MRI Safety in Patients with Implants and Devices

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Multiple Potential Issues

- Case Heating
- Force & Torque
- Vibration
- Device Interactions
- Lead Heating
- Stimulation

Patient Screening

All Patients should be completely screened prior to each and every MR exam by trained individuals (at least one screening should be by Level 2 personnel). Having successfully undergone an MR procedure in the past, is not an indication that a future procedure may be safely performed.

Labeling

ASTM Standard F2503® Defines Three Terms:

- MR Safe
- MR Unsafe
- MR Conditional

MR Safe

An item that poses no known hazards in all MR environments

* Any item that is metallic, magnetic or electrically activated will not be labeled as “MR Safe”
MR Unsafe
An item that is known to pose hazards in all MR environments

MR Conditional
An item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use

Passive Devices
http://2.bp.blogspot.com/-teq7Ao_S4SE/ULw2BMaFsmI/AAAAAAAAEz8/OEKXk4sKS44/s320/Filter.jpg

Active Devices

Intracranial Aneurysm Clips
If unsure of the presence
- Previous radiographs, CT or MR

Clip present: MR should not be performed until it can be documented that the clip is either “safe” or “MR Conditional”

All documentation must be in writing
Verbal histories and histories by non-physicians are not acceptable

ACR Guidance Document 2013 (pg 15 - 16)
Fax copies of reports are acceptable (if legible)

- Clips manufactured 1995 or later for which the manufacturer’s product labeling continues to claim MR Conditional labeling may be accepted without further testing
- Clips manufactured before 1995 require either pretesting (per ASTM F2503 standard) or review of a previous MRI (if available)
- Previous MR (without images) not acceptable

### Intracranial Aneurysm Clips

<table>
<thead>
<tr>
<th>MR Conditional</th>
<th>MR Unsafe</th>
</tr>
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</table>

### Spatial Magnetic Field Gradient

A fixed difference in a magnetic field across space

\[
\frac{\Delta B}{\Delta x}
\]

Force = \( B_0 \frac{dB}{dx} \)

### Spatial Field Gradient Map

1 T/m = 100 G/cm

### Testing Methodology

Measuring the “Deflection Angle”

Generally, if an object/device has a deflection angle of > 45°, it will be labeled as MR Unsafe unless additional test data shows otherwise
Testing Methodology

Measuring the “Deflection Angle”

The system’s maximum spatial gradient is irrelevant. It is the maximum spatial field gradient to which an object will be exposed that may be relevant to safety determinations.

Spatial Field Gradient Map

For certain implants or devices, the spatial field gradient to which an object will be exposed may need to be determined.

Bore Size Differences

1.5 T

Spatial Field Gradient at a given distance from the wall

Ge Optima MR450w
70 cm bore

Spacial field gradient (G/cm) = Distance (D cm)

x = Spatial gradient, G/cm
y = Distance, cm

Spatial Field Gradient at a given distance from the wall

Cntr of bore: 2.6 T/m (260 g/cm)

20 cm FOV 2.8 T/m (280 g/cm)

30 cm FOV 3.0 T/m (300 g/cm)

40 cm FOV 3.3 T/m (330 g/cm)

50 cm FOV 3.8 T/m (380 g/cm)

55 cm FOV 4.2 T/m (420 g/cm)

60 cm FOV 4.7 T/m (470 g/cm)

70 cm (wall) 6.7 T/m (670 g/cm)
Spatial Field Gradient at a given distance from the wall

- Cntr of bore 2.6 T/m (260 g/cm)
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- 70 cm (wall) 6.7 T/m (670 g/cm)

GE Optima MR450w
70 cm bore

- Force = $B_0 (dB/dx)$
- Force = 0 where $B_0 = 0$

Device Heating

- Force = $B_0 (dB/dx)$
- Force = 0 where $dB/dx = 0$
- Isocenter
Historically

SAR
A measure of the rate at which energy is absorbed by the body when exposed to a radio frequency (RF) electromagnetic field

• Estimate of RF power deposited in specific regions of the patient
• Varies with tissue, patient size
• Will vary with MR system vendor
• No standard exists for SAR estimations
• MR system vendors do not publish their proprietary SAR algorithms

B\textsubscript{1+}rms
The positively rotating component of the B\textsubscript{1} field
Useful for imaging

B\text{field}

Electromagnetic Wave

B\text{field}

B\textsubscript{1+} refers to the positive rotating component of the B\text{Field}

B\textsubscript{1+}rms
Statistical measure of the magnitude of the positive rotating component of the B\textsubscript{1} field averaged over the TR
Typically expressed in units of microTesla (\mu T)
Example Display

Sample shown from a Siemens system

Example Display

Sample shown from a Philips system

Example Display

Sample shown from a GE system

Wavelength is based on Frequency

Frequency is based on $B_0$

$$\lambda = \frac{c}{f} = B_0 \cdot \gamma$$

$1.5 \ T \times 42.6 \ MHz/T = 64 \ MHz$

$3.0 \ T \times 42.6 \ MHz/T = 128 \ MHz$

Field Strength, Frequency, Wavelength

Scalp burn from halo

Just because something is not ferromagnetic doesn’t mean it’s not a good conductor

Cervical Fixation Device at 3.0 T

For elongated or closed loop implant or device implant, heating can differ significantly at different field strengths

Images courtesy Frank Shellock, Ph.D.
**FDA: Worse-Case Scenario**

- Wire insulated along its entire length except for the tips
- Oriented superoinferiorly (cylindrical bore magnet)
- Radially positioned to the side of the bore
- 1.5 T: approx 25 - 30 cm
- 3.0 T: approx 12.5 - 15 cm

**MRI-Related Lead Heating: Pacing Lead, No IPG**

1.5 T (1.4-W/kg) vs. 3-T (3-W/kg)

<table>
<thead>
<tr>
<th>Temperature (˚C)</th>
<th>18.00</th>
<th>26.00</th>
<th>34.00</th>
<th>42.00</th>
<th>50.00</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time (sec)</td>
<td>0</td>
<td>350</td>
<td>700</td>
<td>1050</td>
<td>1400</td>
</tr>
</tbody>
</table>

For certain lead lengths, less heating at 3-T/128MHz vs. 1.5-T/64MHz due to differences in resonant wavelength.

**T/R Head Coil vs. Transmit Body / Receive-only Head Coil**

**Two Serious Injuries @ 1.0 T**

Guidelines not followed

**Stents**

Coronary Artery Stents

Single or Multiple

Multiple overlapping stents increase the overall length and may pose a heating issue at higher fields (> 3 T)

**Stents**

Coronary Artery Stents

Single or Multiple

The MR Radiologist is responsible for developing written policies and procedures for dealing with such devices.
Implants and Devices

Use caution with “blanket” policies

**NOT ALL “STENTS” ARE “SAFE”**

Aorfix AAA Flexible Stent Graft

MR Conditional
[http://www.lombardmedical.com](http://www.lombardmedical.com)

Spanner Prostatic Stent

MR Unsafe

Resonance Metallic Ureteral Stent

MR Conditional
[https://www.cookmedical.com](https://www.cookmedical.com)

Implants and Devices

Continually review and update policies/procedures

Implants and Devices

Labeling can change based on testing and clinical data

Resolution Clip: MR Conditional

Implants and Devices

New devices are introduced all the time

“Decisions based on published MR safety and compatibility claims should recognize that all such claims apply only to specifically tested conditions, such as static magnetic field strengths, static gradient magnetic field strengths and spatial distributions, and the strengths and rates of change of gradient and radiofrequency (RF) magnetic fields.”
“...one should never assume MR compatibility or safety information about a device if it is not clearly documented in writing.”

Final determination of whether or not to scan any given patient with any given implant, foreign body, etc., is to be made by the level 2 MR personnel—designated attending MR radiologist, the MR medical director, or specifically designated level 2 MR personnel following criteria for acceptability predetermined by the medical director.

Labeling for Implants and Devices

Identify the Device

Determine MR Labeling

MR Conditional

MR Unsafe

What are the conditions?

Stop

Can you provide them?

Excludes Referring Physician
Labeling for Implants and Devices

Identify the Device

Determine MR Labeling

The Radiologist must assess the available information and make a risk vs benefit decision for that patient.

All procedures dealing with assessment of implants or devices must be documented in writing.

Information Sources

- Patient Medical Record
- Device manufacturers web site
- mrisafety.com
- magresource.com

The label contains information for thousands of implants, devices, materials, and other products. The objects in the list are divided into major categories to facilitate access and review of pertinent information.

To properly utilize the list, particular attention must be given to the information indicated for the highest risk magnetic field strength useful for testing and the USFII information indicated for a given object.

Specific MR information is to be obtained from the manufacturer's literature.
Good reference book for MRSO/MRMD

Conditions of Use Can Include:

- Static Field (B0)
- Radio Frequency Field
- SAR
- B1 rms
- Duration of Single Series or Entire Scanning Session
- Type of Coil
- Spatial Gradient
- Time-Varying Gradient Slew Rate
- Landmarking / Centering
- Patient Height
- Location of Device Implantation
- Patient Monitoring

Questions?