole-body MRI

-
- Make sure the settings and parameters of the MR scanner used meet all the conditions for whole body scanning listed in Section 1.1.1.

Warning: Do **NOT** conduct whole body MRI scans 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 Head Scan

- 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 scanning listed in Section 1.1.2.
- It is critical to ensure that the transmit/receive head 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 Modulation Technologies 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.

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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? | <input type="checkbox"/> Yes | <input type="checkbox"/> 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. | <input type="checkbox"/> Yes | <input type="checkbox"/> 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? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 4. | Is the device ready for whole-body MRI? Verify by checking “MRI Readiness” with the patient Remote Control or Clinician Programmer. See Section 4.1 or Appendix B: Clinician Programmer, Whole Body MRI Readiness Check. | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| 5. | Did you confirm that the patient does not have an implanted device/part other than the Axonics SNM implant system? | <input type="checkbox"/> Yes | <input type="checkbox"/> No (contact the appropriate device manufacturers for MRI eligibility of those systems) |
| | Is this patient whole body MRI eligible? (see next page) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

- If the answers to all 5 questions are Yes, the patient is eligible for whole body MRI.
- If any of the answers to questions 1-4 are No, the patient is NOT eligible for whole body MRI.
- 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 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.

Appendix B: Clinician Programmer, Whole Body MRI Readiness Check

If the patient has the old patient Remote Control (manufactured before May 1st, 2020, and does not have the MRI Readiness check capability), whole-body MRI readiness check can be performed using the Clinician Programmer instead. The following instructions summarize how to check the implanted device for whole-body MRI readiness, For detailed instructions on the use of Axonics' Clinician Programmer, refer to Axonics' Clinician Programmer Manual.

- Use the Clinician Programmer to communicate with the patient's Neurostimulator
- Perform an impedance measurement. Press the "Ω" button on the Patient Device screen of the Clinician Programmer (indicated by the red arrow in Figure 4) to determine the integrity of the patient's Neurostimulator.
 - If no open or short circuits are detected, the SNM system is ready for MRI whole-body scan.
 - If open or short circuits are detected, the "Ω" symbol next to that electrode will be red (highlighted with red circles in Figure 4), indicating that the integrity of the patient's SNM system is compromised. This patient is **NOT** eligible for MRI whole-body scan.
 - If the Clinician Programmer cannot communicate with the device, MRI scan eligibility cannot be determined. This patient is **NOT** eligible for MRI whole-body scan.

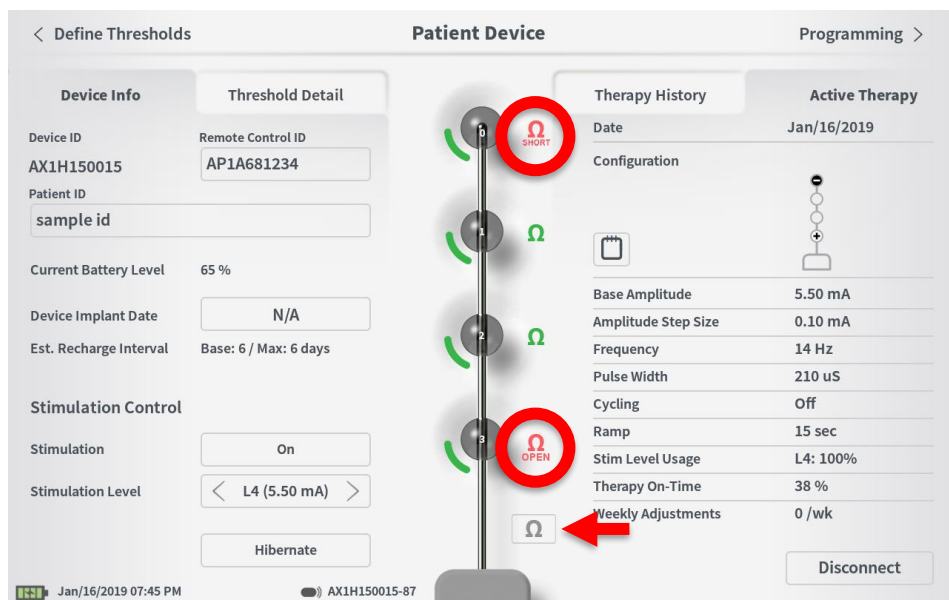


Figure 4: "Patient Device" screen on the Clinician Programmer

- If the patient has the patient Remote Control at the time of the MRI appointment, connect to the Neurostimulator with the patient Remote Control and turn stimulation off. Check the battery status on the Patient Remote to see if the light is green. If it is not green, charge the Neurostimulator and reperform this step until the battery status light on the Patient Remote is green.

Note: Do not bring the patient Remote Control into the MR scanner room.
- If the patient does not have the patient Remote Control at the time of the MRI appointment, use the Clinician Programmer to check that the battery status is above 30%. If not, charge the Neurostimulator until the batter level is at least 30%. Turn stimulation off with the Clinician Programmer before scanning.



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