FDA Guidelines for Magnetic Resonance Equipment Safety

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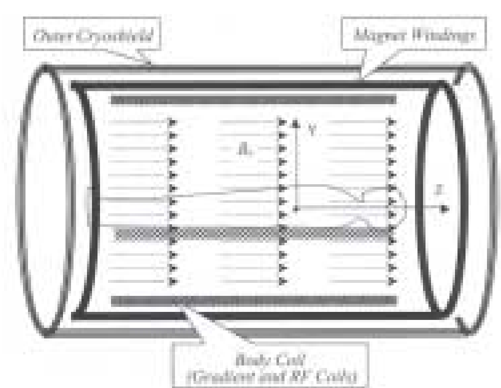
Outline

I. Introduction
II. Static Magnetic Field
III. Radio Frequency (RF) Magnetic Field
IV. Gradient Magnetic Fields
V. Implanted Medical Devices

I. Introduction

1. **Magnetic fields in MRI**
2. **Safety concerns**
3. **Safety organizations**
4. **Safety standards**
5. **IEC/FDA operating modes for MRI diagnostic equipment**

Magnetic Fields in MRI



Main static field – aligns spins
Radio frequency field (fm band) – flips spins)
Gradient field used for spatial encoding the image

Safety Concerns in MRI

Force and torque on magnetic materials – cause – static magnetic field
Heating – cause – RF magnetic field used to flip spins
Nerve stimulation – cause – gradient magnetic fields used for spatial encoding
Implanted medical devices - all of the above

MRI Safety Organizations

International Electrotechnical Commission (IEC)
Food and Drug Administration (FDA)
National Electrical Equipment Manufacturer's Association (NEMA)
American Society for Testing and Materials (ASTM)
American College of Radiology (ACR)

MRI Safety Standards

IEC 60601-2-33 – Requirements for the Safety of MR Equipment for Medical Diagnosis
FDA – Guidelines for Premarket Notifications for MR Diagnostic Devices
NEMA MS 1 through 9 – Safety and Performance Standards
ASTM – Test Methods for MR Safety of Implanted Medical Devices
ACR – Site Safety Guidelines

IEC/FDA Operating Modes for MRI Diagnostic Equipment

Normal Mode – Will not cause stress – suitable for all patients
First Level Controlled Mode – may cause stress – requires medical supervision and positive action by operator to enter
Second Level Controlled Mode

II. Static Magnetic Field

1. **Magnetic force and torque on objects**
2. **Force vs. distance from magnet**
3. **Comparison of force on object in 1.5T and 3.0T scanners**
4. **IEC/FDA requirements for static magnetic fields**
5. **Status of high field MRI safety studies**

Force on Magnetic Dipole in Increasing Magnetic Field

Field lines, B, compress at magnet opening
Produce inward radial components, Br, of field
Resultant attractive force into magnet

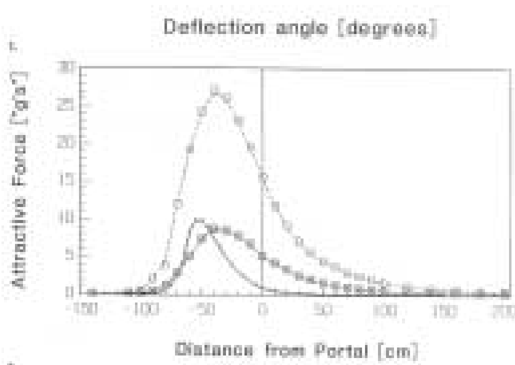
Torque on Magnetic Dipole in Magnetic Field

Magnetized material acts like dipoles
Magnetic field produces torque to align dipole with field
No net force in uniform field

Basic Force and Torque Relations

T = mxB
F = grad(m*B)
Force on paramagnetic or unsaturated ferromagnetic object is maximum where product of B and grad B is maximum
Force on saturated ferromagnetic object is maximum where grad B is maximum

Force vs. Distance from Magnet Entrance



Increases very rapidly as approach magnet
Increases approximately as square of field strength
Depends on type of magnet (open, self-shielded, etc.)

Comparison of 1.5T and 3.0T Scanners

Force on paramagnetic material (e.g. stainless scalpel) is 5 times greater on the 3T system
Force on ferromagnetic object (e.g. steel wrench) is 2.5 times greater on 3T system

IEC/FDA Requirements for Static Magnetic Fields

Field maps must be supplied by manufacturer
Regions over 5 gauss – controlled access
Normal mode (suitable for all patients) up to 2T
First level controlled mode (medical supervision) up to 4T
IEC – over 4T requires IRB approval
FDA – over 4T requires investigational device exemption (IDE)

<u>Status of High Field MRI Safety Studies</u>

Systems up to 8T in operation on human subjects
Subjects monitored for ECG, heart rate, respiration, etc.
Cognitive studies have been done on a limited number of subjects
Safety studies indicate no serious adverse effects
Only effects seen so far are temporary and not serious (vertigo, nausea, metallic taste, etc.)

III. <u>Radiofrequency (RF) Magnetic Field</u>

1. **RF heating in MRI – theory**
2. **RF heating in clinical MRI**
3. **How a scanner estimates SAR**
4. **IEC/FDA limits for whole body and localized heating**
5. **Measuring SAR – pulse energy and calorimetric methods**

<u>RF Heating in MRI – Theory</u>

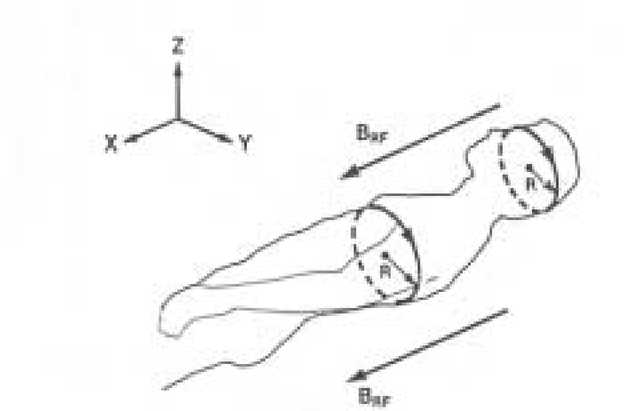


FIG. 1. Model used for estimating surface power absorption in the body. The rf field $B_{rf}\sin(2\pi\nu t)\,\hat{x}$ induces an electric field of amplitude $E = \pi\nu B_{rf} R$ at the surface of a circular section of radius R, where $\hat{x}$ is a unit vector in the x direction.

Heating is inductive (Faraday Law)
Power increases approximately as square of frequency and radius
Power increases approximately as square of field strength and patient size
Most heat is deposited on perimeter of body where it can be more easily dissipated
Regions with high resistance can cause focal heating

RF Heating in Clinical MRI

Concerns are core (whole body) and localized heating
Not practical to routinely measure temperature of patients
Use Specific Absorption Rate (SAR) to estimate temperature increase
SAR = absorbed power/mass (e.g watts/kg)
SAR of 1 W/kg would increase temperature of an insulated slab about 1 degree C/hour

How a Scanner Estimates SAR

Scanner runs a calibration routine
Determines energy needed to get a 90 and 180 degree flip
Adds up energy of all RF pulses in a sequence and divides by pulse repetition time (TR) to get power
Divides by patient weight to get whole body SAR
Peak local SAR is usually estimated as 2.5 times higher on most scanners

IEC/FDA Limits for Whole Body Heating

Normal mode limit (suitable for all patients) – 0.5 degrees C or 2 W/kg
First level controlled mode (medical supervision) – 1.0 degrees C or 4 W/kg
Second level controlled mode – greater than 1 degree C or 4 W/kg (requires IRB approval)

IEC/FDA Limits for Localized Heating

Head normal mode limit – 38 degrees C or 3.2 W/kg averaged over head mass
Torso normal mode limit – 39 degrees C or 10 W/kg over any 10 grams
Extremities normal mode limit – 40 degrees C or 10 W/kg over any 10 grams
No first level for head, torso or extremities

Methods for Measuring SAR

Developed by National Electrical Manufacturers Association (NEMA)
NEMA Standard MS-8 – Characterization of SAR for MRI Systems
Two basic methods – pulse-energy method and calorimetric method
Used by manufacturers to calculate SAR for their scanners

Pulse-Energy Method for Measuring Whole Body SAR – Equipment

Directional coupler to measure forward and reflected power
Oscilloscope to measure peak-to-peak voltages
Non-loading phantom to measure coil losses
Loading phantom to measure sample losses

Calorimetric Method for Measuring Whole Body SAR

Use insulated loading phantom
Measure temperature increase
Calculate absorbed energy and SAR

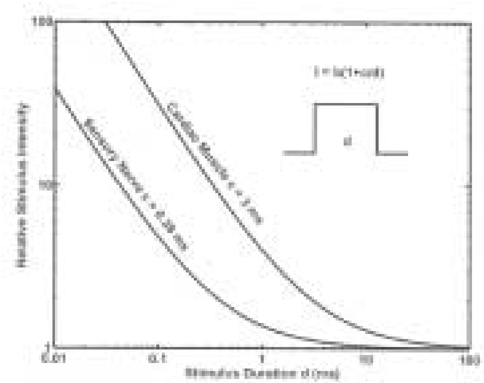
IV. Gradient Magnetic Fields

1. **Gradient coils and current waveforms**
2. **Effects on patient (nerve stimulation)**
3. **Relationship between pulse duration and stimulation threshold**
4. **IEC/FDA limits**

MRI Gradient Coils and Current Waveforms

Apply linear magnetic fields for spatial encoding
Trapezoidal pulses – pulse train for echo planar imaging

Hyperbolic Relationship Between Pulse Length and Stimulation Threshold



dB/dt = b(1+c/d)
b = rheobase
c = chronaxie
c = 3 msec for cardiac muscle
c = 0.38 msec for nerves
d = duration of stimulus
Nerve stimulation begins as barely noticeable, but can be uncomfortable or painful
Large variations in patient response to stimulation

New IEC/FDA Limits for Gradients

Old limit was dB/dt = 20 T/sec for normal mode
Now three ways to satisfy requirements
- **Direct determination (volunteer studies)**
- **Default dB/dt limits for whole body gradients**
- **Default E field limits for all types of gradients**

Direct Determination of Gradient Limits

Applies to whole body and special purpose gradients
Observe stimulation threshold in at least 11 volunteers
Check different pulse durations and axes
Normal mode limit at 80% of observed mean threshold
First level limit at 100% of observed threshold

Default Limits for Whole Body Gradients in Terms of dB/dt

Normal mode – dB/dt = 0.8rb(1+0.36/tau)
First level – dB/dt = 1.0rb(1+0.36/tau)
Rb = rheobase = 20 T/sec
Tau = stimulus duration (msec)

Default Electric Field Limits for All Gradients

Normal mode – E = 0.8rb(1+0.36/tau)
First level – E = 1.0rb(1+0.36/tau)
Rb = rheobase = 2.2 volts/m
Tau = stimulus duration (msec)

New IEC Limits for Combined Gradient Output

Weighted quadratic addition rule or validated alternative
Default or directly determined weight factors for the different gradient directions
In 1995 standard dB/dt was measured with all gradients pulsing simultaneously (more conservative)

V. Implanted Medical Devices

1. **Safety concerns**
2. **Theory**
3. **ASTM measurement methods**
4. **Example – RF heating of neurostimulator**

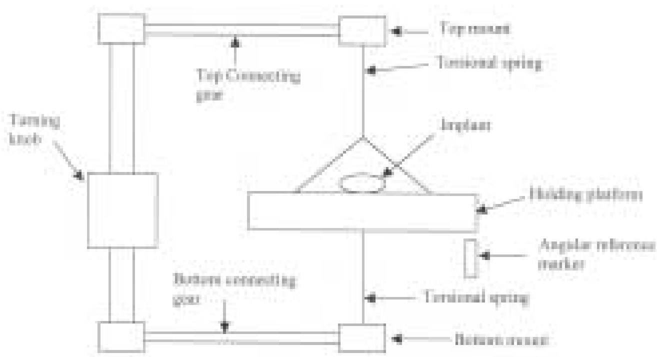
Safety Concerns for Implanted Medical Devices

Force and torque on magnetic materials
RF heating
Induced voltages/currents on implant – altered operation

ASTM Force Measurement Method

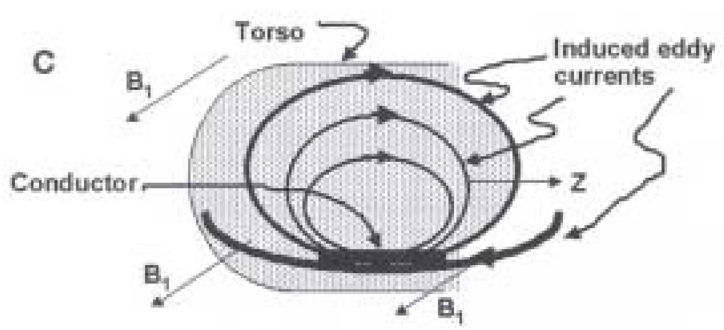
Suspend implant from string
Position so that implant is at position of maximum attractive force
Measure string angle
At 45 degrees attractive force = gravity

ASTM Torque Measurement Method



Implant placed on holder suspended by calibrated torsional spring
Apparatus placed at magnet center
Torque determined from deflection angle

RF Heating of Implant – Theory



Eddy currents are induced in human body by RF magnetic field
A conductor, such as a wire, concentrates these currents and may produce intense localized heating at the tip of the wire

<u>ASTM Implant Heating Measurement Method – Phantom</u>

Phantom material should simulate human electrical and thermal properties
Use saline solution to simulate conductivity
Use gelling agent to prevent convective heat transfer

<u>ASTM Implant Heating Measurement Method – Procedure</u>

Place implant in phantom to simulate actual position in human body
Place fiber optic probes in reference position and positions where heating is expected to be the greatest
Apply at least 1 W/kg
Measure temperature rise over at least 15 minutes
Should be less than 3 degrees C

<u>Example – RF Heating of Neurostimulator</u>