MRI Conditional Devices and Patient Safety
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Outline
• MRI Conditional Overview
• Spatial Gradient Hazards
• RF SAR Hazards
• Device Registries

MRI Labeling: Objects
• MR Safe: Completely nonmetallic
• MR Conditional: can be safe in MR environment under certain known conditions
• MR Unsafe: demonstrated attractive forces in magnetic field

ACR Advanced Document on MRI Safe Practices 2013
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
**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?**

![Image of RF conditions graph](image_url)

© Siemens Healthcare
**RF SAR**

- **Specific Absorption Rate**
- 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

• 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?

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