MRI Conditional Devices and Patient Safety

David W. Jordan, Ph.D.
Senior Medical Physicist

University Hospitals Case Medical Center
School of Medicine Case Western Reserve University

Outline

- MRI Conditional Overview
- Spatial Gradient Hazards
- RF SAR Hazards
- Device Registries

MRI Labeling: Objects

ACR Guidance Document on MR Safe Practices: 2013

- MR Safe: **Completely nonmetallic**
- MR Conditional: can be safe in MR environment under certain known conditions
- MR Unsafe: demonstrated attractive forces in magnetic field

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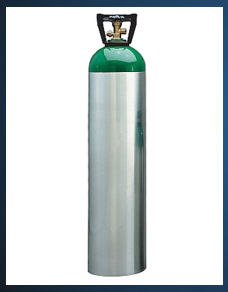

www.magmedix.com

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Conditions of Concern

- Static Field Strength (B_0)
- Static Spatial Gradient
- SAR (RF heating)
- Gradient Strength (time varying)
- Gradient Speed or Slew Rate

Not all implants/devices will specify limits for all of these!

A device is MR conditional if:

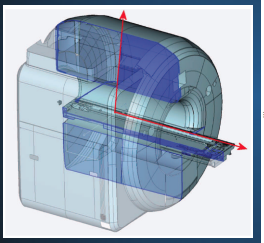
- Potential harm to patient;
- (or) Potential harm to staff or other personnel;
- (or) Potential damage to device;
- (or)Potential damage to MR imaging system;
- (or) Potential negative impact on MR imaging

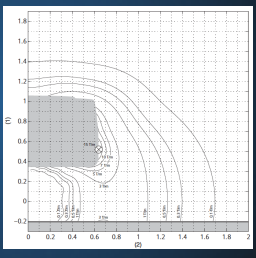
- For ANY condition(s) of MR environment

GRADIENT CONDITIONS

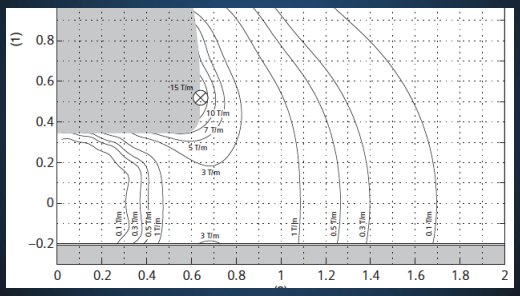
Spatial Gradients

Field Gradient Contour Plots





Field Gradient Contour Plots



Field Gradient Contour Plots

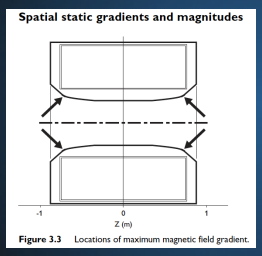


Figure 3.3 Locations of maximum magnetic field gradient.

$$|\text{grad}|B|| \leq 8.0 \text{ T/m}$$

Field Gradient Contour Plots

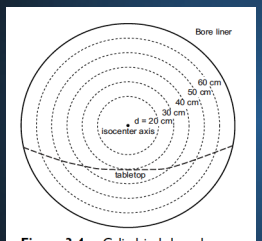


Figure 3.4 Cylindrical shaped spaces around isocenter axis

	[T/m]	[Gauss/cm]
On the patient axis	2.5	250
Cylindrical shape of 20 cm diameter	2.6	260
Cylindrical shape of 30 cm diameter	2.8	280
Cylindrical shape of 40 cm diameter	3.1	310
Cylindrical shape of 50 cm diameter	3.7	370
Cylindrical shape of 60 cm diameter	4.7	470

Product Labeling Example

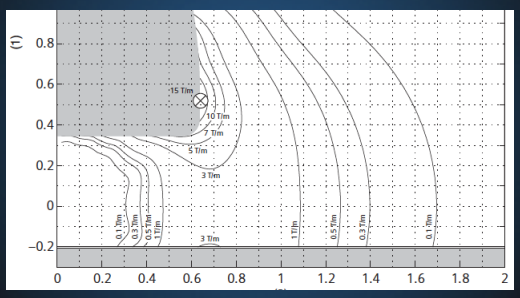
"Non-clinical testing has demonstrated that the XXX is MR Conditional. A patient with this XXX can be scanned safely immediately after placement under the following conditions:

Static Magnetic Field:

Static magnetic field of 3.0 Tesla or less.

Highest spatial magnetic gradient field of 720 gauss/cm"

Are the conditions met in this scanner?



RF CONDITIONS

RF SAR

- **S**pecific **A**bsorption **R**ate
- W/kg
- (think of as a thermal “dose rate”)
- MRI RF amplifier outputs rated in kW
  - Modern designs up to 30 kW

RF Heating

- Dependence on:
  - MRI output power
  - Patient mass
    - Within transmit coil volume
  - Frequency
  - Size and shape of implant
  - Conductivity
  - Heat sink / physiological cooling

Product Labeling Example

“Non-clinical testing has demonstrated that the XXX is MR Conditional. A patient with this XXX can be scanned safely immediately after placement under the following conditions:

MRI-Related Heating:

Maximum whole-body-averaged specific absorption rate (SAR) of 2 W/kg for 15 minutes of scanning (i.e., per scanning sequence)”

Estimating SAR

- Scanner may show % (of what?)
- IEC / FDA Limits for Heating:
  - Normal Mode:
    0.5° C temperature rise, or 2 W/kg whole body
  - First Level Controlled Mode:
    1.0° C temp. rise, or 4 W/kg whole body
  - Second Level Controlled Mode:
    >1.0° C or > 4 W/kg
    (IRB approval only)

Localized SAR Limits

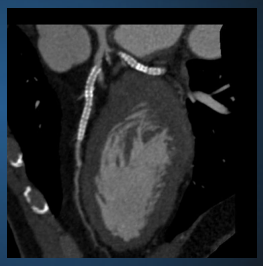
- Head normal mode:
  3.2 W/kg averaged over head mass
- Torso normal mode:
  10 W/kg over any 10 grams of tissue
- Extremities normal mode:
  10 W/kg over any 10 grams of tissue

(no First Level limits for localized modes)

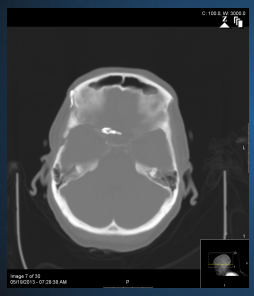
DEVICE REGISTRIES

Device Registries

- Tool for assessing device labeling vs. magnet, scan conditions
- Specific conditions must be met
- Acceptance varies from magnet to magnet, protocol to protocol



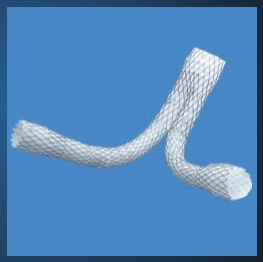
Device Registries



- Enhanced device information e.g. “The List” at www.mrisafety.com
- Must still be assessed for each scanner, sequence/protocol
- Do not rely on what others have done

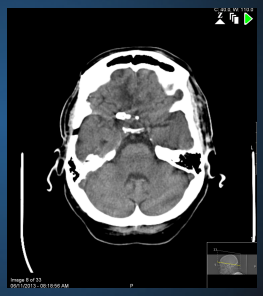
Device Registries

- “Cheat sheet” for each device for:
  - YOUR staff
  - YOUR magnets
  - YOUR scan protocols
- Share experiences within institution/ system as new devices emerge



Presence and Identity of Devices

- Establish registry with surgeons
- Make, model, serial number, date of implant
- MRI safety notes where appropriate



Summary

- Assess device manufacturer's detailed "MRI Conditional" requirements
- Spatial gradient and RF SAR conditions are most challenging for technologists
  - Most likely to be denied unnecessarily
- Local/institutional device registry can save time and duplication of effort, avoid errors.

Thanks! / Questions?

Dave Jordan
david.jordan@uhhospitals.org
(216) 286-6911

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