Testing Methods and Standards for Magnetic Resonance (MR) Safety and Compatibility of Medical Devices - Update

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Introduction

Important product groups interacting with MR

• vascular implants
  stents, filters, clips, valves

• interventional instruments
  catheters, guidewires, endoscopes,

• orthopedic implants
  prostheses, fixation devices

• active implants and medical electrical devices
  robots, monitoring equipment, injectors

• surgical instruments
  prostheses, fixation devices

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The MR environment

- Controlled area
- MR cabin or Magnet room
- MR-imaging volume
- MR system
- 0.5 mT line
- e.g. technical room

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Subjects and Methods

Why is MR testing required for medical devices?

Magnetic induced forces and torques, which affect medical devices in the static magnetic field are dangerous for patients, users and equipment.

magnetic force $F_m$, force due to gravity $F_g$, static magnetic field strength $B_0$, magnetic torque $T_m$ (here: in the fringe field), deflection angle $\alpha$, rotation angle $\theta$


Image extracted with permission from Taylor & Francis: G. Schaefers et al., Testing methods for MR safety and compatibility of medical devices, Minimally Invasive Therapy. 2006; 15:2; 71–75

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Why is MR testing required for medical devices?

**RF heating** caused by induced voltages and currents at current nodes is dangerous for patients and users of MR techniques.

Heating caused by conductive loops $^1$

Temperature may rise also, if $L_{\text{wire}}$ is $< \text{or} > \lambda/2_{\text{tissue}}$ $^1,3$

at 0.2 T: $\lambda/2_{\text{tissue}} \approx 1.96$ m
at 1.5 T: $\lambda/2_{\text{tissue}} \approx 0.26$ m
at 3.0 T: $\lambda/2_{\text{tissue}} \approx 0.13$ m

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Ref.: $^1$modified to A. Oppelt et al., from presentation


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RF heating aspects of leads by courtesy of J. Helfer et al., Biophan Inc., USA

Temperature profile from mathematical modeling of active fixation pacemaker lead in an MRI field.

The thermal conductivity of the lead transports substantial heat creating a physically separated region of peak temperature
Switched gradient magnetic fields contribute negligible to induced heating, but dynamic gradient magnetic fields can cause nerve stimulation and can lead to induced currents in conductive structures.

Factor of approx. 100 to 1000 between RF frequency (MHz) and gradient frequency (kHz)

\[
\frac{dB}{dt} \text{ is dependent on gradient magnetic field vector and position (x,y,z) within the gradient coil}
\]

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Why is MR testing required for medical devices?

Computer simulation

- Assistance for MR safety testing

E- and H-field of an MR active implant (resonant circuit) at 42,6 MHz


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- Evaluation of MR characteristics of medical devices
- H- and E-field components, resonant frequencies of electrical conductive structures and MR active devices with resonant circuits
- SAR and temperature distribution, worst-case estimation

Qualitative results of numerical investigation of hip prostheses in a human torso phantom in MRI, red = high values, blue = low values  
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Why is MR testing required for medical devices?

Safe functioning

- **of the external device** used with MR. Any interferences caused by the MR environment on
  - active/ non-active device systems? *(inhibition of elec. circuits/ mechanical components (levers, etc.))*
  - RF sensitive devices? *(Electromagnetic compatibility)*
  - high **acoustic noise** level of the MR system? *(interferences with sensors, systems, etc.)*

- **of the MR system** *(patient safety, image quality)* Any interferences caused by the external device?
  - RF emitting devices *(Electromagnetic compatibility)*

- **between different external medical devices** *(implant, instrument, etc.)* within the MR environment
Why is MR testing required for medical devices?

RF interferences (stripes and dots)
- RF emitting devices (Electromagnetic compatibility)
  - stripes and dots are caused by periodic emitted signals inside the RF cabin
  - dots caused by synchronous signals
  - stripes caused by unsynchronous signals


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Why is MR testing required for medical devices?

RF interferences (stripes and dots):
- RF emitting devices (Electromagnetic compatibility)

possible reasons:
- unshielded cables and electronic devices, e.g.
  - monitoring systems
  - switched power supplies
  - computer clocks

Image by courtesy of Dr. H. Kugel, Department of Clinical Radiology, University of Muenster, Muenster, Germany

4Arnulf Oppelt (ed.): Imaging Systems for Medical Diagnostics. Publicis Corporate Publishing, Erlangen 2005
Why is MR testing required for medical devices?

**MR Imaging artifacts**
- influences to the magnetic field cause **image distortion**

Susceptibility artifacts are dependent on several parameters, for example:

- Strength of $B_0$
- Orientation to $B_0$
- Susceptibility of device’s material
- Direction of phase encoding
- Technique of sequence (SE/GRE)
- Time of echo

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6Image extracted with permission of from Taylor & Francis: G. Schaefers et al., Testing methods for MR safety and compatibility of medical devices, Minimally Invasive Therapy. 2006; 15:2; 71–75

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Why is MR testing required for medical devices?

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• Orientation to $B_0$
• Susceptibility of device‘s material
• Direction of phase encoding
• Technique of sequence (SE/ GRE)
• Time of echo

Holding arm ($\varnothing \approx 40$ mm) for e.g. instruments, by courtesy of Dr. M. Vogele, Medical Intelligence, Schwabmunich, Germany

Why is MR testing required for medical devices?

**MR Imaging artifacts**
- Electromagnetic shielding of RF signals is causing void of MR information

RF artifacts are dependent on several parameters, for example:
- Strength of $B_0$
- Orientation to MR coils
- Conductivity of device's material
- Design geometry of the device
- Flip angle, strength of $B_1$

Artifacts lead to difficulty with follow-up examination of patients with already implanted devices or if using unsuitable instruments/devices

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Results
Testing issues for medical devices used with MR

- Magnetic induced displacement force
- Magnetic induced torque
- Radio frequency (RF) induced heating
- Gradient and RF induced voltages
- Safe functioning of the external device within the MR environment
- Safe operation of the MR system

MR image artifacts and quality issues
- Susceptibility artifacts (dependent on material)
- RF artifacts of implants and devices in the imaging volume (signal shielding and amplification effects)
- RF artifacts in the MR image due to RF emission
- Signal-to-Noise ratio (SNR)
- $B_0$-Field homogeneity (image uniformity/ spatial distortion)

List is not limited to above mentioned issues
Current situation of medical devices in conjunction with MRI

MR system manufacturers

"Patient with implants have a contraindication for MRI"

Notified authorities

"concerned about patient safety"
"recommend MR testing for labeling of devices"

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further research necessary

Patients with implants

"could have clinical indication for MR examination"

Clinicians/MR users

"want to use advantages of MRI for patient diagnosis"
"get help by MR testing results"

MR testing of medical devices according to international standards

Implant manufacturers

"require guidance for developing MR safe/conditional devices"
The historically definition* of MR safety and compatibility

MR safe - The device, when used in the MR environment, has been demonstrated to present no additional risk to the patient or other individuals, but may affect the quality of the diagnostic information.

MR compatible - The device, when used in the MR environment, is MR safe and has been demonstrated to neither significantly affect the quality of the diagnostic information nor have its operations affected by the MR device.

• Report MR test conditions
• MR safe for one set of condition
• Consider more extreme MR conditions

Definitions and icons extracted, with permission, from “ASTM F2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment”, copyright ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428. A copy of the complete standard may be purchased from service@astm.org, website: www.astm.org.

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The **active** definitions of MR safety: **MR Safe**

MR Safe—an item that poses **no known hazards in all MR environments**.

(in addition, icons have a black white option)

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The **active** definitions of MR safety: **MR Conditional**

MR Conditional—an item that has been demonstrated to **pose no known hazards in a specified MR environment with specified conditions of use.** Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required.

(in addition, icon has a black and white option)

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The **active** definitions of MR safety: **MR Unsafe**

MR Unsafe—an item that is known to pose hazards in all MR environments.  

(in addition, icon has a black white option)

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"MR compatibility" - MR Image Artifacts

An MR image artifact is not considered as a direct safety issue by ASTM F2503-05 Standard Practice for Marking Medical Devices and therefore handled as separate issue, but

- artifact information provide **important help for the physician** before MR scanning of a patient with implant or other item

- a statement about MR image artifacts produced by an implant/ item **should be included in the product labeling/patient implant card**
“Radiopacity“ of medical devices

- Evaluation of the transparency of materials to X-rays
- Required to stay compatible with the commonly used X-ray imaging techniques
  - Materials with low artifact behavior can have a minor X-ray attenuation
  - X-ray suitable materials can produce MR image artifacts

MR safety, MR image artifacts and radiopacity should be considered as interconnected system

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Current standards for MR safety and compatibility testing

IEC
- 60601-2-33 Medical electrical equipment - Particular requirements for the safety of magnetic resonance equipment for medical diagnosis

ASTM
NEW F2503 - Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment

Standard Test Method for Measurement
- F2052 - of Magnetically Induced Displacement Force on Medical Devices in MR-environment
- F2213 - of Magnetically Induced Torque on Medical Devices in the MRE
- F2182 - of Radio Frequency Induced Heating Near Passive Implants During MRI
- F2119 - for Evaluation of MR Image Artifacts from Passive Implants

Detailed Information for testing is provided in above standards
FDA recommends ASTM test methods for device approval

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Standards considering MR testing for medical devices

- ISO 14630:2005 Non-active surgical implants -- General requirements
- ISO 9713:2002 Neurosurgical implants -- Self-closing intracranial aneurysm clips
- ISO 7197:1997 Neurosurgical implants -- Sterile, single-use hydrocephalus shunts and components
- ISO 5840:2005 Cardiovascular implants -- Cardiac valve prostheses
- EN 14299 - Non active surgical implants. Particular requirements for cardiac and vascular implants. Specific requirements for arterial stents.

MR testing is required for heating, movements and evaluation of image artifacts for product labeling

...and requirements against interferences from external electrical and magnetic fields

- EN 45502-1:1998 Active implantable medical devices. General requirements
- EN 45502-2-1:2003 Active implantable medical devices. Particular requirements (cardiac pace makers)
FDA guidelines for Industry and Staff considering MR testing for medical devices

- Non-Clinical Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems, 2005
- Implantable Radiofrequency Transponder System for Patient Identification and Health Information, 2004
- Implantable Middle Ear Hearing Device, 2003
- Cardiovascular Intravascular Filter 510(k) Submissions, 1999
- Medical Devices with Sharps Injury Prevention Features, 2005
- Intravascular Administration Sets Premarket Notification Submissions [510(k)], 2005

Guidelines contain MR safety recommendations in general up to detailed information and links to ASTM test methods

- **Obsolete**: A Primer on Medical Device Interactions with Magnetic Resonance Imaging Systems, 1997 contains appendix with questions of MR safety issues regarding risk analysis
MRI statement for device approval

The FDA asks for MR safety and compatibility testing of devices

Regarding MRI compatibility, a suggested labeling statement is: The [device name] has been shown to be MR safe at field strengths of 1.5 Tesla or less, a maximum spatial gradient of [___], gradient magnetic fields of [___] or less and a maximum whole body averaged specific absorption rate (SAR) of [___] for [___] min of MR imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the [device name].

Examples for MRI statements from recent device approvals

5.4.1 MRI Statement

The [device name] Coronary Stent has been shown to be MRI safe immediately following implantation at field strengths of 1.5 tesla or less, a maximum spatial gradient of 450 gauss/cm, gradient magnetic fields of 6.3 mT/m or less and a maximum whole body averaged specific absorption rate (SAR) of 1.2 W/kg for 15 minutes of MR imaging. MR imaging quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.
5.3.1 MRI

Through non-clinical testing, the stent has been shown to be MRI safe at field strengths of 3.0 Tesla or less, a maximum spatial gradient of 3.3 Tesla/meter and a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg for 15 min of MRI.

Stent should not migrate in this MRI environment. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3.0 Tesla or a maximum spatial gradient higher than 3.3 Tesla/meter.

In this testing, the stent produced a temperature rise of less than or equal to 0.5°C at a maximum whole body averaged specific absorption rate (SAR) of 2.0W/kg for 15 min of MRI. The effect of heating in the MRI environment for overlapping stents or stents with fractured struts is not known.

MRI quality may be compromised if the area of interest is in the exact same area as or relatively close to the position of the stent.

Magnetic Resonance Imaging (MRI)
The stent has not been tested for safety in the MR environment. Therefore, MRI scans should not be performed on patients post-implantation until the stent has completely endothelialized to minimize the potential for migration. For a conventional uncoated 316L stainless steel stent, this period is usually considered to be 8 weeks. This device has not been evaluated for heating in the MR environment.

ref.: from publicized FDA approvals on the Internet

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Conclusion

• Magnetic resonance in medicine is a dynamic and innovative field with an increasing number of cases and associated products.
• Implants, instruments, and other medical devices interact with MR techniques and thus create safety risks and incompatibility.
• International MR testing and safety standards are required for minimizing risks and guiding the manufacturing of MR safe and compatible products.
Goals of MR standards for medical devices

- Increase of safety for patient and user of MR techniques, as well as for MR equipment and additionally used devices
- Meet the needs of manufacturers of MR safe and compatible devices for providing optimal patient care-increasing diagnostic accuracies in future.
- Enable the use of the advantages of MR technology to patients with implants and the application of additionally devices
Thank you very much for Your attention!