Frequently Asked Questions: MRI with the Axonics System

The following FAQs pertain to MRI with the Axonics System and are meant to serve as additional clarification to the MRI Guidelines found at www.axonics.com/MRI. It is important to read the entire MRI guidelines prior to conducting or recommending an MRI examination on a patient with the Axonics System.

- **What terms are used for MRI labeling of implantable medical devices?**

  Implantable medical devices are labeled as **MR Safe**, **MR Conditional** or **MR Unsafe** based on their safety profiles in a Magnetic Resonance (MR) environment. **MR Safe** devices pose no known hazards and do not require additional scanning restrictions for the MRI exam. **MR Conditional** devices have been demonstrated to be safe only if certain conditions are met. These conditions are specified by the manufacturer and must be strictly followed. **MR Unsafe** devices are prohibited in the MRI scanner room because they pose unacceptable risks to the patient and medical staff. The Axonics implantable SNM system is an MR Conditional device, as are many other implantable medical devices such as pacemakers, spinal cord stimulators, and deep brain stimulators.

- **Why is the Axonics System MR Conditional?**

  As with any implanted medical device, there are potential risks from undergoing an MRI scan. These risks include, but are not limited to, device heating, vibration, malfunction, unintended stimulation, etc. that are caused by various MRI fields. The Axonics implantable SNM system components were carefully designed to mitigate these potential hazards. The Axonics System has undergone extensive testing to assess its safety under MRI exposure. The testing is compliant with ISO/TS 10974:2018, the international standard used to evaluate MRI safety with implantable devices, and other applicable standards. The testing has demonstrated that patients with the Axonics System can be safely scanned in an MR system under certain conditions specified in our MRI guidelines at www.axonics.com/MRI.

- **Do newly implanted patients need to wait a certain amount of time before having an MRI scan?**

  No, there is no post implantation wait time required for having an MRI scan because there is no MRI specific risk associated with a new implant if our MRI guidelines are followed. However, be aware and considerate of the incision wound from the implant. Because MRIs often require lying still for a long period, it may be uncomfortable for a patient to undergo MRI if the wound is not healed.

- **What are Circularly Polarized (CP) and Multichannel-2 (MC-2) modes?**

  Circularly Polarized (CP) mode is a widely used mode that a MR scanner uses to generate RF field. It sometimes also refers to Quadrature mode. It can typically be selected from the MR scanner console.

  Multichannel-2 (MC-2) is another RF field generation mode using two independent RF sources. It sometimes also refers to as 'B1 shimming'. It is employed by many modern 3T MR scanners to improve RF field homogeneity and hence enhance image quality.

  The Axonics System is labeled for CP mode or MC-2 mode under certain conditions specified in our MRI guidelines at www.axonics.com/MRI.

- **What coil configuration can be used for a whole-body scan?**

  A whole-body scan can be performed using an integrated whole-body RF transmit and receive coil. In addition, a whole-body RF transmit coil with any receive-only coil may also be used to scan the body part of interest under the conditions specified for whole-body RF transmit coil. Please refer to the latest guidelines for your region at www.axonics.com/MRI.

- **What coil configuration can be used for a head scan?**

  A head scan can be performed with a detachable head RF transmit/receive volume coil or a whole-body RF transmit coil with a head receive-only coil, under the conditions specified in the Axonics MRI guidelines. Please refer to the latest guidelines for your region at www.axonics.com/MRI.

- **What coil configuration can be used for extremity scan?**

  Upper and lower extremity scan can be performed with a detachable extremity RF transmit/receive volume coil (e.g. wrist coil, knee coil) or a whole-body RF transmit coil with an extremity receive-only coil, under the conditions specified in the Axonics MRI guidelines. Please refer to the latest guidelines for your region at www.axonics.com/MRI.

- **How can a patient complete an MRI session if it lasts longer than the continuous scan duration limit of 30-min?**

  It is important to note that the 30 minutes of continuous scanning time can be sufficient for most MRI sessions. However, for more involved MRI body scans that require longer than 30 minutes of continuous scanning time, the MR technologist should separate the scans into multiple sessions. It is not necessary to schedule the 2nd MR scan session to a different day.

- **What is the required wait time for scans that last longer than 30 minutes?**

  No wait time is required for head scans or extremity scans using a detachable RF transmit volume coil.
  In the United States and Canada, a minimum wait time of 5 minutes is required for whole-body scans if the continuous scan reaches 30 minutes.
  In regions where CE marking (select countries in Europe) and TGA (Australia) approval are recognized, there is no wait time specified between sessions for whole-body scans. However, each MRI facility may have a general protocol for the wait time.

- **If my patient has other implanted devices, is the patient still eligible for MRI?**

  MRI eligibility can only be determined when all MRI safety information has been reviewed. If your patient has implanted devices other than the Axonics System, check the MRI safety information of those devices. If the other devices impose additional restrictions on MRI, those restrictions must be followed. Consult with the appropriate implant device manufacturers if you have further questions regarding other devices.

- **If my patient has two Axonics devices, is the patient still eligible for MRI?**

  If your patient has two Axonics Systems implanted for bilateral sacral neuromodulation therapy, the patient may be eligible for whole-body MRI scans with the whole-body RF transmit coil if all parts of the two systems are at least 20 mm away from each other. Please check the latest guidelines at www.axonics.com/MRI to ensure your patient meets the complete requirements for whole-body MRI.

  Your patient is still eligible for MRI when using a detachable head/extremity RF transmit/receive volume coil.

- **Is the MR image quality affected by the specified SAR levels?**

  Under the specified SAR levels for both 1.5T and 3T, MR images with reasonable quality can be obtained. The maximum Whole Body Specific Absorption Rate (WB SAR) of 2 W/kg for 1.5T MR scanners as specified in our US MRI Guidelines is the highest SAR level allowed under the "Normal Operating Mode". This SAR level allows for an efficient MRI scan of any part of the body.

- **Is there a B1+RMS limit for the Axonics System?**

  B1+RMS is a relatively new metric and mostly used on MR scanners with newer software. Our 3T labeling provides B1+RMS and WB SAR limits for whole-body MRI. Please check the latest guidelines at www.axonics.com/MRI for specific conditions. Our FDA-approved 1.5T MR labeling allows for WB SAR of 2 W/kg in the Normal Operating Mode with no additional limit on the B1+RMS level.

- **What is the extent of image artifact for the Axonics System?**

  An example of image artifact generated from our in-vitro testing is shown below. Note that the extent of image artifacts is dependent on multiple factors. Careful choice of MRI sequence parameters and location of the imaging plane may minimize MR image artifacts.

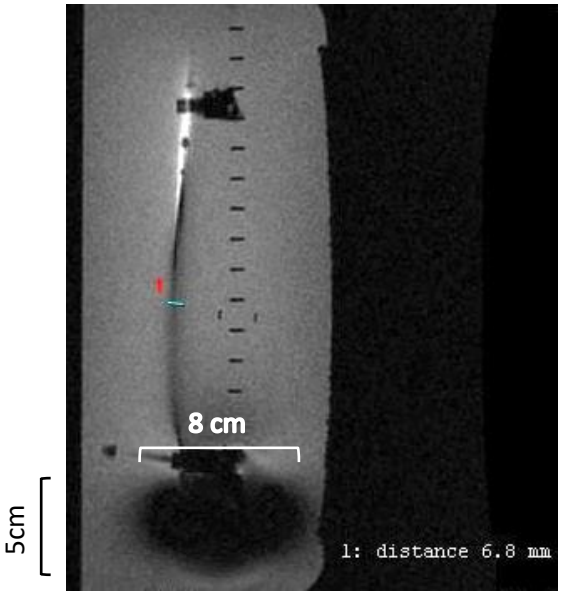

Figure 1: Image artifact from a spin echo sequence generated by a 1.5T MR scanner (Axonics neurostimulator with lead)

The MRI technician is encouraged to use scan parameters that minimize image artifacts. General principles for imaging include, but are not limited to:

- using imaging sequences with stronger gradients for both slice and read encoding directions.
- using higher bandwidth for both RF pulse and data sampling.
- choosing an orientation for the read-out axis that minimizes in-plane distortion.
- using a spin echo sequence (instead of gradient echo sequence), whenever possible.
- using a shorter echo time for gradient echo sequences, whenever possible.

- **How soon can a patient turn their stimulation back on after an MR session?**

  The patient can turn the stimulation back on right after an MR session. There is no wait time required. Note that a patient Remote Control should not be brought into a MR scanner room.

- **How soon does a patient need to get their device settings checked after an MR scan?**

  If a patient turns their stimulation back on and still feels stimulation in the same location, then the device is operating normally. A device settings check can be done at the next regular appointment with the physician.

- **When is MRI Readiness Check required?**

  MRI Readiness check is required when using a whole-body RF transmit coil.

  MRI Readiness check is not required for head or extremity scans when using a detachable RF transmit volume coil. For these scans, the patient can undergo MRI after the INS stimulation is turned off. All other MR conditions must still be followed.

- **If a patient has a Remote Control that does not have the MRI Readiness check capability (a Remote Control that is manufactured before May 1st, 2020), how can the SNM system be checked for whole-body MRI eligibility?**

  If a patient has a Remote Control manufactured before May 1st, 2020, the Clinician Programmer should be used to check the SNM system for whole-body MRI eligibility. The patient Remote Control can then be used to turn Stimulation off prior to MRI scan if the patient meets all the requirements. Please refer to the latest guidelines for more details at www.axonics.com/MRI.

- **What happens if there is a flashing red light on the patient Remote Control prior to or after the MRI Readiness check is done (for Remote Controls with the MRI Readiness check capability)?**

  The blinking red indication, which is reserved for patient Remote Control errors, is stopped when MRI Readiness check mode is entered. Therefore, the MRI Readiness check can still be performed. After the MRI is performed, the patient should then contact their physician's office or Axonics representative to address the flashing red light on their Remote Control.

- **What happens when there is already a solid red light on the new patient Remote Control (indicating system fault) prior to or after the MRI Readiness check is done?**

  A red solid light on patient Remote Control indicates an issue(s) with the SNM system and the patient is not eligible for a whole-body MRI. However, the patient may still be allowed for a head or extremity MRI scan using a detachable RF transmit volume coil after the INS stimulation is turned off. The patient should then contact their physician's office to notify them of the solid red light.