Practical Aspects of MR Imaging Safety Test Methods for MR Conditional Active Implantable Medical Devices

Louai Al-Dayeh, MD, PhD*, Mizan Rahman, PhD, Ross Venook, PhD

KEYWORDS

• AIMD • Implants • Medical devices • MR imaging safety • ISO/TS 10974

KEY POINTS

- MR Conditional implants undergo a wide range of well-developed test methods before receiving FDA approval under the specified conditions of use.
- MR imaging safety test methods for implants are empirical, measurement-based, or numerical modeling-based.
- Conditions of use for MR Conditional devices include a combination of factors that are not easily extrapolated.

INTRODUCTION

Because MR imaging, the unique nonionizing imaging modality, uses three different types of electromagnetic (EM) fields (static, gradient, and radiofrequency [RF]), a patient inside the MR scanner is prone to these fields' interaction with the body. Hence, MR safety standards, such as IEC60601-2-33,[1] dictate limits on field exposure levels and characteristics to reduce patient risks from hazards including RF burns, local and whole-body heating, peripheral nerve stimulation, and cardiac stimulation, among others. Although these risks are well-established, and MR imaging systems have a strong history of safe use, there are many reports of different types of adverse events, including in the Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience database.[2]

If the patient has an implantable medical device, there are added safety concerns for the patient because of the interactions of these fields with the implant. These potential hazards, along with several unfortunate patient injuries related to interactions between MR scanners and implanted devices,[3–8] historically led to appropriately conservative default consideration of implantable devices as being contraindicated for MR imaging. In the mid-1990s, passive medical devices (without any internal power source), such as stents, began to get MR Conditional labeling following guidelines and published safety standards of ASTM International (formerly known as American Society for Testing and Materials)[9,10] and recommended MR imaging safety guidelines per early publications on the subject.[11,12] Because of the many different types of interactions, and potential patient harms, active implantable medical

All authors are employees of Boston Scientific Neuromodulation Corp.
Boston Scientific Neuromodulation, 25155 Rye Canyon Loop, Valencia, CA 91355, USA
* Corresponding author.
E-mail address: louai.aldayeh@bsci.com

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devices (AIMDs; those relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity[13]) continued to be contraindicated at most sites.

Since the first successful MR imaging safety labeling of an implanted Deep Brain Stimulation (DBS) system by Medtronic (Minneapolis, MN) approximately 20 years ago, with significant limitations on applied fields, AIMD manufacturers have come a long way in designing their implants with MR safety in mind and in assessing what conditions of MR scanning (eg, limits of RF and/or gradient) can allow MR imaging without compromising patient safety. The first successful FDA labeling of an MR Conditional pacemaker by Medtronic in 2011[14] marked the beginning of the recent era in which many more patients with implanted devices from manufacturers across the industry now have access to MR imaging through MR Conditional labeling.

What facilitated getting to the current state of MR Conditional devices today is a joint effort that started in 2006 across the MR imaging safety community, including representatives from implanted device manufacturers, scanner manufacturers, and regulatory bodies. Experts in each area formed a joint working group that participated in various technical venues helping to shape and update multiple standards. A major outcome of this effort was publication of an international technical specification (TS), ISO/TS 10974, documenting guidelines on the assessment of MR imaging safety for patients with an AIMD. The first version of this TS published in 2012,[15] and the second updated version published in 2018.[16] The work is ongoing, and the group is updating and transitioning the TS into an international standard, with expected publication in 2021 or 2022.

To have a specific focus, this article mainly addresses AIMDs with extended leads (eg, cardiac leads or neuromodulation leads), that is, an implanted pulse generator (IPG) plus one or more leads (see **Fig. 1** for a representative spinal cord stimulator).

RELEVANT FACTS TO COUNTER MISCONCEPTIONS ABOUT MR IMAGING SAFETY TESTING OF ACTIVE IMPLANTABLE MEDICAL DEVICES

- There are many types of potential patient hazards, which require comprehensive testing. It is not simply about magnetic materials or RF burns.
- Most implants that allow MR imaging scanning are MR Conditional; there is practically no "MR Safe" active implant. In general, if the implant has metallic components, it is either MR Conditional or MR Unsafe.
- What is MR Conditional is a specific device/system (specific pulse generator + specific lead) per the device's formal MR imaging safety label conditions listed in its instructions for use/manual.
  - No generalizations of MR safety can be made about any other device/system from the same manufacturer or other manufacturers (eg, lead extensions that are not included in the MR label, and not MR Conditional).
- Mixing and matching a pulse generator from an MR Conditional device/system with leads from another MR Conditional device/system does not make the new combination MR Conditional. There is typically no testing or data available to assess such combinations.
- Fractured leads, abandoned leads, and other damaged or nonfunctional implants are typically not assessed for safety, and their level of risk is unknown.
- There are no strong guidelines on how to safely scan a patient with multiple AIMDs (eg, a pacemaker and a spinal cord stimulator). Even if each system is MR Conditional by itself, the multisystem combination is not in general labeled for MR Conditional safety, because of the lack of testing on such combinations.
- Almost all present safety testing and MR Conditional labeling of implants is for either 1.5-T or 3-T cylindrical bore MR imaging scanners (or both). Open-bore systems, and higher- or lower-field scanners, typically are not included in testing standards or in MR Conditional labels.
- If an MR Conditional device/system is deemed safe in a specific MR field strength (eg, 1.5 T), this has no implication on MR safety of the device within other field strengths (eg, lower B0, such as 1 T, or higher B0, such as 3 T or 7 T). No presumption of safety can be made at any field strength other than the one at which the safety assessment was done, because the RF-dependent properties of the system change significantly (eg, RF wavelength, current deposition on leads, exposure fields in the patient caused by scanner design differences) and could be either more safe or less safe.
- In general, accessories of devices/systems (eg, remote control, charger) are not MR Conditional, and many are MR Unsafe and cannot be brought into Zone 4 (the MR imaging scanner room) of the imaging facility.

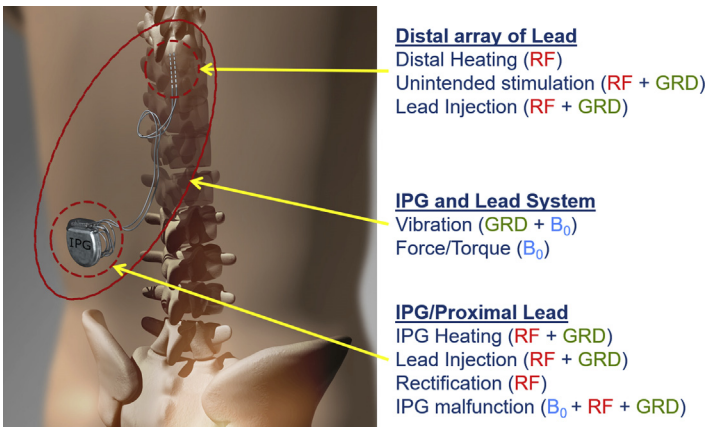

Fig. 1. Illustration of a generic spinal cord stimulator system as an example of AIMD with extended leads. Various potential MR imaging hazards are listed (with reference in parentheses to the causing fields). B0, static field; GRD, time-varying gradient field. Note that understanding the induced fields for an AIMD for RF and time-varying gradients includes surgical implantation variables, such as lead subcutaneous routing and coiling of the lead in the IPG pocket.

MR IMAGING AND ACTIVE IMPLANTABLE MEDICAL DEVICES INTERACTIONS: POTENTIAL SAFETY HAZARDS (PER ISO/TS 10974)

Demonstration of MR Conditional status by implantable device manufacturers (eg, to achieve FDA labeling) involves testing hundreds or thousands of different exposure conditions and modeling many thousands or millions of such potential exposure conditions. This includes exposure in realistic MR imaging scanning environments, benchtop injection testing, and development of appropriate risk assessments though physical experiments and modeling. The quick methods used by some researchers of trying to assess device safety through testing of a handful of configurations of a device within a box of tissue simulating medium (which was common in past decades, and still finds its way into the literature) is simply insufficient. Although it is a helpful first step, or potentially useful in demonstrating hazards, it unfortunately does not meaningfully evaluate safety. This section of the article describes the full range of proper test methods, per established standards, that collectively form the testing package regulatory bodies review for a given MR Conditional device label.

Per ISO/TS 10974:2018[16] the potential safety hazards caused by the MR imaging scanner and AIMD interaction physics are listed in **Table 1**. **Fig. 2** also illustrates these hazards. Each of the three different types of EM fields in a scanner (B0, time-varying gradient, and RF) generate specific interactions and potential safety hazards for patients, as do the different combinations of fields (eg, device vibration is a result of the combination of B0 + time-varying gradient fields).

Most test methods described in various standards do not include explicit acceptance criteria (eg, how many degrees centigrade of temperature rise is acceptable for electrode heating) because the standards must work for many different types of implants. Because the risk level depends on the nature and location of the implant, and tissues surrounding it, each implant manufacturer must set and justify acceptance criteria for each potential hazard according to their internal risk management procedures, subject to review by regulatory authorities. Typically, this includes using internal company data from a combination of relevant history of safe use, human trials, or animal studies, and accepted literature references. Implant manufacturers are also working on creating vertical standards for a specific type of implants with relevant acceptance criteria for these hazards.

Table 2 includes a more detailed view on one way an AIMD manufacturer might consider and address the wide variety of potential safety hazards and acceptance criteria.

TEST METHODS ADDRESSING POTENTIAL SAFETY HAZARDS CAUSED BY MR IMAGING AND ACTIVE IMPLANTABLE MEDICAL DEVICES INTERACTION: PULSE GENERATOR + LEADS

Evaluation of the AIMD for MR imaging hazards involves benchtop testing, modeling, MR scanners, or a combination of these approaches. One way to categorize these evaluations is whether modeling is a part of the assessment or not (**Table 3**).

B0-Induced Force

A displacement force produced by the static magnetic field (B0) on a device containing magnetic materials has the potential to cause unwanted movement of the implanted device.

Table 1
Potential patient hazards and corresponding test methods

Hazard	Test Method	Clause
Heat	RF field-induced heating of the AIMD	8
	Gradient field-induced device heating	9
Vibration	Gradient field-induced vibration	10
Force	*B*0-induced force	11
Torque	*B*0-induced torque	12
Unintended stimulation	Gradient field-induced lead voltage (extrinsic electric potential)	13
	RF field-induced rectified lead voltage	
Malfunction	*B*0 field-induced device malfunction	14
	RF field-induced device malfunction	15
	Gradient field-induced device malfunction	16
	Combined fields test	17

Each clause of the test method document defines the specific conditions for the testing to ensure proper coverage in the MR imaging environment.

From ISO/TS 10974:2018. Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device; with permission.

Force exerted on the device is a function of the spatial gradient of B0 (or the product of B0 and the spatial gradient of B0, depending on whether the materials are greater or less than magnetic saturation) and the mass of magnetic material. This established test method is described in ASTM F2052,[17] is measurement-based, and is typically conducted in a scanner.

The concept of testing is to measure the magnetically induced displacement force of the implant where the spatial gradient is greatest (near the opening of the bore) and compare against the gravitational force acting on the device (because all implanted devices are subjected to the force caused by gravity without patient harm). One version of this test is to suspend the device by a thin string at that location and measure the deflection angle; if it deflects less than 45°, its magnetic force is less than that of gravity.

Implants with a displacement force less than the force of gravity are automatically deemed acceptable. If that force is greater, it still could be acceptable with appropriate justification of an appropriate acceptance criterion to maintain patient safety.

For most AIMDs with extended leads, with the main magnetic components implanted subcutaneously and far from vulnerable structures, B0-induced force is not considered a high-risk hazard. There is real potential for concern if the device is in a sensitive physiologic location (eg, brain aneurysm clip).

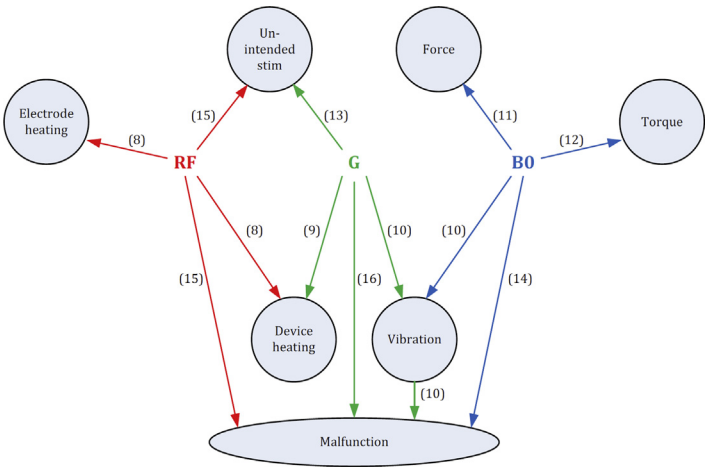

Fig. 2. Relationship between MR imaging scanner output fields RF, gradient (G), static (B0), and hazards (ISO/TS 10974 test method clause numbers in parentheses). (*From* ISO/TS 10974:2018. Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device; with permission.)

Table 2
Example list of MR imaging–AIMD safety hazards, each of which generates requirements that an AIMD manufacturer must assess with appropriate test methods and rationale

Requirement	10,974 Clause	Details of Meeting Requirement	Rationale/Source
RF-induced lead heating patient harm limit	8	When exposed to RF fields, heating of the lead shall not exceed XX CEM 43°C[21]	ISO/TS 10974 Tissues around lead heating acceptance criteria MR imaging environment exposure durations, levels
Device (IPG) heating patient harm limit: Gradient-induced RF-induced	8 9	When exposed to combined RF and gradient fields, the thermal exposure of tissue surrounding the pocket shall not exceed XX CEM 43°C	ISO/TS 10974 Tissues around stimulator heating acceptance criteria MR imaging environment exposure durations, levels MR imaging EMC acceptance criterion
Gradient-induced vibration patient harm limit	10	When exposed to combined static and gradient fields, the pressure exerted by implanted IPG or leads on the tissue shall not exceed XX psi	ISO/TS 10974 MR imaging vibration tissue damage acceptance criteria MR imaging environment exposure durations, levels
B0-induced force patient harm limit	11	When exposed to static field: Translational force on the IPG shall not exceed XX N Translational force on any implantable system components shall not exceed the weight of the component	ASTM F2052 MR imaging force torque acceptance criterion MR imaging environment exposure durations, levels
B0-induced torque patient harm limit	12	When exposed to static field: Torque on the IPG shall not exceed XX Nm Torque on all implanted system components shall not exceed the weight times the length of the longest side of the component	ASTM F2213 MR imaging force torque acceptance criterion MR imaging environment exposure durations, levels

(*continued on next page*)

Table 2
(*continued*)

Requirement	10,974 Clause	Details of Meeting Requirement	Rationale/Source
Electric potential patient harm limit Gradient-induced, extrinsic RF-induced and RF rectification	13 15	When exposed to combined RF and gradient fields: The current conducted by the IPG shall not exceed a pulse charge limit of XX μC in each electrode Amplitude of the current pulse shall not exceed XX μA in IPG stimulation-off condition Amplitude of the current pulse shall be within specified tolerances in IPG stimulation-on condition	ISO/TS 10974 MR imaging environment exposure durations, levels
RF-induced device malfunction limit	15	When exposed to RF field, the IPG shall pass EMC criteria during and following exposure	ISO/TS 10974 MR imaging environment exposure durations, levels MR imaging EMC acceptance criterion
B0-induced device malfunction limit	14	When exposed to static field, the IPG shall pass EMC criteria during and following exposure	ISO/TS 10974 MR imaging environment exposure durations, levels MR imaging EMC acceptance criterion
Gradient-induced device malfunction limit	16	When exposed to gradient field, the IPG shall pass EMC criteria during and following exposure	ISO/TS 10974 MR imaging environment exposure durations, levels MR imaging EMC acceptance criterion
Combined fields, induced device malfunction limit	17	When exposed to combined static, RF and gradient fields, the IPG shall: Pass EMC criteria during and following exposure Retain its complete functionality during and following exposure	ISO/TS 10974 MR imaging environment exposure durations, levels MR imaging EMC acceptance criterion
Combined fields, image artifacts or distortion		Image artifacts caused by the presence of IPG + leads shall be evaluated per ASTM F2219	ASTM F2119[22]

Abbreviations: CEM 43°C, cumulative number of equivalent minutes at 43°C temperature; EMC, electromagnetic compatibility; N, Newton (force unit); Nm, N m (torque unit); μC, micro Coulomb (charge unit).

Table 3
Categorization of MR imaging safety assessments, based on whether or not electromagnetic modeling is involved

Six MR Imaging Safety Assessments Rely on Benchtop Testing and/or MR Imaging Scanners Without Modeling	Three MR Imaging Safety Assessments Rely Heavily on Modeling (in Addition to Measurement-Based Testing)
1. B0-induced force	7. RF field-induced heating of the AIMD
2. B0-induced torque	8. Unintended stimulation from RF field-induced lead voltage
3. Gradient field-induced vibration	9. Unintended stimulation from gradient field-induced lead voltage (extrinsic electric potential)
4. Gradient field-induced device (IPG) heating	
5. Device (IPG) malfunction (B0 field and/or RF field and/or gradient field-induced)	
6. Combined fields test	

B0-Induced Torque

Magnetically induced torque, produced by the static magnetic field (B0), has the potential to cause unwanted movement of a device containing magnetic materials (rotating the implant to align it with the B0 field).

Torque is sensitive to B0 and should be measured at a location where the static magnetic field is homogeneous (eg, the isocenter of an MR scanner). This established test method is described in ASTM F2213,[18] is measurement-based, and is typically conducted in a scanner.

Experimental approaches to conducting torque testing vary in complexity and applicability. Some methodologies are only applicable to devices that experience little to no torque, whereas others are appropriate for devices that experience significant torque and must be more rigorously quantified to assess safety.

Most implantable devices, including AIMDs with extended leads, experience measurable torque but have no trouble passing a reasonable acceptance criterion. There is real potential for concern if the device is in a sensitive physiologic location (eg, brain aneurysm clip).

Gradient Field-Induced Vibration

Time-varying gradient magnetic fields from an MR scanner induce eddy currents on the conductive surfaces of an AIMD. These eddy currents produce a time-varying magnetic moment that interacts with the static magnetic field (B0) causing vibration of the conductive surfaces and, subsequently, the device. The primary potential for patient harm, because the vibration of the device is typically very low-amplitude because of the high frequency of oscillation, arises from possible breakage of internal components that lead to malfunction of the device, which could result in compromised functionality or lack of therapy from the device.

Vibration is sensitive to B0 and gradient dB/dt. This test is described in ISO/TS 10974:2018,[16] is measurement-based, and is conducted in a scanner or using a shaker table.

There are two methods for testing. One method requires the use of an MR scanner and provides higher accuracy with an increase in test burden, whereas the other method uses a shaker table and uses conservative approximations to reduce test burden after initial calibration testing in an MR scanner. Because most conceived failures are caused by fatigue fractures of internal components, the concept of testing is to expose the implant to extended periods of vibration and confirm full device functionality afterward.

Test duration represents the cumulative patient scan time over the lifetime of a typical AIMD. Guidelines in the standard establish, based on prior clinical experience, that conservative total MR imaging scan time exposure ranges from 2.5 hours to 7.5 hours, if looking at the top 0.8% of the population to the top 0.01% of the population, respectively.

For medium- or small-sized IPGs, and non-life-sustaining devices, vibration is not considered a high-risk hazard. Larger devices typically vibrate more, with potentially greater likelihood of device damage.

Gradient Field-Induced Device (Implanted Pulse Generator) Heating

The time-varying gradient dB/dt fields during MR imaging sequences induce eddy currents on conductive AIMD enclosures and other conductive internal surfaces, such as battery components and circuit ground planes, and can result in device heating.

IPG heating is sensitive to average or root-mean square (RMS) gradient field amplitude $|dB/dt|$, with

secondary dependence on the gradient waveform characteristics (shape and frequency). It is greatest when the device is located where the gradient field |dB/dt| RMS is maximum and when the device is oriented so that the gradient field vector is orthogonal to the AIMD surfaces with the largest conductive area. This heating also scales strongly with device radius (larger devices heat more).

This test is described in ISO/TS 10974:2018.[16] It is measurement-based, with preferential use of a laboratory gradient coil, amplifier, and function generator that can simulate clinical gradient field exposure. Alternatively, testing may be conducted using a clinical MR scanner.

Testing may be conducted using one of two tiers for the gradient waveform shape. Tier 1 uses a conservative waveform shape, and tier 2 allows the characterization and use of a clinically relevant waveform. Tier 2 is most useful for AIMDs with larger conductive surfaces.

The standard calls for a test duration that is the maximum allowed scan duration as specified by the AIMD MR Conditional labeling, or 30 minutes. All other testing parameters are determined by the AIMD manufacturer to reflect conservative clinical use conditions for their device.

The key concern is local tissue heating because of radiant heat from the IPG. For most AIMDs with extended leads, this is not considered a high-risk hazard, although some MR Conditional labels have suggested using an ice pack near a subcutaneous device if the patient reports local heating sensations near the device (IPG).

Device (Implanted Pulse Generator) Malfunction (B0 Field and/or Radiofrequency Field and/or Gradient Field-Induced)

Exposure to the scanner's B0 field and/or RF field and/or gradient field could have certain effects on an AIMD, such as but not limited to:

- B0: Device reset, reprogramming, magnetic remanence, battery drain, and permanent damage.
- B1: Failure to deliver the intended therapy, reprogramming, device reset, permanent damage, and tissue stimulation caused by RF rectification.
- Gradient: Failure to deliver intended therapy, memory corruption, or temporary or permanent loss of device programmed settings.

These effects are transient or permanent and might create a safety hazard that impacts the AIMD patient. Malfunction also has different implications per the patient's dependence on the device (eg, whether it is a life-sustaining therapy, such as a pacemaker, or not).

The assessment is sensitive to a function of B0, peak B1, and peak dB/dt.

Three tests (one per MR field) are described in ISO/TS 10974:2018[16] in elaborate details, including specifying a mixture of radiated and benchtop tests.

- For B0: Implants are divided into three classes with various testing complexities. For many AIMDs with IPG + lead, it is sufficient for their class to meet the test requirement with no specific B0 susceptibility orientations required, and for those, monitoring is done in accordance with a combined field test requirement (eg, the test is done in scanner, with all three fields active).
- For B1 and gradient: The field level and induced voltages are found via a combination of computational modeling (see the later section on modeling) and exposure testing. Challenge testing of the device circuitry for malfunction includes benchtop injected voltage tests using sources of waveforms with appropriate shapes and magnitudes that reflect MR-relevant sequences.

The IPG should pass the acceptance criterion established by the device manufacturer based on the intended functionality (ie, confirm expected device functionality) after the implant is exposed to each one of the three fields as described previously.

Combined Fields Test

The combined fields test provides field exposures typically encountered in clinical MR imaging examinations. It establishes an in vitro evaluation of the AIMD functioning under simultaneous exposure to the static, gradient, and RF magnetic field conditions. Unlike the maximal exposures required in the rest of measurement-based tests, this test exposes the AIMD to representative levels and temporal patterns of all three MR magnetic fields simultaneously.

This measurement-based assessment is conducted in a scanner and is sensitive to (a function of) B0, RF peak, and dB/dt Peak. The test is described in ISO/TS 10974:2018.[16]

The combined fields test is performed using an AIMD (the IPG and the connected leads) positioned in a tissue-simulating media phantom and placed inside an MR scanner. The AIMD is exposed to a series of MR imaging sequences (representing various common and clinically relevant protocols) performed at different landmarks

or simulated patient positions within the bore. The concept of testing is to expose the implant to the clinical combined fields and confirm expected device functionality during and after the exposure.

This test is viewed as redundant to device (IPG) malfunction testing. However, it is required to make sure the device is actually tested in radiated environment under clinical conditions. In addition, benchtop exposure tests are typically more stringent, because they can apply higher-than-expected injection levels.

MR IMAGING SAFETY ASSESSMENTS WITH ELECTROMAGNETIC MODELING

ISO/TS 10974:2018[16] has tiered approaches to modeling where the low tier is easily implementable but overestimates the needed assessment, and modeling in higher tiers is more complex but more accurate (with less overestimation). Practically, for AIMDs with extended leads, tier 3 is the highest tier that is attainable with acceptable accuracy.

Tier 3 includes modeling the EM environment surrounding the AIMD to obtain the incident electric fields potentially picked up by the AIMD, together with measurements of how the AIMD handles such incident fields.

The process includes running a computer simulation: using a hardware model of the scanner coil itself, whether an RF birdcage coil or a gradient coil, and anatomic models of humans as representative samples per the device's patient characteristics. EM simulations (RF or gradient) are run using these models in all relevant clinical landmarks or patient positions to mimic the EM environment of the scanner. Modern simulations, across a range of human body models, and with a range of MR imaging scanner coil models, can give the EM field distribution everywhere inside the anatomic models across a range of potential MR examination circumstances.

The First Element Needed for Modeling, Tangential Electric Fields

For the three assessments that rely heavily on modeling (see **Table 3**), tier 3 modeling requires that, along the lead path in every anatomic model, the tangential vector of the electrical component (E-tan) of the incident fields be extracted from the EM simulation. **Fig. 3** shows the E-tan magnitude of example DBS and Spinal Cord Stimulation (SCS) routings, for a specific landmark in an MR scanner with an RF body coil.

The Second Element Needed for Modeling, the Transfer Function

For RF (the first two of the three assessments in **Table 3**) the transfer function[19] is needed, which is really a characterization of how a particular AIMD (ie, a specific IPG + lead combination) behaves as an RF Antenna in the scanner environment.

For safety purposes benefiting the patient, we want the AIMD to be a bad antenna in the EM environment of the MR imaging scanner. The transfer function of an AIMD (when exposed to a uniform E-tan excitation) is measured in benchtop RF injected setup (**Fig. 4**) or simulated. The transfer function is a 1D vector (having the length of the lead under test) of complex values (term *S* in Equations 1 and 2) whose magnitude shows the resonance lengths of the AIMD (see **Fig. 5**), which is the frequencies at which the AIMD is a good antenna.

Discussed next are the three MR safety assessments that rely on modeling.

Radiofrequency Field-Induced Heating of the Active Implantable Medical Device (Lead Electrode Heating)

Patient harm caused by RF-induced lead electrode heating is a function of absolute temperature, duration of the temperature, and individual

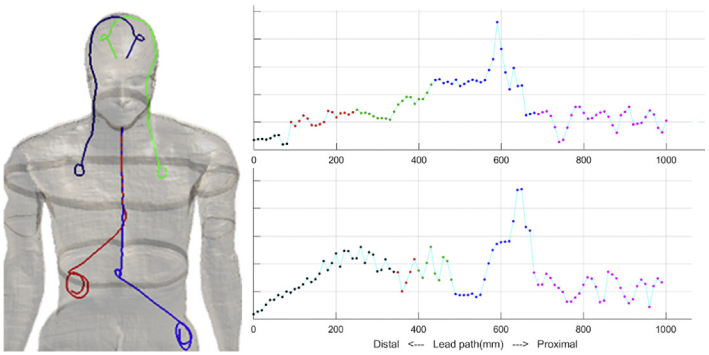

Fig. 3. (*Left*) Human model with two DBS and two SCS lead routings (pathways). (*Upper Right*) RF E-tan magnitude of one DBS routing. (*Lower Right*) RF E-tan magnitude of one SCS routing.

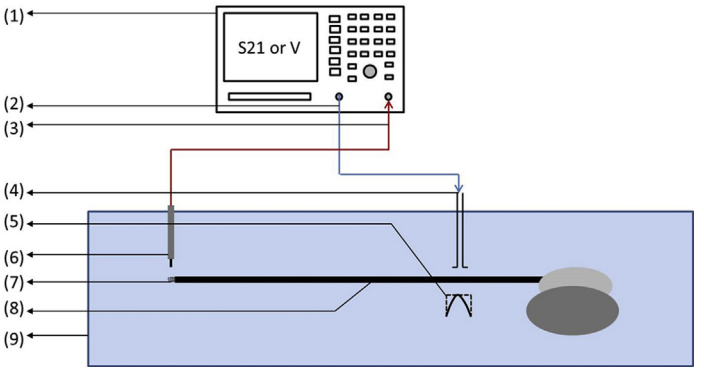

Fig. 4. The transfer function benchtop RF injected setup: Vector Network Analyzer (1), RF source (2), sense input (3), transmitting antenna (4), localized E-tan (z) (5), coaxial antenna (6), tip electrode (7), the AIMD (lead + IPG) (8), and tissue simulating phantom (9). (*From* ISO TIR 21900:2018. Guidance for uncertainty analysis regarding the application of ISO/TS 10974; with permission.)

implant considerations. The assessment is sensitive to (a function of) B1 RMS, and the test method is described in ISO/TS 10974:2018.[16]

The concept of this assessment is:

- Benchtop/scanner: The AIMD (the IPG and the connected leads) is positioned in a tissue-simulating media phantom and placed inside an RF birdcage (designed for testing or of a scanner) and lead electrode heating is measured under various incident field conditions (multiple lead pathways and/or RF exposures).
- Simulation: Using simulation of this benchtop setup (in vitro), the E-tans are extracted for all clinical lead pathways.
- Benchtop or simulation: The transfer function of the AIMD is measured in benchtop injected setup or simulated.
- A predictive model of heating (and/or power) is established using the dot product of E-tans and transfer function per the following formula[19]:

$$P = A\left|\int_0^l S_{\text{hotspot}}(z)E_{\tan}(z)dz\right|^2 \qquad \textbf{Equation 1}$$

Where P is power (or heating), A is scaler imbedding the linear fit of the AIMD model and the incident field levels, S is the transfer function, E-tans are the in vitro tangential electrical incident fields, and dz is the spatial distance increment along lead length.

- The previous formula, which describes how the AIMD model is derived, is also applied to the extracted E-tans of the human (in vivo) simulations. This often results in thousands to millions of heating predictions, accounting

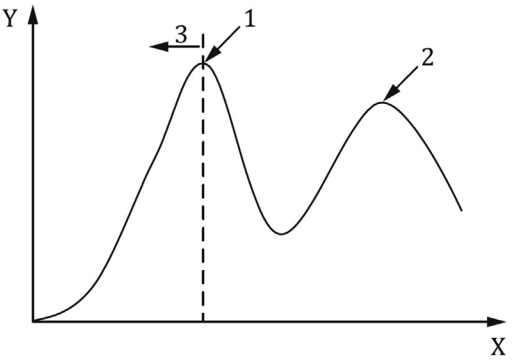

Fig. 5. When the AIMD is exposed to a uniform E-tan excitation, the transfer function is obtained via measurements in benchtop RF injected setup or simulation. The peaks in its magnitude represent resonance lengths. The example here shows two resonance lengths. (*From* ISO/TS 10974:2018. Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device; with permission.)

Key

1 first resonance
2 second resonance
3 below resonance
X AIMD length
Y deposited power at hotspot

for all clinical lead pathway scenarios and imaging conditions (human models, RF coils, and landmarks).
- Experimental exposure tests yield normalization factors that tie the heating results to specific B1 + RMS levels, allowing prediction of heating under any desired B1 + RMS, and MR imaging normal mode or first level mode Specific Absorption Rate (SAR) conditions.
- The heating acceptance criterion for the tissue surrounding the electrodes dictates what RF limit is appropriate for this specific AIMD.
  - If the results of this assessment determine that this particular AIMD lead electrodes heat up tissue surrounding the electrodes up to X degrees Celsius under MR imaging normal mode SAR, and if the acceptance criterion threshold for these tissues heating is greater than this X level, then scanning under normal mode is safe for this AIMD.
  - However, if the acceptance criterion for these tissues heating is lower than this X level, then safe scanning requires dialing down the RF level in the scanner environment to lower than the MR imaging normal mode limit, all the way to the level at which heating is lower than the acceptance criterion threshold. That RF exposure level will be deemed acceptable and will be expressed in B1 + RMS (and its corresponding SAR) as the RF limit in the MR Conditional list of the device label.

Unintended Stimulation from Radiofrequency Field-Induced Rectified Lead Voltage

This assessment is similar to the lead electrode heating. However, it is sensitive to (a function of) B1 peak. The test is described in ISO/TS 10974:2018.[16]

The concept of this assessment is as follows:

- Benchtop/scanner: The AIMD (the IPG and the connected leads) is positioned in a tissue-simulating media phantom and placed inside an RF birdcage (designed for testing or of a scanner) and lead injection voltage toward the IPG is measured under various incident field conditions (multiple lead pathways and/or RF exposures).
- Simulation: Using simulation of this benchtop setup (in vitro), the E-tans are extracted for all clinical lead pathways.
- Benchtop or simulation: The transfer function of the AIMD is measured in benchtop injected setup or simulated.
- A predictive model of injection voltage is established using the dot product of E-tans and transfer function per the following formula:

$$V = A \int_0^l S(z) E_{\tan}(z) dz \qquad \textbf{Equation 2}$$

Where V is the voltage level, A is scaler imbedding the linear fit of the AIMD model and the incident field levels, S is the transfer function, E-tans are the in vitro tangential electrical incident fields, and dz is the spatial distance increment along lead length.

- The previous formula, which describes how the AIMD model is derived, is also applied to the extracted E-tans of the human (in vivo) simulations. That results in thousands to millions of RF level predictions accounting for all clinical lead pathway scenarios and imaging conditions (human models, RF coils, and landmarks).
- The proper B1 peak values reflecting various RF coil types in clinical scanners are used in this assessment.
- The IPG should pass the acceptance criterion established by the device manufacturer based on the intended functionality when this voltage level is injected into the IPG.

Unintended Stimulation from Gradient Field-Induced Lead Voltage (Extrinsic Electric Potential)

Various scenarios of intralead, interlead, or between electrodes and a conductive IPG enclosure can result in current flow through the IPG and could cause unintended stimulation to tissue in contact with the electrodes. This assessment is similar to the RF field-induced rectified lead voltage. However, per the nature of gradient fields, it does not rely on a transfer function. The assessment is sensitive to (a function of) dB/dt peak. The test is described in ISO/TS 10974:2018.[16]

The concept of this assessment is as follows:

- The injection voltage assessment is established using the extracted E-tans of the human (in vivo) gradient simulations:

$$V = \int E \cdot dl \qquad \textbf{Equation 3}$$

Where V is the voltage level, E are the in vitro tangential electrical incident fields, and dl is the spatial distance increment along lead length.

- That results in thousands to millions of voltage predictions accounting for all clinical lead pathway scenarios and imaging conditions (human models, gradient coils, and landmarks).
- The IPG should pass the acceptance criterion established by the device manufacturer based on the intended functionality when this voltage is injected into the IPG.

Learning points for radiologists on scanning patients safely per implant MR labels:

- For an MR Conditional AIMD, the labeling conditions take care of the safety issues as long as clinical conditions stay within them per the device MR imaging instructions for use. That is, the clinical team does not need to deal with specific AIMD-MR risk-benefit decisions, if the conditions are be met as per the MR Conditional labels.
- Some implants allow scanning under the MR imaging scanner normal mode, which does not usually pose a challenge to MR technologists in performing safe and effective examinations.
- Other implants may have limits on time-varying gradients (not likely) and/or RF, which is the most common limit (typically expressed as B1 + RMS and/or SAR limits).
- Implants with a zonal (landmark) restriction typically have a restriction based on sensitivity to B1 + RMS.
- Implants with coil-type restriction (eg, a head coil–only MR label) are also related to RF restriction based on sensitivity to B1 + RMS (although B1 peak is different for various coils). Head-only Tx coils expose the patients to RF fields only within the head coil. In devices only cleared for head coil transmission, if the RF body coil activates, or if the RF coil is a receive-only head coil, it could present a significant patient hazard.
- For those implants with RF limit of B1 + RMS (and its corresponding SAR limit), using the B1 + RMS based limit is better (less restrictive), provided the scanner shows B1 + RMS. This is because the SAR limit is the minimum value for the range of SAR values corresponding to this one B1 + RMS limit (ie, for each B1 + RMS value, the corresponding SAR is a range because SAR is a function of body weight and landmark).
- Not obeying the RF limits of MR Conditional label can lead to exceeding the acceptable limit for patient harms that are sensitive to B1 + RMS/SAR and/or RF coil type restrictions and/or zone landmark restrictions, most importantly electrode heating. The most prominent example, documented in 2005, is a DBS patient who was scanned in violation of multiple labeling conditions, leading to a permanent neurologic deficit.[8]
- Device malfunctions are related to B0 field strength, or B1 peak or dB/dt peak levels, parameters that cannot readily be altered presently by an MR technologist in the clinic. Thus, it is important to abide by the MR imaging conditions defined in the label for safe scanning.
- For AIMDs requiring setting up the device in MR imaging mode before scanning, it is important to do so to avoid potential device malfunctions that can occur either during or following MR imaging exposure.
- For AIMDs requiring RF lower than normal mode when the pulse sequence to be used exceeds the implant B1 + RMS/SAR limit,
  - If the scanner is implant friendly, use the recommended option/software. A good example of that is Philips Healthcare (Amsterdam, the Netherlands) ScanWise Implant system.[20] Otherwise, any parameter that affects RF can be adjusted to reduce RF.
  - Use the “Low SAR” option. It is available on most scanners and helps to reduce B1 + RMS/SAR, typically without impacting image quality significantly. Always use this option in combination with one or more options from the following:
  - Increase TR (not to the extent of changing contrast, as in T1-SE sequences), and/or,
  - Reduce the number of slices (slice grouping), and/or,
  - Reduce flip-angle (alpha), reduce refocusing flip angle, or using fewer RF saturation bands.
  - Reduce the number of echoes (echo train length/turbo factor/shot factor).

SUMMARY

MR Conditional labels for AIMDs are developed through rigorous testing by implantable device manufacturers, using methods and guidelines that were developed with contributions from experts in various fields including MR scanner manufacturers, implant manufacturers, and regulatory agencies. Formal instructions for use of MR Conditional implants are the proper source for MR scanning conditions and parameters that can ensure patient safety. The MR imaging safety community is gaining expertise from the use of more MR

Conditional AIMDs and reflecting these learnings with collaborations from experts in the field for the benefit and safety of scanning patients with implants. Patients and clinicians have also benefitted from efforts by MR manufacturers to design more advanced MR imaging scanners and software, including those with options for limiting exposure fields. These have already helped clinicians to provide access to MR imaging for patients with implanted devices, and there are exciting opportunities for improving patient safe access in the future through advancing technologies and continued collaboration in the development of safety testing methods and standards.

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