

Safety Considerations for the Magnetic Field(s) (Static & Gradient Fields)

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Outline

Magnetic Field Safety

- Static Magnetic Field Safety (Static field, Fringe Field)
- Gradient fields (TVMF)
- Bioeffects
 - Long term
 - Reversible
- Patient screening techniques – re magnetic fields
 - How, who, why
 - Implants

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Objectives

Upon completion of this course, the attendee should...

1. Understand the importance of Patient Care in MRI (review of general patient care issues for MRI).
2. Learn safety considerations for the static magnetic field (static field, fringe field) and gradient fields (TVMF)
3. Learn techniques for patient screening & implants as they relate to magnetic fields in MRI

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Safety Considerations for MR Components

- The Main Magnet
- The Gradient Field
- The RF Field



Image courtesy of the
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Siemens 1.5T imaging system

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Biological Considerations

- Static Field
(FDA, Tesla, Bio-effects)
- Radiofrequency
(SAR, FDA, Bio-effects)
- Gradient Field
(FDA, Time-Varied, Bio-effects)



(from the registry exam content specifications)

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MRI Safety Resources

Institute for Magnetic Resonance Safety, Education & Research

www.IMRSE.org

Frank Shellock, PhD, MRI Safety Page

www.mrisafety.com

Emanuel Kanal, MD, PhD

www.radiology.upmc.edu/MRSafety

American College of Radiology White Paper on MR Safety

Commentary

MR Safety and the American College of Radiology White Paper

ACR

"American College of Radiology White Paper on MR Safety", a document that "is intended to be used as a template for MR facilities to follow in the development of an MR safety program."

Excerpt from the ACR White Paper

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MR "Compatibility"

• MR Safe

—"an item that poses no known hazards in all MRI environments"

• MR Conditional

—"an item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. Field conditions that define the specified MRI environment include static magnetic field strength, spatial gradient, dB/dt (time varying magnetic fields), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required."

• MR Unsafe

—"an item that is known to pose hazards in all MRI environments."

• NOT... MR Compatible

—devices that have previously tested and deemed "MR Compatible" will not be changed.... New devices will be deemed **MR Safe**, **MR Unsafe** or **MR Conditional**, since 2005...

New Terminology With Regard to Magnetic Resonance Imaging (MRI) and Implants and Devices
American Society for Testing and Materials (ASTM) International, Designation: F 2503-05, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment. ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, Pennsylvania, 19428, 2005.

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MRI Safety for Everyone!

•Who needs MRI Safety Training?

—Level 2

- Technologists
- Radiologists

•ALL Healthcare Professionals

—Level 2 or Level 1

- Nurses
- Doctors

•Level 1

- Ancillary Staff (Aides, Clerical)
- Transporters

•Others

—Non MR Personnel

- Fireman
- Police
- Visitors



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MR Personnel

• Level 1

Individuals who have passed minimal safety educational efforts to ensure their own safety as they work within Zone III regions will be referred to as Level One MR Personnel (e.g., M.R.I. department office staff, patient aides).

• Level 2

Individuals who have been more extensively trained and educated in the broader aspects of MR safety issues including issues related to the potential for thermal loading/burns, direct neuromuscular excitation from rapidly changing gradients, etc., will be referred to as Personnel (e.g., M.R.I. Technologists, Radiologists, Radiology Department nursing staff).

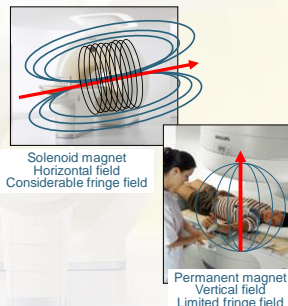
• Non-MR Personnel,

—Patients, visitors, or facility staff who do not meet the criteria of Level One or Level Two MR Personnel.

"The ACR White Paper indicates that the medical director should be primarily responsible for the MR-safety training program." Excerpt from the ACR white paper

Safety Considerations for the Static Magnetic Field

- Main Magnetic Field
 - Within the bore
- Fringe Field
 - Outside the imager
 - Projectiles
- Forces
 - Translational
 - Rotational
- Bioeffects
- FDA Regulations
- Screening



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Imager Considerations - Zoning

Zone I:

This includes all areas that are freely accessible to the general public

Zone II:

This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III

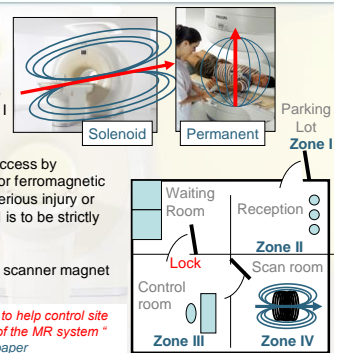
Zone III:

This area is the region in which free access by unscreened Non-MR Personnel and/or ferromagnetic objects and equipment can result in serious injury or death ... All access to at least Zone III is to be strictly restricted, with access ...

Zone IV:

This area is synonymous with the MR scanner magnet room itself;

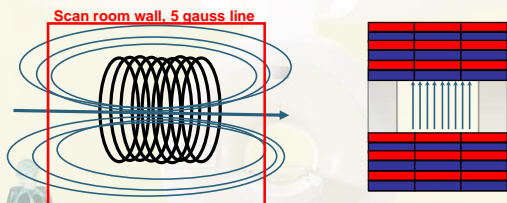
"The concept of designating various zones to help control site access relative to the static magnetic field of the MR system"
Excerpt from the ACR white paper



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Fringe Field Considerations



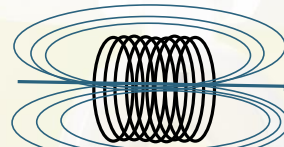
- Magnetic Field strength can be expressed in units of tesla (T) or gauss (g)
- $10,000 \text{ g} = 1 \text{ T}$
- The fringe field is generally expressed in units of gauss
- Isocenter is generally expressed in units of Tesla
- The General Public is to be kept outside the 5 gauss line – of the fringe field!

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Projectiles



- Terminal velocity of a projectile, determined by the mass of the object (and its material) and distance from the magnet.
- “Missile effects” occur when the fringe field draws ferromagnetic materials rapidly into the magnetic field... like a “Missile”!

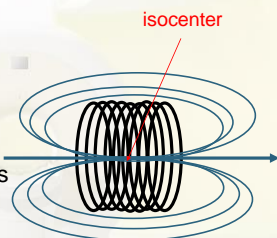
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Magnetic Forces

- Rotational
 - Strongest at isocenter
- Translational
 - Greatest where the fringe field change is most severe (near the bore)
 - Contributes to “missile effects”



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Translational Forces

- Close to the magnet, the field increases in strength rapidly over a short distance.
- Shielded magnets have a very “steep” fringe field and thus can produce very strong translational forces
 - Passive shielding (generally uses metal in the scan room walls to confine the fringe field)
 - Active shielding (generally uses current in coils within the magnet enclosure to confine the fringe field)



Don't bring your scissors (or other ferrous metal) into the MRI scan room

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In the News 2001



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In the News 2004

JMRI 19:141-143 (2004)



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Warning vs Danger Signs

Control Site Access

www.magmedix.com

Courtesy: Anne Marie Sawyer-Glover / Stanford

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Safety for the MR OR

Supplies for MR-OR's:

- Non ferrous Hemostats
- Non ferrous Scalpels
- Weakly ferrous Needles
- MR "safe" monitoring devices and more!



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Ultra High Field MRI – 3.0T and up

- Static Field
 - Projectiles
 - Implants – What has been tested?
 - Artifacts
 - Image Contrast
- RF Field
 - SAR
- Gradient Field
 - dB/dt
 - Noise?



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Bioeffects

- Long term – none known
- Reversible
 - Magnet-hemodynamic Effect:
 - Magnet-hydrodynamic Effect:
 - Elevation of T-wave seen on ECG tracing while the patient is within the bore of the magnet
 - MagnetoPhosphenes:
 - "Stars in your eyes"

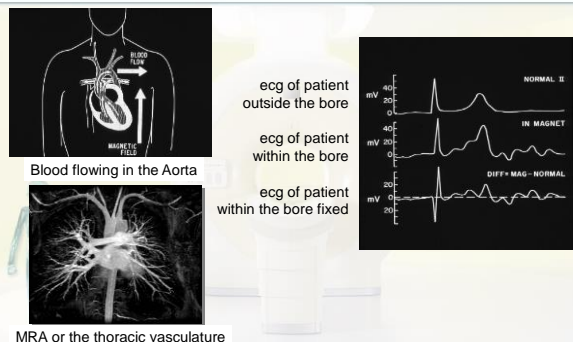
"According to the latest guidelines from the U.S. Food and Drug Administration, clinical MR systems using static magnetic fields up to 8.0-Tesla are considered a "non-significant risk" for adult patients."

Excerpt, Bioeffects of Static Magnetic Fields, Shellock

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Magnet – Hemodynamic Effect



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Magnetophosphenes

Stimulate the retinal phosphenes
Stars in your eyes!



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FDA Limit for Static Field

July 14, 2003

Population	Limit
Adults, children and infants > 1 Month	8 T
Infants 1 month or less	4 T

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Quench Potential for Superconducting Magnets

- Uses Cryogenics
 - Liquid Helium
- Helium Stable as gas
 - Helium 750 (air) to 1 liquid
 - 1,000 liquid liters per magnet
 - 750,000 liters of gas inside the magnet!
- Quench
 - Boil off of cryogen
- Quench Hazards in the MR Scan room
 - Increased pressure, can't open door
 - Reduced room Temperature – Frostbite
 - Reduced Oxygen – Asphyxia



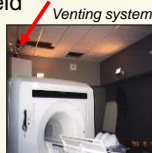
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Ramp down vs quench

- Ramp down
 - controlled removal of cryogenics
 - controlled reduction of magnetic field
- Quench
 - uncontrolled removal of cryogenics
 - cryogenics are designed to vent into the ceiling through a venting system
- Quench Hazards in the MR Scan room
 - Note that the ceiling tiles have fallen out
 - The increased pressure from the quench moved the scan room walls
 - as the result the ceiling tiles fell out



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Safety Considerations

- The Main Magnet
- The Gradient Field
- The RF Field



Image courtesy of the
University of Pennsylvania
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Siemens 1.5T imaging system

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Biological Considerations

- Static field
(FDA, tesla, bio-effects)
- Gradient field
(FDA, time-varied, bio-effects)
- Radiofrequency
(SAR, FDA, bio-effects)



(from the registry exam content specifications)

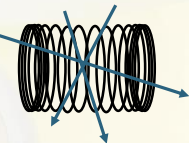
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Gradient Field Safety

- Gradient Units
 - 1 mT/m = 10 g/cm (strength / amplitude)
 - Microseconds (rise time)
 - T/M/S (slew rate- strength & speed)
- Gradient Switching
 - Higher slew rates increase possibility of current induction
- Time varied magnetic fields
- Bioeffects
- FDA Regulations



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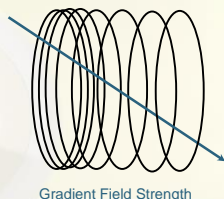
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Gradient Coils

Biological effects of TVMF

- Peripheral nerve stimulation
 - Painful ?
- Magneto-phosphenes
- Acoustic Noise



Produce a gradient field also known as a Time Varied Magnetic Field (TVMF)

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Bio-effects of TVMF

- Peripheral nerve stimulation
 - no loops
 - do not cross hands or legs
- Magneto-phosphenes
 - Stimulate the retinal phosphenes
 - Stars in your eyes!
- Acoustic Noise
 - Hearing protection



According to the FDA, special consideration should be given to certain patient populations (pediatric patients, seriously ill) when performing certain MR procedures that may produce peripheral nerve stimulation

Patients should be instructed to report any painful sensations that occur during the procedure

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Gradient Sounds

- SE T1 Brain
- FSE T2 Brain
- SS FSE
- DWI b = 1000
- Fast 3D Angio

Temporary hearing loss has been reported using conventional sequences.



Earplugs - can reduce noise by 10 to 20 dB

- Recommended for all patients
- Recommended for anyone in scan room
- To reduce temporary, and permanent acoustic damage

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Gradient Magnetic Fields

Produced by gradient Coils

FDA/CDRH
Criteria for Significant Risk
Investigations of Magnetic
Resonance Diagnostic Devices

Issued - 07/14/03

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

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Scans with increased TVMF

- Scans & options
 - high speed gradients
 - EPI
 - Diffusion
 - Perfusion
- No loops within the magnet
- Patients for increased risk of anxiety due to acoustic noise:
 - head trauma
 - elderly
 - pediatric
 - psychiatric disorders



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Patient Care & Safety

- Screening
- Assessment & Monitoring
- Safety Precautions
- Biological Considerations
(from the registry exam content specifications)
- Implants



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Who needs Patient Screening

- Everyone who want to enter the MR environment
- Patient
- Family / Visitors
- Ancillary Staff Education
 - Transport personnel
 - Construction / Maintenance
 - Nursing
 - Patient Support
- Emergency Response
 - Security
 - Fire Department



Anyone who intends to enter The MRI Scan room!

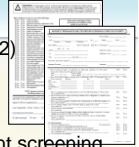
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How should MR Screening be done?

- Should be performed by trained individuals (Level 2)
- Screening should be performed more than once
- Screening with written, verbal interview & "visual" screening
- Screen all visitors as well as patients and document screening
- Screen and document each time a patient presents for an MR exam
- Document & Maintain screening documentation with patients records
- It is prudent to change all patients into a hospital gown, prior to the MR procedure, to avoid any metal from accidentally entering the MR scan room ... and/or to possibly notice surgical scars that the patient may have forgotten.
- Screen everyone that enters the room as if they are having the procedure themselves



Forms available at www.mrisafety.com

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Recommended Screening Forms

Forms available at www.mrisafety.com

- Forms for patients
- Forms for individuals

Screening form for individuals

Screening form for patients

Side 2

Side 1

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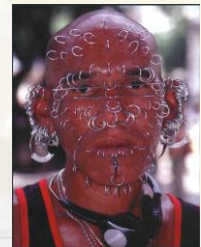
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Why should screening be performed?

To determine...

- MR Unsafe
- ...The big 3 contraindications
 - Pacemaker (some are MR conditional)
 - Metal eyes
 - Aneurysm clip (some are MR conditional)
- MR Safe
- MR Conditional



Some implants are more obvious than others

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Cardiac Pacemaker

CONCLUSIONS Safety was demonstrated in this series of patients with pacemakers at 1.5-T. (J Am Coll Cardiol 2004;43:000-000) © 2004 by the American College of Cardiology Foundation



Basic Pacemakers are still considered a contraindication

Some facilities will scan "basic" pacemakers ONLY IF...

- Non-dependent...
- Patient meets criteria
- With cardiologist, radiologist, company that makes the pacer
- Before, During, and after the exam
- Reset pacer & assess the patient
- **MR Conditional Pacemakers**
 - Have specific Requirements for Scanning
 - Set to "scanning mode" for imaging



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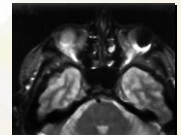


Intraocular Ferrous Foreign Bodies (IFFB)

AJNR Am J Neuroradiology 2000 Feb;21(2):426-33

Cost utility analysis of radiographic screening for an orbital foreign body before MR imaging.

Seidenwurm DJ, McDonnell CH 3rd, Raghavan N, Breslau J.



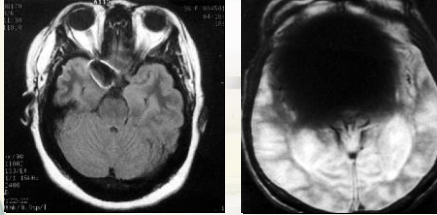
CONCLUSION: Clinical screening before radiography increases the cost-effectiveness of foreign body screening by an order of magnitude, assuming base case ocular foreign body removal rates. Asking the patient "Did a doctor get it all out?" serves this purpose. Occupational history by itself is not sufficient to mandate radiographic orbital screening. Current practice guidelines for foreign body screening should be altered.

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Intracranial Aneurysm Clip



Radiologist is responsible for the decision to scan (risk v benefit)

Just because they have been scanned before, does not automatically make them safe this time!

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Implants in MR

- Medical Risk vs. Benefit Decision
- Be sure to check field strength that the device / implant has been tested
- Up-to-date information is crucial
- **Beware of blanket statements!**

Example: all stents are not safe

• www.mrisafety.com

• www.imrser.org

• www.drkanal.com

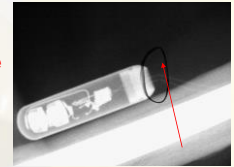
- Concerns for Implants & Devices

• Torque / movement (translational forces)

• Electrical current induction (burns)

• Tissue Heating (burns)

• Device Failure



Bone growth stimulator with broken leads

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Patient Emergency

All MR personnel should be familiar with the procedure for removing a patient from the MR scan room in the event of a medical emergency

- MR "safe" supplies for imaging
- Non-ferrous IV poles
- Non-ferrous Wheel chairs
- Non-ferrous IV poles
- Stretchers
- Non-ferrous IV poles
- MR "safe" monitoring devices & more!



- **"Zone III & Zone IV site access restriction must be maintained during resuscitation and / or other emergencies"**
Excerpt from the ACR White paper on MRI Safety.

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Safety Considerations for the Magnetic Field Static Fields and Gradient Fields

Thank you for your attention!

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