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

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MAYO CLINIC

Disclosures

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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

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

Population	Main static magnetic field greater than (tesla)
adults, children, and infants aged > 1 month	8
neonates i.e., infants aged 1 month or less	4

- Virtually all clinical MR performed at 3.0T or less

2. FDA: Specific Absorption Rate (SAR) limits

Specific Absorption Rate (SAR)

Site	Dose	Time (min) equal to or greater than:	SAR (W/kg)
whole body	averaged over	15	>4
head	averaged over	10	>3.2

- 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

Operating Mode	Whole Body SAR (W/kg)	Head SAR (W/kg)
Normal	2	3.2
First Level Controlled (match FDA limits)	4	3.2

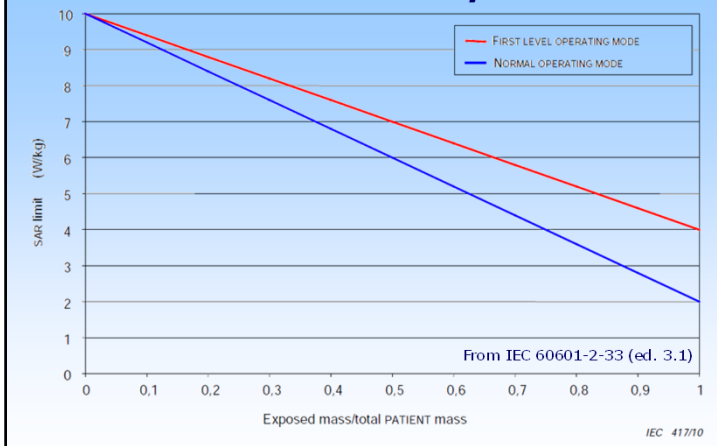
- Normal Operating Mode: No outputs cause physiologic stress
  - suitable for: Any patient with impaired heat regulation
  - pregnant/neonate patients
  - appropriate for some implanted MR Conditional devices
    Use of Normal Mode often NOT sufficient!
    Always check specific package labeling!
- First Level Controlled Mode:
  - controlled by Medical Supervision (suitable for most patients)

IEC/FDA: SAR

Operating Mode	Whole Body SAR (W/kg)	Head SAR (W/kg)
Normal	2	3.2
First Level Controlled	4	3.2

- IEC: Some situations when we can apply higher SAR:
  - these limits for volume transmit: local transmit coils can go higher
  - "Partial Body" prorate 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 "Partial Body" SAR



- See IEC document for more details

IEC/FDA: SAR

Operating Mode	Whole Body SAR (W/kg)	Head SAR (W/kg)
Normal	2	3.2
First Level Controlled	4	3.2

- IEC: Some situations when we can apply higher SAR:
  - Local transmit RF coils (instead of volume transmit)
  - "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's Supplement to SAR:
Root mean square B1+

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

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

(typically ~1-10 μT)

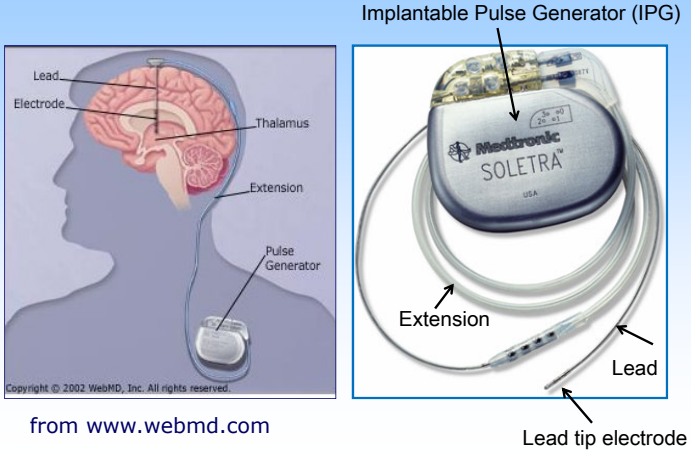
- Advantages:
  - more comparable across vendors than SAR
  - now reported by scanners (in recent software releases)
- Drawbacks:
  - heating depends on both $B1+_{rms}$ and B0 field strength
  - SAR has a long "history" of usage
  - $B1+_{rms}$ limits not yet widely specified for implants

IEC's Supplement to SAR:
Temperature Rise Limits

Operating Mode	Max. Rise of Core Temperature ΔT_{max} (°C)	Max. Core and Local Temperature T_{max} (°C)
Normal	0.5	39
First Level Controlled	1	40

- 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!

DBS System



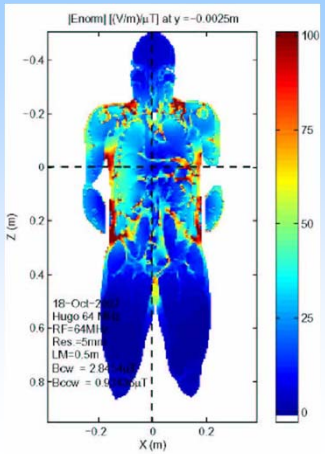
from www.webmd.com

Lead-Tip Heating Model[1]

$$\Delta T = A\left|\int_0^L S_1(z)\,E_{\tan}(z)\,dz\right|^2$$

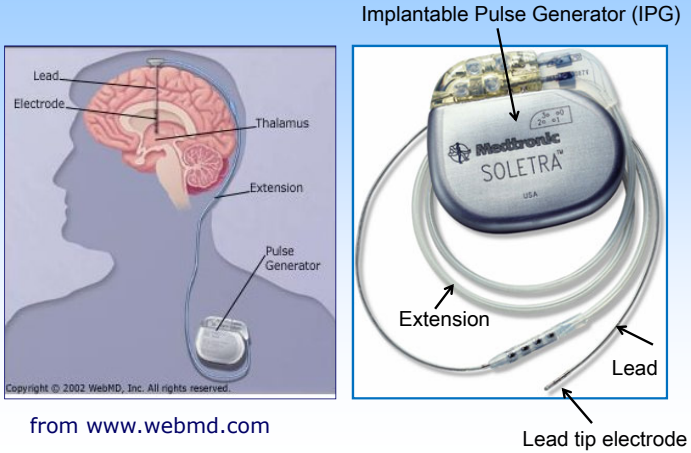
- Temperature rise is expected to increase with conductor length at least up to ½ wavelength
- Simulations also show electric field *E* tends to increase away from the midline

E-field Simulation[1a]



[1]Park et al, JMRI 2007
[1a] Nyenhuis JA General Assembly and Scientific Symposium, 2011 XXXth URSI

DBS System



from www.webmd.com

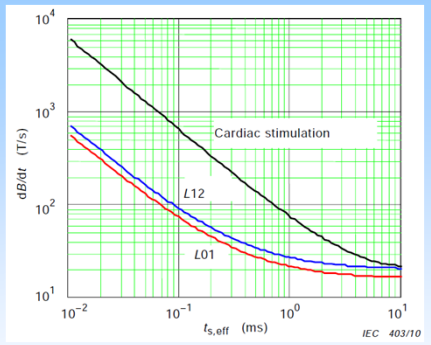
3. FDA: Peripheral Nerve Stimulation

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

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

- 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



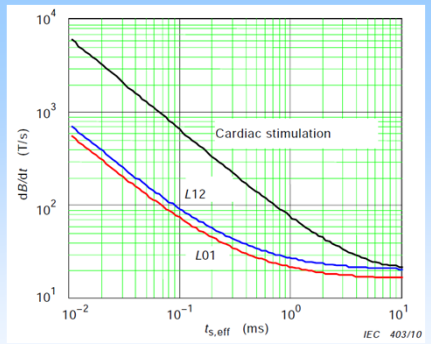
First Level Control

Normal Operating Mode

Adapted from IEC 60601-2-33 (ed. 3.1)

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

IEC/FDA: Nerve Stimulation



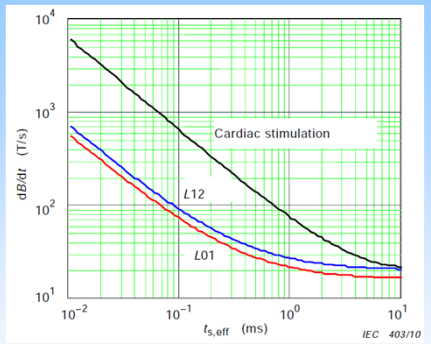
First Level Control

Normal Operating Mode

Adapted from IEC 60601-2-33 (ed. 3.1)

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

IEC/FDA: Nerve Stimulation



First Level Control

Normal Operating Mode

Adapted from IEC 60601-2-33 (ed. 3.1)

- 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

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!

FDA / IEC: Sound Pressure Level Measurement

FDA / IEC: Sound Pressure Level Measurement

	LAeq (dB)	LzPeak (dB)
Ambient noise	70.4	96.5
Localizer	102.1	122
IR_SPGR	101.2	115
3D Fiesta	104.2	117
DTI	108.5	122.5
T2 FSE	100.5	116.4
fMRI	105	118.8
SWAN	104	117

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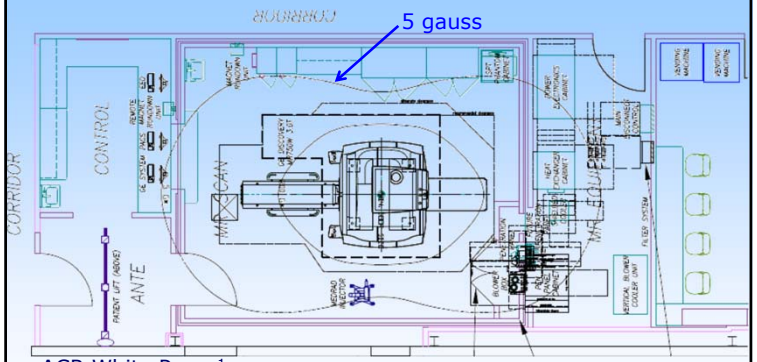
Selected Site Planning Considerations Related to MR Safety

- 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

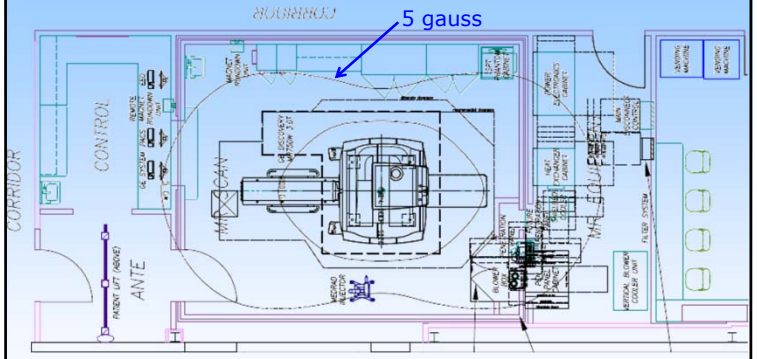
Stray Fields: Routine Considerations



- ACR White Paper[1]:
  - Exclude 5-gauss line (0.5 mT) from Zones I and II
- May require shielding: siliconized steel

[1]Kanal et al., JMRI 2013

Stray Fields: Routine Considerations



- Also consider elevation drawings:
  - stray fields extend vertically

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

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
- ACR Guidance Document on MR Safe Practices: 2013[1]

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

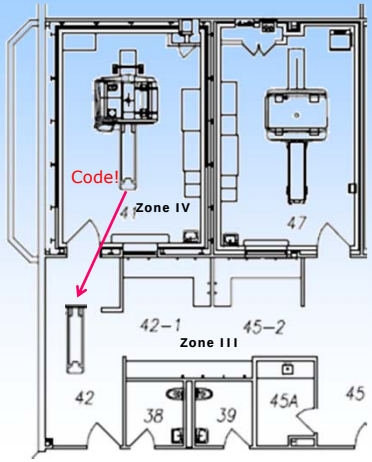
[1]Kanal et al., JMRI 2013

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

Scan Room Door: Swing In or Out?



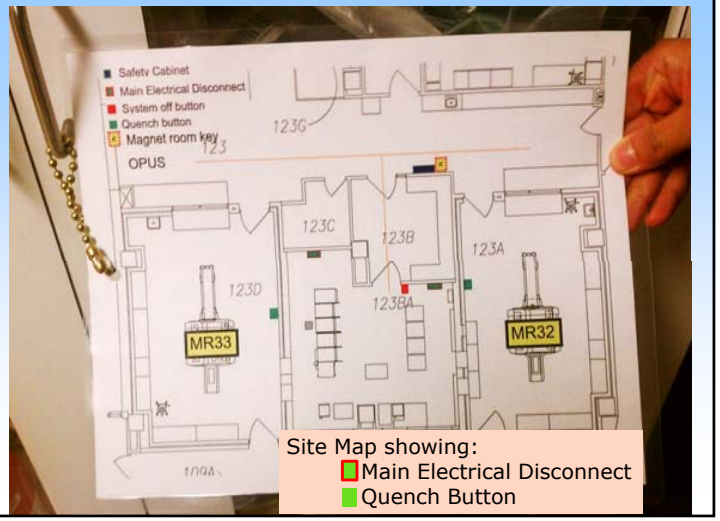
Selected Site Planning Considerations

- Patient communication/visibility
  - intercom, squeeze bulb alarm
  - operator's console window, closed-circuit TV monitoring
- Provisions for ferromagnetic detectors
- "Safety Cabinet"

MRI Safety Cabinet

Non-ferromagnetic:
- 5-min Air Supply mask
- Fire Extinguisher

MRI Safety Cabinet



Site Map showing:
- Main Electrical Disconnect
- Quench Button

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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

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*Couldn't be here today