MR Safety and Compatibility Issues at High Magnetic Fields

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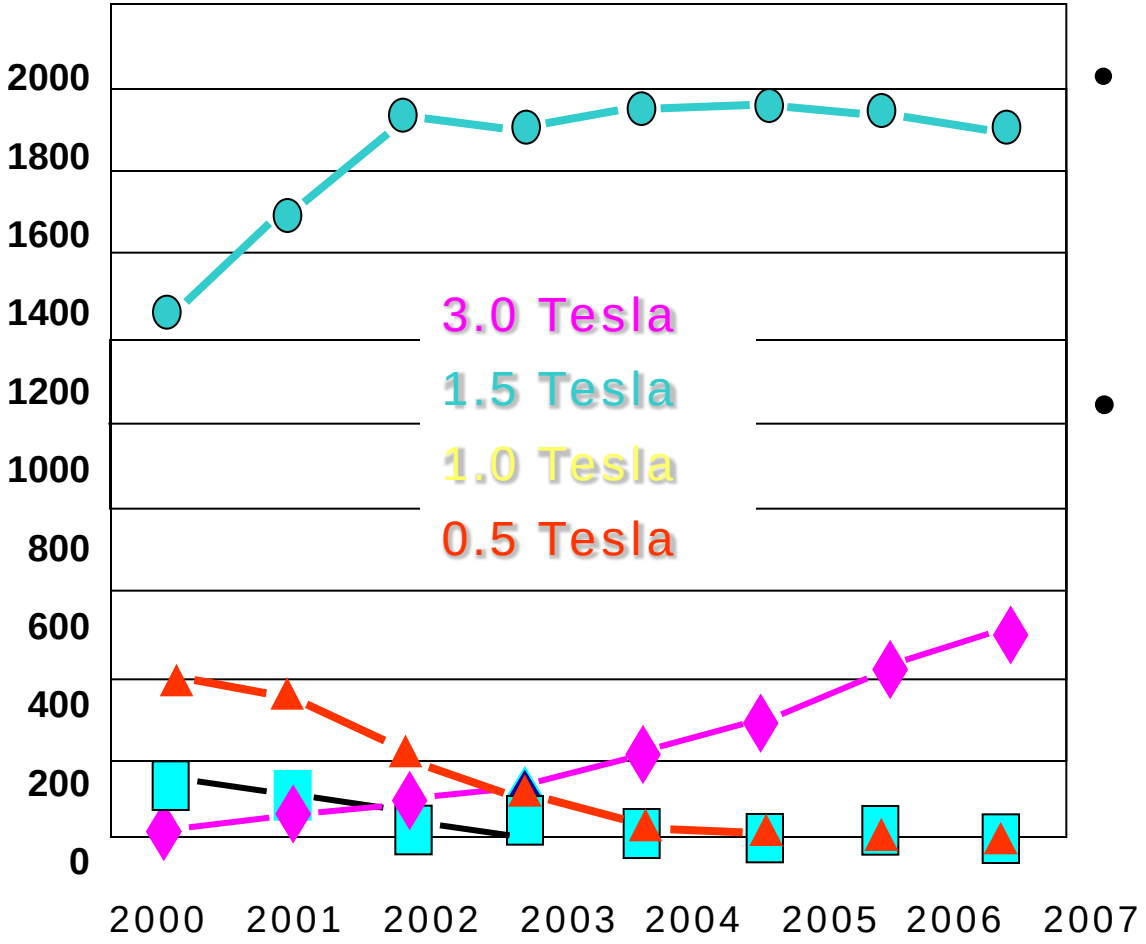
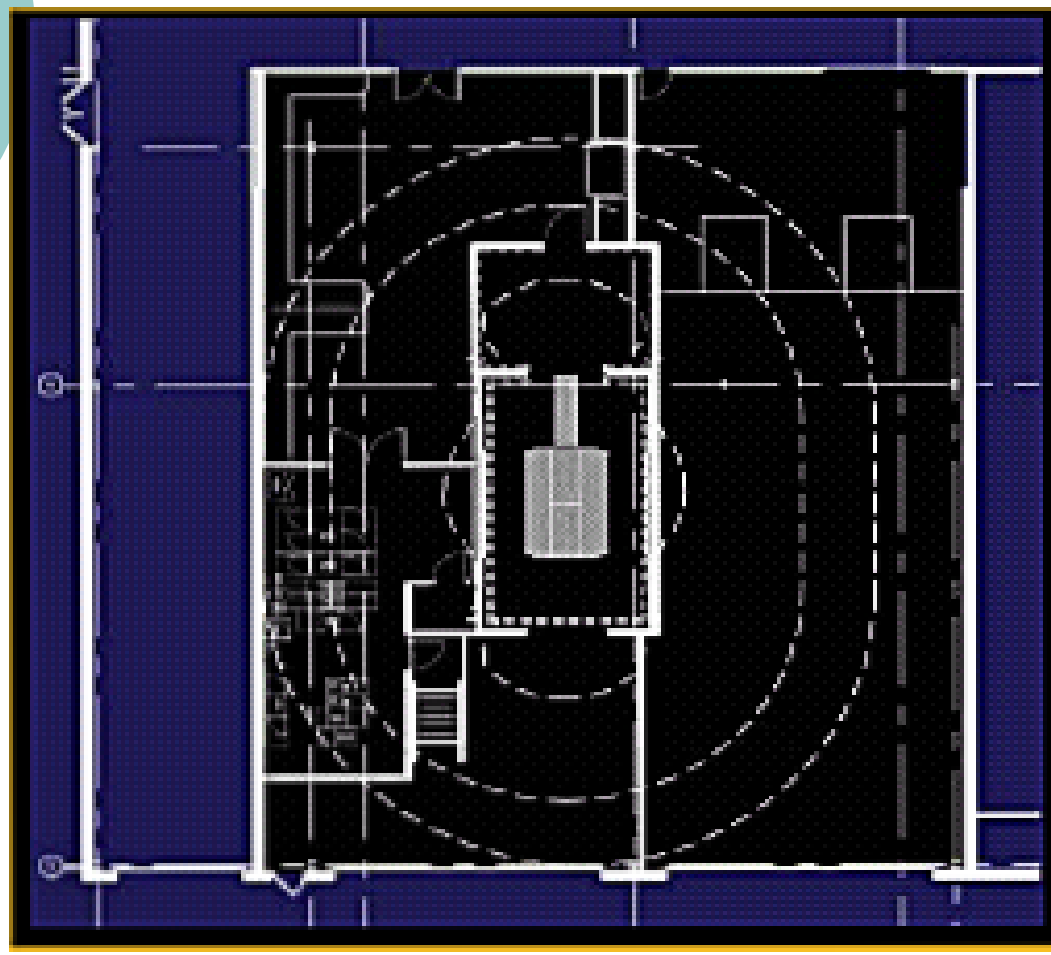
Current MRI Sales Trends



- Approximately 22,500 MRI systems (46% in US) in 2003
- Estimated 7% growth from 2003-2006* (~ 24,000 systems)

*IMV, Ltd. Des Plaines, IL



7T MRI

250 tons of steel
35 ton magnet
2”-6” thick concrete slab

(US$ 9 -10 M)

- MGH/Harvard Univ.
- Ohio State University
- Stanford University
- NYU Med Center
- U Pennsylvania
- U TX Southwestern
- Yale University
- Kennedy-Krieger, MD

Four Safety Concerns Areas in MRI

- Effects of Magnetic Fields on the Patient
  - Strong, static magnetic fields
  - Radio frequency magnetic fields
  - Pulsed magnetic field gradients
- Effects of Magnetic Fields on the Environment
- Acoustic Noise
- Safety Issues with MRI Contrast Agents
- Quenching & Cryogen Boil-off Gases

Effects of Magnetic Fields

Each of the magnetic fields used in MR imaging can be a source of safety concerns:

- Static B_0 field: Physiological effects, projectile motion, medical device displacement and/or interference with normal operation
- Radiofrequency B_1 field: Tissue heating, heating of conductors, interference with patient monitoring equipment
- Gradient fields: Peripheral nerve stimulation, excessive sound pressure levels, interference with patient monitoring equipment

Static Field Safety Issues

Physiological concerns:

- There have been no documented permanent deleterious effects resulting from MR scanning.
- Temporary effects typically all arise from the induced voltages in tissues due to the motion of charged substances through the strong magnetic field ($v \propto dB/dt$):
  - Magnetophosphenes - “flashes of light”
  - Vestibular function - “feeling of vertigo”
  - Taste perversions - “metallic taste”
  - Altered ECG waveforms - elevated T-wave

ICNRP, Health Physics (2009) 97(3):259-261.

Static Field Safety Issues

With regard to any permanent deleterious physiological effects from the static field, Shellock and Kanal[1] report:

> "...static magnetic fields up to 2 T produce no substantial harmful bioeffects, including no alterations of cell growth and morphology, DNA structure and gene expression, pre- and postnatal reproduction and development, visual functions, nerve bioelectric activity, animal behavior, visual response to photic stimulation, cardiovascular dynamics, hematologic indices, physiologic regulation and circadian rhythms, or immune responsiveness."

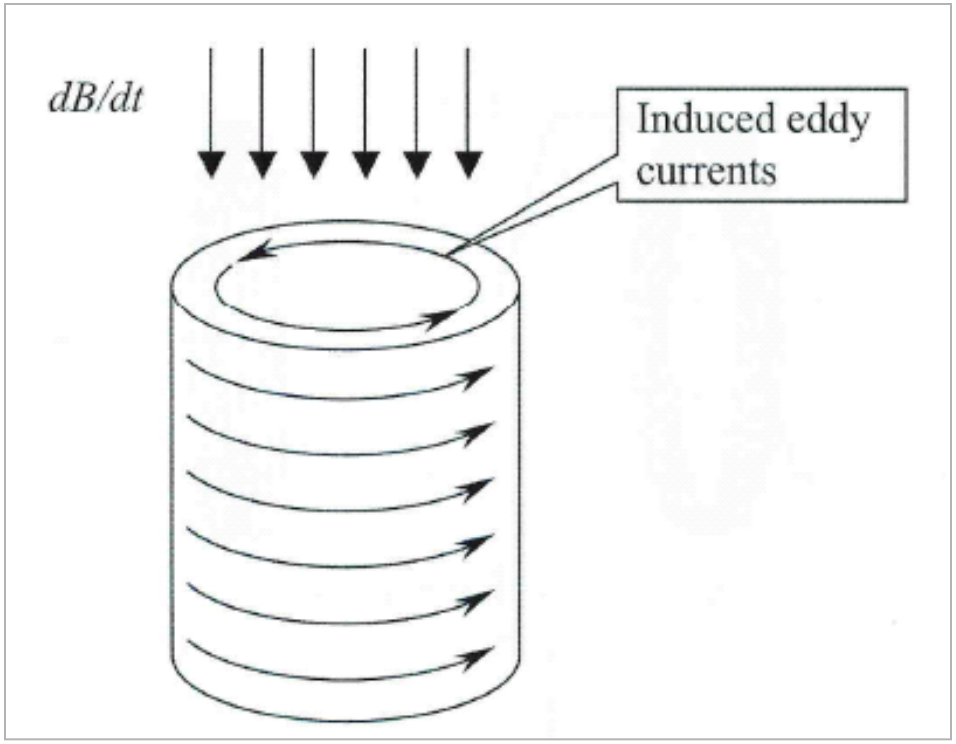
Static Field Safety Issues

FDA Guidelines (7/2003):

- FDA deems magnetic resonance diagnostic devices significant risk when used under any of the operating conditions described below:

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

Faraday's Law of Induction



Nyenhuis et al. , RSNA, 2001

Faraday's Law of Induction in a homogeneous cylindrical conductor. An electric field is produced in a direction perpendicular to the applied magnetic field.

Schaefer & Felmlee, 2001

Specific Absorption Rate (SAR)

- The patient is in an RF magnetic field that causes spin excitation (the B1 field)
- The RF field can induce small currents in the electrically conductive patient which result in energy being absorbed.
- The RF power absorbed by the body is called the **specific absorption rate (SAR)**
- SAR has units of watts absorbed per kg of patient
- If the SAR exceeds the thermal regulation capacity the patient's body temperature will rise.

RF Field Safety Issues

- Tissue heating is primarily due to magnetic induction with a negligible electric field contribution.
- The ohmic heating of the tissue is greatest at the periphery and minimal at the center of the body.
- Head equivalent phantom scans demonstrate significant changes in temperature during an MR only occur less than 4 cm from the edge and do not exceed 1°-2°C for 1.0 and 2.5 W/kg scans for 30 minutes[1].

What Effects the SAR?

- Patient size: SAR increases as the patient size increases – directly related to patient radius
- Resonant frequency: SAR increases with the square of the Larmor frequency
- RF pulse flip angle: SAR increases as the square of the flip angle
- Number of RF pulses: SAR increases with the number of RF pulses in a given time

SAR for Various Scanning Conditions

- 180^0 pulses deposit 4 times the RF power that is required for 90^0 pulses.
- Gradient-echo sequences are only associated with high SAR values when TR < 5ms and $\alpha > 30^o$.
- Fast spin-echo sequences, with the rapidly applied train of 180^0 pulses, are typically high SAR acquisitions.

SAR for Various Scanning Conditions

- Magnetization transfer contrast (MTC) techniques can increase the SAR considerably.
- Even with the very fast acquisition rates, EPI scans are typically not very high SAR acquisitions (few actual RF pulses).
- Using partially parallel imaging methods (SENSE, GRAPPA, ASSET) can significantly reduce SAR by reducing the number of RF pulses required

RF Warming (Lower Extremity)

- During T1W SE scan of legs patient indicated burning/tingling sensation at mid-calf
- Body coil only
- Review shows patients legs bare and calves touching creating a resonant loop
- Place 5 cm foam pad between patient's legs

Warming (Shoulder)

- Elbow warming & coil warming
- Shoulder phased array coil receiver with body coil transmit
- Large patient, elbow opposite positioned near body coil
- Positioning and padding to minimize coupling with RF coils recommended

SAR: IEC Operating Modes

- **Normal Mode** (up to 2 W/kg over 6 minutes):
  - Normal monitoring of patient
- **First Level Controlled Mode**:
  - 2 W/kg to 4 W/kg averaged over 6 minutes
  - Patient may experience a transient but noticeable sensation of warmth on the skin
  - Requires medical supervision & risk/benefit assessment
- **Second Level Controlled Mode**: (> 4 W/kg)
  - Requires IRB approval

RF Field Safety Issues

FDA Guidelines (7/2003):

Specific absorption rates considered to be significant risk

Investigations require approval of an investigational device exemption (IDE) by the FDA Center for Devices and Radiological Health (CDRH):

- >4 W/kg averaged over the whole body for any period of 15 min; or
- >3 W/kg averaged over the head for any period of 10 min; or
- >8 W/kg in any g of tissue in the head or torso; or
- >12 W/kg in any gram of tissue in the extremities, for any period of 5 min

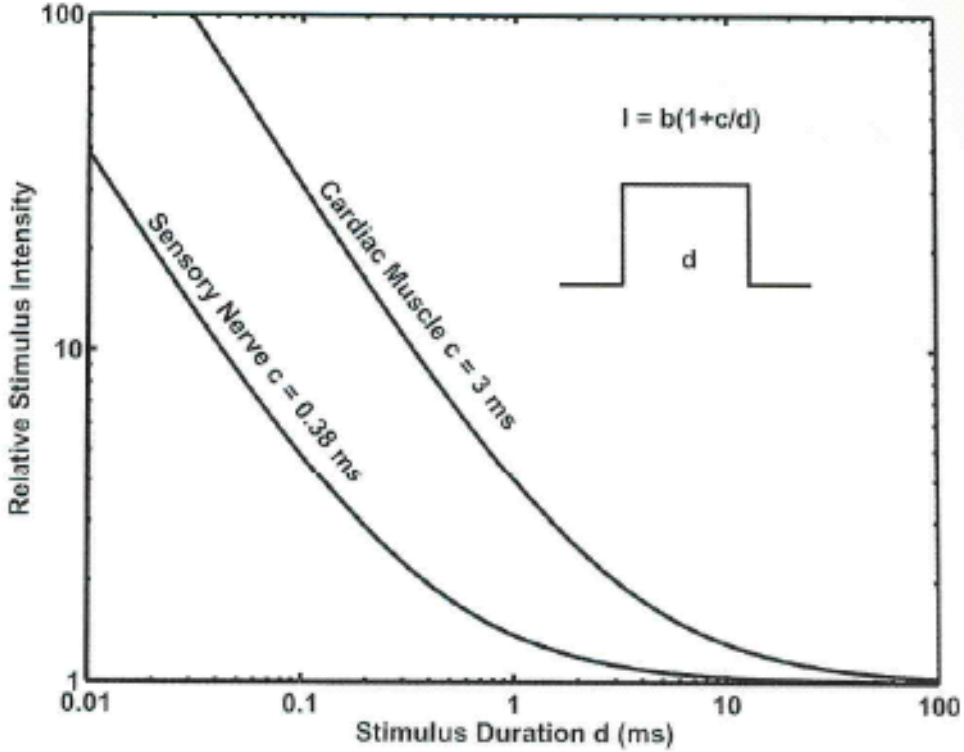
SAR Effects on Pulse Sequences at High B_o (>1.5T)

- Decrease number of slices per study
- Requires decreased flip angles, even in gradient echo sequences
- Requires increase in TR to preserve T1 contrast
- Limits use of Fast Spin Echo imaging
- Parallel imaging techniques increase imaging speed while reducing the number of RF pulses needed –*can help to manage SAR limits at high B_o field*

Concerns from Time-Varying Fields

1. Induced voltages from the time-varying magnetic fields can produce nerve stimulation
   - can distort waveforms on patient monitoring equipment.

Rectangular Gradient Pulse



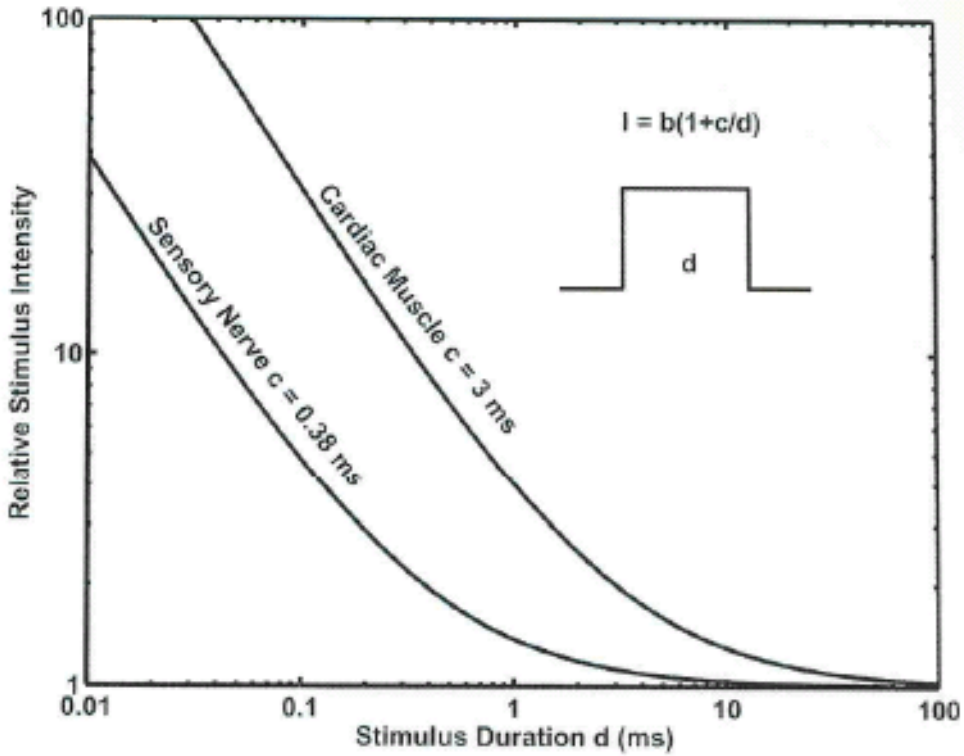
$$\frac{dB}{dt} = B_r \left(1 + \frac{\tau_c}{\tau}\right)$$

B_r = **rheobase** = minimal strength of an electrical stimulus that is able to cause excitation of a tissue

- Strength-duration relationship for single rectangular pulse, showing normalized curves for sensory nerve & cardiac muscle

Nyenhuis, RSNA, 2001

Rectangular Gradient Pulse



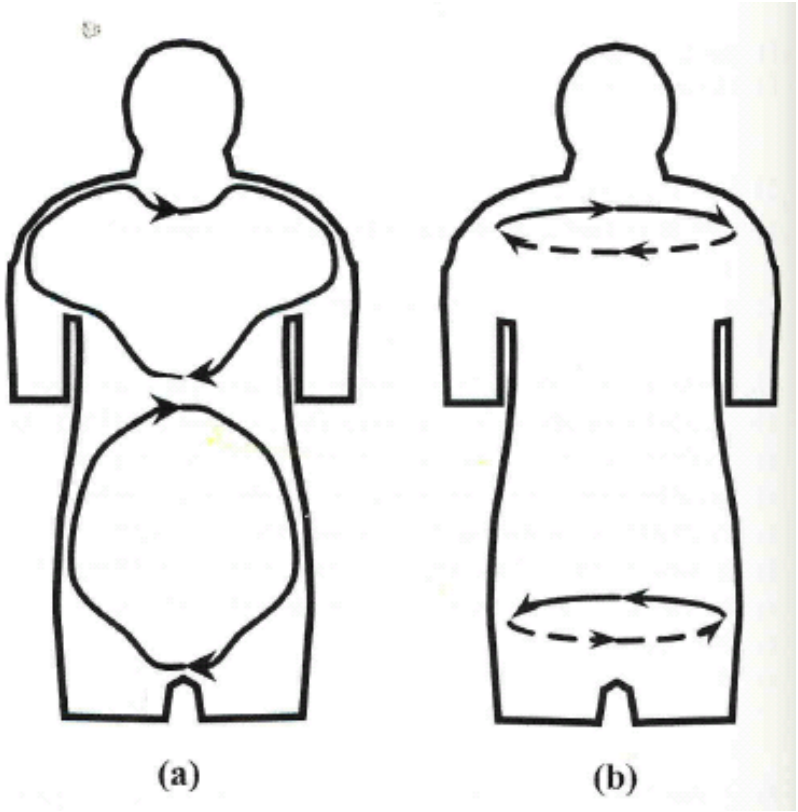
$$\frac{dB}{dt} = B_r\left(1+\frac{\tau_c}{\tau}\right)$$

τ_c **= chronaxie** = a characteristic time constant of the stimulated nerve

- Strength-duration relationship for single rectangular pulse, showing normalized curves for sensory nerve & cardiac muscle

Nyenhuis, RSNA, 2001

Induced Eddy Currents



Nyenhuis et al. , RSNA, 2001

Depiction of induced eddy currents in a patient with the torso at the isocenter of a cylindrical magnet.

a. Eddy currents due to the y-gradient coil

b. Eddy currents due to the z-gradient coil

Chronaxie Time Constants
Magnetic versus electric stimulation

- Recent research suggests that *chronaxie times* determined from electrical stimulation are longer than those arising from magnetic induction
- This study also suggests that electrical stimulation may stimulate cutaneous afferent nerve fibers whereas magnetic stimulation may preferentially activate deeper nerves.

Recoskie BJ et al. **Phys. Med. Biol**. 54 (2009) 5965–5979

Gradient Field Safety Issues

- Naturally, the induced voltages in the conductive tissues increase as the distance from isocenter increases.
- Mean dB/dt thresholds for nerve stimulation:

Peripheral	~60 T/s (Painful @ ~90 T/s)
Respiratory	~900 T/s
Cardiac	~3600 T/s

- Typical high-speed MR scanners in the US are limited to 45 T/s.

Concerns from Time-Varying Fields

2. Auditory sound pressure levels produced by the rapidly switched gradient coils (due to the interaction of the gradient and static field coils) can be excessive.

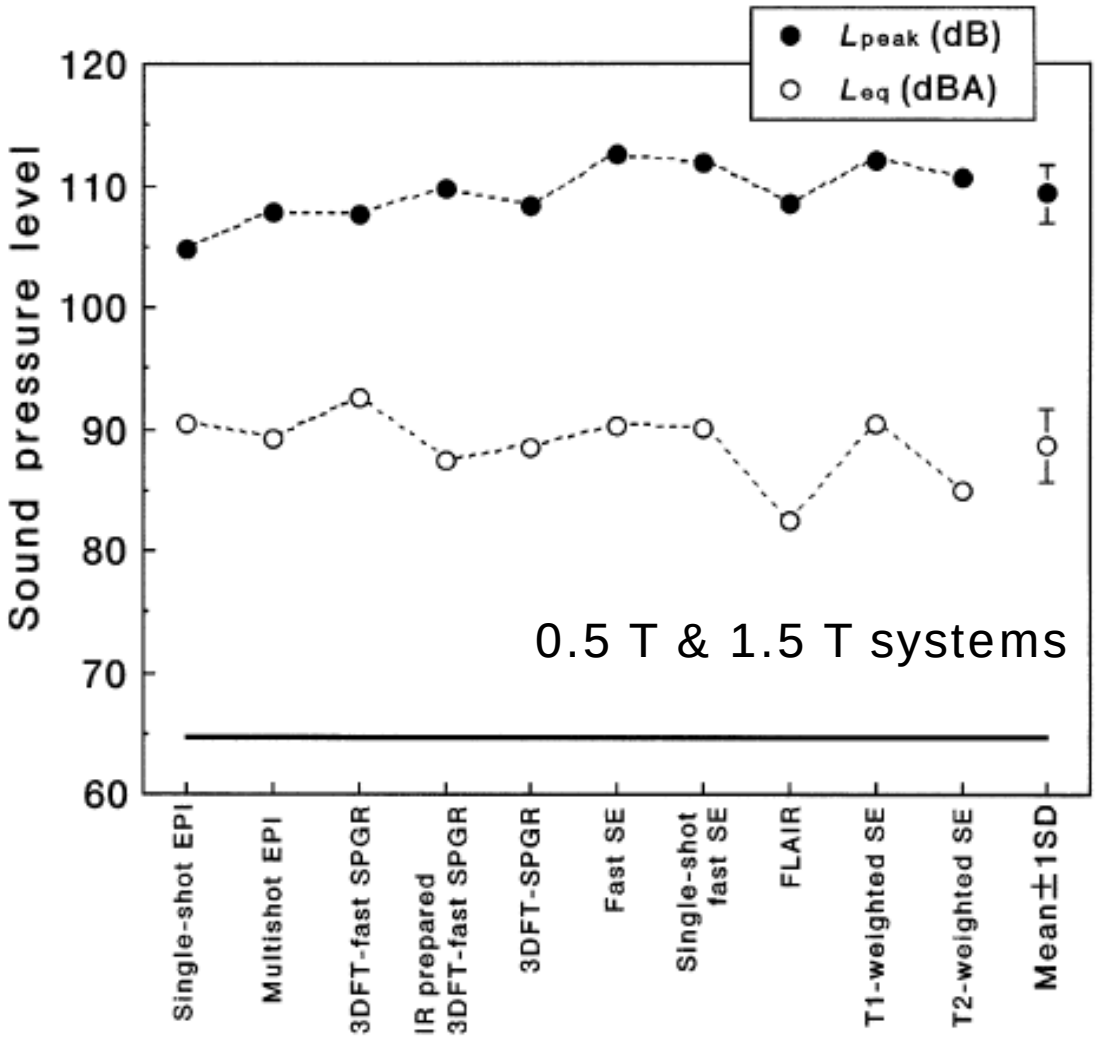
http://electronics.howstuffworks.com/speaker6.htm

Concerns from Time-Varying Fields

- These levels can be up to 100 dBA at isocenter during fast scan techniques[1].
- RF waveforms can be heard at high fields too
  - However, the pressure waves induced are < 20dB above ambient*
- Hearing protection should be used by patients (and others near the magnet bore) during such scans.

*Lin & Wang, **Health Phys.** 98(4):603– 613; 2010

Acoustic Noise



Miyati et al. Frontiers Med. Biol. Engin,10:345–356 (2001)

- If the maximum *A*-weighted sound pressure level (L_{eq}) can exceed 99 dBA, hearing protection shall be required for the safety of the patient.

Permissible Noise Exposures

Occupation Safety and Health Administration (OSHA)	○**90 dBA** (averaged over 8 h/day) ○**105 dBA** (averaged over 1 h/day) ○**140 dB** (unweighted peak values)
Food and Drug Administration (FDA)	reduce to OSHA or ACGIH* level
International Electrotechnical Commission (IEC)	○**99 dBA** (1 h) ○**140 dB** (unweighted peak values in any area)

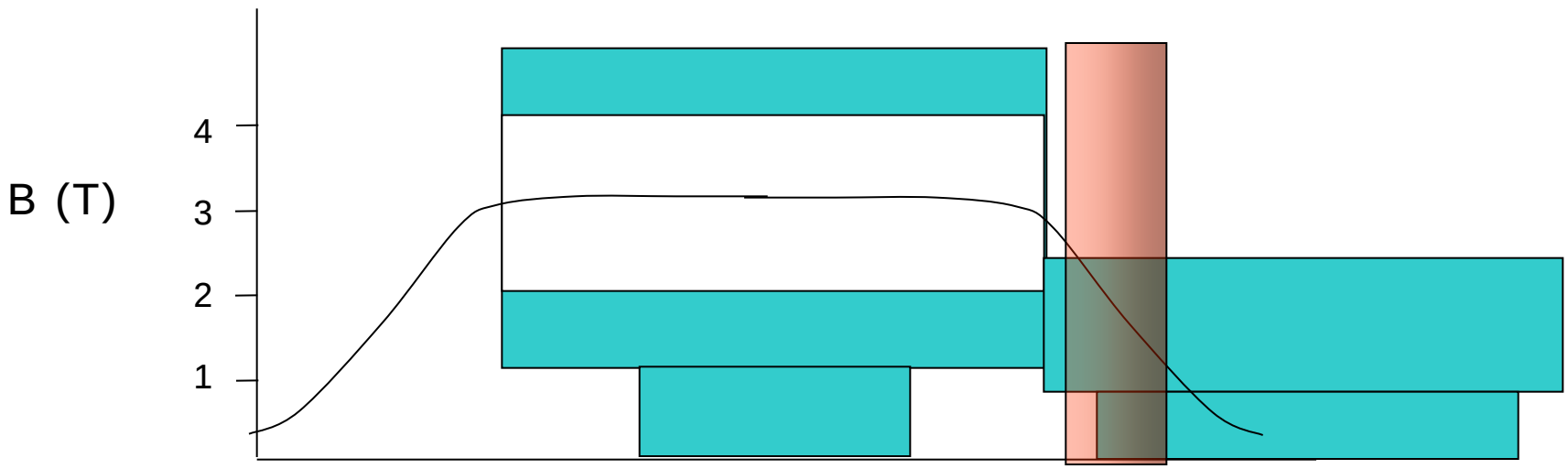
*American Conference of Governmental Industrial Hygienists

UFO's: Unanticipated Flying Objects

- A primary safety concern from the B_o field is prevention of injury from ferrous objects becoming projectiles.
- Examples of objects that have found their way into the bores of MR scanner magnets:
  - Hairpins
  - Stethoscopes
  - Forceps
  - Oxygen cylinders
  - Vacuum cleaners
  - Floor buffers
  - Fork lift tine

Gradient at Edge of Magnet Bore

- The greater the B_o field strength, the greater the static field gradient at the edge of the magnet bore.



3.0T - Safety

- The force of attraction on objects (and implanted devices) is significantly (2.5x – 5.0x) higher with 3.0T magnets compared to 1.5T magnets.
- “MR-safe” at 1.5T does not guarantee an object/device is safe at 3.0T!!!

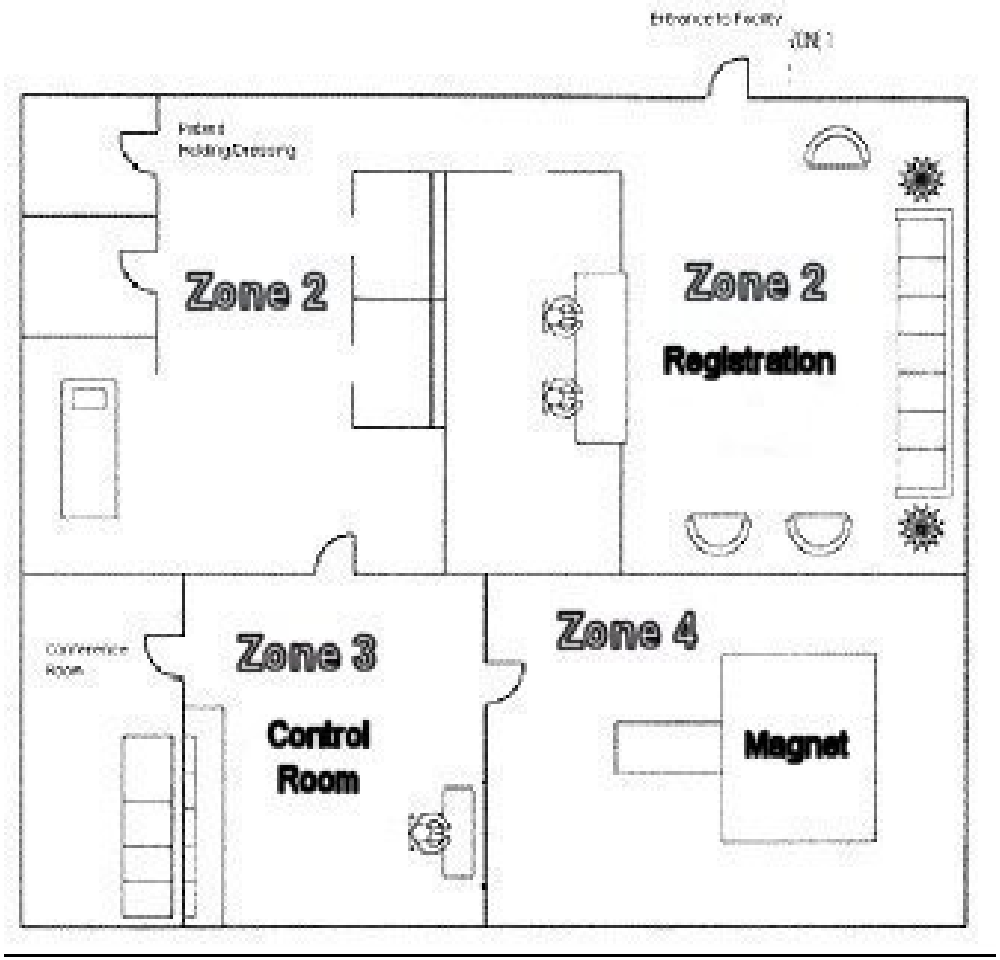
3.0T - Safety

- Since they are self-shielded, the 5 G line for most commercial 3T MRI systems are nearly the same as for the 1.5T scanner from the same manufacturer
  - the field gradient of the static magnetic field is very steep.
  - Therefore, the force of attraction is MUCH higher than for a 1.5T scanner.

Designing a Safe Environment

- Facilities must carefully consider the siting of the magnets to limit scan room entry to authorized personnel who clearly understand the dangers associated with such powerful magnets.
- Preferred siting is single access doors within clear view of the MR technologist(s).
- Cleaning crew and other maintenance personnel must be thoroughly trained.

ACR MRI Safety Zone Concept



[2]*Kanal E., et al. AJR* 2007; 188:1–27

- Zone 1
  - Open access
- Zone 2
  - Preparation and holding
- Zone 3
  - Carefully controlled by MR facility personnel.
  - May be partially within 5 G exclusion zone.
- Zone 4
  - Actual scan room. No admittance w/o documented training and screening.

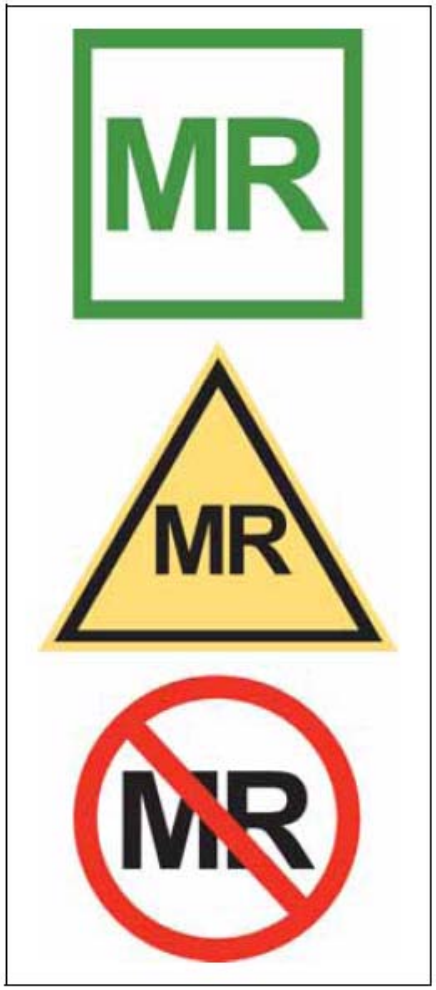
Static Field Safety Issues

Strong magnetic fields can move or displace certain implanted medical devices and/or metal fragments (patient screening is essential!)

- 5 G exclusion zone must be posted for persons with pacemakers and neurostimulators.
- Pacemakers, neurostimulators, cochlear implants, and aneurysm clips are exclusion criteria for MR scanning in the majority of MR centers.

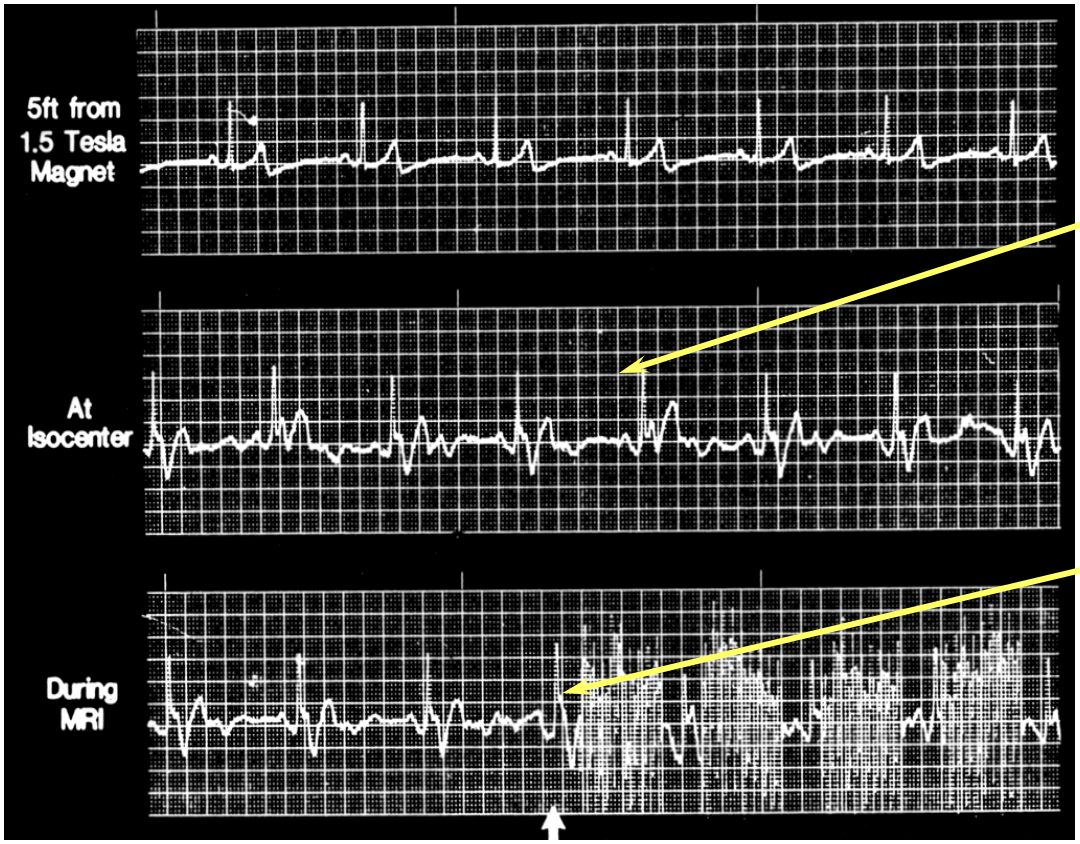
Static Field Safety Issues

- Some ferrous temporary or permanent medical devices are exclusion criteria for patient scans.
- Some contraceptive devices contain enough ferrous material that they could be displaced.
- Some mascaras, eyeliners, tattoos contain cobalt or other metals that can cause discomfort.



FDA/ASTM labeling criteria

Gradient Field Safety Issues - Patient Monitoring



Elevated T-wave

Gated Acquisitions

Ref.: F.G. Shellock and E. Kanal, Magnetic Resonance. Bioeffects, Safety, and Patient Management, Lippincott-Raven Publishers, 1996

The List

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FOR MRI SAFETY, BIOEFFECTS,
AND PATIENT MANAGEMENT

MRIsafety.com

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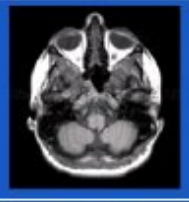

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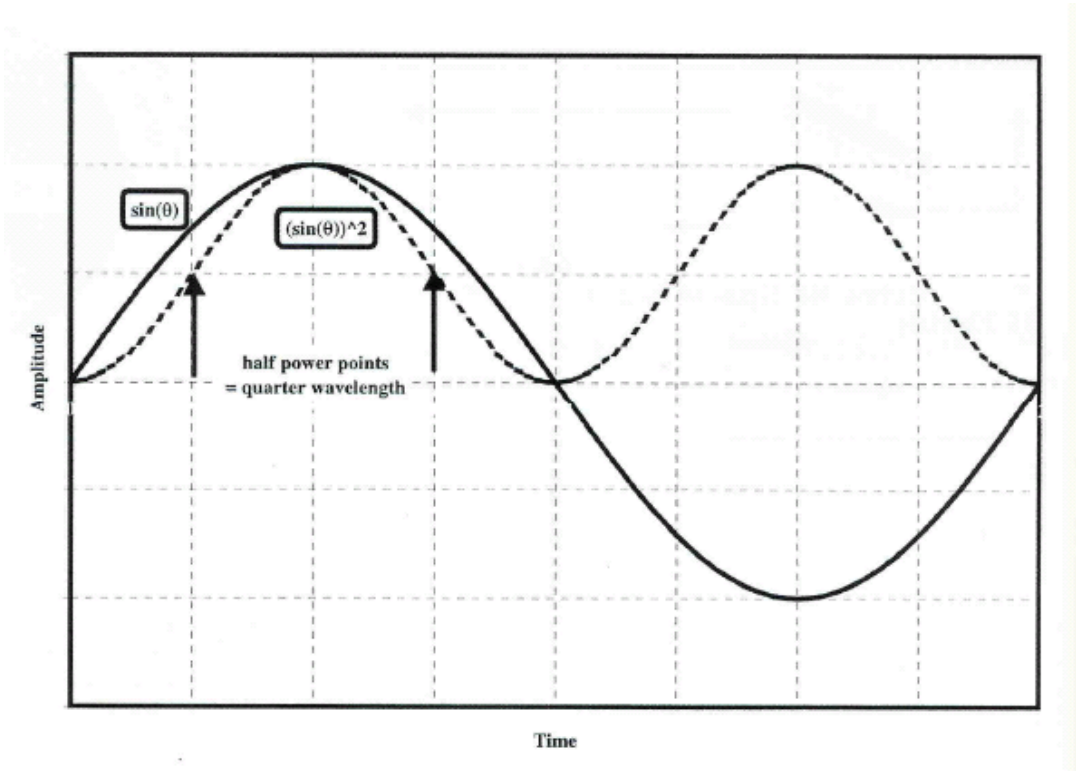
The “Hot Spot”



- Half power points for a standing wave are ¼λ apart.
- At most B_o’s, λ is large.

Very localized heating requires adjacent conductors or other means of constricting current to a small surface area in contact with patients.

RF Field Safety Issues

- Considerable care *must* be taken to insure that no unnecessary conductors are in the magnet bore during scanning.
- All *necessary* conductors, *e.g.*, surface coil leads and ECG leads, should be padded away from the patient, should *not* be allowed to loop, and should, to the extent possible, travel down the center of the magnet bore.

RF Field Safety Issues

- First, second, and even third degree burns due to poorly placed ECG leads have been reported. When possible, use fiber optic-coupled pulse oximeter waveforms for gating and patient monitoring to avoid potential burns from ECG leads and electrodes.
- Technologists/nurse training is essential!

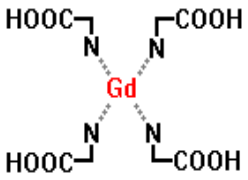
Burn (Shoulder/Biceps)

- Large patient complained of arm burning during shoulder imaging w/ FSE. After scan red welt noted on arm on side opposite from being imaged.
- Toro array coil receiver coil used with body transmit
- A conductive loop may have been set up cable ground/guard and patient

Burn (Lower Limb)

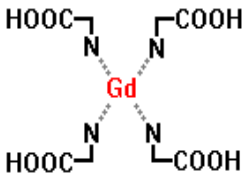
- Patient complained of leg tingling and warming during renal imaging, red welt found near receiver coil cable that was running along patient's leg
- RX: Torso array coil; TX: Body coil
- A conductive loop was set up between cable ground/guard and patient

Contrast Agent Safety Issues



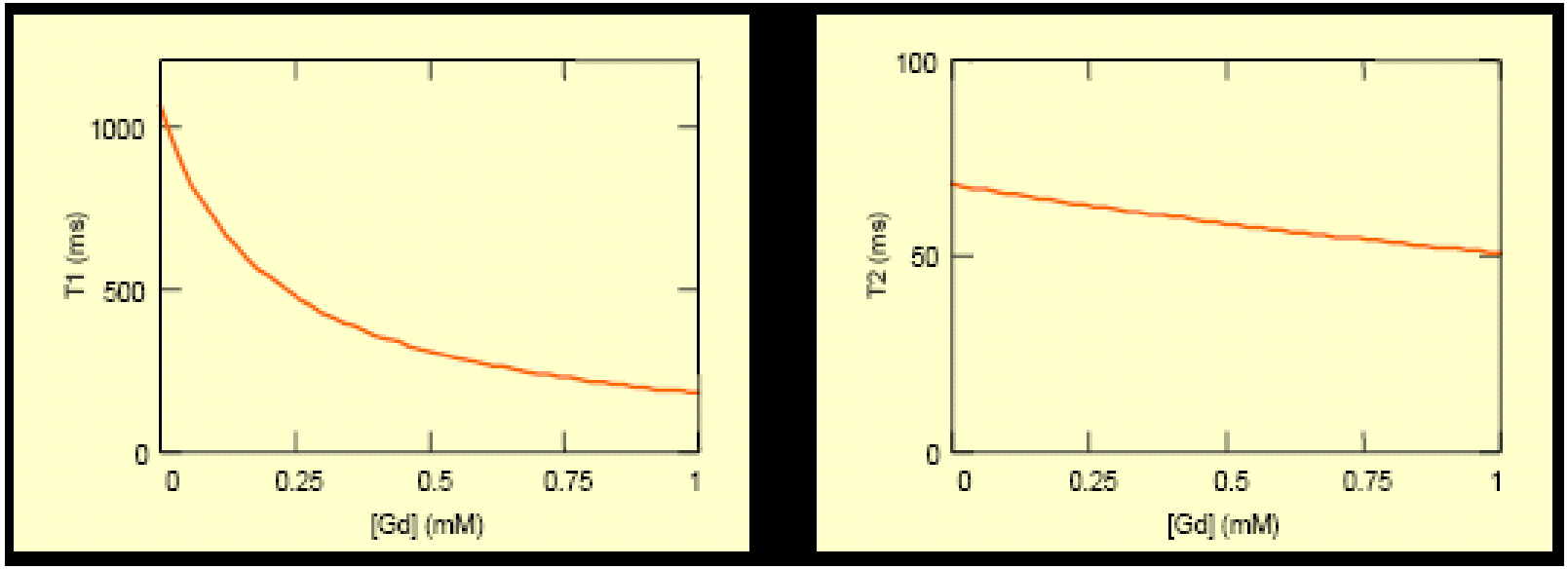
- MR contrast agents currently used in high volume are based on paramagnetic lanthanide series element gadolinium (Gd).
- Dominant effect is a shorter T_1 relaxation time of H_2O protons in close proximity to the Gd atom.
- Gd is toxic. Is tightly chelated to a biocompatible, readily-eliminated agent.

Contrast Agent Safety Issues



- Osmotic loads of the common Gd-based contrast agents are typically less than 1/5th of those measured for iodinated contrast agents.
- Biological half-life of most Gd contrast agents is roughly 1.5 hr.

Paramagnetic Contrast Agent Effects



Effects of increasing Gd-DTPA concentration on T_1 (left) and T_2 (right) relaxation times in gray matter ($T_{1,0}$ = 1055 ms, $T_{2,0}$ = 68 ms). Note the dominant effect on T_1 relaxation times.

Common Commercial Gd Contrast Agents

- Most common Gd-based contrast agents:
  - Magnevist™
    chelating agent: DTPA - ionic, linear structure
  - Omniscan™
    chelating agent: DTPA-BMA - non-ionic, linear structure
  - Prohance™
    chelating agent: HP-DO3A - non-ionic, macrocyclic ring structure
- All have similar safety profiles, low osmotic loads (8.8-27.4 mOsm), MR relaxivities, and incidence of adverse reactions (~2-4%).

Nephrogenic Fibrosing Dermopathy

- Administration of Gd contrast agents is likely a necessary factor development NFD in patients with severely impaired renal function
- FDA has requested the Gd contrast agent manufacturers to add a new boxed warning and a new Warnings section to their labels to describe the risk of developing NSF.
- Application of Gd contrast in MR Angiography and MR perfusion imaging is still considered “off-label” use

Guidance with Gd Contrast Agents

- *When a patient with moderate to end-stage kidney disease needs an imaging study, select imaging methods other than MRI or MRA with a gadolinium-based contrast agent for the study whenever possible. If these patients must receive a gadolinium-based contrast agent, prompt dialysis following the MRI or MRA should be considered.*

  (FDA 2006)

- At 3T the relaxivity of Gd contrast agents nearly doubles
  - doses can be lowered to achieve image enhancement comparable to those obtained at 1.5 T

MR and Pregnancy

- Traditionally, most MR imaging centers in the U.S. either:
  - do not scan pregnant patients (36% in 1988),
  - or require certification from the referring physician that he/she realizes the patient is pregnant and still feels that other non-ionizing forms of diagnostic imaging are inadequate,
  - or that the MR examination would provide important information that would otherwise require exposure to ionizing radiation.[1]

MR and Pregnancy

- Contrast agent effects on the developing fetus are not readily known.
  - However, some intravenous MR contrast agents have been shown to cross the placenta and are excreted by the fetal bladder.
- The rates of clearance form the amniotic fluid and fetal circulation are unknown.
- Contrast agents should not be administered to pregnant patients without a careful cost-benefit analysis and informed consent.[2]

MR and Pregnancy
Pregnant Healthcare Workers

- In 1990, Shellock and Kanal conducted a survey of female MR technologists and nurses at most clinical MR facilities in the U.S.[1]
- Five categories analyzed: spontaneous abortion rate, preterm delivery (<39 weeks), low birth rate (<5.5 lbs), infertility (>11 mo to conceive), and gender of offspring.
- Data indicated there were no statistically significant changes in the five areas studied for MR workers relative to other workers.

MR and Pregnancy
Pregnant Healthcare Workers (cont'd)

- Shellock/Kanal recommendations[1]:
  - Pregnant healthcare workers be permitted to continue performing MR procedures, to enter the scan room, and attend to the patient.
  - However, the worker should avoid remaining in the scan room during actual operation of the system.
  - (Based on conservative position, not any demonstrated adverse effects.)

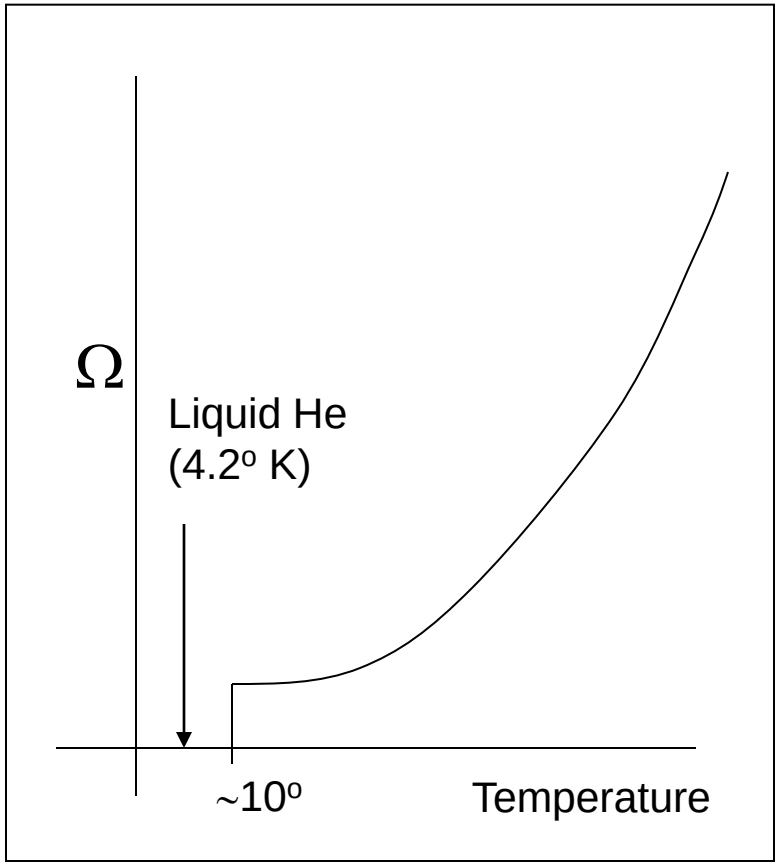
Pediatric MRI Safety

- Devices used for monitoring and support in the neonatal intensive care unit must be MRI compatible.
- All caregivers, who will accompany participants, must become familiar with the principles of MRI safety.
- Acoustic noise levels experienced by infants in the scanner must be below 80 dB.
- Imaging protocol must be designed to ensure that it does not increase the risks of sedation.

Schmidt & Downie, **Accountability in Research**, 16:153–173, 2009

Quenching & Cryogen Boil-off

1. Small part of windings warm up & becomes resistive
2. Magnet L resists change
3. Large voltages (kV) generated
4. Heat dissipates rapidly (MJ)
5. Helium boils off
6. Coils and other magnet parts melt



Quenching Guidelines

- All personnel and patients should be immediately evacuated from the scanner room
- Make sure no cryogens (white clouds of gas) are vented into the room
- Restrict police and firemen from entering room with equipment until magnet is completely powered down

Summary

- At 3 Tesla:
  - Danger from injuries due to flying ferrometallic objects increases – *improved security is required*
  - Danger from RF heating goes up – *restricts uses of certain pulse sequences*
  - Dangers from Gd contrast agents can be reduced by decreasing doses

Resources

- ACR website: http://www.acr.org/SecondaryMainMenuCategories/quality_safety/MRSafety.aspx
- Institute for Magnetic Resonance Safety, Education, and Research: http://www.imrser.org/default.asp
- http://www.mrisafety.com (The “List”)
- FDA websites:

http://www.fda.gov/cdrh/ode/guidance/793.html

http://www.fda.gov/cder/drug/infopage/gcca/default.htm

References

1. F.G. Shellock and E. Kanal, *Magnetic Resonance. Bioeffects, Safety, and Patient Management*, 2nd edition, Lippincott-Raven Publishers, New York, 1996.
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4. American Institute of Architecture – "New Standard of Practice for the Design of MRI Facilities " - http://www.aia.org/nwsltr_print.cfm?pagename=aah_jrnl_20051019_mri