An Overview of the Medical Physicist’s Roles in MR Safety for our Large Clinical Practice

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Outline

• A “large” clinical practice
• Review of FDA and IEC physical limits
• A few Site Planning considerations
• Safety Education
• MR Safety Committee

Disclosures

Grant Support: NIH
Rochester, Minnesota Campus

Mayo Clinic MR Practice

- Mayo Clinic Rochester Campus:
  - 26 Clinical MRI scanners
  - A variety of:
    - GE and Siemens
    - 1.5T and 3T
    - 60 and 70 cm bore
  - ~75,000 MR exams per year

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FDA and IEC Limits for MR

- U.S. Food and Drug Administration (FDA) criteria
- International Electrotechnical Commission (IEC)
  - 82 member countries
  - develop standards
  - IEC 60601-2-33 (ed. 3.1) sets limits pertaining to MR
- As 6/30/13, FDA required manufactures to comply w/ IEC 60601
- Physicist’s role with these limits:
  - become familiar with them
  - use our training and background to interpret them
  - provide guidance to Radiologists and other medical professionals in a team setting
**FDA Significant Risk Operation for MR**

- Last Updated: June 20, 2014
- Sets limits pertaining to 4 physical aspects of MR:
  1. Main Static Magnetic Field
  2. Specific Absorption Rate (SAR)
  3. Gradient Field Rate of Change (Peripheral Nerve Stimulation)
  4. Sound Pressure Level (Acoustic Noise)

- Staying below the stated limits
  - non-significant risk (NSR) operation for physical parameters
    (although other risks may be present in exam)

**1. FDA: Main Static Magnetic Field**

![Main Static Magnetic Field Table]

- Virtually all clinical MR performed at 3.0T or less

**2. FDA: Specific Absorption Rate (SAR) limits**

<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>&gt;4</td>
</tr>
<tr>
<td>head</td>
<td>averaged over</td>
<td>10</td>
<td>&gt;3.2</td>
</tr>
</tbody>
</table>

- These limits are “absolute” maxima:
  - FDA does not define operating modes

- In 2013, FDA adopted the IEC limits for MRI manufacturers
  - IEC: Normal and First Level Operating Modes

**IEC/FDA: SAR**

<table>
<thead>
<tr>
<th>Operating Mode</th>
<th>Whole Body SAR (W/kg)</th>
<th>Head SAR (W/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>2</td>
<td>3.2</td>
</tr>
<tr>
<td>First Level Controlled</td>
<td>4</td>
<td>3.2</td>
</tr>
</tbody>
</table>

- Normal Operating Mode: No outputs cause physiologic stress
  - suitable for: Any patient with impaired heat regulation
  - pregnant/neonate patients
  - appropriate for some implanted MR Conditional devices
  - Use of Normal Mode often NOT sufficient!
  - Always check specific package labeling!

- First Level Controlled Mode:
  - controlled by Medical Supervision (suitable for most patients)
### IEC/FDA: SAR

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- IEC: Some situations when we can apply higher SAR:
  - these limits for volume transmit: local transmit coils can go higher
  - "Partial Body" prorates SAR up to a maximum of 10 W/kg
  - based on 6-min averaging period (10 s period: 2x limits)
  - Second Level Controlled mode required to go higher (IRB only)

- IEC: Other times we must adhere to a lower limit:
  - SAR limits reduced based on increased room temp: 25-32°C

### IEC “Partial Body” SAR

- See IEC document for more details

### IEC’s Supplement to SAR: Root mean square B1+

- B1+ is the useful component of the RF field at center of transmit coil

\[
B_{1+RMS} = \sqrt{\frac{\int_0^{t_x} (B_{1+}(t))^2 \, dt}{t_x}}
\]

(typically ~1-10 μT)

- Advantages:
  - more comparable across vendors than SAR
  - now reported by scanners (in recent software releases)

- Drawbacks:
  - heating depends on both B1+_{rms} and B0 field strength
  - SAR has a long “history” of usage
  - B1+_{rms} limits not yet widely specified for implants
• Temperature rise is ultimately what we care about...
  • ...but it is difficult to estimate
  • SAR (or B1+rms) is correlated and a convenient surrogate
• Implanted devices:
  • higher localized temperature rise at lead tip → Lower SAR limits!

### IEC’s Supplement to SAR: Temperature Rise Limits

<table>
<thead>
<tr>
<th>Operating Mode</th>
<th>Max. Rise of Core Temperature $\Delta T_{\text{max}}$ ($^\circ$C)</th>
<th>Max. Core and Local Temperature $T_{\text{max}}$ ($^\circ$C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>0.5</td>
<td>39</td>
</tr>
<tr>
<td>First Level Controlled</td>
<td>1</td>
<td>40</td>
</tr>
</tbody>
</table>

### Lead-Tip Heating Model

$$\Delta T = A \int_0^L S_1(z) E_{\text{tan}}(z) dz$$

• Temperature rise is expected to increase with conductor length at least up to $\frac{1}{2}$ wavelength
• Simulations also show electric field $E$ tends to increase away from the midline

*Park et al, JMRI 2007
 Nyenhuis JA General Assembly and Scientific Symposium, 2011 XXXth URSI

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### DBS System

- Implantable Pulse Generator (IPG)
- Lead tip electrode

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### E-field Simulation

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3. FDA: Peripheral Nerve Stimulation

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

\[
\frac{dB}{dt} \propto \frac{dG}{dr} \times r = \text{gradient slew rate} \times (\text{some characteristic length})
\]

- Some older GE MRI systems (TwinSpeed): Whole body vs. Zoom
- This FDA limit qualitative: clearly to be taken as a maximum
- IEC provides a more quantitative limit

IEC/FDA: Nerve Stimulation

- \( t_{\text{eff}} \) is gradient ramp time, typically \( \sim 0.1-1 \text{ ms} \)
- PNS can be uncomfortable, safety concern w/ implanted devices and wires
- MRI operates far below the cardiac stimulation threshold

IEC/FDA: Nerve Stimulation

- Operator chooses First Level Control or Normal mode for dB/dt (GE)
- Other scanners: accept/decline pop-up for First Level operation (Siemens)
- Normal Operating Mode: increases minimum TE and echo spacing

IEC/FDA: Nerve Stimulation

- 2-parameter empirical fit:
  \[
  \frac{dB}{dt}_{\text{First Level}} = \left( \frac{20 \text{T/s}}{s} \right) \times \left( 1 + \frac{0.36 \text{ ms}}{t_{\text{eff}}} \right)
  \]
- Asymptote = 20 T/s in First Level, 80% in Normal mode

IEC/FDA: Nerve Stimulation

- Adapated from IEC 60601-2-33 (ed. 3.1)
4. FDA/IEC: Sound Pressure Level

- Peak unweighted sound pressure level > 140 dB
- A-weighted root mean square (rms) sound pressure level > 99 dB(A) with hearing protection in place (the IEC states equivalent limits)

- A-weighted criterion: Exceeded without hearing protection
  - gradient noise typically in 95-115 dB(A) range
  - typical earplugs attenuate 25-35 dB(A)

- Hearing protection required!

Outcomes

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- Safety Education
- MR Safety Committee
Selected Site Planning Considerations Related to MR Safety

- Restrict access to Zones III and IV
- Fringe (stray) fields
  - bloom field
- Adequate cryo-venting
  - quench button location(s) and covers
  - scan room door to swing IN or OUT of magnet room?
- Code response area in Zone III (ante room)
  - removable table or trolley system

Stray Fields: Routine Considerations

- ACR White Paper¹:
  - Exclude 5-gauss line (0.5 mT) from Zones I and II
  - May require shielding: siliconized steel

Stray Fields: Other Considerations

- Bloom field (during quench)
  - field lines can bloom ~2x more distant from magnet
  - only occurs during a quench of an actively shielded magnet
    - extremely rare event!
  - Details depend on the specific magnet design (ask vendor)
    - typically lasts ~30 seconds

¹Kanal et al., JMRI 2013
Scan Room Door: Swing In or Out?

- Some older guidance was to have door swing out
- We design our rooms to have the doors swing IN

by itself, an appropriate means of pressure relief. In a severe positive pressure situation unlatching an outward-swinging door might permit the door to burst open with tremendous pressure, potentially injuring person(s) opening the door. If used as the only means
- Swing IN gives more room in a code situation

*Kanal et al., JMRI 2013*

Scan Room Door: Swing In or Out?

- Want/need scan room to be RF-tight....NOT airtight!
  - copper exhaust grille in Zone IV ceiling, near door along with Fan system, as recommended in ACR white paper

Selected Site Planning Considerations

- Patient communication/visibility
  - intercom, squeeze bulb alarm
  - operator’s console window, closed-circuit TV monitoring
- Provisions for ferromagnetic detectors
- "Safety Cabinet"
Non-ferromagnetic:
• 5-min Air Supply mask
• Fire Extinguisher

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MR Safety Education Audiences
• Technologists’ Inservice
• New Radiology Residents
• New non-Radiology Residents (focus on implanted devices)
• Research postdocs and graduate students
• Nurses and CRNA’s
• Interpreters
• Cleaning Staff
• (Campus) Security
• City Firefighters
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MR Safety Committee

• Interdisciplinary membership comprises:
  • Radiologists
  • MR Physicists
  • Technologists
  • Nurses
  • MR Service personnel
  • Administration
  • Anesthesia personnel
• Problem solving rather than regulatory focus:
  • We advise other Committees charged with regulatory compliance (e.g., MedWatch reporting)

MR Safety Committee Activities

• Generate and review policies
• Generate and review guidelines (e.g., implanted devices)
  • aim to provide the Radiologist and Medical team latitude
• Generate online safety test for Zone III keycard access
• Review safety incidents and near misses
  • look for root causes in a non-judgmental manner
  • can a process be improved?
  • is additional education needed?

MR Safety Committee Activities

• Weigh risk-benefit ratio in specific “high-risk” MR exams
  • can another imaging modality provide the answer?
  • what are the physics behind the risks?
    • could the manufacturing labeling be overly conservative?
  • has a similar exam been reported in the peer-reviewed literature?
  • is a similar exam being performed routinely outside the US?
  • what type of patient consent will be needed?
    • none?
    • oral consent?
    • written consent?
    • is this scanning research? Will IRB guidance be needed?
• Interdisciplinary nature of the team is key
Acknowledgement

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*Couldn't be here today