**3.2 Patient Care & MRI Safety**

# Safety Considerations for the Magnetic Field & MR System Components

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## Outline

- Magnetic Safety
  - -Static field
  - -Fringe Field
- Bioeffects
  - -Long term
  - -Reversible
- Patient screening techniques
  - -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)
3. Learn techniques for patient screening & implants

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## Safety Considerations for MR Components

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

*Image courtesy of the*
*University of Pennsylvania Health Systems*
*Siemens 1.5T imaging system*

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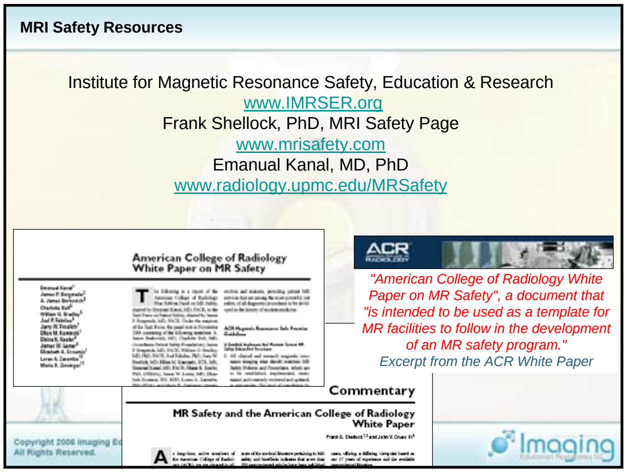
## Biological Considerations

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

(from the registry exam content specifications)



## MRI Safety Resources

Institute for Magnetic Resonance Safety, Education & Research
www.IMRSER.org
Frank Shellock, PhD, MRI Safety Page
www.mrisafety.com
Emanual Kanal, MD, PhD
www.radiology.upmc.edu/MRSafety

American College of Radiology White Paper on MR Safety

*"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*

Commentary

MR Safety and the American College of Radiology White Paper

Frank G. Shellock and John V. Crues III

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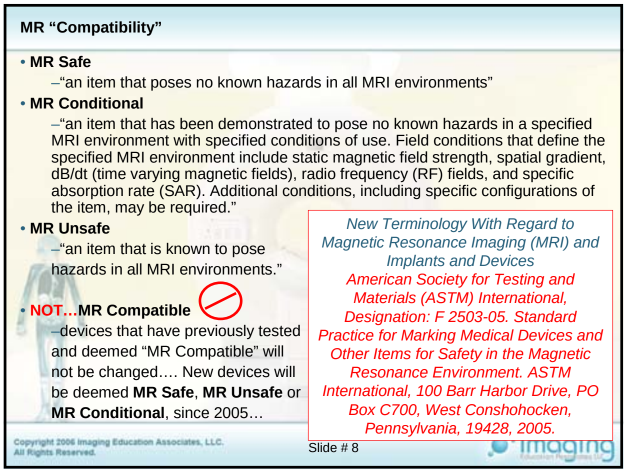

## MR "Compatibility"

- **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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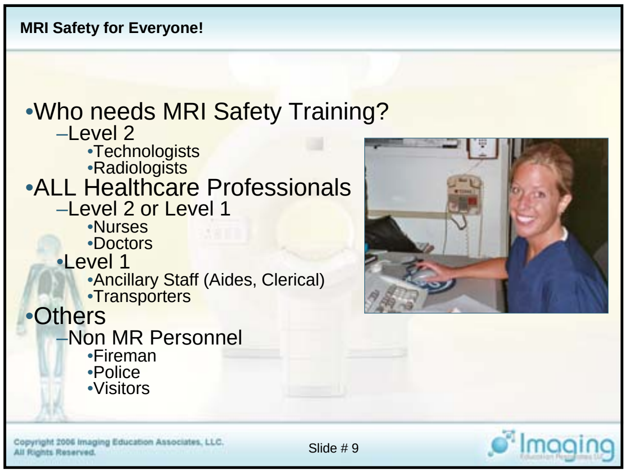

## MRI Safety for Everyone!

- 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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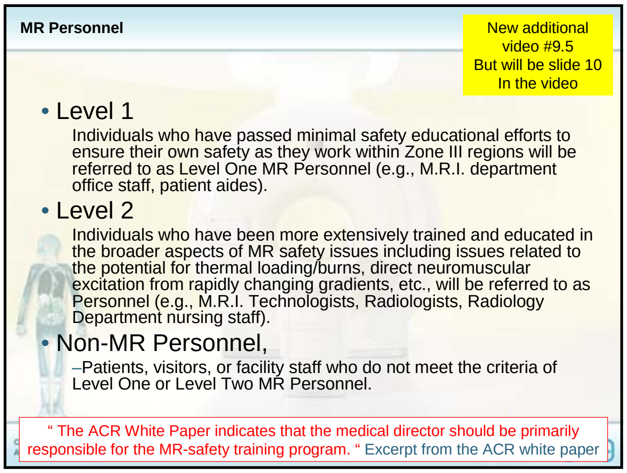

## MR Personnel

New additional video #9.5
But will be slide 10
In the video

- 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

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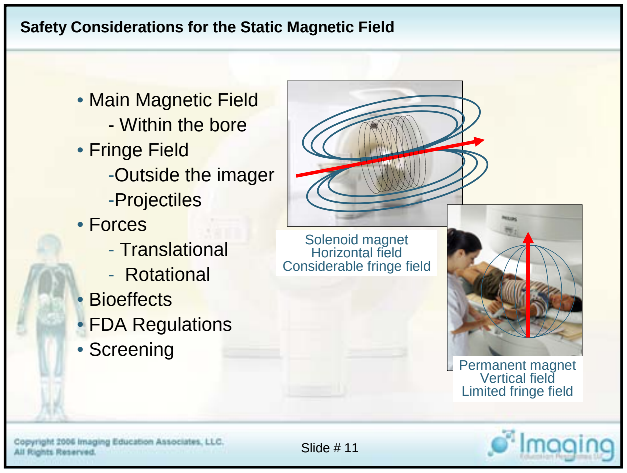

## Safety Considerations for the Static Magnetic Field

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

Solenoid magnet
Horizontal field
Considerable fringe field

Permanent magnet
Vertical field
Limited fringe field

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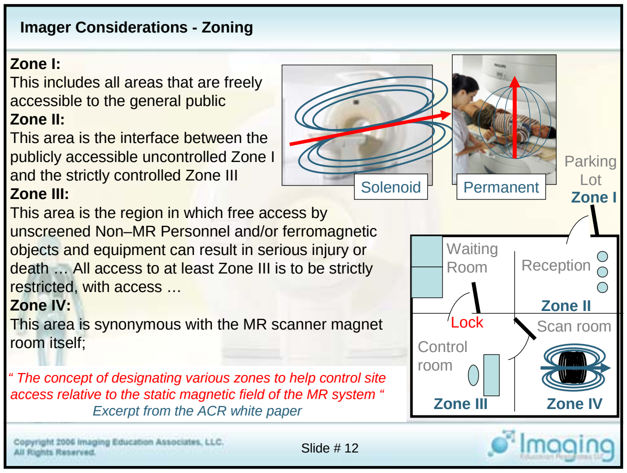


## Imager Considerations - Zoning

**Zone I:**
This includes all areas that are freely accessible to the general public

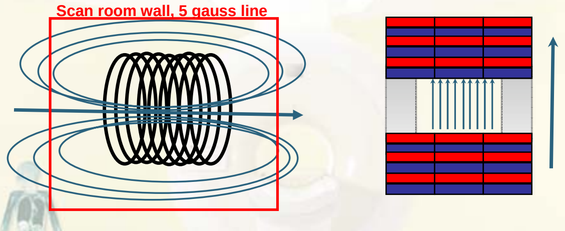
**Zone II:**
This area is the interface between the publicly accessible uncontrolled Zone I and the strictly controlled Zone III

**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*

## Fringe Field Considerations



- Magnetic Field strength can be expressed in units of tesla (T) or gauss (g)
- 10,000 g = 1 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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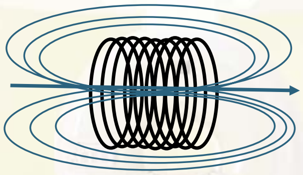
## Projectiles



- Terminal velocity of a projectile, determined by the mass of the object (ant 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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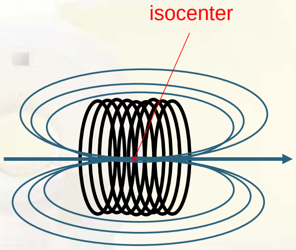
## Magnetic Forces

- 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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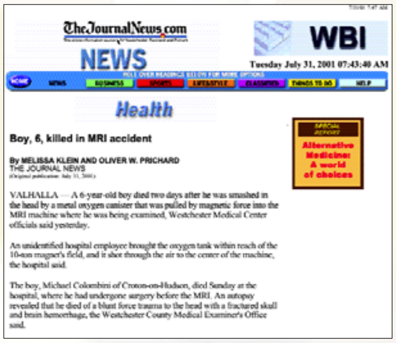
## In the News 2001



TheJournalNews.com

NEWS

WBI

Tuesday July 31, 2001 07:43:40 AM

Health

**Boy, 6, killed in MRI accident**

By MELISSA KLEIN AND OLIVER W. PRICHARD
THE JOURNAL NEWS
(Original publication: July 31, 2001)

VALHALLA — A 6-year-old boy died two days after he was smashed in the head by a metal oxygen canister that was pulled by magnetic force into the MRI machine where he was being examined, Westchester Medical Center officials said yesterday.

An unidentified hospital employee brought the oxygen tank within reach of the 10-ton magnet's field, and it shot through the air to the center of the machine, the hospital said.

The boy, Michael Colombini of Croton-on-Hudson, died Sunday at the hospital, where he had undergone surgery before the MRI. An autopsy revealed that he died of a blunt force trauma to the head with a fractured skull and brain hemorrhage, the Westchester County Medical Examiner's Office said.

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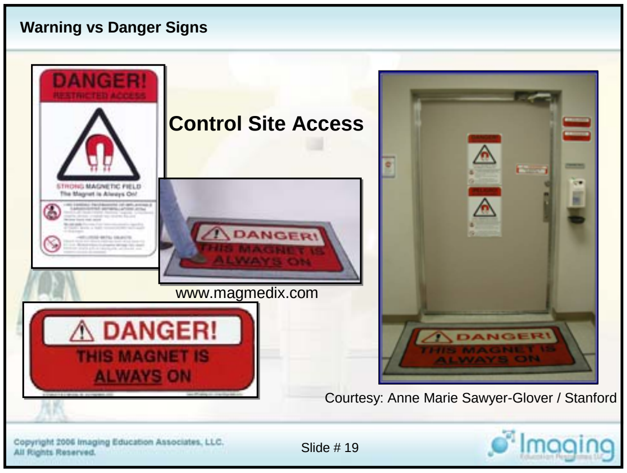
## In the News 2004

JMRI 19:141-143 (2004)

Clinical Note

**Size "H" Oxygen Cylinder: Accidental MR Projectile at 1.5 Tesla**

Patrick M. Colletti, MD



### Warning vs Danger Signs

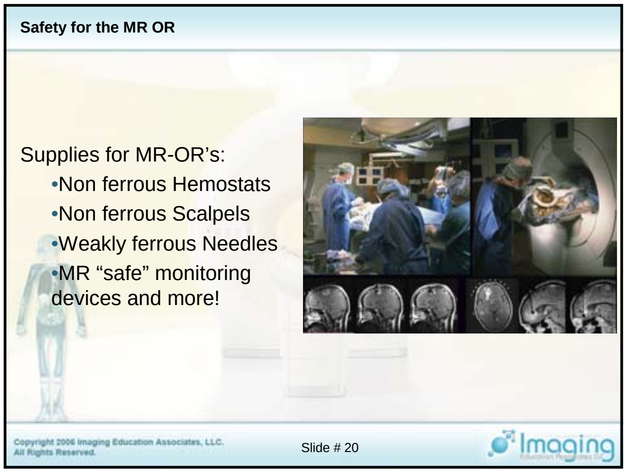
DANGER!
RESTRICTED ACCESS
STRONG MAGNETIC FIELD
The Magnet is Always On!
DANGER! THIS MAGNET IS ALWAYS ON

**Control Site Access**

www.magmedix.com

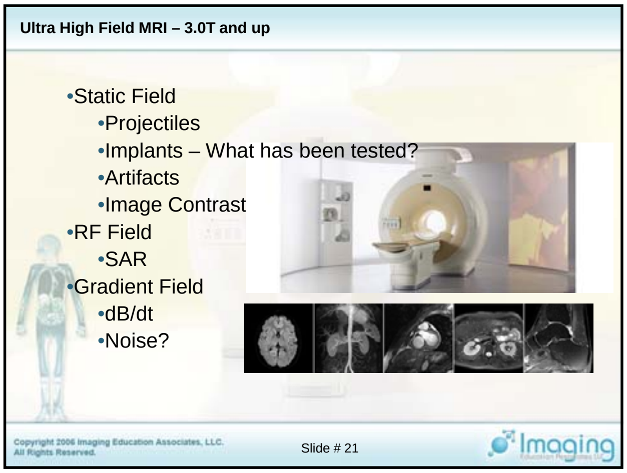
DANGER!
THIS MAGNET IS
ALWAYS ON

Courtesy: Anne Marie Sawyer-Glover / Stanford



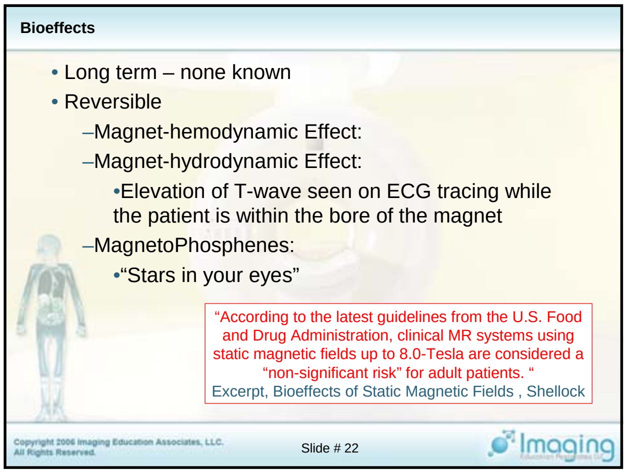
### Safety for the MR OR

Supplies for MR-OR's:
- Non ferrous Hemostats
- Non ferrous Scalpels
- Weakly ferrous Needles
- MR "safe" monitoring devices and more!



### Ultra High Field MRI – 3.0T and up

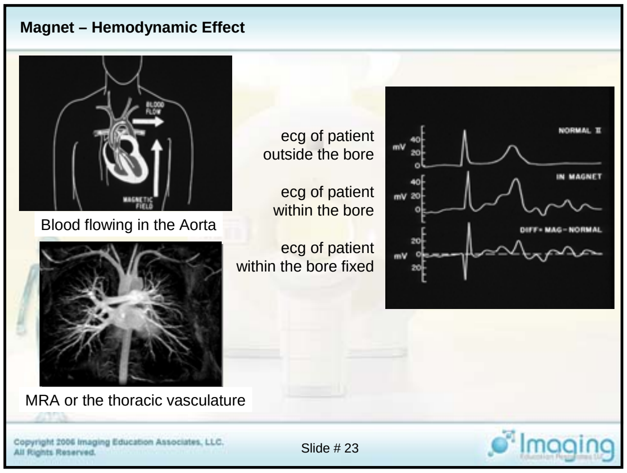
- Static Field
  - Projectiles
  - Implants – What has been tested?
  - Artifacts
  - Image Contrast
- RF Field
  - SAR
- Gradient Field
  - dB/dt
  - Noise?



### 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



### Magnet – Hemodynamic Effect

BLOOD FLOW
MAGNETIC FIELD
NORMAL II
IN MAGNET
DIFF= MAG - NORMAL
mV
40
20
0

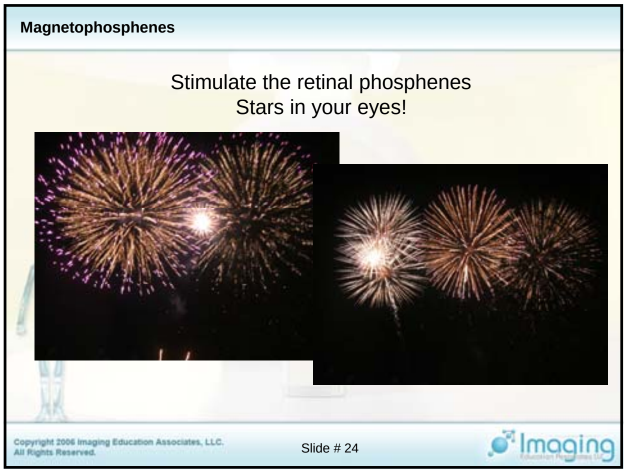
Blood flowing in the Aorta

ecg of patient outside the bore

ecg of patient within the bore

ecg of patient within the bore fixed

MRA or the thoracic vasculature



### Magnetophosphenes

Stimulate the retinal phosphenes
Stars in your eyes!

## 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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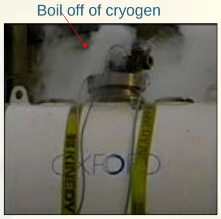
## Quench Potential for Superconducting Magnets

- Uses Cryogens
  - Liquid Helium
- Helium Stable as gass
  - 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 – Forstbite
  - Reduced Oxygen – Asphyxia


Boil off of cryogen

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## Ramp down vs quench

- Ramp down
  - controlled removal of cryogens
  - controlled reduction of magnetic field
- Quench
  - uncontrolled removal of cryogens
  - cryogens 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

*Venting system*

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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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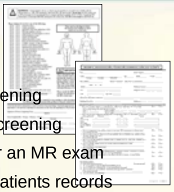
## How should MR Screening be done?

- 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

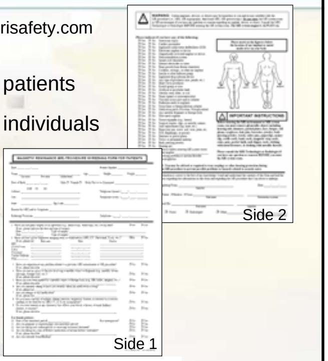

Screening form for patients

## Recommended Screening Forms

Forms available at www.mrisafety.com

Screening form for individuals

- •Forms for patients
- •Forms for individuals



Side 2

Side 1

Screening form for patients

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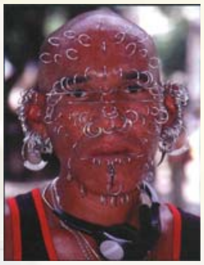
## Why should screening be performed?

To determine…

- MR Unsafe
- …The big 3 contraindications
  - -Pacemaker
  - -Metal eyes
  - -Aneurysm clip
- MR Safe
- MR Conditional



Some implants are more obvious than others

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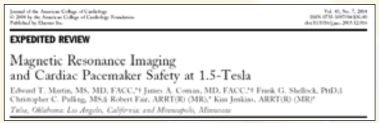
## Cardiac Pacemaker



Journal of the American College of Cardiology
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Published by Elsevier Inc.

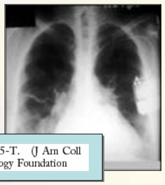
Vol. 43, No. 7, 2004

**EXPEDITED REVIEW**

Magnetic Resonance Imaging
and Cardiac Pacemaker Safety at 1.5-Tesla

Edward T. Martin, MS, MD, FACC,*† James A. Coman, MD, FACC,*† Frank G. Shellock, PhD,‡ Christopher C. Pulling, MS,§ Robert Fair, ARRT(R) (MR),* Kim Jenkins, ARRT(R) (MR)*

*Tulsa, Oklahoma; Los Angeles, California; and Minneapolis, Minnesota*



**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

Still considered a contraindication

**Some facilities will scan pacemakers ONLY IF…**

- Non-dependent…
- Patient meets criteria
- With the cardiologist, radiologist, company that makes the pacer
- During, and after the exam
- Reset pacer & assess the patient

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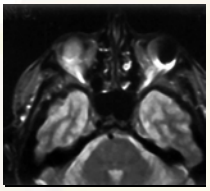
## Intraocular Ferrous Foreign Bodies (IFFB)

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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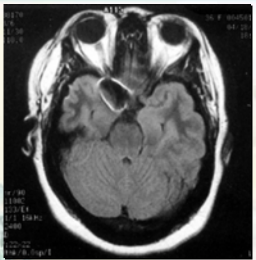
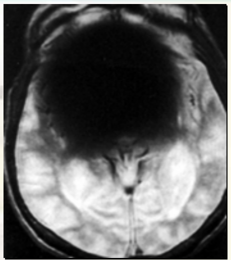
## Intracranial Aneurysm Clip



Less ferrous



More ferrous

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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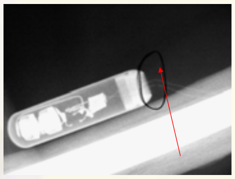
## Implants in MR

- •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

# 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

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

*Image courtesy of the University of Pennsylvania Health Systems*
*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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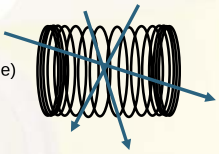
## Gradient Field Safety



- 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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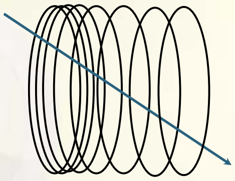
## Gradient Coils

Biological effects of TVMF

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



Gradient Field Strength

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

## 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

## Gradient Magnetic Fields

Produced by gradient Coils

FDA/CDRH
Criteria for Significant Risk
Investigations of Magnetic
Resonance Diagnostic Devices
Issued - 07/14/03

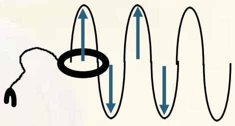
> "Any time rate of change of gradient fields (dB/dt) sufficient to produce severe discomfort or painful nerve stimulation."

## 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

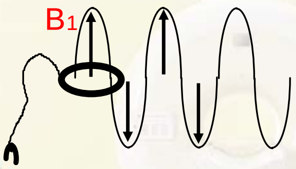
## RF Field Safety

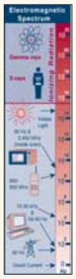


- RF
  - –Power
  - –Wavelength
- Bio Effects
  - –RF Heating
    - More problematic when dealing with metallic materials within the imaging volume of the magnet
    - Different issues with higher field strengths
    - Varies with system
  - –SAR
- FDA Regulations

## Radiofrequency Coils

Produced by RF signals





- Produce electromagnetic radio waves
- Oscillating Field
- B1 field
- Non-ionizing radiation

The FDA limits the absorption of radiofrequency (RF) to 4.0 watts/kilogram (w/kg) for whole body absorption averaged over 15 minutes for clinical imaging.

## Bioeffects of RF

Nonionizing Electromagnetic Radiation

- Most of the RF power used in MR imaging is transformed into heat that is absorbed in the patient's tissues
- Bioeffect of RF absorption is heating of tissue
- FDA limits to an increase in core body temperature of 1'C

## Radiofrequency Fields

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

Issued - 07/14/03

Specific Absorption Rate (SAR)

| Site | Dose ≥(W/kg) | Time (min) | SAR |
|---|---|---|---|
| whole body | averaged over | 15 | 4 |
| head | averaged over | 10 | 3 |
| head or torso | per gram of tissue | 5 | 8 |
| extremities | per gram of tissue | 5 | 12 |

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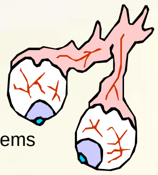
## Scans with increased RF



- Scans & options
  - Magnetic Transfer MTI
  - Fast Spin Echo FSE
    - More heat / more RF pulses
    - Double the flip, 4 x the power
- Patients with compromised thermoregulatory systems
  - higher risk for RF effects
- Patients with higher risk
  - cardiovascular disease, hypertension, diabetes, fever, elderly & obese
  - Certain medications can alter thermoregulatory response to heat load.
  - Areas of Particular Concern
    - Eyes
    - Testis

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## Burn Possibilities

- Report of permanent brain injury from DBS probe (burn during MR exam) at 1.0 T
  - Some can only be scanned with transmit/receive head coil
  - Before scanning be sure the coil is receive only!
  - Be sure that a device/implant is safe before scanning
- Report of 3rd degree burn (1.5T) with ICP catheter

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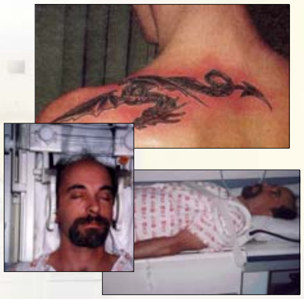
## Other Burn Possibilities

- Tattoos
- Metal in transdermal patches
- Metallic leads/probes
  - Coil cables
  - ECG leads
- Risk increases with field strength



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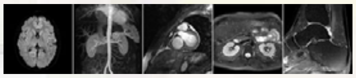
## Ultra High Field MRI

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



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## MRI & Pregnancy - Patients

SMR Safety Committee -

"MR Imaging may be used in pregnant women if other nonionizing forms of diagnostic imaging are inadequate or if the examination provides important information that would otherwise require exposure to ionizing radiation."

## MRI & Pregnancy – Health Care Workers

Technologists can enter the scan room
Can position the patient
But…
Recommended not to enter …
while RF & gradients are running

## Contrast Safety

- Extravasation
- Nephrotoxcitity
- Adverse Events

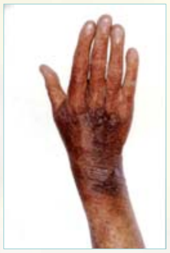
## Extravasation

Animal studies do show moderate necrosis

Osmolality a consideration

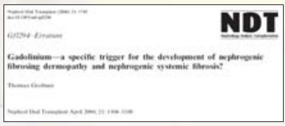
Not as big of a issue as with ionic iodinated contrast

Investigative Radiology 2002 July;37(7):393-8



## Nephrotoxicity

- Standard IV use/doses
  - Not nephrotoxic (usually)
- Iodinated contrast equivalent doses or IA use for DSA
  - Nephrotoxicity has been reported
  - Debatable if gadolinium performs better than low osmolar iodinated agents
- Patients in Renal failure
  - Nephrogenic fibrosing dermopathy
  - Nephrogenic systemic fibrosis



NDT

**Gadolinium—a specific trigger for the development of nephrogenic fibrosing dermopathy and nephrogenic systemic fibrosis?**

Thomas Grobner

## Adverse Reactions

Minor reactions occur with all agents in a low percentage of cases

The current 5 agents have similar safety profiles

Anaphylactoid reactions are rare

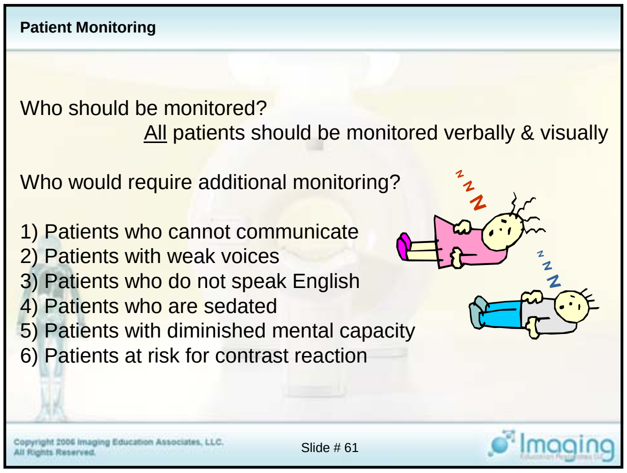
Have occurred with all agents

Sites should be prepared to treat a reaction

V. Runge, *Topics in Magnetic Resonance Imaging*, 2001, Aug; 12(4):309 - 14

## Recommendations for Claustrophobic Patients - ACR

1. Prepare the patient (explaination)
2. Allow a family member to accompany
3. Maintain verbal/visual contact
4. Headphones
5. Monitor – distraction
6. Virtual reality
7. Feet-first
8. Prone
9. Mirrors or prism glasses
10. Blindfold
11. Lights
12. Fan
13. Lemon or vanilla scent
14. Relaxation techniques
15. Systematic desensitzation
16. hypnosis



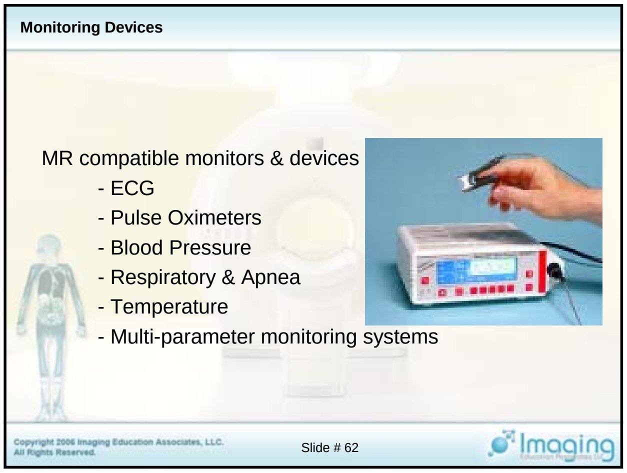
**Patient Monitoring**

Who should be monitored?

All patients should be monitored verbally & visually

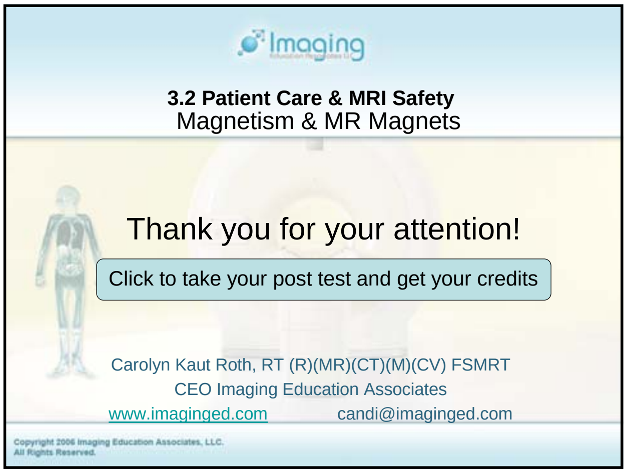
Who would require additional monitoring?

1) Patients who cannot communicate
2) Patients with weak voices
3) Patients who do not speak English
4) Patients who are sedated
5) Patients with diminished mental capacity
6) Patients at risk for contrast reaction



**Monitoring Devices**

MR compatible monitors & devices
- ECG
- Pulse Oximeters
- Blood Pressure
- Respiratory & Apnea
- Temperature
- Multi-parameter monitoring systems



### 3.2 Patient Care & MRI Safety
### Magnetism & MR Magnets

Thank you for your attention!

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