MRI Safety:
Medical Implants and Other Concerns

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Basic Safety concerns:
Foreign Objects (metals)
Projectile Hazards (ferrous materials)
Screening:
Patients, Devices
Medical Implants:
What to do? – a reality check
What should be your concerns?
Note: NO DISCUSSION OF CONTRAST AGENT SAFETY TODAY
Here’s the way that we summarize MR safety to the GRU community at large:

The MRI environment can be a fairly safe place to work ... ... if you follow a few IMPORTANT rules.
Rule #0: **Giving yourself an extra 1-2 seconds to consider a situation, for MR safety sake, is rarely ever a problem (even during a code).**

What am I about to do? What does this involve?

What do I have on my person?

**Stop, consider, then act.**
Ten Basic GRU MR Safety Rules

Rule #1: NEVER ENTER THE MRI ROOM WITHOUT PERMISSION FROM AN MRI TECHNOLOGIST

Rule #2: THE MRI MAGNET IS ALWAYS ON (24 hrs a day, 365 days a year).

Rule #3: MRI ZONES INDICATE AREAS OF ACCESS.
Ten Basic GRU MR Safety Rules

Rule #4: **DEVICES THAT ARE NOT LABELED AS “MR SAFE” SHOULD BE CONSIDERED **UNSAFE UNDER SOME OR ALL CIRCUMSTANCES **IN THE MR SCANNER ROOM.**

Rule #5: **FERROUS OBJECTS CAN BE ATTRACTED TO AN MR MAGNET**
Ten Basic GRU MR Safety Rules

Rule #6: BEFORE ENTERING THE SCAN ROOM, PAY ATTENTION TO **OBJECTS IN YOUR POSSESSION**.

Rule #7: FOREIGN OBJECTS **WITHIN** THE BODY CAN POSE A HAZARD **WITHIN** THE SCAN ROOM.

Rule #8: MEDICAL IMPLANTS DESERVE SPECIAL ATTENTION.
Ten Basic GRU MR Safety Rules

Rule #9: PATIENTS WITH ANEURYSM CLIPS ARE ONLY ALLOWED IN THE MR SCAN ENVIRONMENT IF THEIR PRIMARY PHYSICIAN SIGNS AN ATTESTATION TO THE SAFETY OF THE CLIP.

Rule #10: BEFORE ATTEMPTING CRITICAL CARE, MEDICAL STAFF MUST REMOVE A PATIENT FROM THE MR SCAN ROOM DURING A CODE.
In the MR environment in general...metals are NOT your friends.

- All metals are good electrical conductors.
- Conductor = mobile electrons (e.g., wires)
- Why do electrons want to move around?
  - Electric fields = 0 inside conductor
  - Magnetic fields = constant inside conductor.
In the MR environment in general...metals are NOT your friends.

- Outside conductor: Oscillating EM field (i.e., RF excitation)
  - Inside conductor: stimulated oscillating b-field
  - Electrons move inside the conductor to balance non-constant b-field

Moving charges = current
Current $\rightarrow$ heat ($P=IV$)  (**Problem #1 with metals**)

Heat or current may be bad/extreme under certain conditions.
When is heat/current bad (metal or otherwise)?

• Tissue conduction of heat away from metal is poor (large patients)
• Close proximity of current/heat to nerves (pain).
• Patient forms current loops using body.
• Proximity to RF transmit coils (sides of bore).
  Double whammy(current/heat) – arm touching side of bore and forming a body loop.
• Medical devices
In the MR environment in general...metals are NOT your friends.

When should we worry about heat/current?

• Dimensions of metal object “tune” it to the oscillating frequency.
So, what can we do about it?

Shouldn’t allow wires/cables to touch skin → avoid thermal burns. Use pads/thick blanket.

Padding between arms and body/legs.

Non-MR-compatible leads in scanner are bad.

No loops in wire → avoid antennas!

No touching the side of bore – pads.
Projectile Hazards and MR Safety
FERROUS OBJECTS CAN FLY INTO THE MAGNET WITH GREAT SPEED AND FORCE. (Problem #2 with metals)

Some metals are not ferrous... but can YOU tell the difference by eye?
Flying metal can be deadly

A child was killed in New York (2001) by a flying oxygen cylinder, similar to the gas tank shown here.

http://simplyphysics.com/fling_objects.html#
The MRI magnets are ALWAYS ON (24 hours/day, 365 days/year).

http://simplyphysics.com/flying_objects.html#

http://www.youtube.com/watch?v=6BBx8BwLhqg

→ Chair attracted by well over 1500 lbs of force into an MR research magnet. Of similar weight…
An incident recently occurred at an outpatient imaging center in western New York State, in which a firearm spontaneously discharged in a 1.5-T MR imaging environment with active shielding.
Other Projectile Accidents at Other Places

• Scissors from a physician assistant in scan room flew into MR tech's forehead (trip to the OR).
• Patient thrown into magnet with gurney (foot, ankle fractures).
• Flat-screen monitor (research) was brought into scan room...flew into volunteer's face.
Accidents have occurred on our site.

These two incidents were preventable. Fortunately, no one was hurt.
Code carts NEVER go into MRI room!

Carts can become projectile objects. Bringing a cart into the room with a patient in the MR scanner could harm or kill the patient and staff.
All of the above items are MR unsafe (except the MR CONDITIONAL ventilator). However, none were labeled as unsafe. Why not?

They contain a lot of metal.

DO NOT TRUST UNLABELED ITEMS AS MR SAFE!
Screening: Mechanisms

Why should we screen devices or people?
**MR Safe** – Item poses NO KNOWN HAZARDS in all MR environments. Absolutely no metal present in device.

**MR Conditional** – Item poses no known hazards IN A SPECIFIED MR ENVIRONMENT WITH SPECIFIED CONDITIONS OF USE. May contain some steel or conductive materials.

**MR Unsafe** – ITEM POSES A HAZARD IN ALL MR ENVIRONMENTS. Ferromagnetic ("steel") substances.
“MR Conditional” devices are safe only under certain conditions.

Conditions can vary widely for each device.

If you do not know what the conditions are for a particular device, ASK FOR HELP, and DO NOT ASSUME!
Notice the “MR Conditional” sticker on the ventilator.

Clearly, the conditions for safety were NOT MET.
Screening tool #0: Screening form
Screening tool #1: Ferroguard Detectors

First line of defense:

Pros: everything is screened

Cons: immunity to the sound
Screening tool #2: Hand-held Metal Detectors

Second line of defense:

Pros: MR techs will pay attention to it.

Cons: takes a bit of time...and, detects ALL metals.
Screening tool #3: Survey Magnet

MR Techs and the relevant personnel in a service can and will survey equipment with a magnet before taking it in the room.

MR Techs also bring the equipment into the room, exclusively.
When is a “sandbag” not a sandbag?

This innocent-looking “sandbag” was not surveyed (name says it all, right?)

Flew towards magnet, knocked top of coil off patient and hit him in the face. He was O.R., but...this was preventable by survey.

Moral of the story? Vigilence in surveying unlabeled objects is not silly.
Other precautions at our institute:

MR technologists are the *MR gatekeepers* and the local resource for safety.
Signage indicates the different zones.
Other precautions at our institute:

Every patient puts on a gown.

Every patient is wanded at this point.

Equipment taken in by techs, to specified places.
Equipment Placement in the Room

Infusion pumps
MR Conditional: $B<150 \text{ gauss}$
They can fly.

Anesthesia Carts and Ventilators–
Drager: $B<400 \text{ gauss}$
Datex-Ohmeda: $B<300 \text{ gauss}$
Gas cylinders, too

Marking multiple gauss lines could lead to confusion and potential accidents.
Tethering of carts is one low-brow solution.

→ Tether from wall at a distance that is safe. Tether is farther away than line of safety, to prevent accidents. Tether is NOT structurally strong enough to prevent device from going in magnet – just a mechanism to serve as a reminder.
Two markers: 100 Ga line and “the box”
Patient Screening “Anecdotes”

On the worth of self-report

Tale 1: hidden knives
Tale 2: Aneurysms
Medical Implants

What role can/does the Medical Physicist play?
What role am *I* expected to play?

Determine safety of devices day-to-day (boots on the ground)

Monitor safety during MR scans

Develop protocols

Suggest/draft policies
Practical steps for determining safety

1. Identify device (card, etc)
   - Yes: Consult literature, books, websites
   - No: None available

2. Identify scan conditions
   - Yes: Consult with Radiologist on how to proceed
   - No: Never "safe" with standard protocol

3. Recommend/monitor protocol
   - Safe sometimes
   - Always "safe"

4. Patient signs disclosure
   - Yes: scan
   - No: No scan
What concerns exist with medical implants? MR Unsafe (e.g., defibrillators, some aneurysm clips)

MR Conditional issues (management) --
Movement within the body – B0, dB/dx
  (e.g., pumps)
Heating – RF
  (e.g., leads)
Malfunction – B0, RF, dB/dt
  (e.g., stimulators)
Device destruction – B0, RF, dB/dt, dB/dx
  (e.g., Baclofen pumps)
Many Medical Implants are safe ONLY for a given set of conditions → MR CONDITIONAL.

Example: Medtronic's SureScan Pacemaker System (Revo and Advisa models) can be scanned under certain conditions.

However, MR exam of the chest before 2013 was unsafe...including the HEART!

That’s changed now, but ...
Many Medical Implants device requirements change dramatically over time.

Medtronics Pacemakers:
pre-2011: None
2011: Surescan – Revo,
       1.5T, but no body Tx over chest
2013: Surescan – Revo, Advisa,
       chest requirements ok now

Ensura surescan, not approved for scanning in US (so get docs from proper website: .com, vs. .eu)
Many Medical Implants device requirements change dramatically over time.

Cyberonics Vagal Nerve Stimulators:

Dec. 2008 -- Only 1.5T, only head Tx/Rx, <1.3 W/kg for a 154.5 lb patient, dB/dt < 10 T/sec

Oct. 2011 -- 1.5T and 3T, head or extremity Tx/Rx only, <3.2 W/kg head averaged (non-human), dB/dx<720 Ga/cm
Physics Concerns: B0

Biological effects of static magnetic fields

“In general, there is no conclusive evidence for irreversible or significant biological effects related to acute, short-term exposure of humans to static magnetic field strengths up to 2.0 T.”

FDA Guidance

<table>
<thead>
<tr>
<th>Population</th>
<th>Main static magnetic field greater than (tesla)</th>
</tr>
</thead>
<tbody>
<tr>
<td>adults, children, and infants aged &gt; 1 month</td>
<td>8</td>
</tr>
<tr>
<td>neonates i.e., infants aged 1 month or less</td>
<td>4</td>
</tr>
</tbody>
</table>
B0 – where we’re going?

Atkinson, et al, JMRI, 26: 1222-7, 2007 (9.4T)

“No statistically significant changes in heart rate, systolic ...diastolic BP, end-tidal CO2, respiratory rate, peripheral arterial O2 sat, or skin temperature were observed...”

Below: 6 min acquisition for 3mm isotropic Na images.
Physics Concerns: B0

For implants, issues include torque and force on ferrous parts, and induced magnetism →

- Malfunction (reed switches)
- Destruction
- Motion (3T vs. 1.5T)

If it is safe at 1.5T, IT IS NOT NECESSARILY SAFE AT 3T (Field issues)

If it is safe at 3T, IT IS NOT NECESSARILY SAFE AT 1.5T (RF Resonance issues)
Aneurysm Clips ...

In 1992, a patient *suffered a hemorrhage and died* after an aneurysm clip in her brain shifted while she was on a table preparing for an MRI procedure.

If a clip is safe at 1.5T, IT IS NOT NECESSARILY SAFE AT 3T.
Physics Concerns: B1 (RF)

Biological effects of RF magnetic fields

- RF magnetic fields are oscillating magnetic fields
- These fields produce heating of tissue
- Energy deposited (degree of heating) is measured by the Specific Absorption Rate (SAR) in units of Watts/kilogram

<table>
<thead>
<tr>
<th>Site</th>
<th>Dose</th>
<th>Time (min) equal to or greater than:</th>
<th>SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>whole body</td>
<td>averaged over</td>
<td>15</td>
<td>4</td>
</tr>
<tr>
<td>head</td>
<td>averaged over</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>head or torso</td>
<td>per gram of tissue</td>
<td>5</td>
<td>8</td>
</tr>
<tr>
<td>extremities</td>
<td>per gram of tissue</td>
<td>5</td>
<td>12</td>
</tr>
</tbody>
</table>

Overall FDA SAR Safety Guidance for MR Devices
Physics Concerns: B1 (RF)

For implants, issues include
induction of current (dB/dt)

→ heating
  Burning of tissue
  Heating of leads
  Device damage

→ stimulation of leads
How do we gauge safe distance from a scanner?

We have a fringe field map on site for each magnet.
\[ F \propto \nabla (M \cdot B) \]

B = local B-field
M=stimulated field in metal object

Faster changes in fringe field, stronger force.

Even worse (m increases in increasing field) ... but ...
Physics Concerns: dB/dx

Force $\sim \frac{d}{dx} (M \cdot B)$

What does all of this mean for us?

Old 1.5T – large fringe field/lower field – less force per change in distance.

New 3Ts – small fringe field/higher field – small changes in distance lead to large changes in force.

So, if some piece of equipment gets too close, you will know this only when it’s too late.
Physics Concerns: dB/dx

For implants, issues include

• Pulling of device (<6 wks, or in general)
• Big issue – dB/dx maps not readily available.
• In theory, scanning of foot with a stimulator near the MR opening could ALSO allow for significant dB/dx via gradient coils.
• D. Jordan, J. Och, AAPM(WG on magnetic resonance testing and quality assurance) are working on this.
• We use our old, passively-shielded 1.5T when we have dB/dx concerns.
Physics and Concern: dB/dt

Biological effects of time varying (gradient) magnetic fields

Nerve stimulation

**Gradient Fields Rate of Change**

Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation

**Table 2-5 Threshold Limit Operating Actions**

<table>
<thead>
<tr>
<th>Operating Mode</th>
<th>STL% or T/s Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>US: 66% of STL IEC: 20 T/s (unless you accept message prompt)</td>
</tr>
<tr>
<td>First Level (controlled mode)</td>
<td>Requires you to click the [Accept] button to proceed when the Clinical mode dB/dt or SAR limits are exceeded, but Second Level mode has not yet been reached.</td>
</tr>
<tr>
<td>Second Level (controlled mode)</td>
<td>Requires research key and IRB or Human Ethical Committee approval of the research to be conducted</td>
</tr>
</tbody>
</table>
Stimulation Threshold Levels

Mean Cardiac
Stimulation Threshold

Mean Respiratory
Stimulation Threshold

Mean Painful Nerve
Stimulation Threshold

Mean Peripheral Nerve
Stimulation Threshold

T/s = Tesla per second

0 - 20 T/s = clinical mode
>20 T/s = First or Second Controlled Modes*

* Limited by IRB or Human Ethical Committee

Typical Operating Range

59
Physics Concerns: dB/dt

For implants, issues include:

- Stimulation of leads
- Damage to device
- Overstimulation of patient

- For reference, 200 T/m/sec is high-performance today \(\rightarrow\) 200mT/msec over a meter
- 50 mT/m maximum strength is high-performance.

- When we are concerned (e.g., neurostimulators), we remove these sequences from the protocols:
  1. EPI \(\rightarrow\) No DWI nor PWI
  2. MRA

Expert Panel on MR Safety: Emanuel Kanal, MD, A. James Barkovich, MD, Charlotte Bell, MD, James P. Borgstede, MD, William G. Bradley Jr, MD, PhD, Jerry W. Froelich, MD, J. Rod Gimbel, MD, John W. Gosbee, MD, Ellisa Kuhni-Kaminski, RT, Paul A. Larson, MD, James W. Lester Jr, MD, John Nyenhuis, PhD, Daniel Joe Schaefer, PhD, Elizabeth A. Sebek, RN, BSN, Jeffrey Weinreb, MD, Bruce L. Wilkoff, MD, Terry O. Woods, PhD, Leonard Lucey, MD, and Dina Hernandez, BSRT

Because there are many potential risks in the MR environment and reports of adverse incidents involving patients, equipment and personnel, the need for a guidance document on MR safe practices emerged. Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. As the MR industry changes the document is reviewed, modified and updated. The most recent version will reflect these changes.

Key Words: MR safety; MR; MR safe practices

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Questions?

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