

Active Implants in MRI: The MRI Industry's Perspective

Michael Steckner, PhD, MBA

Toshiba Medical Research Institute USA

Disclosure

- Employee of Toshiba
- Chair of NEMA/MITA (industry organization) MR Technical committee
- Co-convenor of ISO/IEC JWG (Joint Working Group) for TS 10974 (Active Implant Safety in MRI)
- Member of IEC MT40 responsible for IEC 60601-2-33 (MRI safety standard)

Acknowledgements

- The support of:
 - The nearly 200 people who over the last nine years have participated in JWG activities
 - My IEC MT40 colleagues (IEC 60601-2-33, MR safety standard) as we have debated how best to enable implant safety in MR scanners for our customers and patients
 - Hans Engels, Philips (retired), the first MRI co-convenor for JWG and former MT40 chair who originally proposed the concept of coordinating MRI outputs to implant appropriate levels in the original JWG work description

Short Outline of Next Three Presentations

- To provide an update on the extensive work done by Active Implant and MR vendors to:
 - enable patients with active devices to safely receive MR scans
 - further the MRI imaging performance of MR Conditional devices by accurate testing and labeling
 - Carefully consider end user needs (MR technologists etc) to develop practical workflow, labeling etc

Presentation Outline

- A little history and context to our confusing and difficult situation
- What is being done to resolve aspects of this problem
- The structured approach to MR conditional testing per ISO TS10974
- The new MR operational option that limits FIELD outputs (FPO:B)
- Summary

Terminology Magic Decoder Ring (1)

- Implants: passive OR active. For this presentation, usually active
- AIMDs: **A**ctive **I**mplanted **M**edical **D**evelopments. e.g.:
 - **pacemakers**, defibrillators,
 - nerve stimulators, bladder, sphincter etc stimulators
 - cochlear implants
 - drug pumps
 - monitoring devices
- ISO (for implants), IEC (for MRI), JWG: two international standards groups, “Joint Working Group” when they work together

Terminology Magic Decoder Ring (2)

- ASTM 2503-13 definitions:
 - *MR Safe*—an item that poses no known hazards resulting from exposure to any MR environment...
 - *MR Unsafe*—an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.
 - ***MR Conditional*—an item with demonstrated safety in the MR environment within defined conditions...**

MR Conditional is defined as: an item...

- | | |
|-----|--|
| 95% | 1. with demonstrated safety in the MR environment within defined conditions |
| 0% | 2. that poses no known hazards resulting from exposure to any MR environment |
| 5% | 3. that poses no known hazards in any MR environment because all design issues resolved |
| 0% | 4. which poses unacceptable risks to the patient, medical staff or other persons within the MR environment |
| 0% | 5. that poses no known hazards in any MR environment if it has been turned off |

Correct Answer

- #1 MR Conditional: an item with demonstrated safety in the MR environment within defined conditions...
- **Wrong Answers:**
 - an item that poses no known hazards resulting from exposure to any MR environment... [MR Safe]
 - an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment. [MR Unsafe]
 - An item that poses no known hazards in any MR environment because all design issues resolved [That would make it safe]
 - An item that poses no known hazards in any MR environment if it has been turned off [Not helpful for passive implants]

Implants (not) in MRI, in the beginning

- Historically, implants have been contra-indicated in MRI:
 - Attractive force concerns,
 - Particular concern for active devices with long leads (e.g. pacemakers) and the potential for significant local heating/tissue burning,
 - Implants not initially designed to consider MRI safety issues,
 - A lack of tools to evaluate implants for MRI safety factors

Implants in MRI, early technology improvements

- More recently:
 - Implants redesigned to eliminate ferrous components where possible
 - A growing deep awareness of the factors in MRI/implant interactions
 - Major engineering efforts to design implants which can be scanned in MRI
 - Collaborative efforts between MR and AIMD vendors
 - Development of test procedures to quantify degree of “MR Condition” (ASTM series, more recently TS10974 etc)

The Current Situation (1)

- MRI system information used by implant vendors to support their claims intended for other purposes, or unavailable. e.g.:
 - SAR for patient heating evaluation, not for determining device heating
 - attractive forces information originally for auxiliary devices (e.g. contrast injection pumps) compatibility testing, not force/torque on implants
 - MR vendors do not show sequence max dB/dt values, nor currently provide for operator control
- MRI vendors now releasing more information:
 - B1+rms RF field information for better device labeling (better than SAR)
 - More clarity on how MRI vendors exactly compute spatial field gradients (SFG), define Transmit Coil technology, frequencies of operation etc

The Current situation (2)

- Coordination between regulatory bodies (e.g. FDA), Implant and MRI vendors on consistent use of terminology e.g.:
 - Formal Transmit Coil technology definitions (started, to be continued)
 - **“Spatial Field Gradients”** as defined in IEC 60601-2-33 NOT “spatial gradient” or “spatial gradient magnetic fields” etc! (recently adopted by the FDA in their most recent implant guidance document – thank you!)
 - **FYI: Next edition of IEC standard formally defines SFG maxima location OUTSIDE covers**
 - FDA efforts to create device label templates that are consistent, use information that is actually available
- Much progress to-date, still a long ways to go... a significant learning burden for MR technologists (understand old labeling, learn the new and evolving labels) etc

Which terminology/definition combination is correct?

- 0% 1. “Spatial Gradient”, maxima covers on
- 0% 2. “Spatial Gradient”, maxima covers off
- 11% 3. “Spatial Field Gradient”, maxima covers off
- 78% 4. “Spatial Field Gradient”, maxima covers on
- 11% 5. “Spatial Gradient Magnetic Fields”, maxima covers on

Correct Answer

- #4 “Spatial Field Gradient”, maxima covers on
 - For many years the five major MR vendors (GE, Hitachi, Philips, Siemens, Toshiba) have released SFG info as “covers on”. Now an explicit requirement in next revision of the IEC MR safety standard (ed. 3.2)
- **Wrong Answers:**
 - “Spatial Gradient”, maxima covers on
 - “Spatial Gradient”, maxima covers off
 - “Spatial Field Gradient”, maxima covers off
 - “Spatial Gradient Magnetic Fields”, maxima covers on

A short Introduction to Relevant Standards

- Standards almost always voluntary (certainly true for MRI)
- IEC 60601-2-33 (maintenance team MT40): responsible for MRI and patient MRI safety
- ISO TS 10974 (JWG): interactions between MRI scanner and implanted device
 - A “horizontal” standard attempting coverage of all active implants, but no requirements
- ISO SC6 (responsible implant committee): responsible for implants and the safety of the implant patient
 - The emerging “vertical” standards responsible for specific active implant types, including requirements

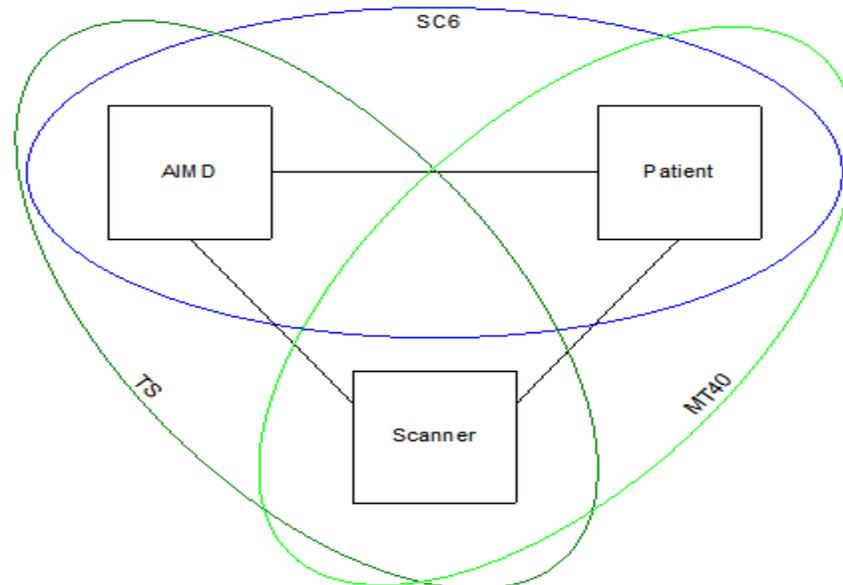


Figure from TS10974

IEC 60601-2-33 (ed 3.2). MRI Safety Standard

- International standard responsible for MRI safety, recognized by all MRI vendors
- Now including the release of additional information, improved clarity, as negotiated with JWG, recently FPO:B
- Revision of contra-indication statements:
 - First a lowering of concern to generically recognize the existence of MR Conditional labelled implants
 - Now a progression of statements from contra-indication (for devices with **NO** MR conditional label) to cautionary (MR conditional devices)

ISO/IEC Joint Working Group (JWG) TS 10974

- September 2006, Vienna. Joint symposium between Implant and MRI vendors. Agreement to collaborate, focus on active implants
- JWG formed to create test methods to help evaluate for MR conditional labeling of Active Implants in MRI scanners
 - TS 10974 “Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device”
 - First edition published 2012 (200 pages)
 - TS = Technical Specification (not mature enough to be a full international standard)
 - Second edition meeting cycle, draft 2nd edition nearly complete. Imminent to be distributed for International vote, commentary (300+ pages?)
 - Curt Sponberg, Medtronic (lead convenor)
- 20 international development meetings since 2006, nearly 200 people involved, meeting attendance can be 50+

TS 10974. AIMD/MRI interactions

- providing guidance to AIMD vendors about 7 hazards, 10 tests to evaluate devices
- With good tests, good MR Conditional labels possible. If labeling accurate, safety margins under better control. **Off-label scanning not a good idea!**

General hazards to the patient	Test requirement
Heat	RF field-induced heating of the AIMD
	Gradient field-induced device heating
Vibration	Gradient field-induced vibration
Force	B_0 -induced force
Torque	B_0 -induced torque
Extrinsic electric potential	Gradient field-induced lead voltage
Rectification	RF field-induced rectified lead voltage
Malfunction	B_0 field-induced device malfunction
	RF field-induced device malfunction
	Gradient field-induced device malfunction ^a

Table from TS10974

Controlling MRI scanner outputs for AIMDs

- SAR, PNS (peripheral nerve stimulation): MRI patient physiology factors
- AIMDs interact with the fields of an MRI per laws of **PHYSICS**
- **WHAT IF:** MRI scanner outputs controlled to levels that do not damage the AIMD **AND** do not cause patient harm?
 - Depends on the type of implant (Does it have leads? How big? etc)
 - Level of technology (we are in the relatively early days)
 - Are the MRI outputs too low for reasonable diagnostic images? (Any performance restriction will have some clinical practice impact)
- Fixed Parameter Option: Basic (FPO:B)
 - An option to limit MRI scanner outputs
 - Compatible with “Normal Mode” and “1st level controlled Mode” labeling
 - Just published in standard, not yet released in any MRI, AIMD

FPO:B Definition

- **1.5T ONLY**
- Approximately equivalent to normal mode limits, but some 1st level sequences may run
- The user will never see, or need to know these numbers

Table 201.107 FPO limits applicable for cylindrical MR SYSTEMS

Physical Parameter	FPO:B
Nominal static magnetic field strength	1,5 T
Applicable coils	Birdcage WHOLE BODY RF TRANSMIT COIL Birdcage HEAD RF TRANSMIT COIL CIRCULARLY POLARIZED RF shall be applied.
$B_{1+ PEAK}$	$\leq 30 \mu\text{T}$
$B_{1+ RMS}$	$\leq 3,2 \mu\text{T}$
$(dB/dt PEAK)_{FPO}$	$\leq 100 \text{ T/s}$
$(dB/dt RMS)_{FPO}$	$\leq 56 \text{ T/s}$

NOTE 2 Cylindrical MR systems with elliptical PATIENT apertures can meet requirements for FPO:B.

How FPO:B might be implemented

- Confirm the patient has an FPO:B labeled device
- If required by AIMD labeling, change AIMD mode of operation prior to bringing patient into magnet room
- Select FPO:B during patient registration. **ALL** future scanner operations now restricted for the duration of the study
- Follow all other AIMD MR conditional requirements (e.g. scan time, landmark etc restrictions) found on the label
- **Only use with FPO:B labeled devices**
- FPO:B may have other uses for patients without implants (e.g. restrict patient scanning to approximately normal mode if thermoregulatory compromised)

Which FPO:B statement is correct?

- 25% 1. enabled during registration, no further precautions required
- 2% 2. can be safely applied to any implant
- 66% 3. is just one of the MR Conditional label instructions
- 5% 4. will be available at all field strengths
- 2% 5. will be turned on a “per sequence” need

Correct Answer

- #3 FPO:B is just one of the MR Conditional label instructions
 - **Please follow all label instructions**
- **Wrong Answers:**
 - enabled during patient registration no further precautions required
 - [It will be enabled during patient registration, but there may be additional label instructions to follow]
 - can be safely applied to any implant
 - [The implant must be labelled as FPO:B]
 - will be available at all field strengths
 - [Just 1.5T at the present time]
 - will be turned on a “per sequence” need
 - [On for the entire study]

Futures

- TS10974 2nd edition to publish early 2016
- Start work on 1st edition of International Standard (publish ~2020)
 - Improve quality of tests, clarity of document, consider 3T (?)
- FPO:B is a trial case, collect user feedback. If successful:
 - A 3T variant?
 - Lower and/or higher power variants?

Summary

- **Follow the MR Labeling!**
- New technology always welcome, implementation and execution have been challenging!
- Reliable tests now available, being improved. Should result in high quality MR Conditional labeling. Safety margins under tighter control
- Concerted major and coordinated efforts to solve problems, improve workflow, educate users
- Can anticipate more devices with a range of labeling.
- **Follow the MR Labeling!**