Electromagnetic Fields:

Effects / Volumes / Forces / Harms

Tobias Gilk - September 22, 2022

Tobias Gilk,
MRSO, MRSE

- Past Member ACR MRI Safety Committee
- Contributing Author 2007, 2019 & 2020 ACR MRI Safety Guidance
- Founding Board Member / Past Chair ABMRS
- International Trainer on MRI Safety

ABMRS Content Disclosure

This presentation is not sponsored by or affiliated with the American Board of Magnetic Resonance Safety (ABMRS).

As a member of the the Board of the ABMRS, I am prohibited from speaking on specific examination question content, but permitted to provide education on MRI safety concepts and principles.

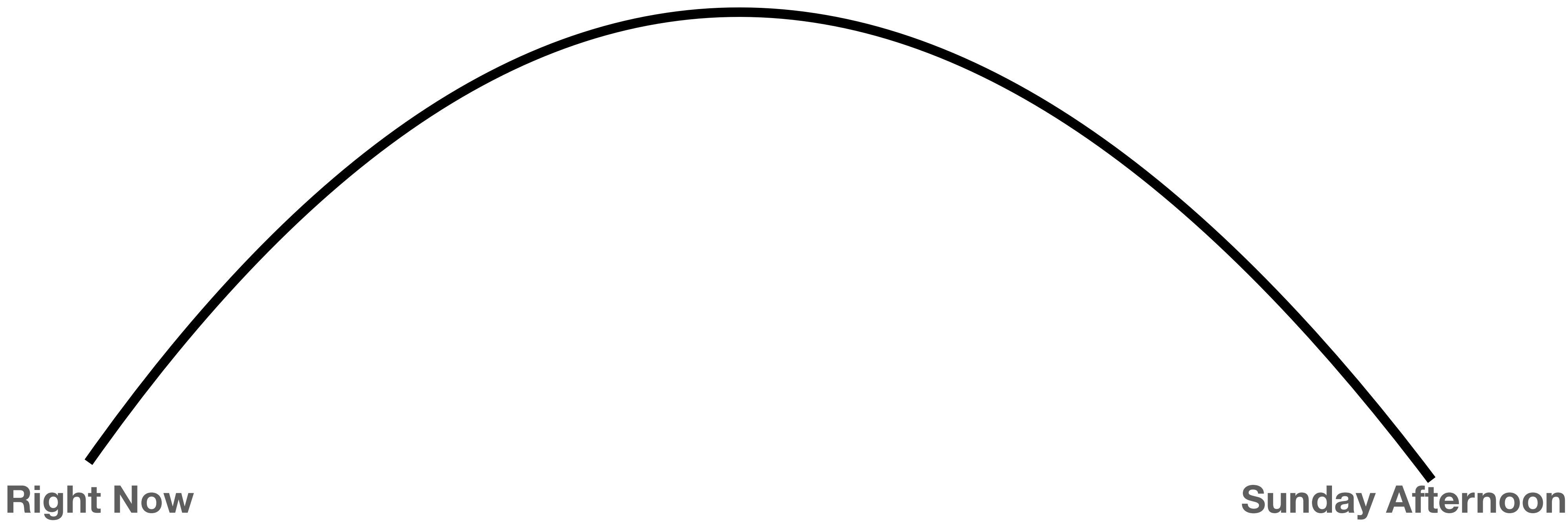
This presentation is not an exam preparation for any examination.

Rules of the Road

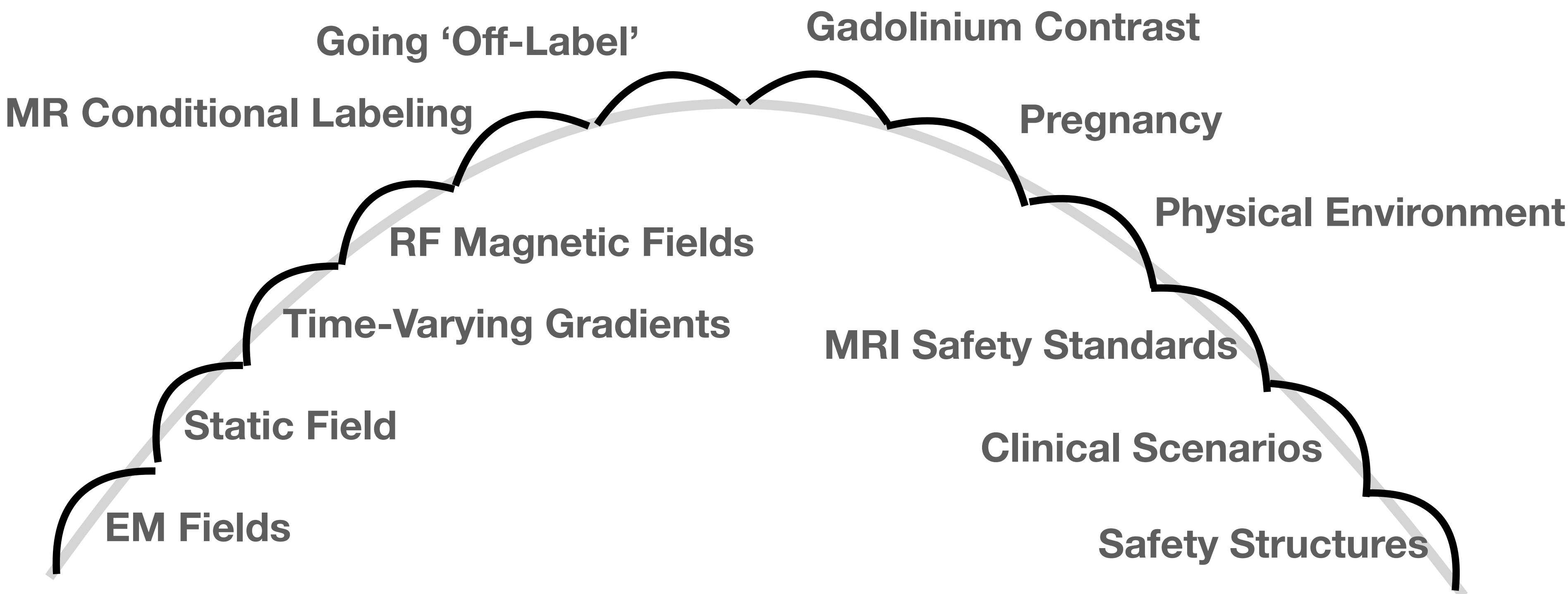
- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

The Arc

The “Big Picture”



The Arc

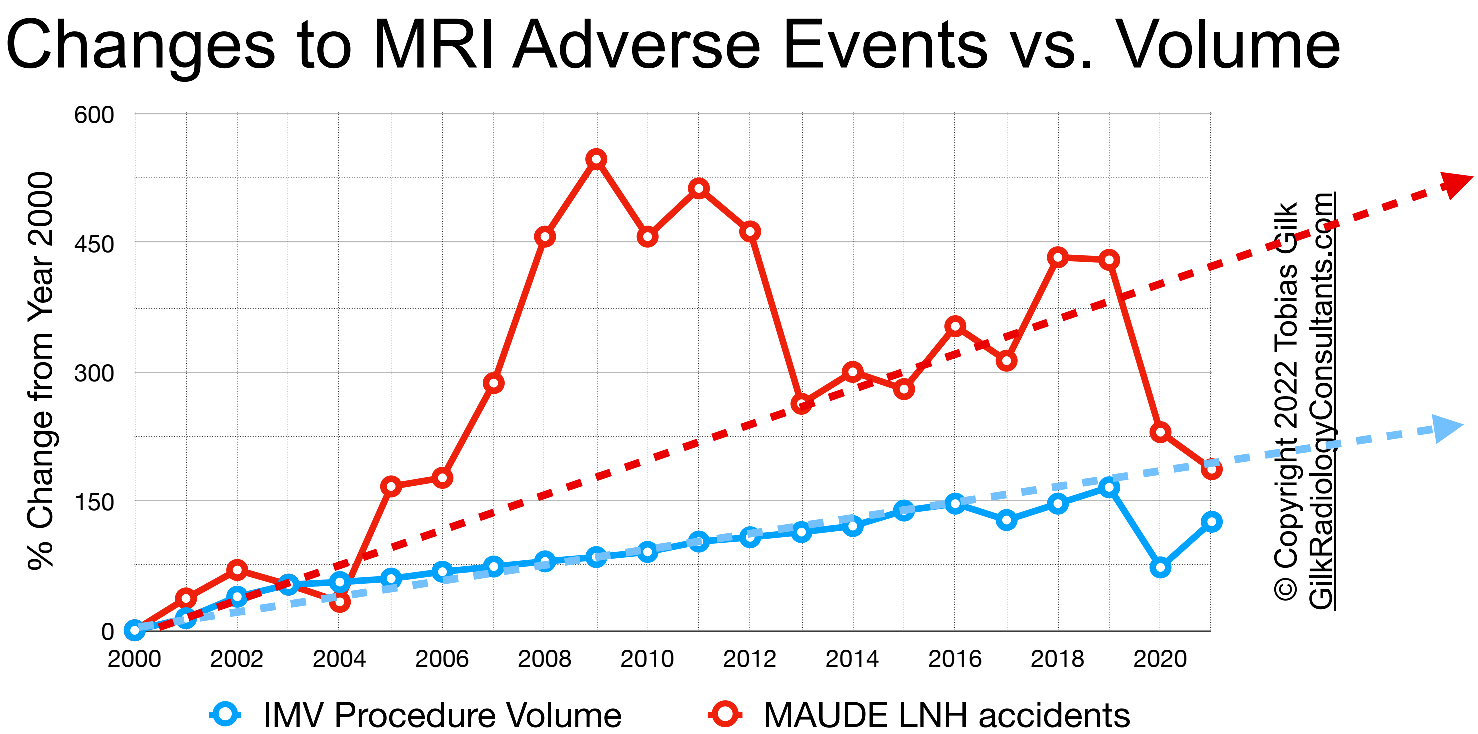

Going ‘Off-Label’
Gadolinium Contrast
MR Conditional Labeling
Pregnancy
Physical Environment
RF Magnetic Fields
Time-Varying Gradients
MRI Safety Standards
Static Field
Clinical Scenarios
EM Fields
Safety Structures

But There's Only One Way We All Get There…

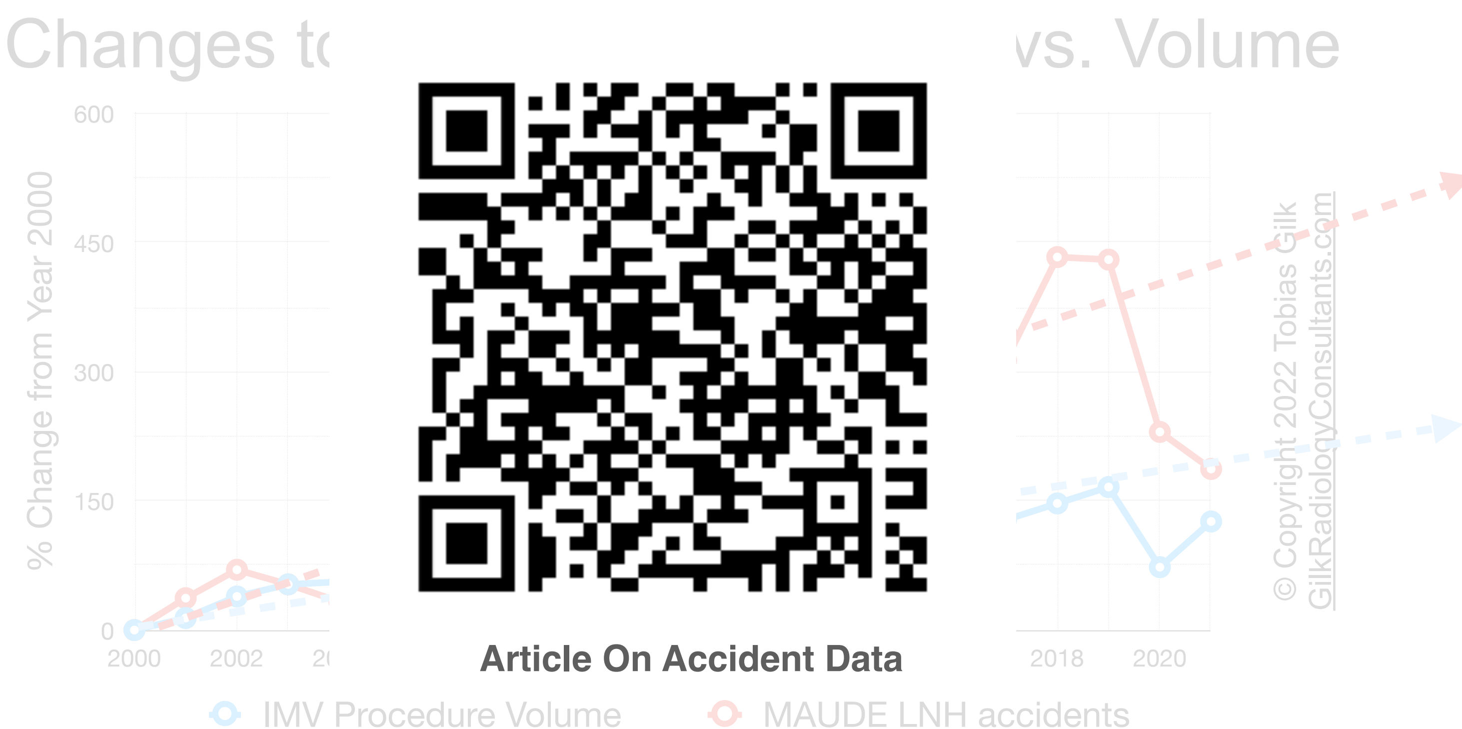
TRUST!

State of MRI Safety

State of MRI Safety



State of MRI Safety



Article On Accident Data

State of MRI Safety

Risk Factors

MRI Systems

- Higher Field Strengths
- Active Shielding
- Faster / More Powerful Gradients
- Greater RF

Clinical Usage

- High-Acuity Patients
- Emergent / Trauma
- Image-Guided Procedures
- Anesthesia / Sedation

Patient Cohort

- Heavier
- Sicker
- More Implants / Devices

State of MRI Safety

⤴ Practice Improvements

We *are* doing better today (compared to 20 years ago), but our improvement is slower than risk-factor growth.

Outline

Electromagnetic Fields

- Intro
- Static Magnetic Field (where, when, what, why)
- Time-Varying (Imaging) Gradient Magnetic Field (where, when, what, why)
- Radio Frequency Magnetic Field (where, when, what, why)
- Exposure Model of Risk
- Q & A

"If you don't know what you're exposing a patient (or device) to, you can't begin to perform an MR risk-assessment."

— Me

MRI Has
A Vocabulary Problem…

MRI Has
A Vocabulary Problem…

Coil

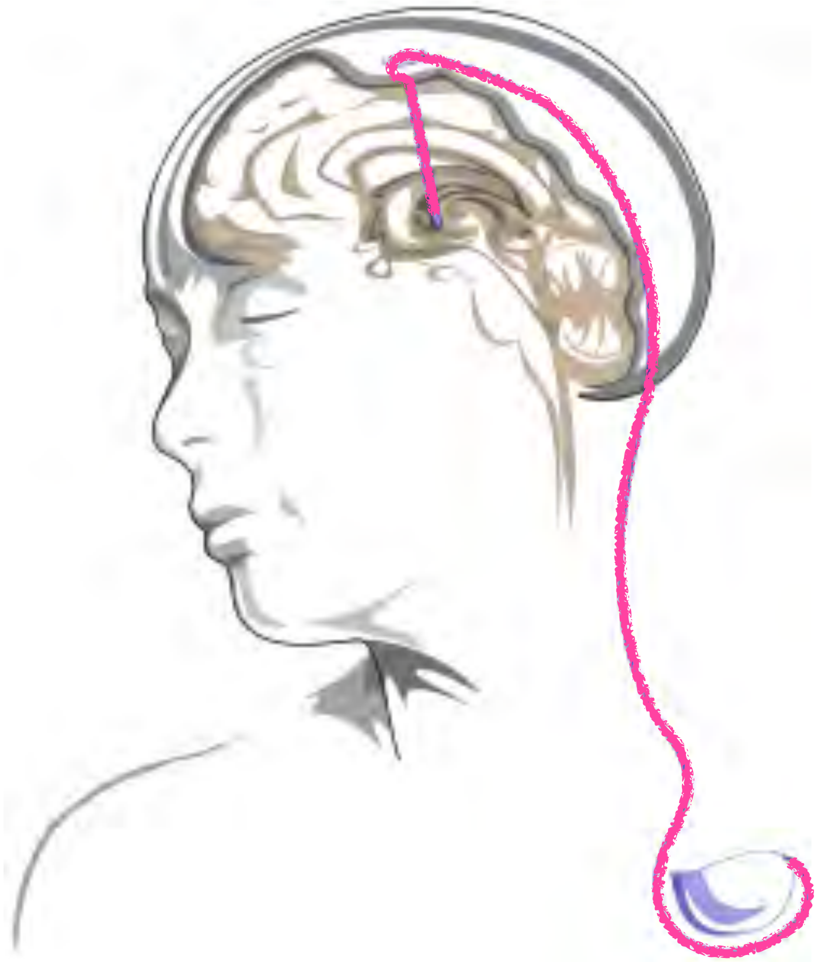
Gradient

Before We Start…

What Could Go Wrong?

- DBS Patient (6’ tall, 200 lbs)
  - MR Conditional at 1.5T
  - “T/R Head Coil Only”
  - 0.1 W/kg
- Indicated Study Is For A Knee

  Would You Consider It?



MRI

Three Electromagnetic (EM) Fields

- Static Magnetic Field
- Time-Varying (Imaging)
  Gradient Magnetic Field
- Radio Frequency Magnetic Field

MRI

Three Electromagnetic (EM) Fields

- Static Magnetic Field
- Time-Varying (Imaging) Gradient Magnetic Field
- Radio Frequency Magnetic Field

MRI Safety Information

MR

MR Conditional

A patient with the BestCompany AlwaysOpenStent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Additional MR Safety information may be found at www.bestc.com/alwaysopenstent or by calling 1800-XXX-XXXX

Parameter	*Condition of Use / Information*
Static Magnetic Field Strength (B_0)	≤3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	30 T/m (3000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (i.e., quadrature drive)
RF Transmit Coil	Any Transmit RF Coil may be used.
RF Receive Coil	Any Receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Scan Duration and Wait Time	Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
MR Image Artifact	The presence of the AlwaysOpenStent may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

Figure X1.1 Exemplar MR Conditional IFU language for a passive item intended to enter the bore of a MR system.

Static Magnetic Field

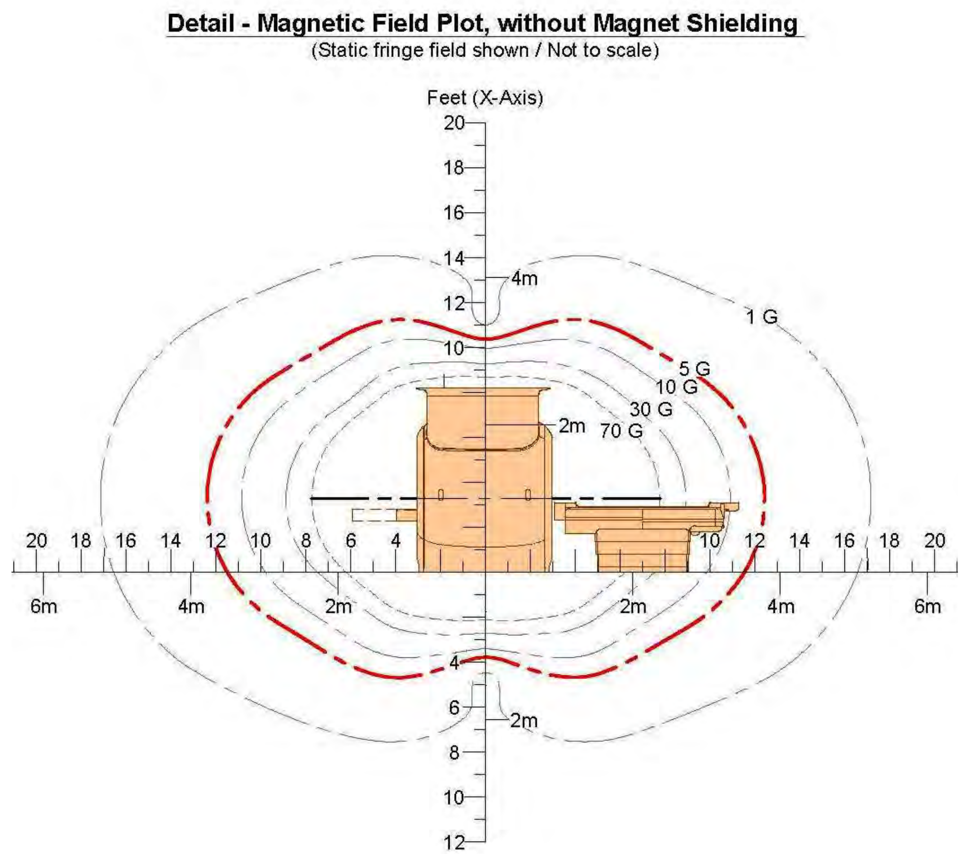
Agenda

- When & Where
- Field Strength (B0) & Spatial Field Gradient (SFG)
- Units & Measures
- Plots & Graphs
- Physical Effects
- Physiologic Effects

Static Magnetic Field

When & Where?

- Always On
- Increases w/ Proximity
  (max usually near mouth of bore)
- Magnetism Not Contained By
  Conventional Construction



Static Magnetic Field

Field Strength & SFG

Field Strength

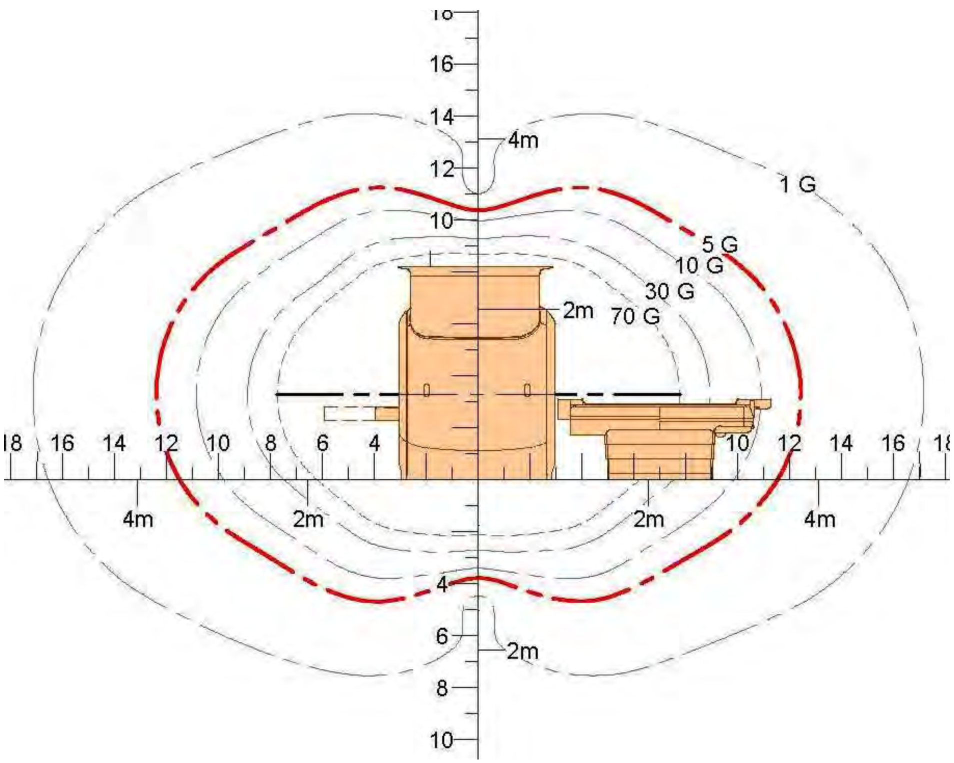
- Single-Factor Measure
- 'Nominal' Field Strength
  (e.g., "1.5 T" or "3.0 T")
- Fringe Field Strengths
  (e.g., 5 Gauss, 100 Gauss)

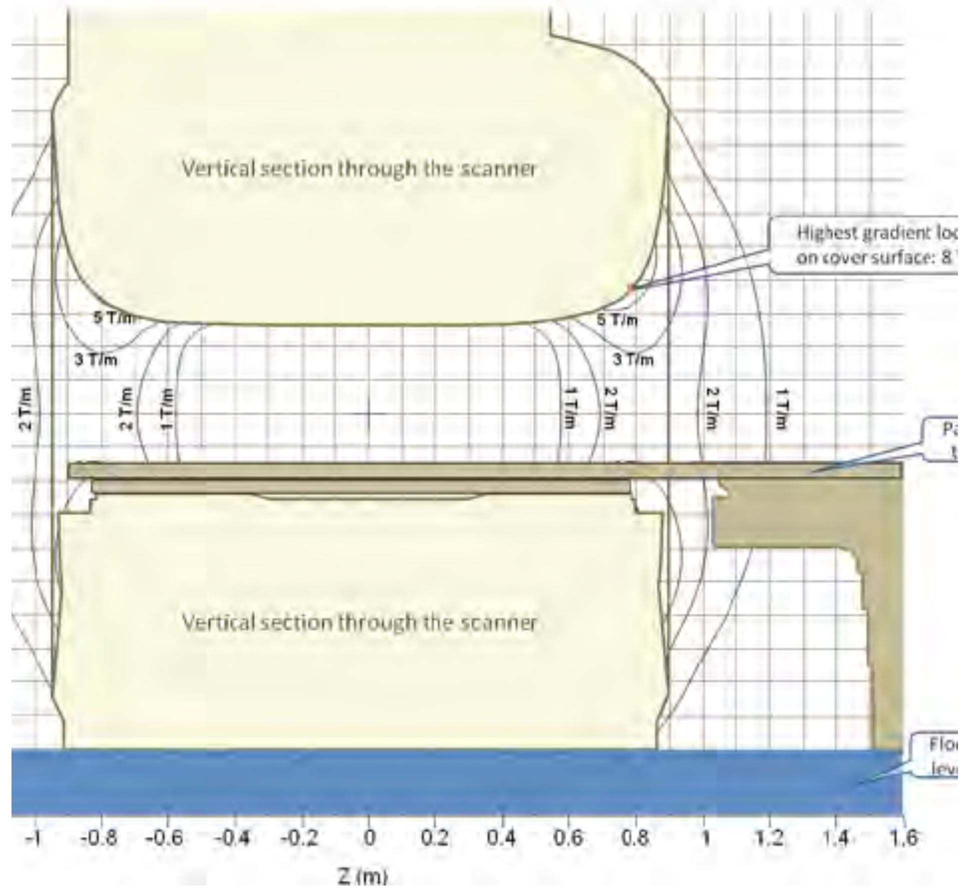
Spatial Field Gradient

- Two-Factor Measure
- Change In Field Strength Over Distance
- "Steepness" Of Magnetic Field
- Depicted in G/cm or T/m

Static Magnetic Field

Plots & Graphs

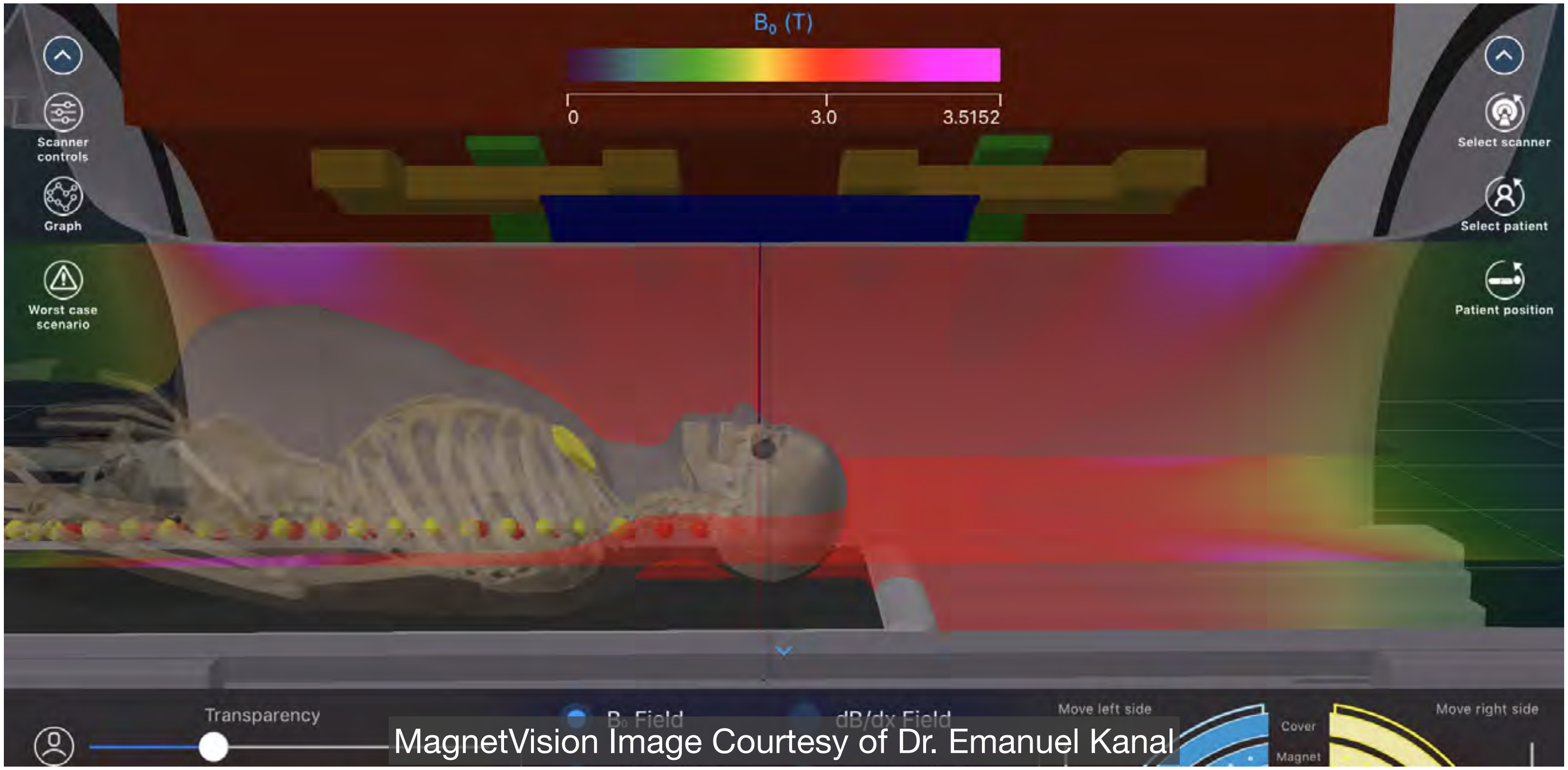




Static Magnetic Field

Plots & Graphs

B0 Magnetic Field Strength

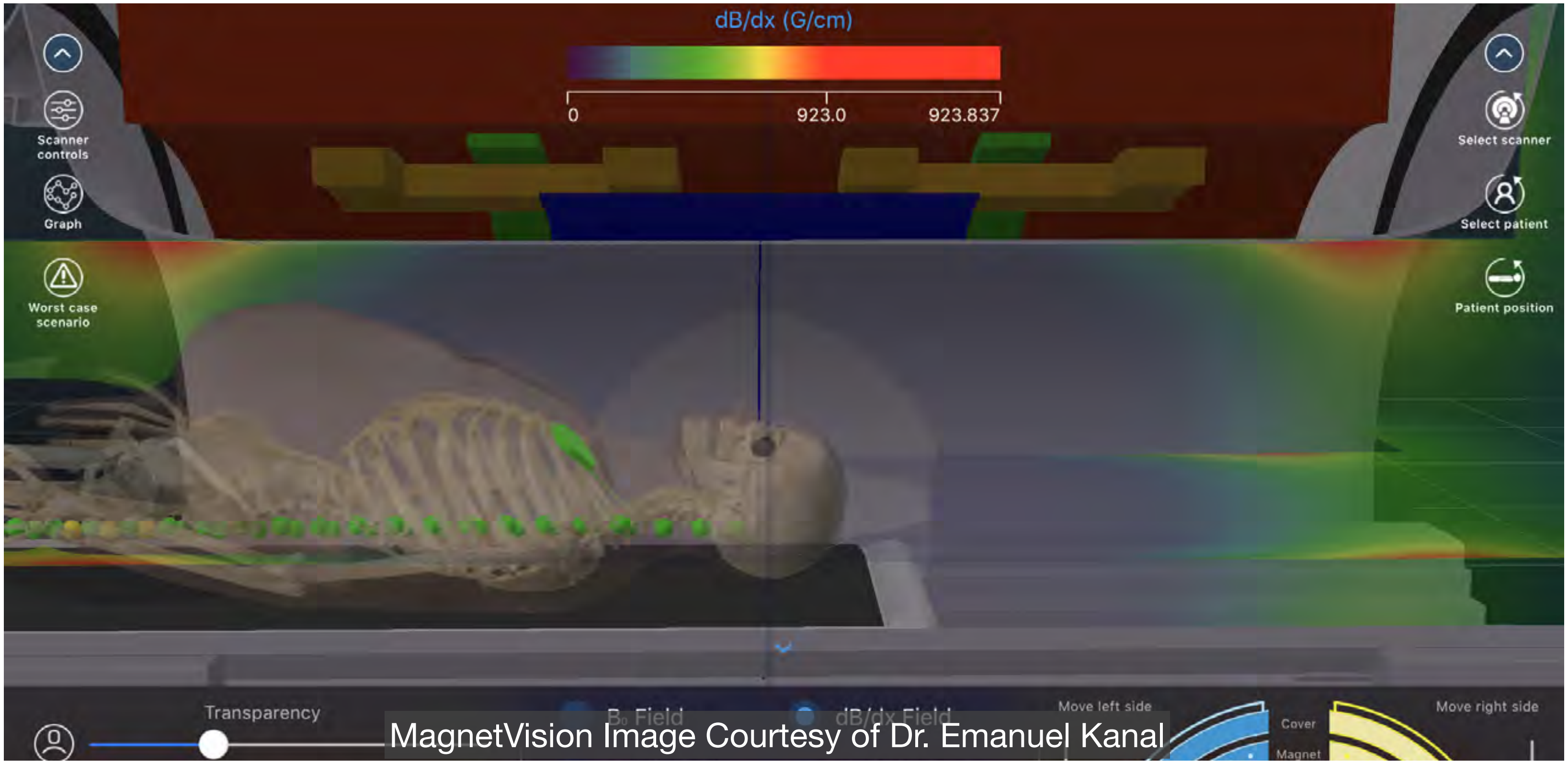


MagnetVision Image Courtesy of Dr. Emanuel Kanal

Static Magnetic Field

Plots & Graphs

Spatial Field Gradient



MagnetVision Image Courtesy of Dr. Emanuel Kanal

Static Magnetic Field
Physical Effects

- Torque / Rotation (Function of B0)
- Translation / Attraction (Primarily Function of SFG)
- Lenz Force (Faraday's Law of Induction)

Static Magnetic Field
Physiological Effects

- Inner-Ear Effects (vertigo, nystagmus)
- Flow Potential (ECG interference, S-T segment elevation)
- Magneto Hydrodynamic Effect (MHD)

Time-Varying (Imaging) Gradient Magnetic Fields

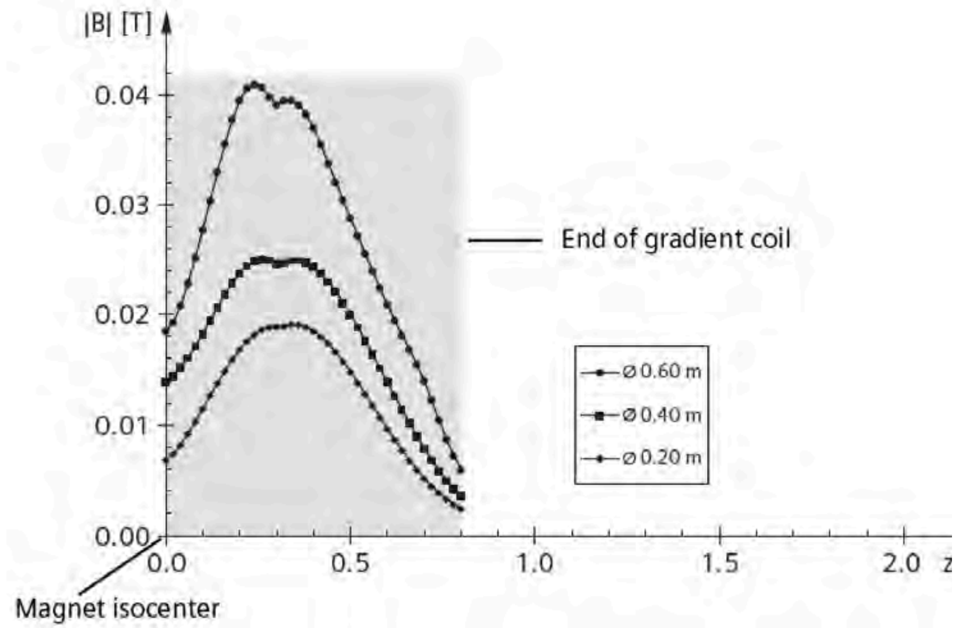
Agenda

- When & Where
- Amplitude (strength), Slope (steepness), Slew (time & distance change)
- Units & Measures
- Plots & Graphs
- Physical Effects
- Physiologic Effects

Time-Varying Gradients

When & Where?

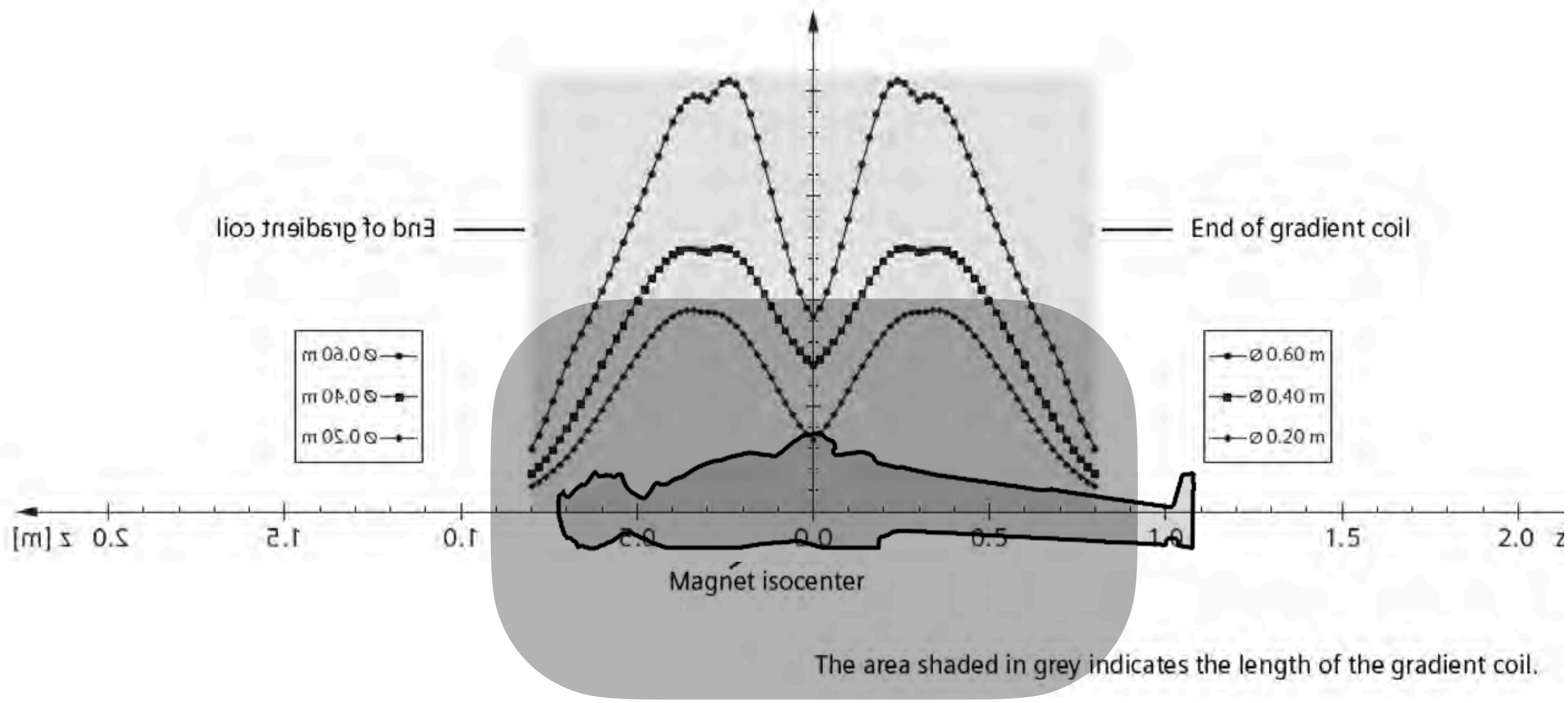
- On Only During Imaging
- Close To Minimum At Isocenter
- Max ~30 cm S-I, Radially
- Drops Rapidly Further Than 30 cm
- Functionally Insignificant Beyond Face Of Bore



The area shaded in grey indicates the length of the gradient coil.

Time-Varying Gradients

When & Where?



Time-Varying Gradients

Amplitude, Change Rate, Slope

Amplitude

- Single-Factor Measure
- Maximum Change In Effective Field Strength
- Usually Represented In Milli (m) Tesla (T), or mT

Change Rate

- Two-Factor Measure
- Change In Strength Over Time ($\Delta B/\Delta t$)
- Usually Represented In T/s, or mT/s

Slope

- Two-Factor Measure
- Like Spatial Gradient, Change In Strength Over Distance ($\Delta B/\Delta x$)
- Usually Represented In T/m, or mT/m

Time-Varying Gradients

Rise-Time, Slew

Rise-Time

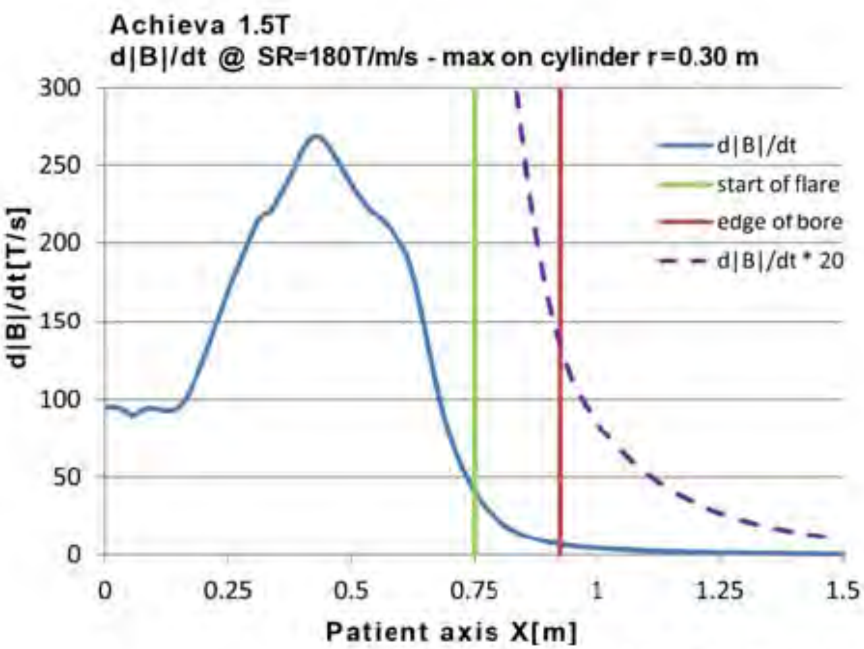
- Single-Factor Measure
- Time Required To Go From Gradients Off To Full Power
- Usually Represented In Milli (m) seconds (s), or ms

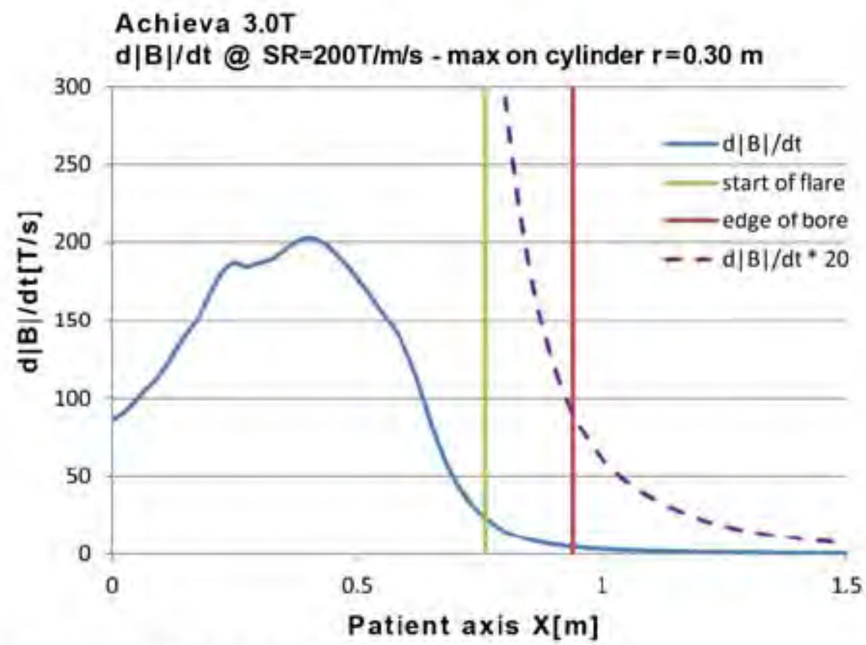
Slew

- Three-Factor Measure
- Most Complete Measure Of Gradients (strength, distance, time)
- Usually Represented In T/m/s or mT/m/ms

Time-Varying Gradients

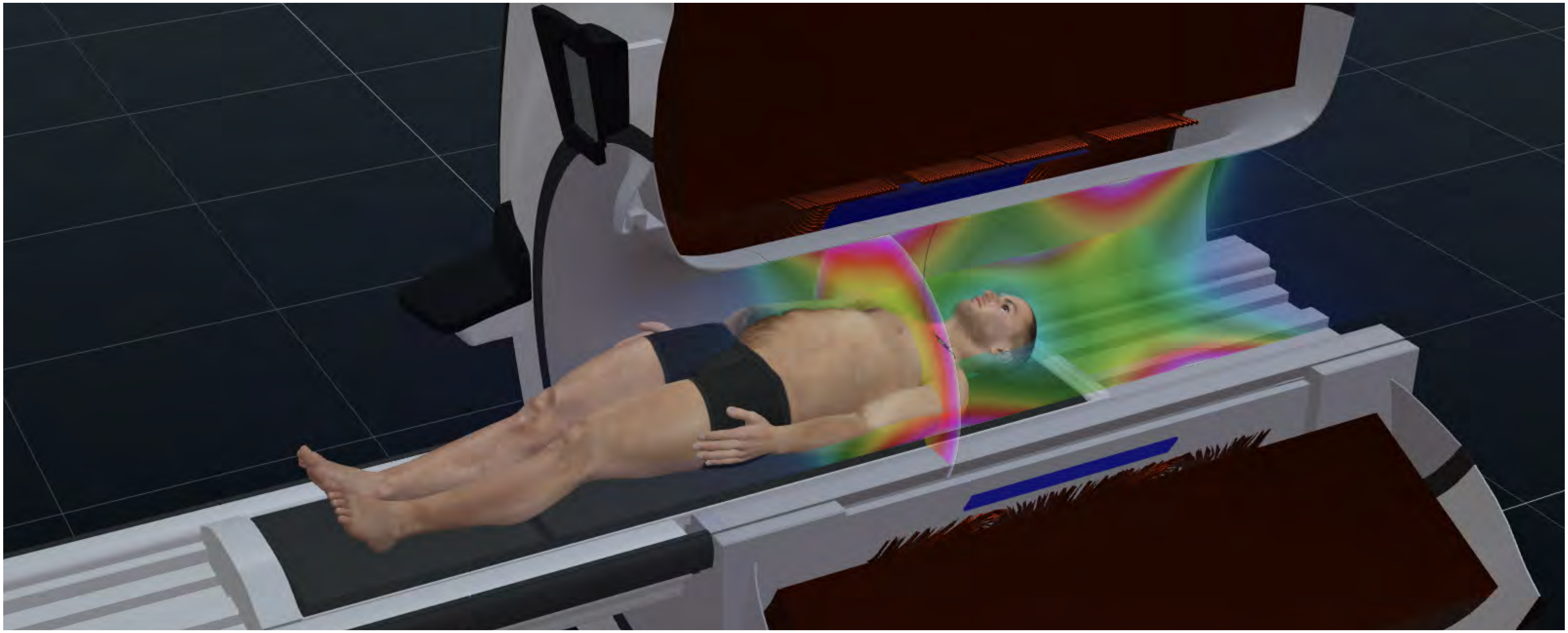
Plots & Graphs





Time-Varying Gradients

Plots & Graphs



Time-Varying Gradients

Physical Effects

- High-Frequency Vibration
- Faraday’s Law of Induction (TVG-Induced Voltages)

Time-Varying Gradients
Physiological Effects

- Peripheral Nerve Stimulation (PNS)
- Lead-Potentiated Neuromuscular Stimulation
- False-Feedback Of Active Devices (Inappropriate Therapy)

Radio Frequency (RF) Magnetic Fields

Agenda

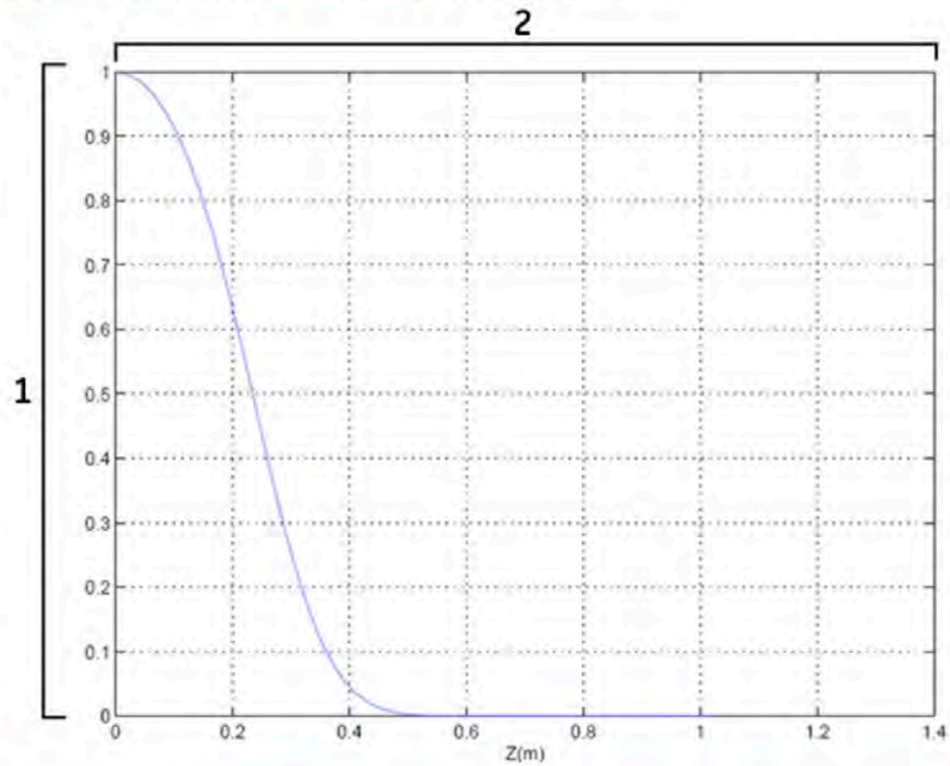
- When & Where
- Collimation??
- Units & Measures (SAR, SED, $B1+_{RMS}$)
- Plots & Graphs
- Physical Effects
- Physiologic Effects

RF Magnetic Fields

When & Where?

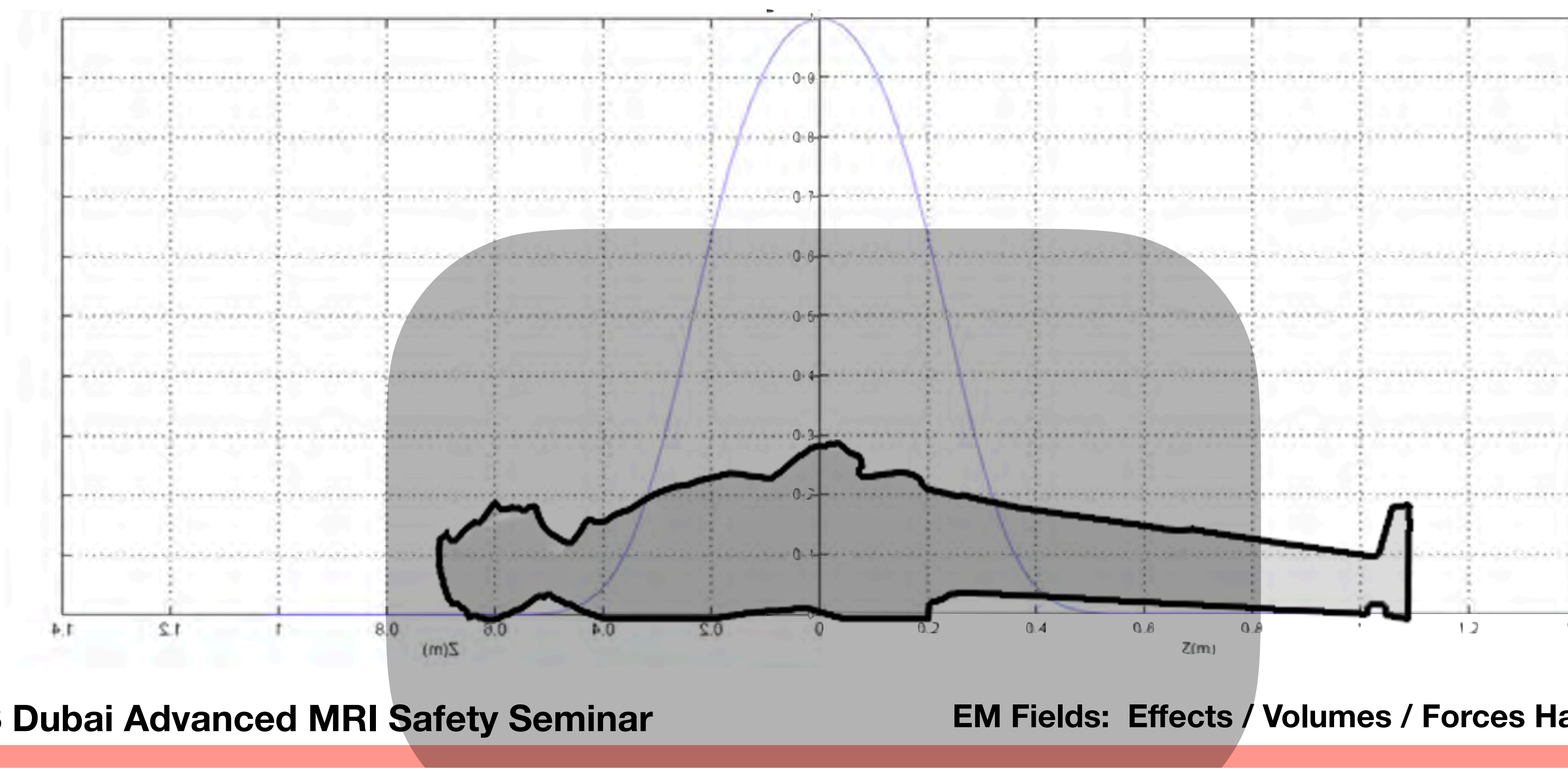
- On Only During Imaging
- What Manufacturers Tell You
  (vs. what's real)
- Drops Rapidly Further Than 30 cm
- Functionally Insignificant Beyond Face Of Bore
- Collimation?

Figure 2-2: Plot of the Square of B1 Normalized to Isocenter for the Body Birdcage Coil on Axis.



RF Magnetic Fields

When & Where?



RF Magnetic Fields

SAR, SED, $B1+_{RMS}$

SAR

- Measures *Rate* Of Absorbed Energy Averaged Across Mass
- Whole Or Partial Body
- Useful For Diffuse Thermal Loading (but on device labels for focal heating risk?!?)

SED

- SAR x Time
- Assumes All Heat Energy Remains In Patient (No Shedding Of Thermal Load)
- Pop-Up Warnings
- Lock-Outs

$B1+_{RMS}$

- Standardized Across Vendors / Platforms
- Measure Of Absorbed Energy
- Also Poor For Focal Heating Risk, But Generally Safer & More Permissive Than SAR

RF Magnetic Fields

SAR, SED, $B1+_{RMS}$

SAR

- Watts Per Kilogram (W/kg)
- Whole Body Averaged
- Head
- Extremity (Partial Body)

SED

- Joules Per Kilogram (J/kg), or Thousand (kilo) Joules Per Kilogram (kJ/kg)
- Joule = Watts x Seconds

$B1+_{RMS}$

- Micro (One-Millionth) Tesla, μT

RF Magnetic Fields

Plots & Graphs

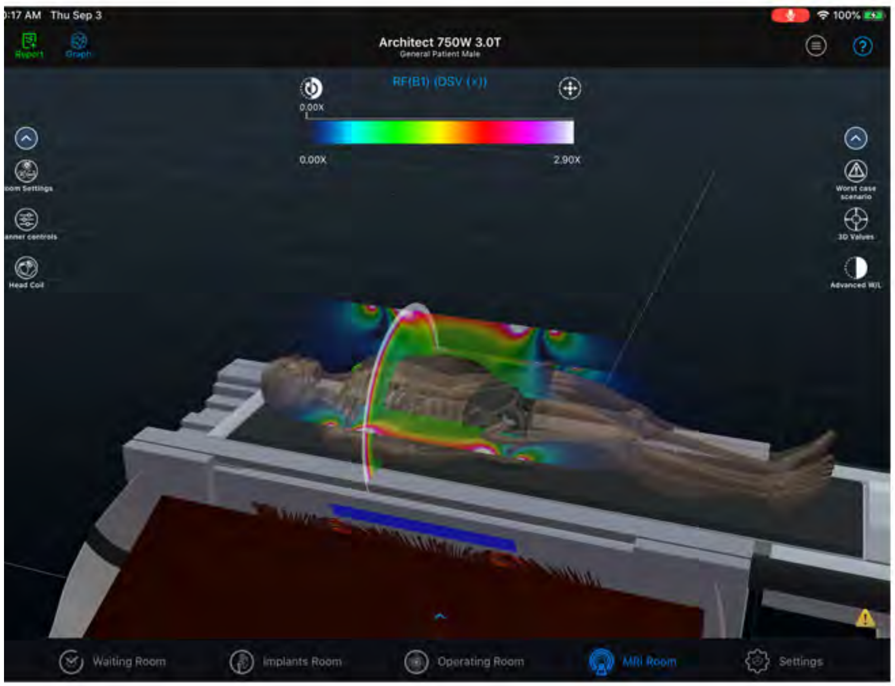


Figure 2-6: Plot of the Square of B1 Normalized to Isocenter for the Body Birdcage Coil on Axis.

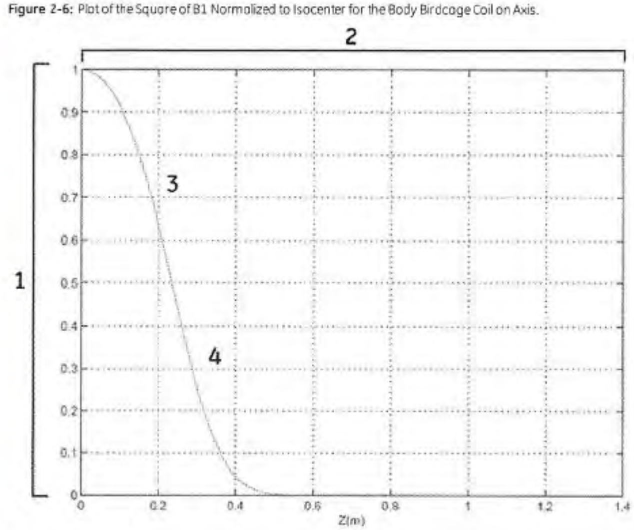
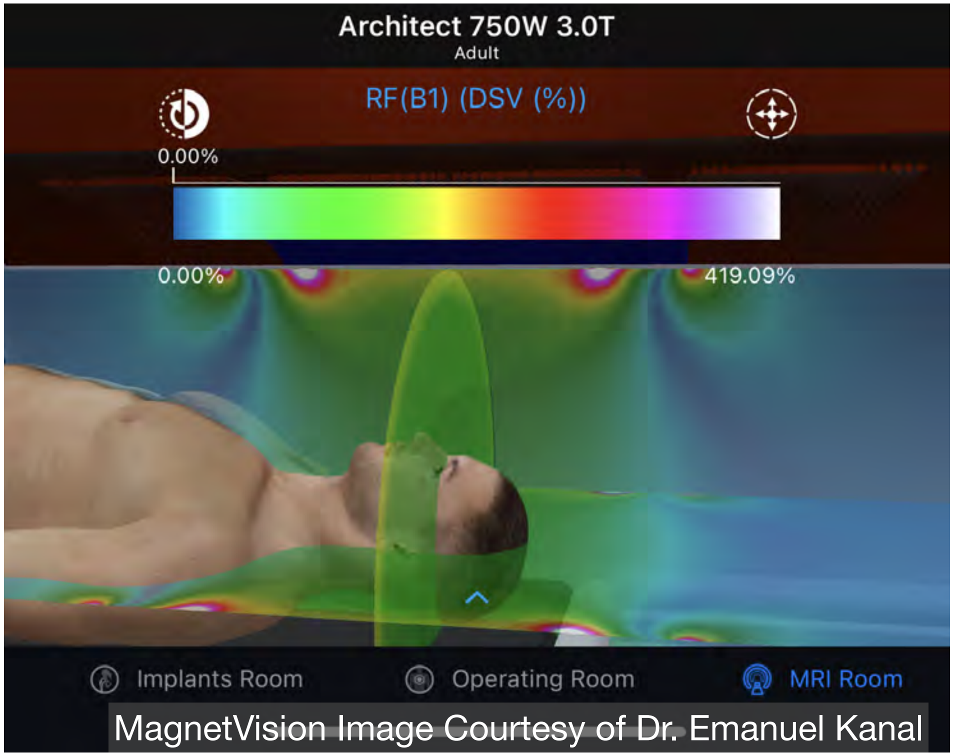


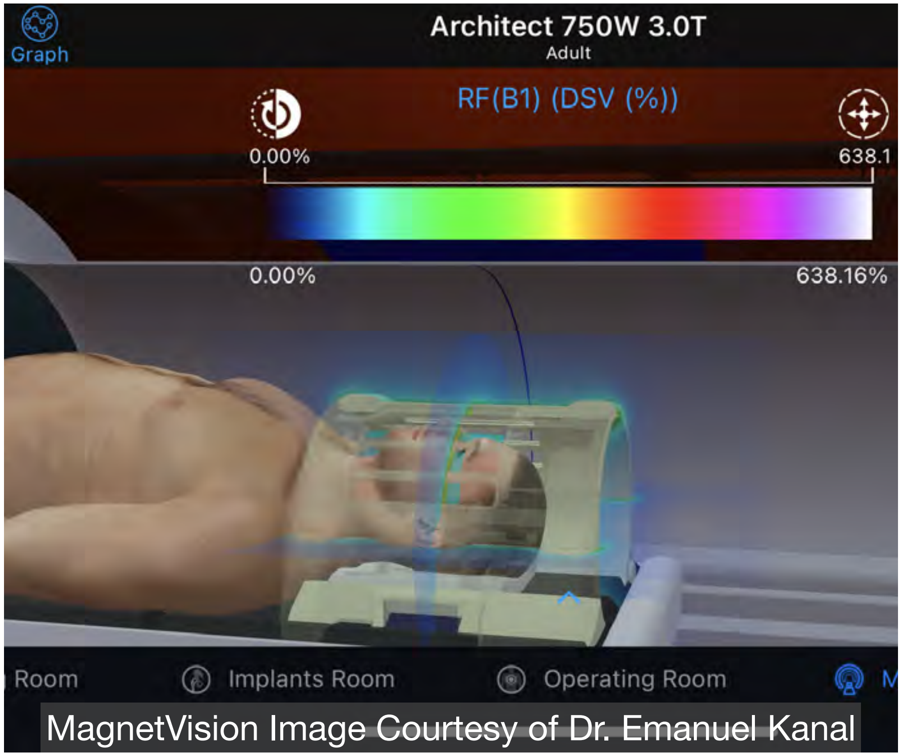
Table 2-12: Image legend

#	Description
1	Square of B1 normalized to isocenter.
2	Square of B1 normalized to isocenter for body birdcage coil on axis.
3	The point (0.707) at which RF transmission is reduced by 3 dB from maximum at isocenter.
4	The point (0.316) at which RF transmission is reduced by 10 dB from maximum at isocenter.

RF Magnetic Fields

Plots & Graphs





RF Magnetic Fields
Physical Effects

- Diffuse Heating
- Faraday's Law of Induction (RF-Induced Voltages)
  - Focal Resistance (Focal Heating)

RF Magnetic Fields

Physiological Effects

- See Physical Effects

Risks Are A Function Of Exposure

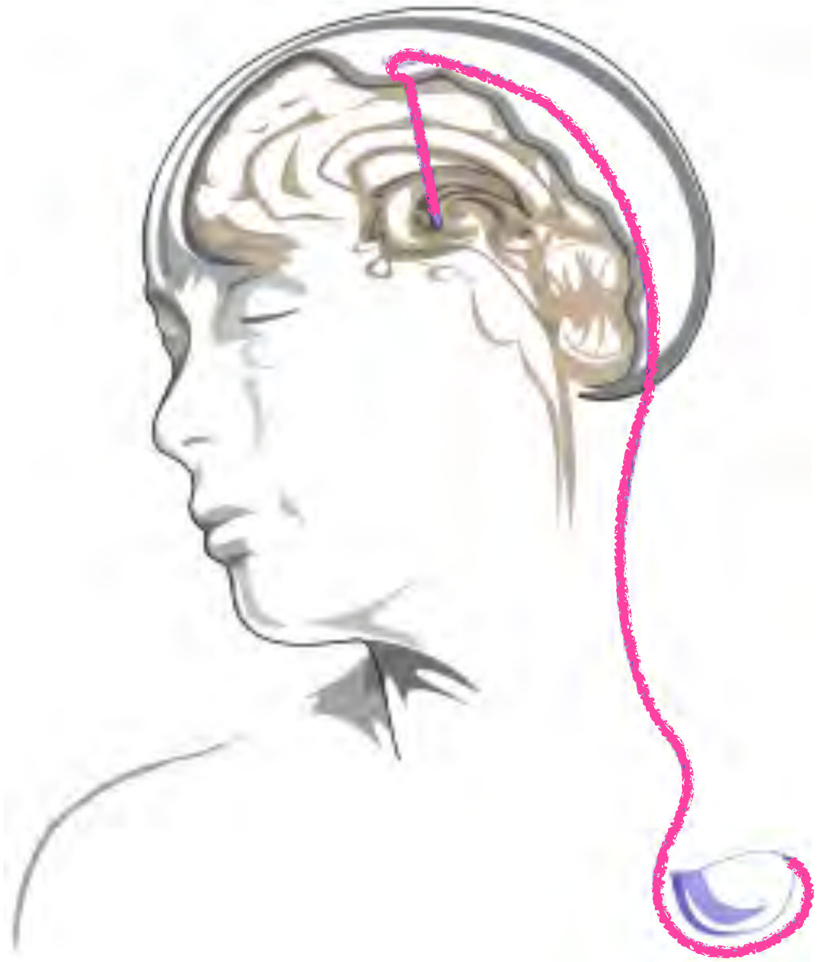
- If Exposure Is Zero, What Is Risk?

Do You Remember…

Would You Consider?

- DBS Patient (6’ tall, 200 lbs)
  - MR Conditional
  - “T/R Head Coil Only”
  - 0.1 W/kg

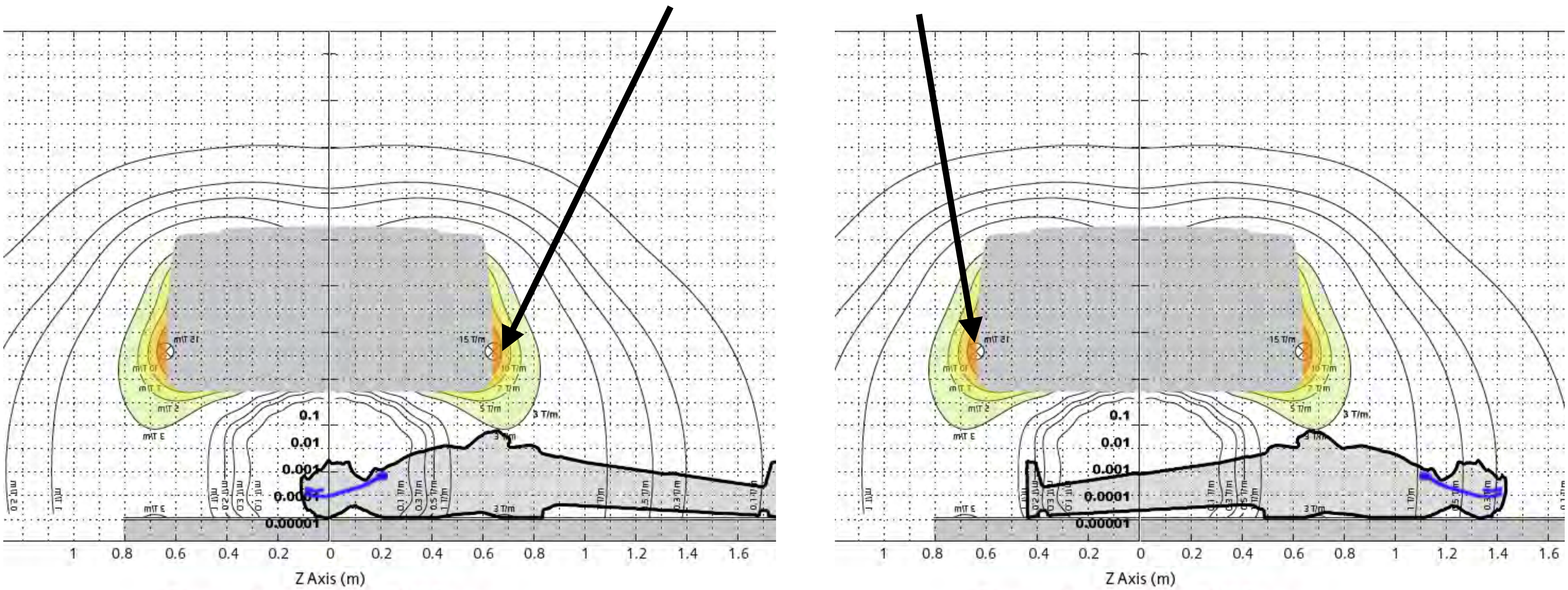
- Indicated Study Is Knee



Do You Remember…

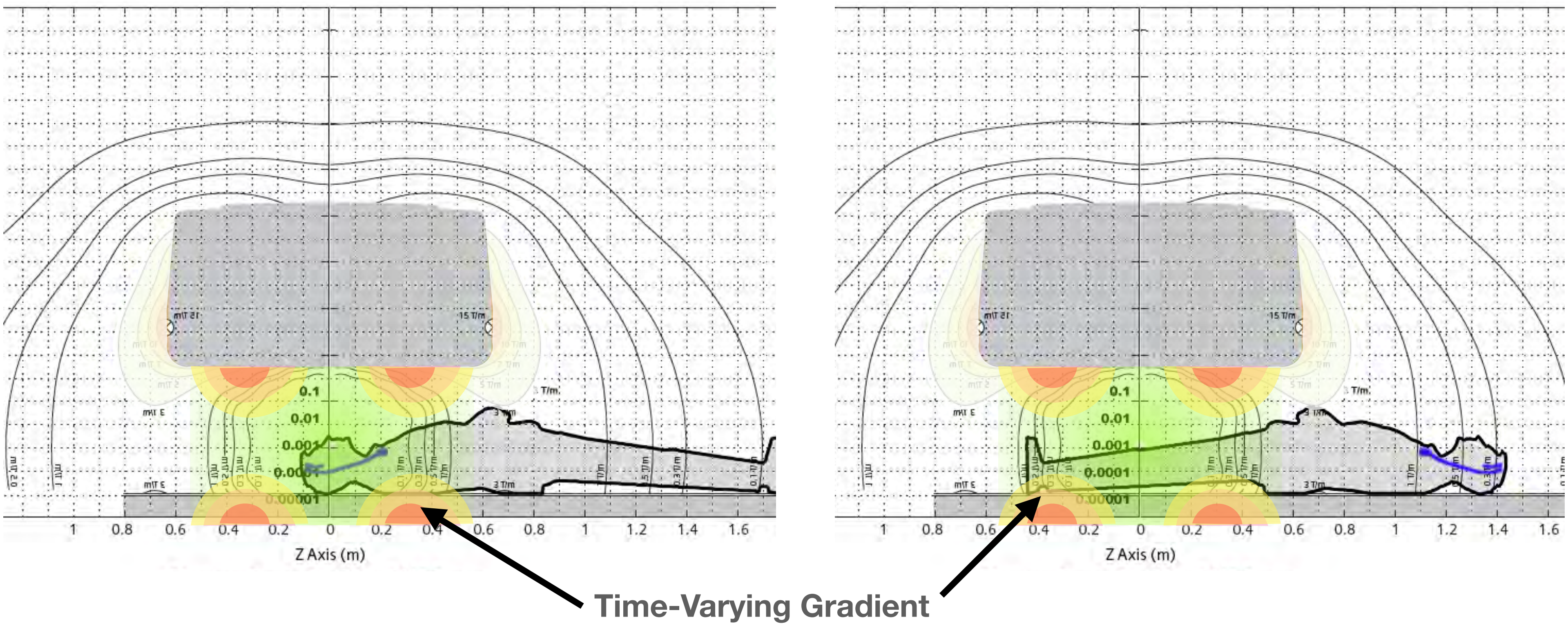
Would You Consider?

Spatial Gradient



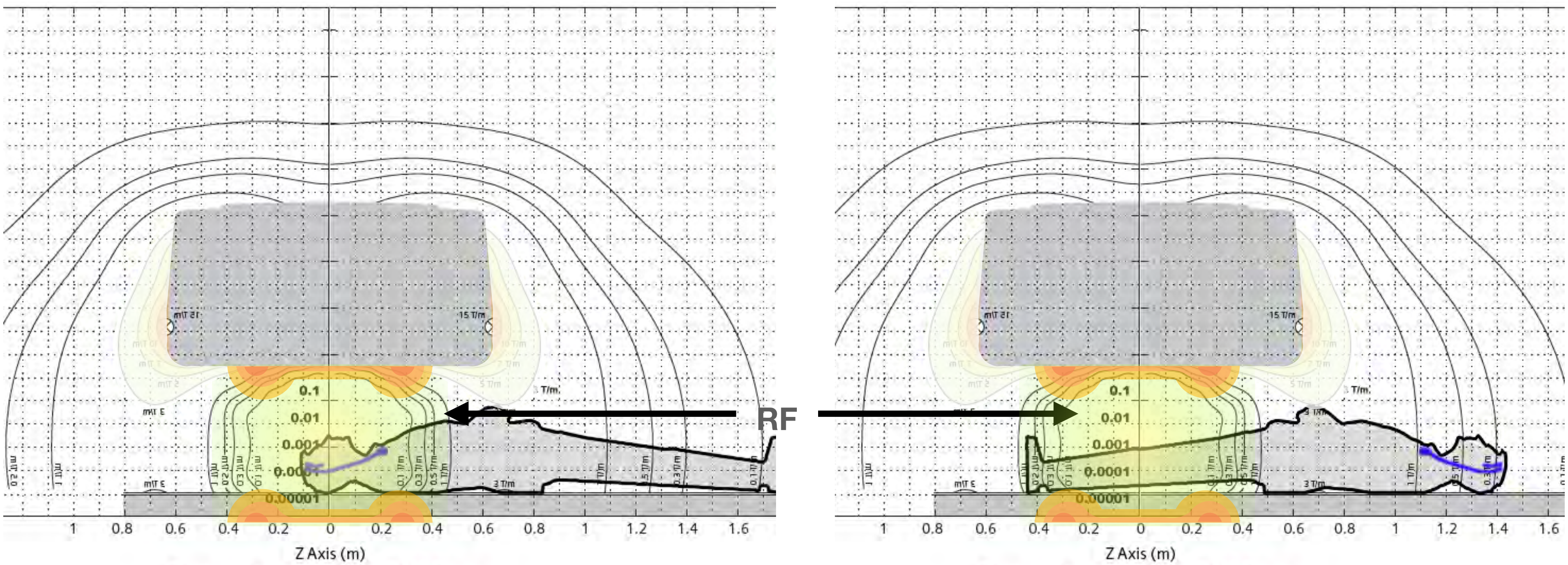
Do You Remember…

Would You Consider?



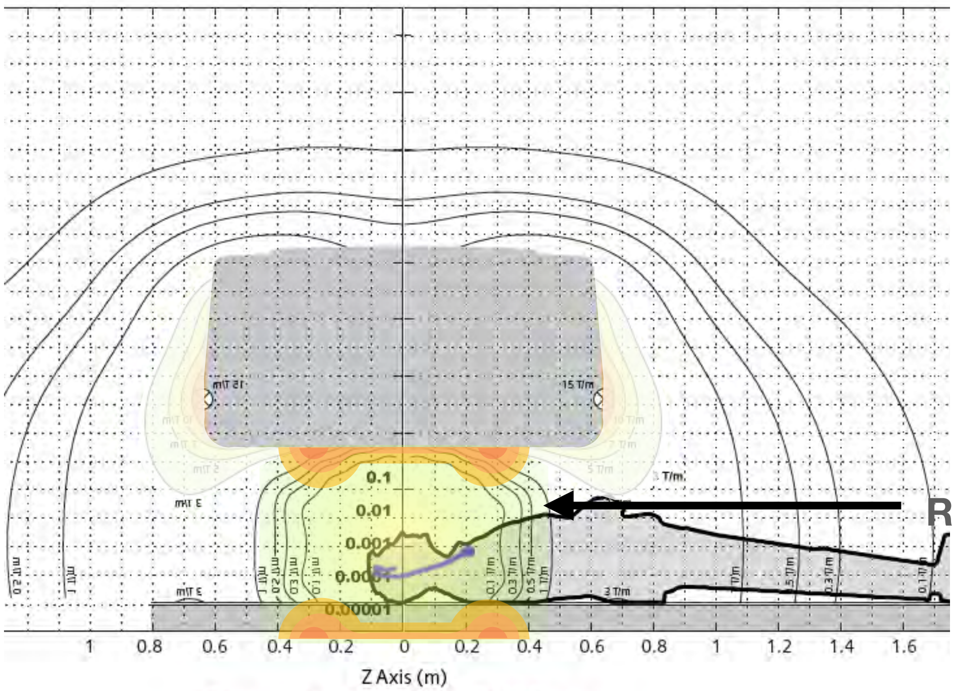
Do You Remember…

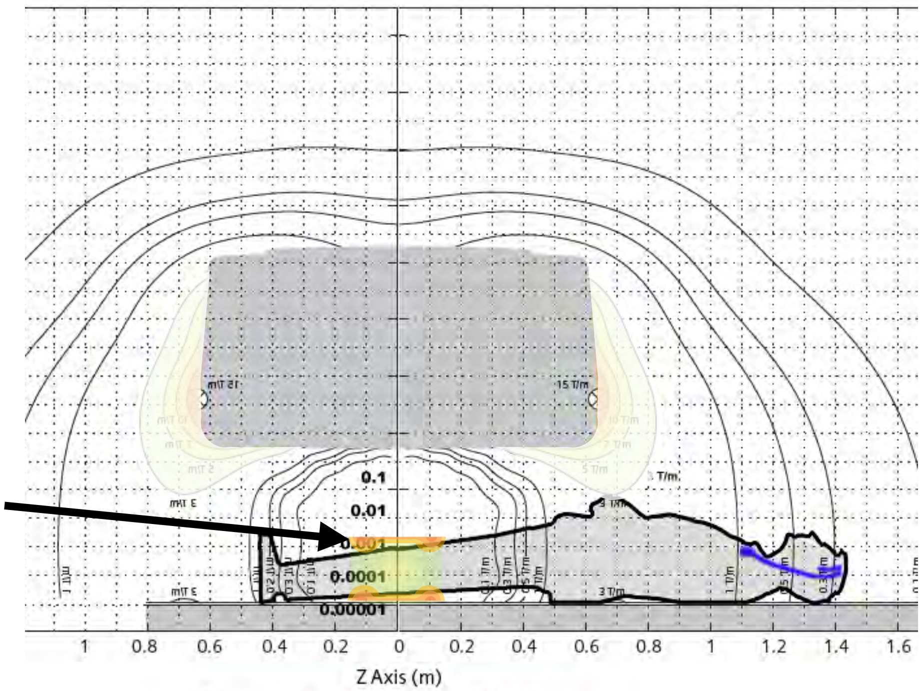
Would You Consider?



Do You Remember…

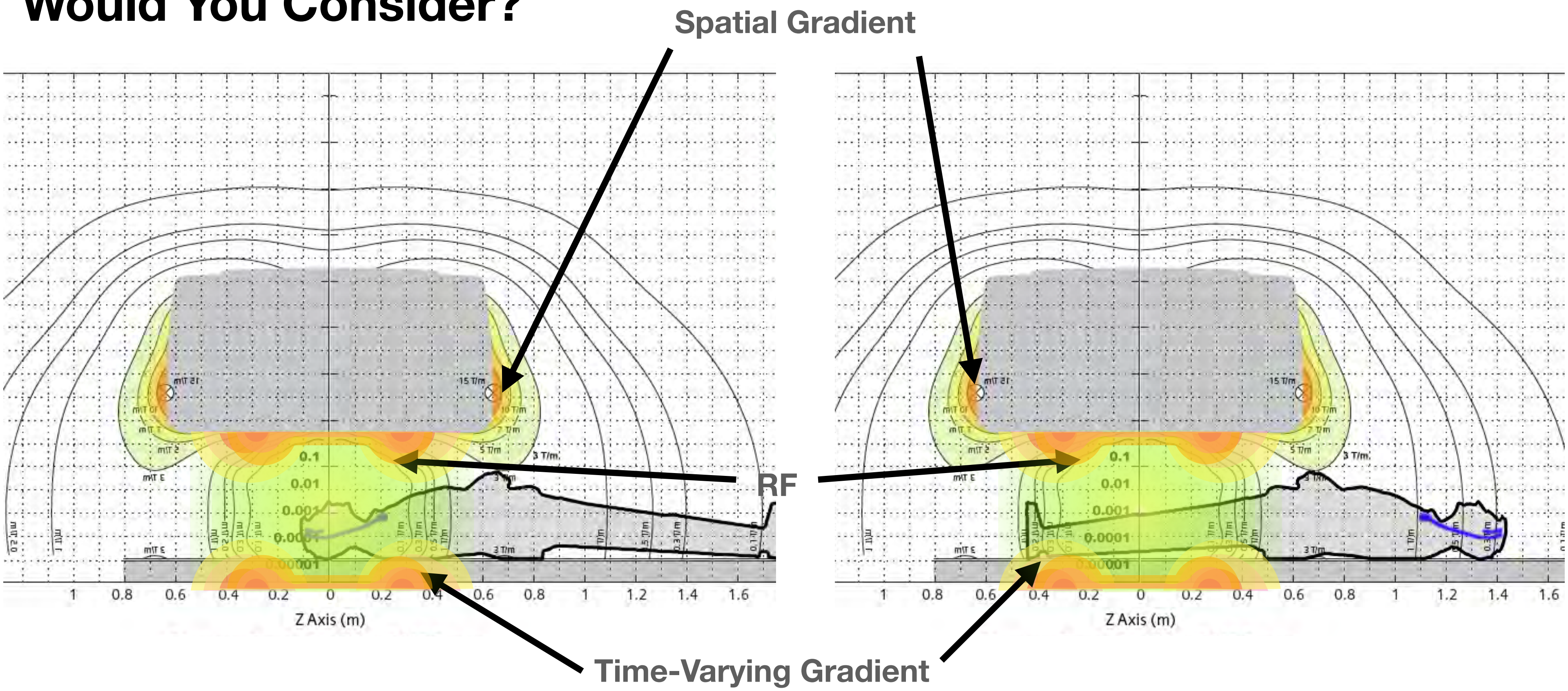
Would You Consider?





Do You Remember…

Would You Consider?

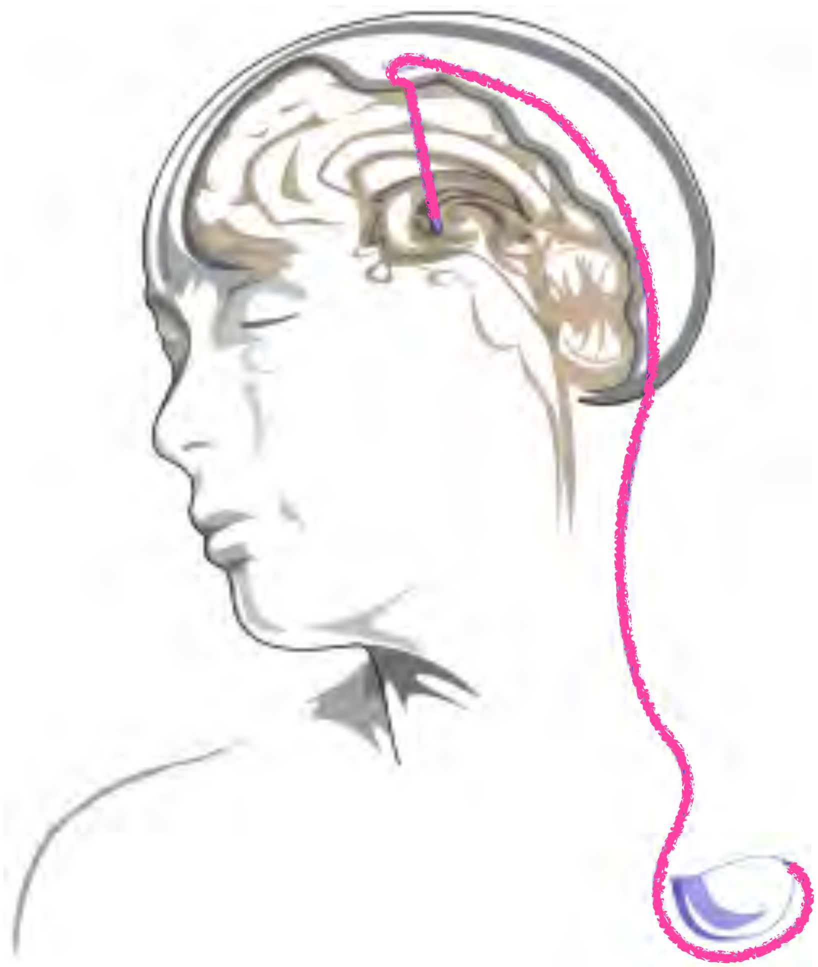


Do You Remember…

Would You Consider?

- DBS Patient (6’ tall, 200 lbs)
  - MR Conditional at 1.5T
  - “T/R Head Coil Only”
  - 0.1 W/kg

- Indicated Study Is Knee



Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

Static Magnetic Fields:

Effects / Volumes / Forces / Harms

Tobias Gilk - September 22, 2023

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

Static Magnetic Fields

- Intro
- Fields / Distributions / Units
- Magnets, Magnetism, & Magnetic Materials
- Physical Forces / Bioeffects
- Q & A

"If you don't know what you're exposing a patient (or device) to, you can't begin to perform an MR risk-assessment."

— Me

Static Magnetic Field

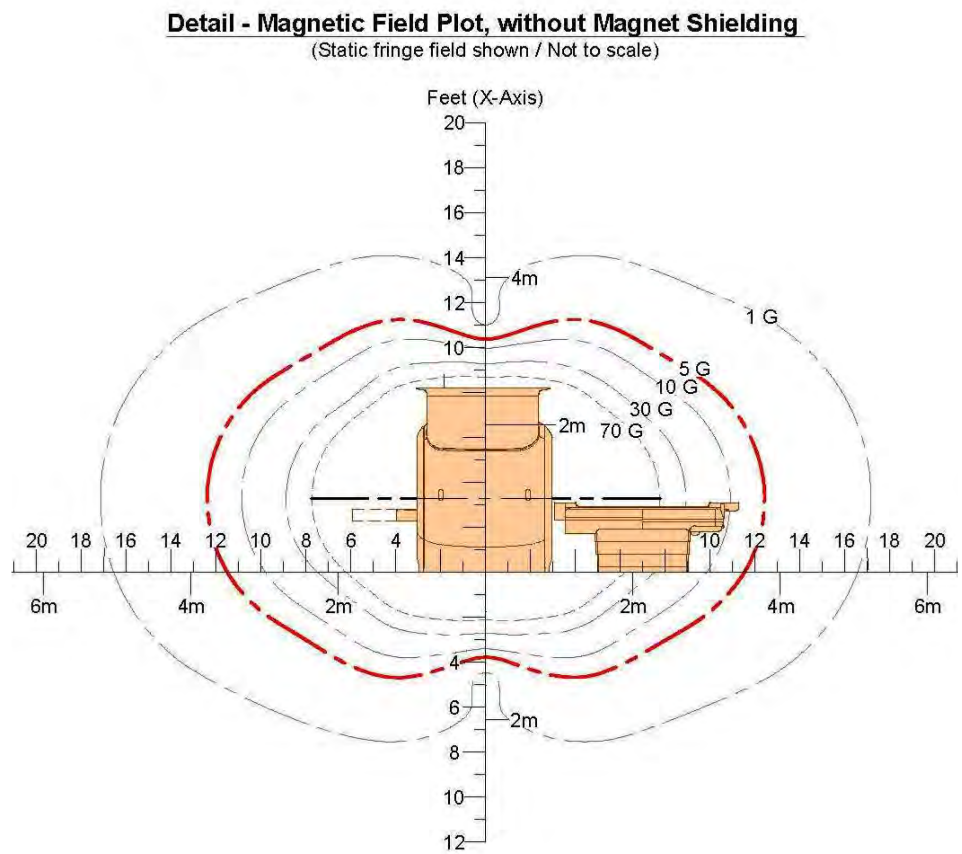
Recap & Advance

- When & Where
- Field Strength (B0) & Spatial Field Gradient (SFG)
- Units & Measures
- Plots & Graphs
- Physical Effects
- Physiologic Effects

Static Magnetic Field

When & Where?

- Always On
- Increases w/ Proximity
  (max usually near mouth of bore)
- Magnetism Not Contained By
  Conventional Construction



Static Magnetic Field

Modes

Normal Mode

- 0T ≦ 4T

First Level Controlled Operating Mode

- 4T ≦ 8T

Second Level Controlled Operating Mode

- > 8T

201.3.208
FIRST LEVEL CONTROLLED OPERATING MODE
mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

Static Magnetic Field

Field Strength & SFG

Field Strength

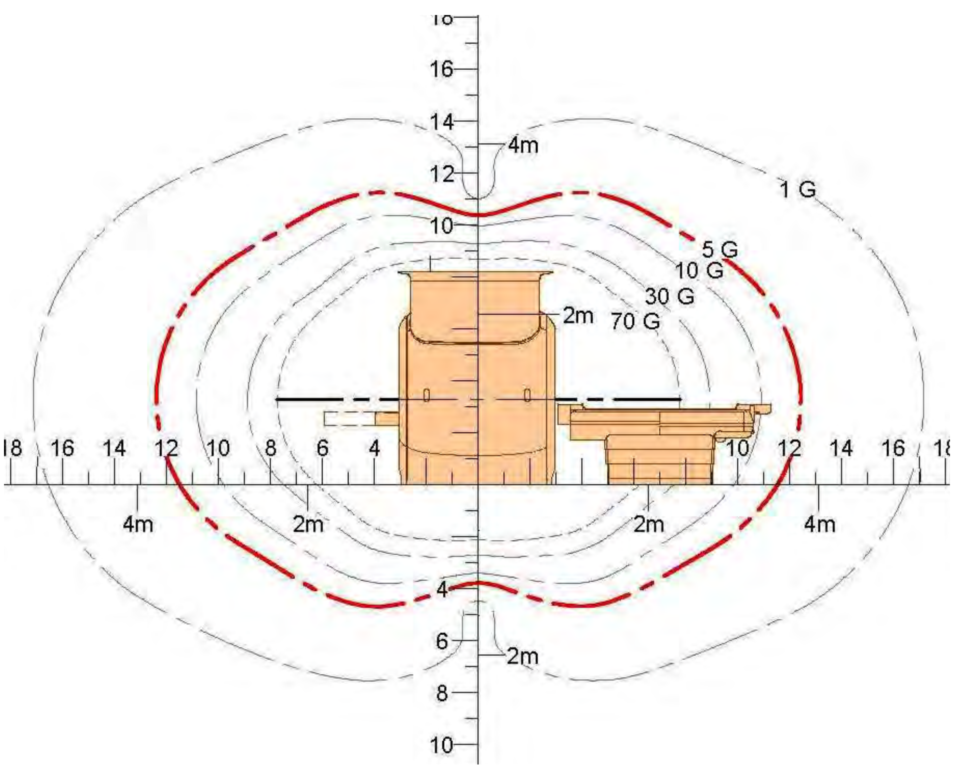
- Single-Factor Measure
- 'Nominal' Field Strength (e.g., "1.5 T" or "3.0 T")
- Fringe Field Strengths (e.g., 5 Gauss, 100 Gauss)

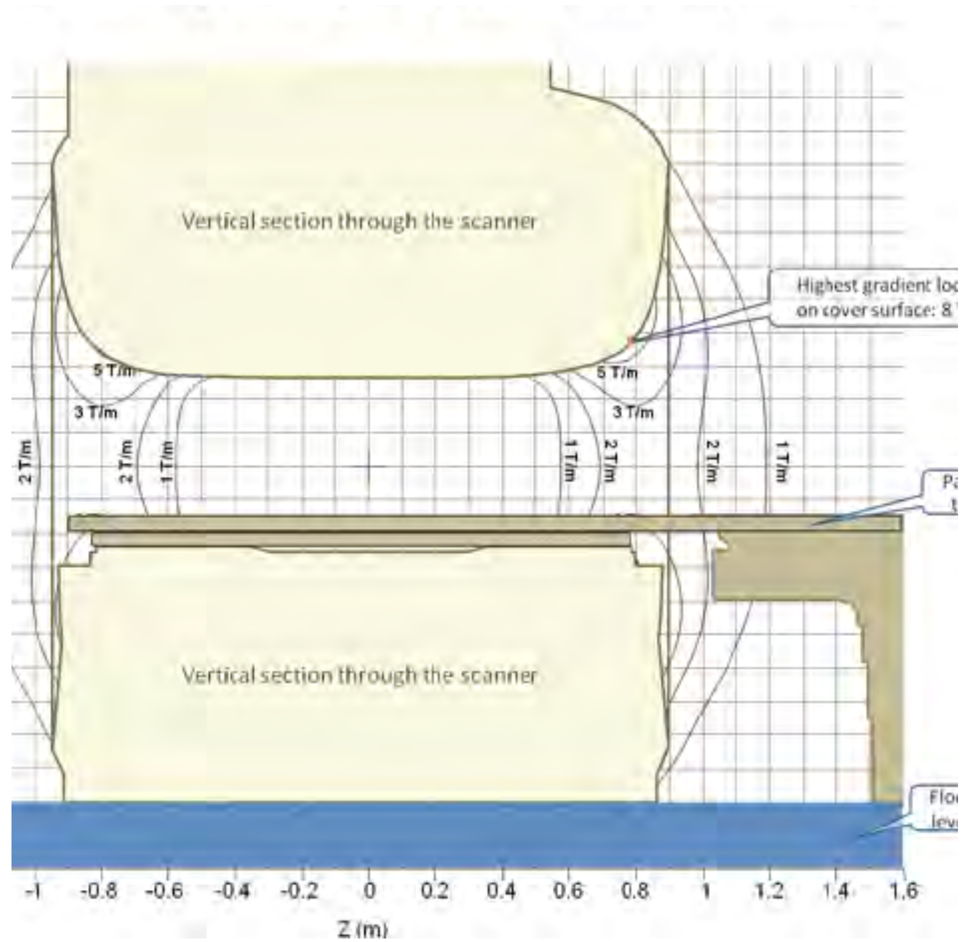
Spatial Field Gradient

- Two-Factor Measure
- Change In Field Strength Over Distance
- "Steepness" Of Magnetic Field
- Depicted in G/cm or T/m

Static Magnetic Field

Plots & Graphs

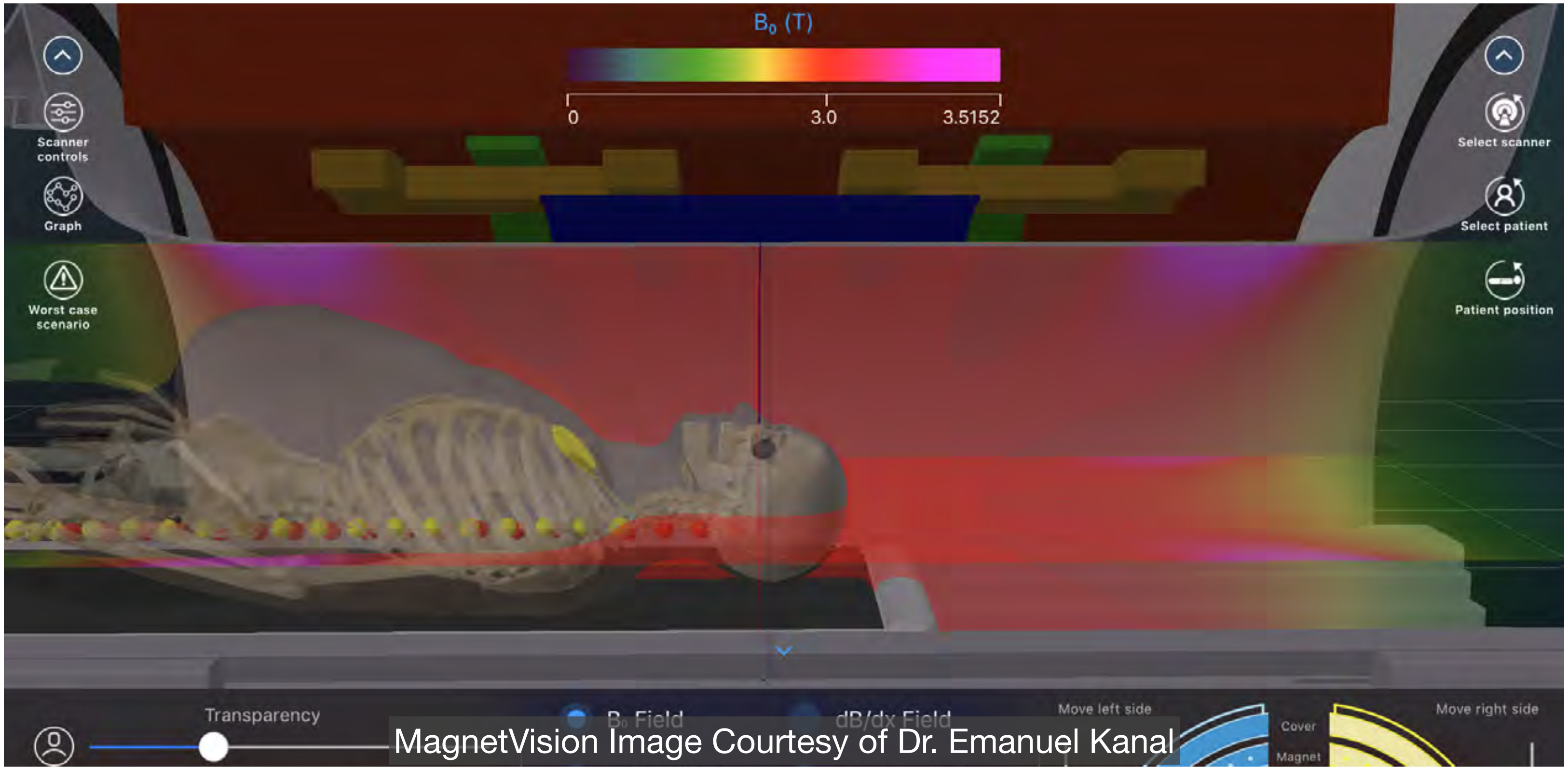




Static Magnetic Field

Plots & Graphs

B0 Magnetic Field Strength

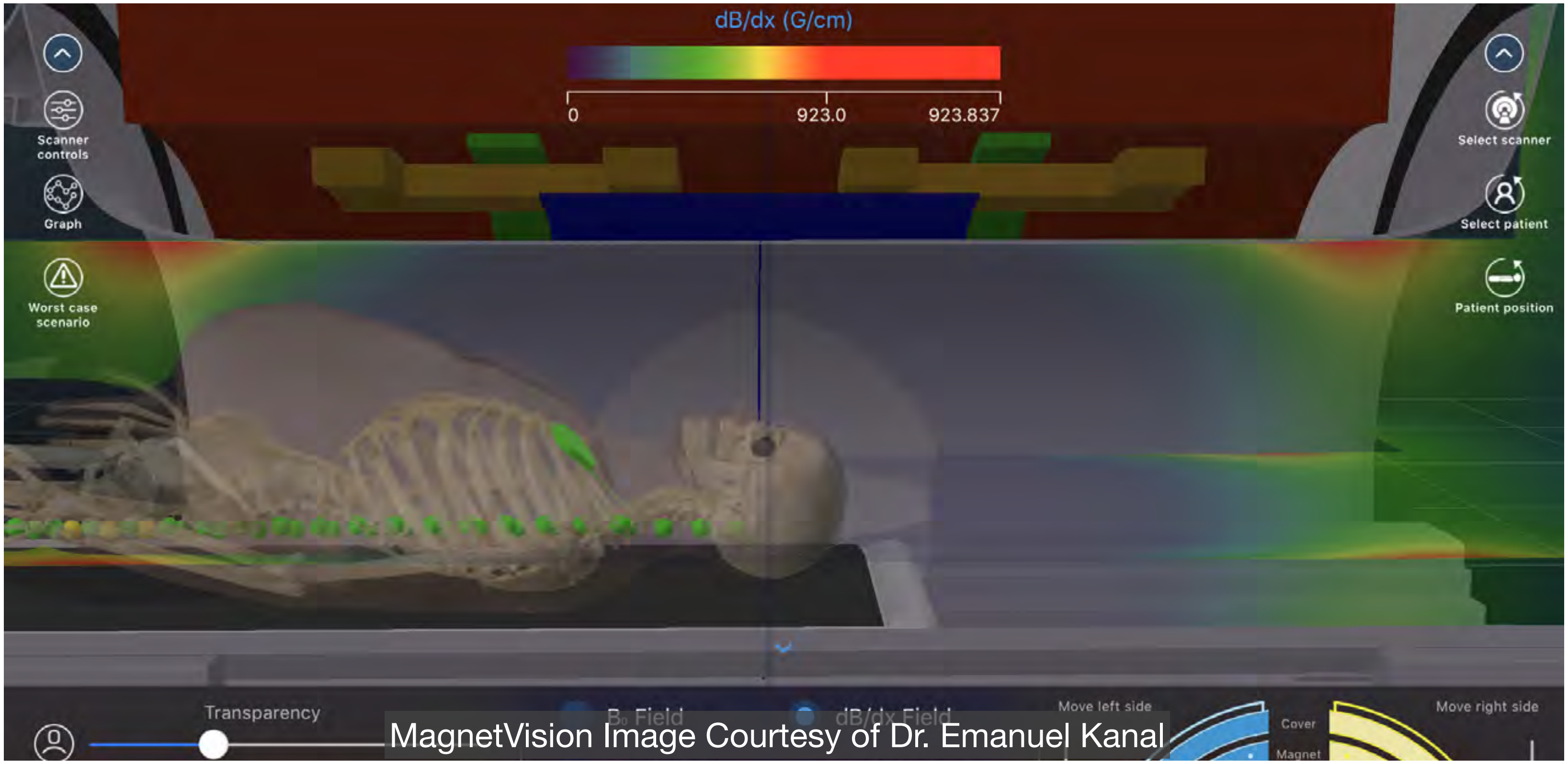


MagnetVision Image Courtesy of Dr. Emanuel Kanal

Static Magnetic Field

Plots & Graphs

Spatial Field Gradient



MagnetVision Image Courtesy of Dr. Emanuel Kanal

Static Magnetic Field

Magnets / Magnetism / Magnetic Materials

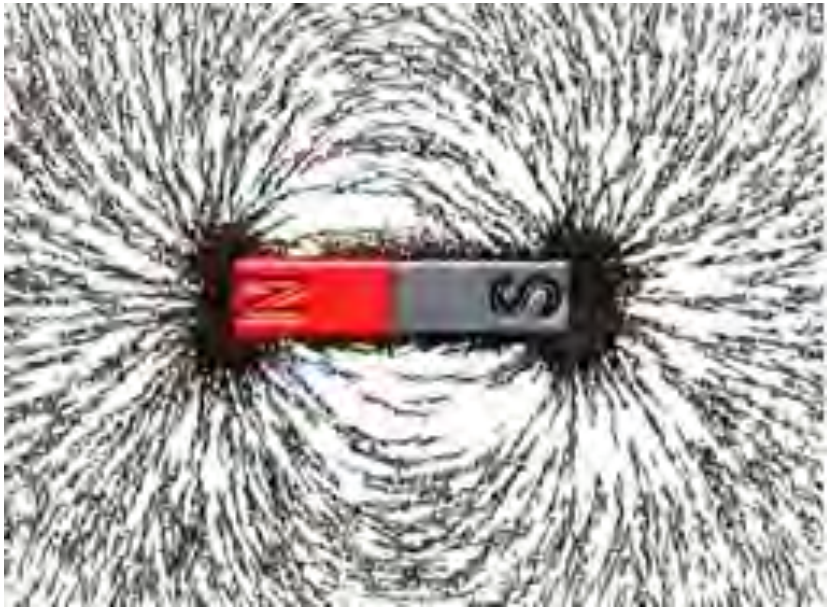
Static Magnetic Field

Magnets & Magnetism

- Poles
- Orbital Path (not ray)
- Flux Density

Static Magnetic Field
Magnetic Poles

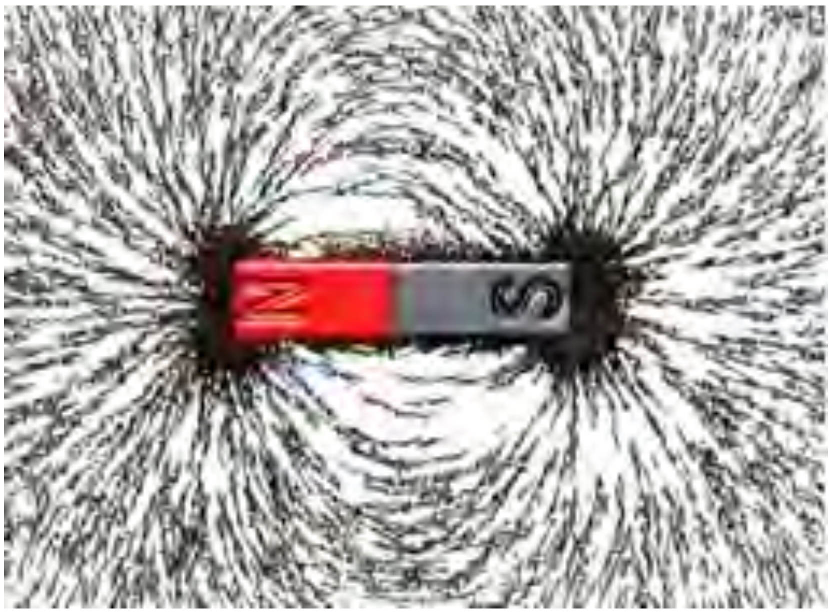
- Magnetic Energy Travels From One Magnetic Pole to The Other



Static Magnetic Field

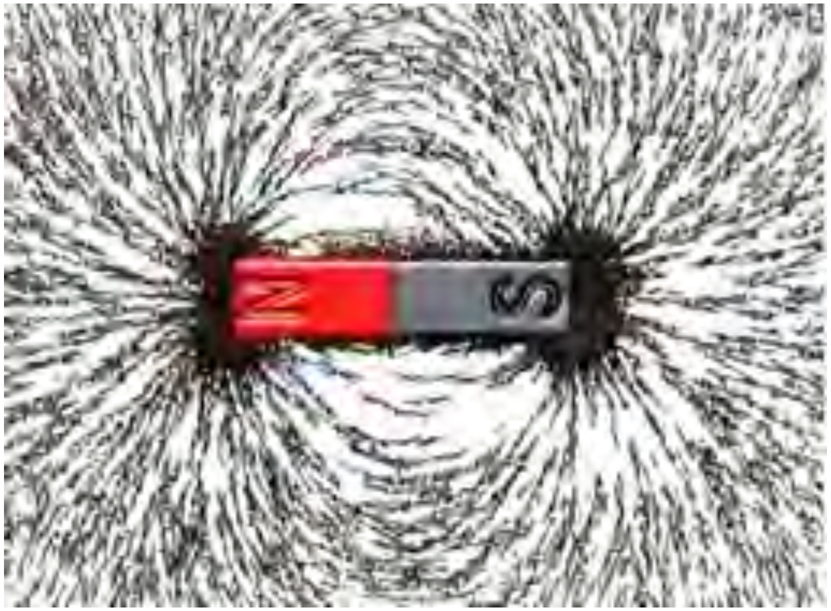
Magnetic Orbital Path

- Magnetism takes an Orbital Path



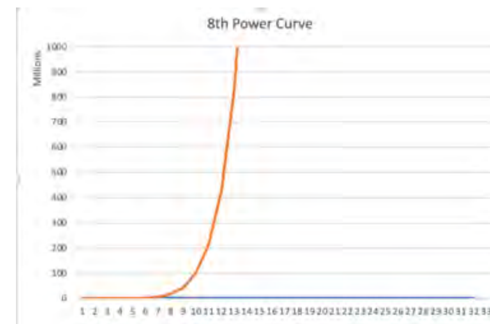
Static Magnetic Field
Magnetic Flux Density

- What We Measure As Field Strength Is The Density of Those Orbits



Static Magnetic Field

Inverse-Square (X^{-2}) Law?



- Simple Magnet (e.g., bar magnet) —> Inverse-Cube (X^{-3})
- Actively-Shielded MRI —> Inverse-Fifth (X^{-5})

- Simple Magnet *Interacting With* Actively-Shielded MRI

$$(X^{-5}) + (X^{-3}) = (X^{-8})$$

If Interaction Field Strength Is 100 Gauss at 1m, What Is It At 0.5m?

$2^8 = 256$ 256 x 100 Gauss = 2.56 Tesla

Static Magnetic Field
Magnetic Materials

- Ferromagnetic / Paramagnetic / Diamagnetic
  - Iron-Filings / Magnetic ‘Domains’
- Stainless Steel
  - Ferritic
  - Austinitic
- Materials Frequently Found in Implants
  - Nitinol, 316L Stainless, Titanium Alloys (CP)

Static Magnetic Field

Physical & Physiological Effects

Static Magnetic Field
Physical Effects

- Torque / Rotation (Function of B0)
- Translation / Attraction (Primarily Function of SFG)
- Lenz Force (Faraday's Law of Induction)

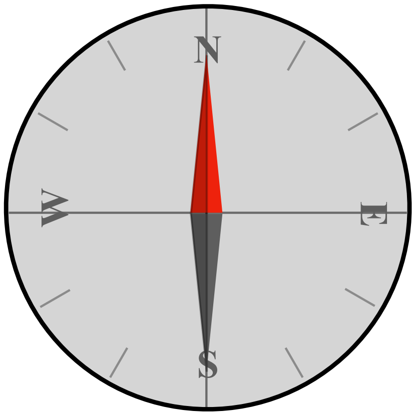
Static Magnetic Field
Torque

- ‘Magnetizability’ of Object
- Length of Object
- Orientation of Object (relative to magnetic field)
    - Vertical Field Magnets

Static Magnetic Field

Torque - Magnetizability

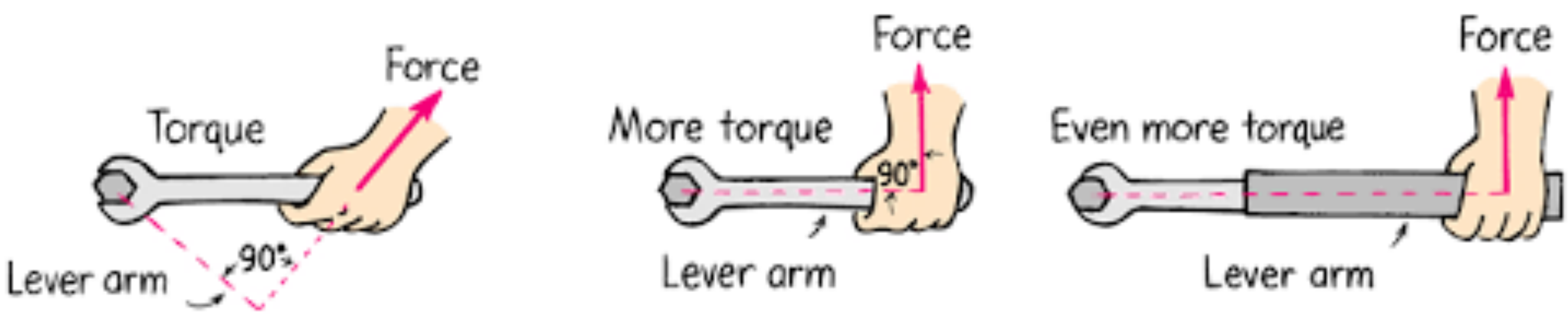
- Anyone Who Has Played With Magnets Know Some Materials Are Magnetizable, Some Are Not.
- Torque Requires Magnetizable Materials
  - Such As: Iron, Nickel, Cobalt (and many of their alloys)
  - Not: Copper, Brass, Aluminum, Titanium



Static Magnetic Field

Torque - Length

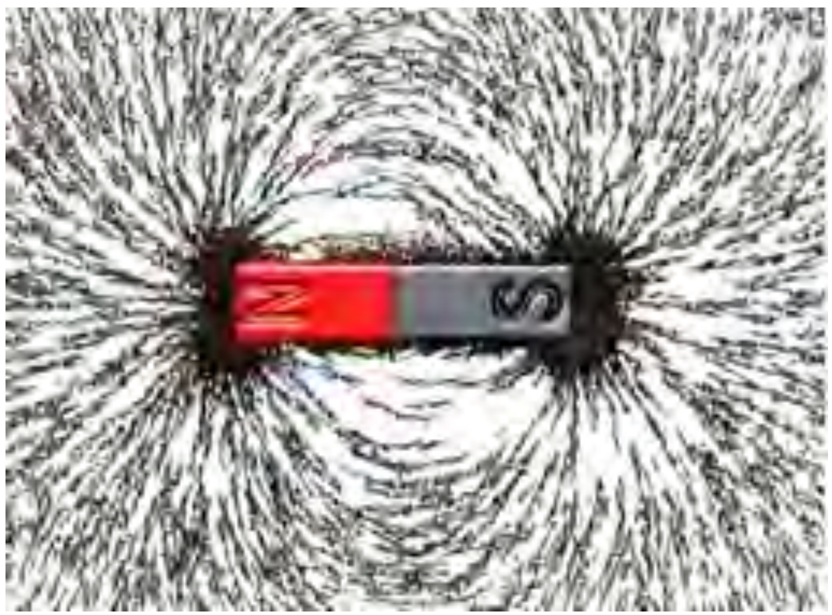
- The Longer (Less Sphere-Like) An Object Is, The More Torque It Can Produce

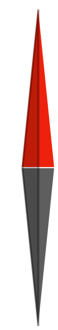


Static Magnetic Field

Torque - Orientation to Mag Field

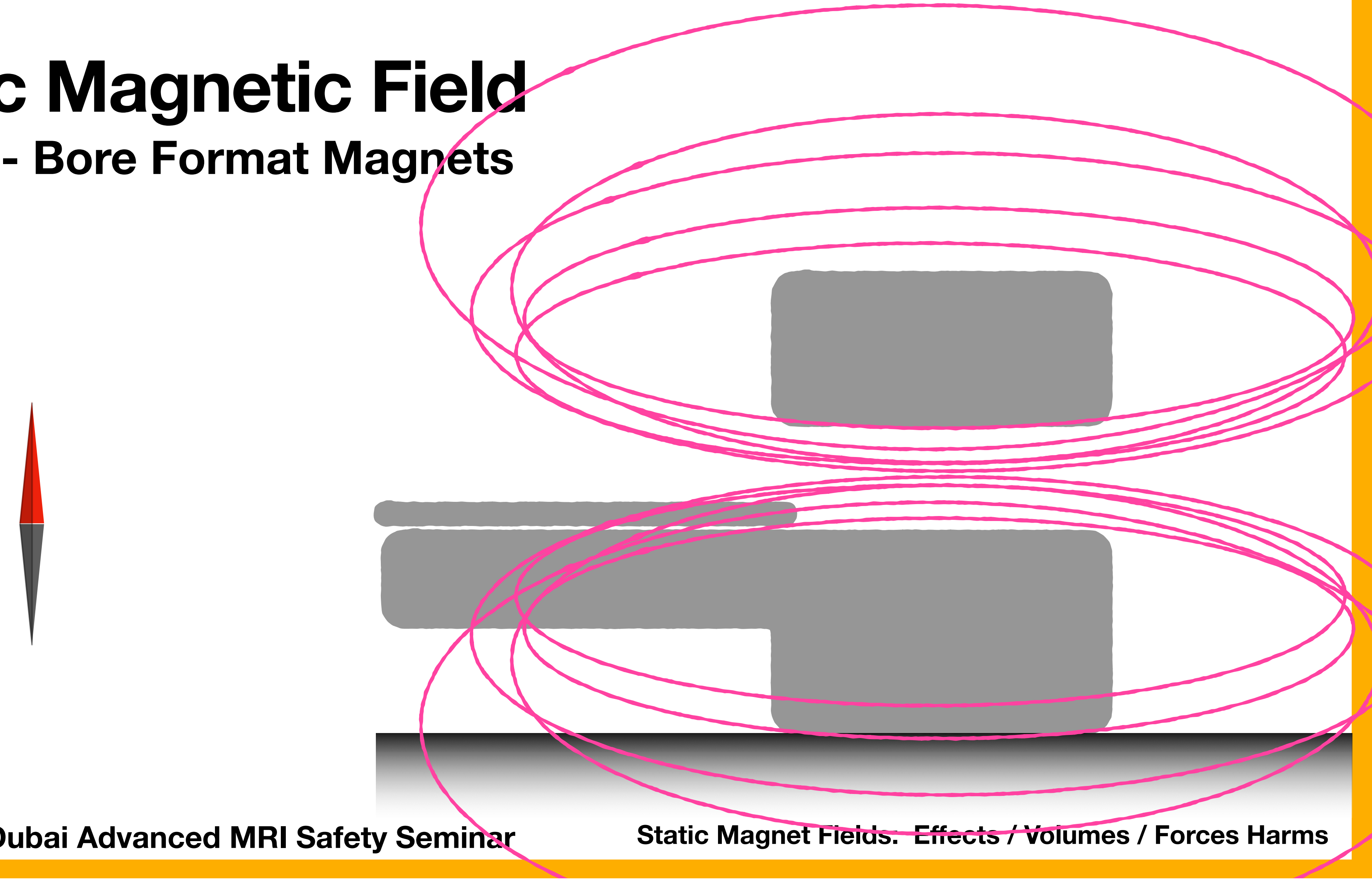
- The Iron Filings In This Photo Show Us The Lines of Force





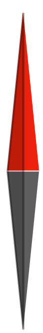
Static Magnetic Field

Torque - Bore Format Magnets



Static Magnetic Field

Torque - Vertical Field Magnets



Static Magnetic Field

Torque - Can You Multiply By Zero?

How Magnetic?	X	How Elongated?	X	Field Exposed?

Static Magnetic Field

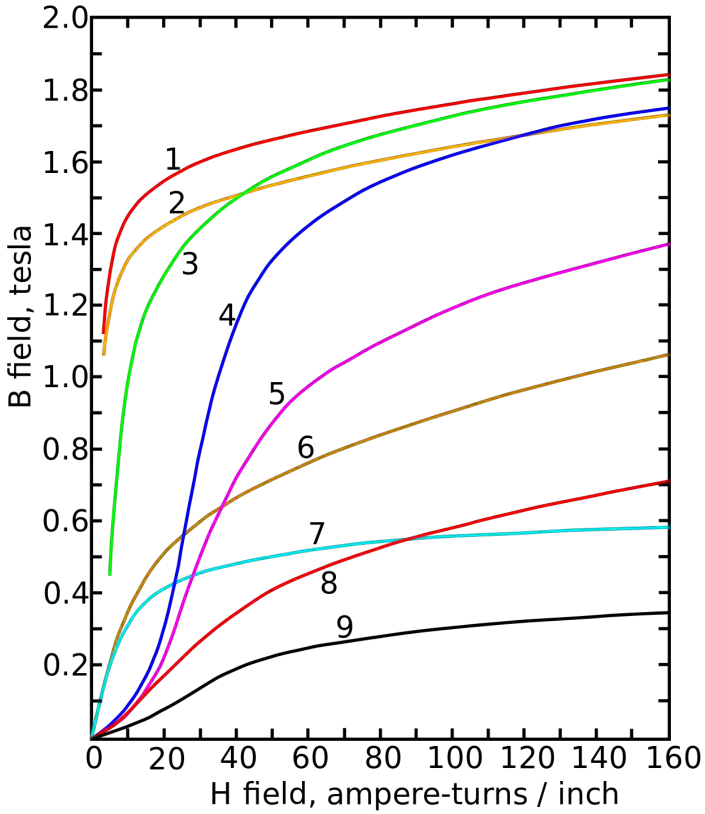
Translation

- ‘Magnetizability’ of Object
- Length of Object
- Experienced Spatial Field Gradient (SFG)
- Orientation of Object (relative to magnetic field)
- Vertical Field Magnets

Static Magnetic Field

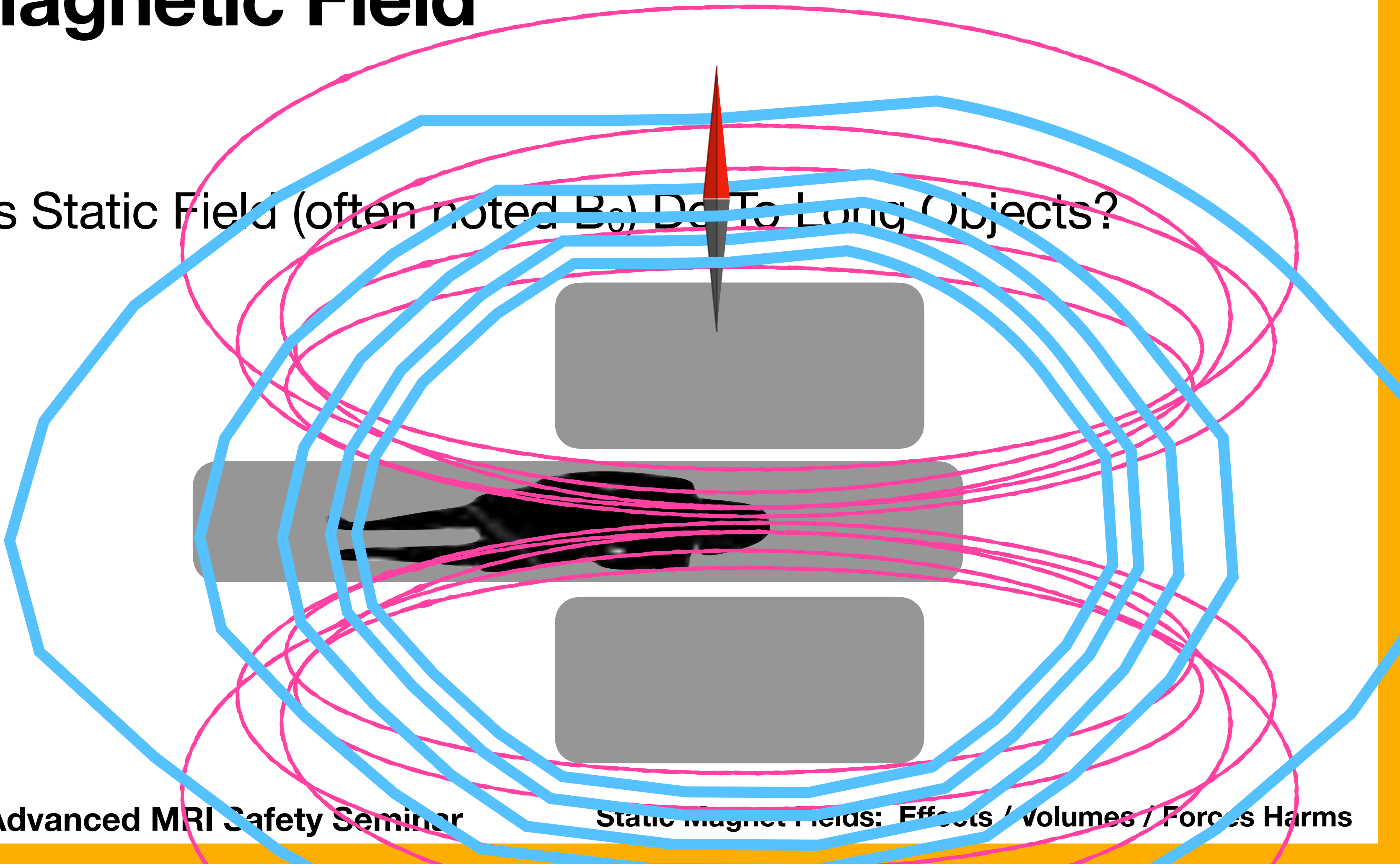
Translation - Magnetizability

- Magnetic Saturation
- For Many Steel Materials, Saturation Achieved Very Quickly
- Once Saturation Achieved, Spatial Field Gradient (SFG) Main Driver of Translation.

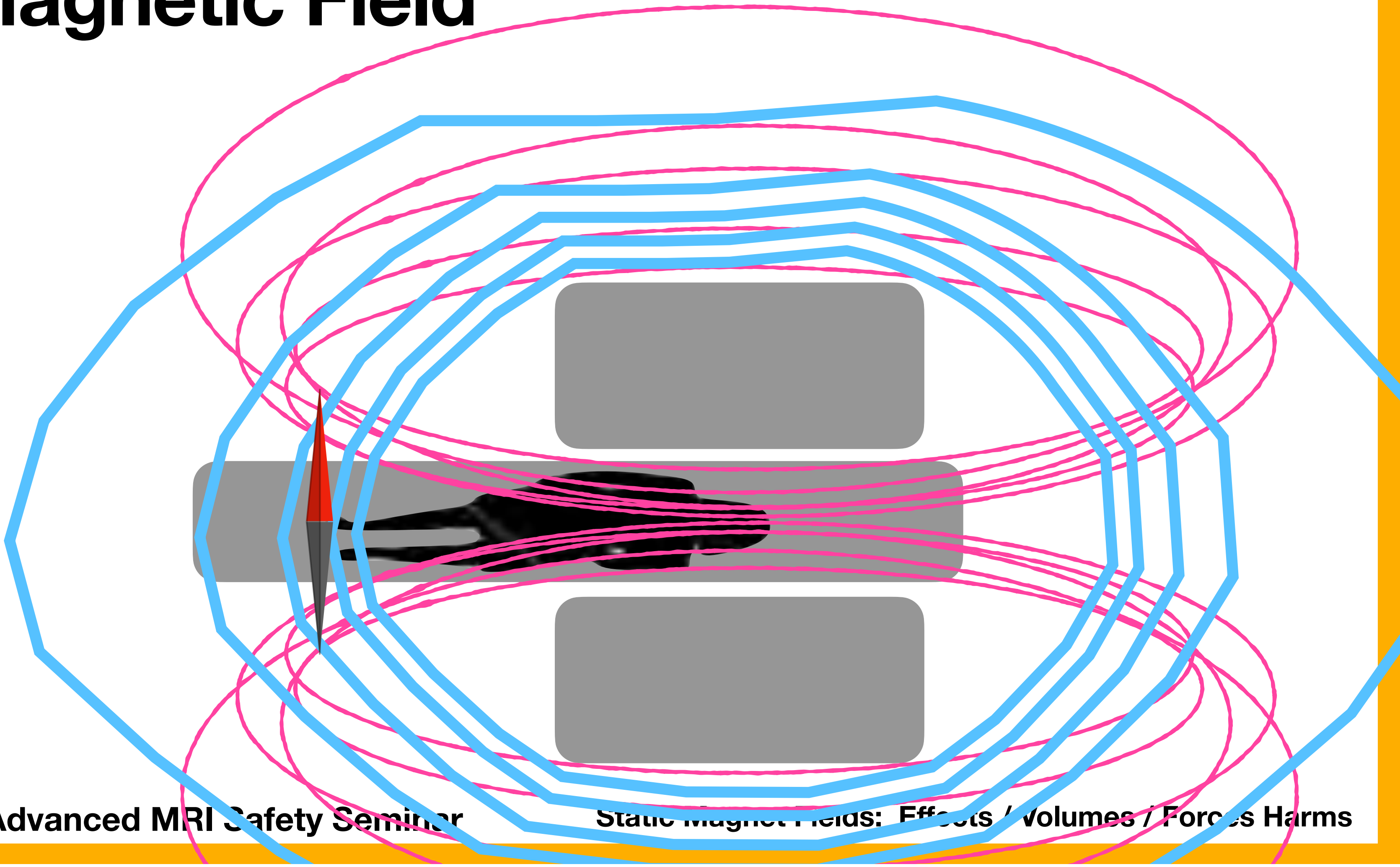


Static Magnetic Field

- What Does Static Field (often noted B_0) Do To Long Objects?



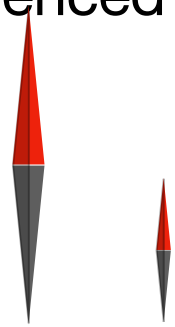
Static Magnetic Field

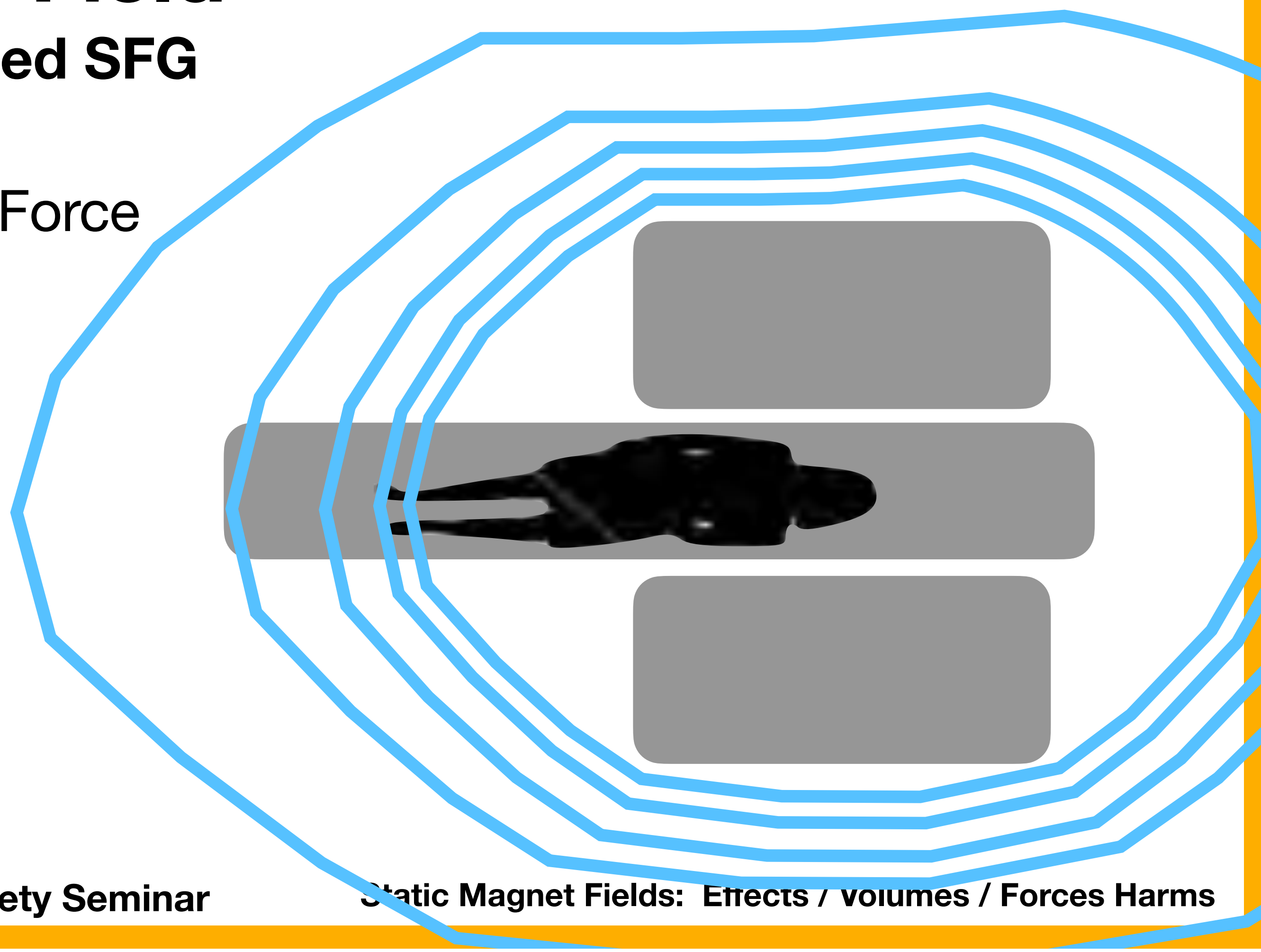


Static Magnetic Field

Translation - Experienced SFG

- Translation (Attractive) Force Primarily Driven By Experienced SFG

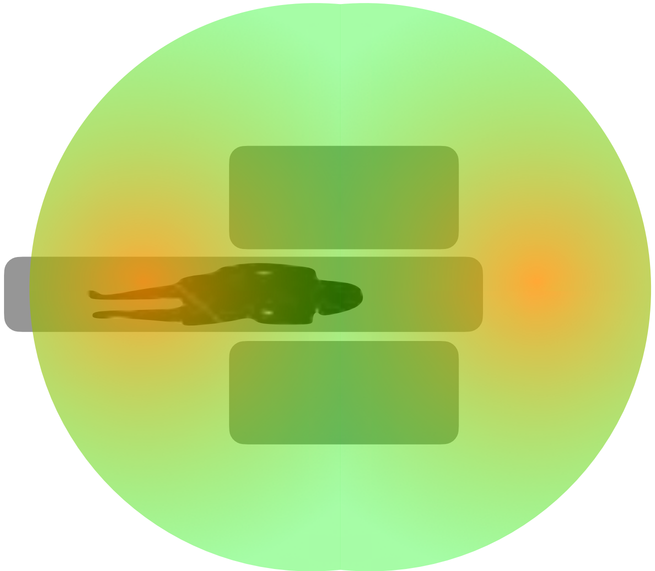




Static Magnetic Field

Translation - Orientation (Bore Format Magnets)

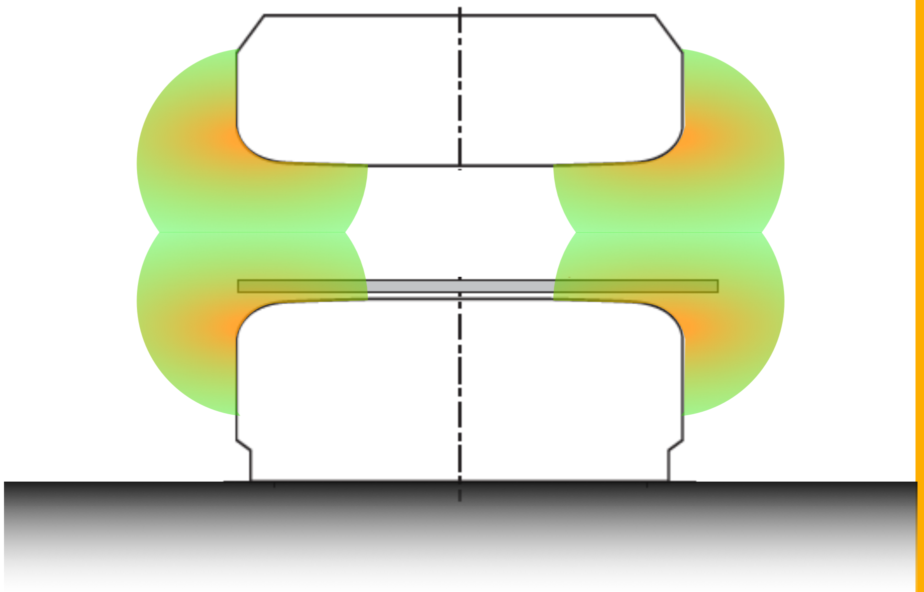
- The More Gauss Lines An Object Crosses, The More Powerful The Attractive Force
- Torque Works To Create Maximum Translational Force Near Mouths Of Magnet
- Torque Works To Create Less Translational Force Along Sides Of Magnet



Static Magnetic Field

Translation - Vertical Field Magnets

- Vertical Field (HFO) Magnets' Attractive Forces Increase More Quickly Near Perimeter Of Magnets (Top & Bottom)



Static Magnetic Field

Translation - Can You Multiply By Zero?

How Magnetic?	X	Mass of Object?	X	Length of Object?	X	SFG Experienced?

Static Magnetic Field

Lenz

- Electrical Conductivity of Object
- Size of Object
- Rate of Motion
- Spatial Field Gradient

Static Magnetic Field

Lenz - Example

https://twitter.com/gunsnrosesgirl3/status/1542481509092933632

Static Magnetic Field

Lenz - Faraday's Law

- An Electrical Conductor Experiencing a Changing Magnetic Field Will Generate an Electric Voltage

- A Changing Electrical Current Will Generate a Magnetic Field

Static Magnetic Field

Lenz - Electrical Conductivity

- Unlike Torque & Translation, Lenz's Forces Don't Need Magnetizable Materials.
- Electrical Conductivity Is The Key Ingredient
- Electrically Conductive Materials Include Titanium, Stainless Steel, Gold
- The Better Electrical Conductor, The ⤴️ Potential Lenz's Forces

Static Magnetic Field

Lenz - Size of Object

- To ⤴️ Lenz's Forces, Make The Object Bigger
- To ⤵️ Lenz's Forces, Make The Object Smaller

Static Magnetic Field

Lenz - Rate of Motion

- To ⤴️ Lenz's Forces, Move The Object Faster
- To ⤵️ Lenz's Forces, Move The Object Slower

Static Magnetic Field

Lenz - Spatial Field Gradient

- To ⤴️ Lenz's Forces, Move The Object Through Greater SFG
- To ⤵️ Lenz's Forces, Move The Object Through Smaller SFG

Static Magnetic Field

Lenz Force - Can You Multiply By Zero?

Electrical Conductivity? **X** Size of Object? **X** Rate of Motion? **X** SFG Experienced?

Static Magnetic Field

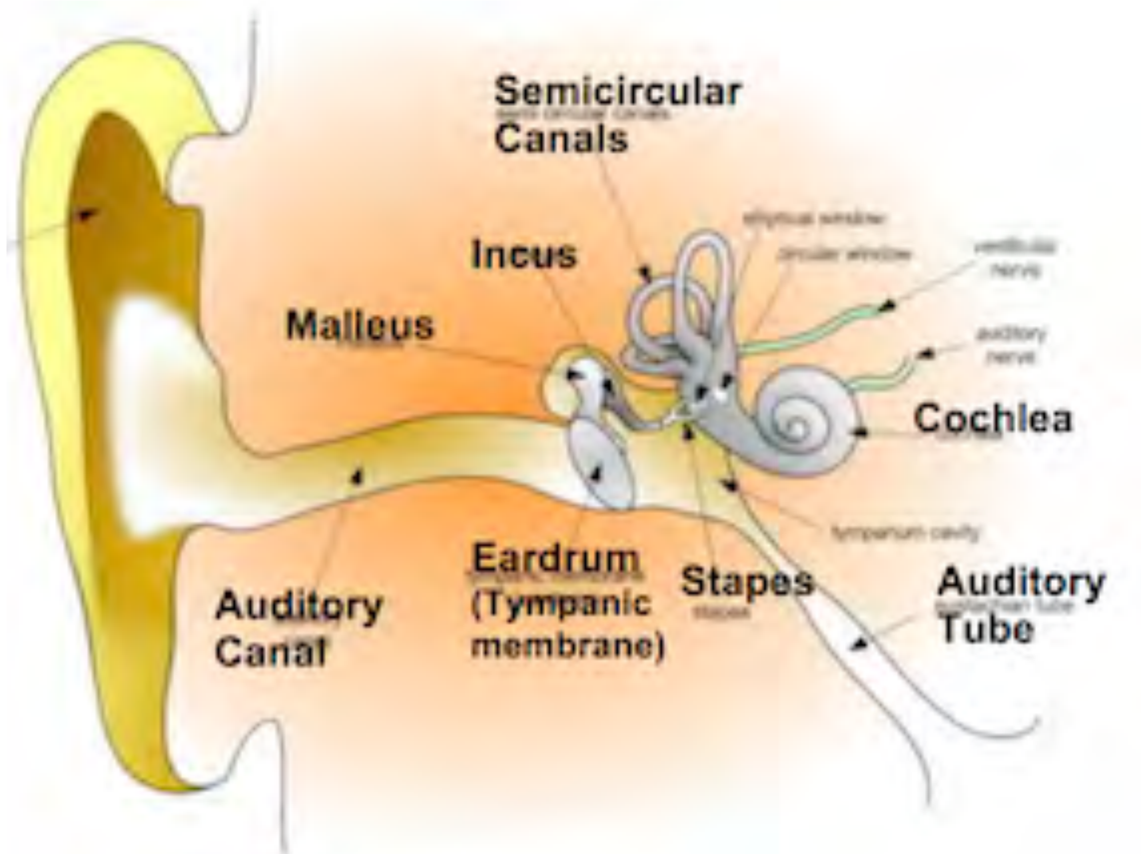
Physiological Effects

- Inner-Ear Effects (vertigo, nystagmus)
- Flow Potential (ECG interference, S-T segment elevation)
- Magneto Hydrodynamic Effect (MHD)

Static Magnetic Field

Inner-Ear Effects

- Ionic Fluid In Cochlea



Static Magnetic Field

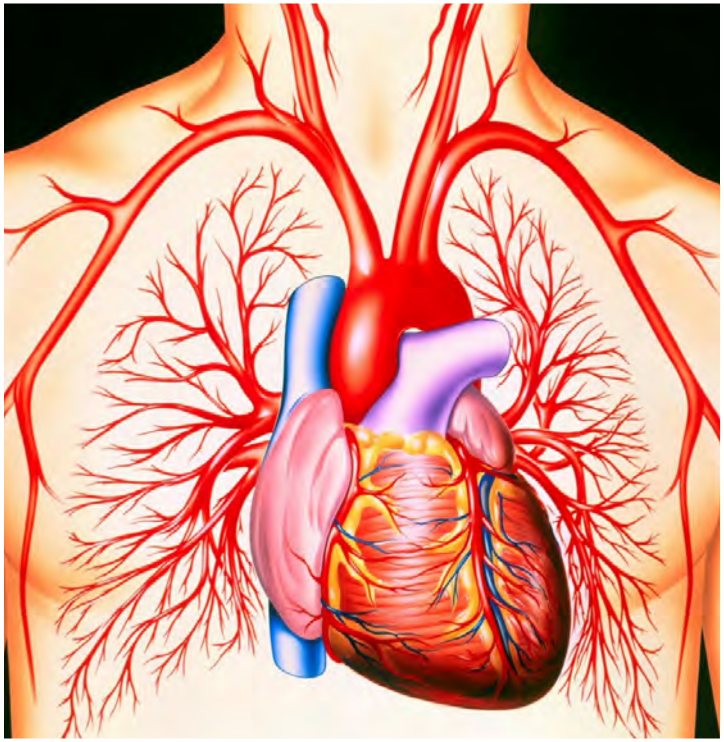
Flow Potential (ECG Disruption)

- Bloody Faraday's Law
- Blood Is Charged (Electrically Conductive)
- Conductor Moving Through Magnetic Field?
- EKG is a Volt Meter
- Electrical Systole
- Elevated S-T Segment

Static Magnetic Field

Magneto Hydrodynamic Effect

- Bloody Lenz's Force
- Blood Is Charged (Electrically Conductive)
- Conductor Moving Through Magnetic Field?
- What Does A Changing Electrical Current Generate?
- 3mm - 5mm Of Additional Mercury Column



Static Magnetic Field

Ferromagnetic Detection

Static Magnetic Field

Ferromagnetic Detection

Static Magnetic Field

Ferromagnetic Detection

- Slightly Misnamed Technology —> Actually Magnetic Field Detectors
- Detect Changing Magnetic Fields Around Them
  - Fields Originating From Magnetizable Objects

Static Magnetic Field

Ferromagnetic Detection

- Sensitivity Region
  - Exclude Sources of Interference (You, Step Back)
  - Include Subject Being Screened (Get Them Close)
- Potentials For Environmental Triggers

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

Time-Varying Gradients:

Effects / Volumes / Forces / Harms

Tobias Gilk - September 22, 2023

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

“If you don’t know what you’re exposing a patient (or device) to, you can’t begin to perform an MR risk-assessment.”

— Me

Time-Varying Gradients

Recap & Advance

- When & Where
- Units & Measures
- Plots & Graphs
- Physical Effects
- Physiologic Effects

Time-Varying Gradients

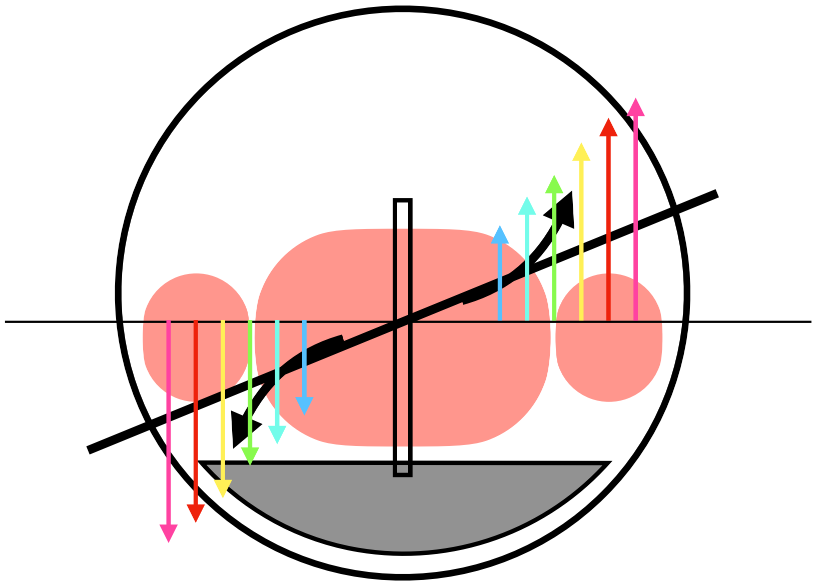
What Are They?

- Rapidly fluctuating magnetic field
- Changing 1,000s or 10s of 1,000s of times per second (in the human auditory range)

Time-Varying Gradients

Why?

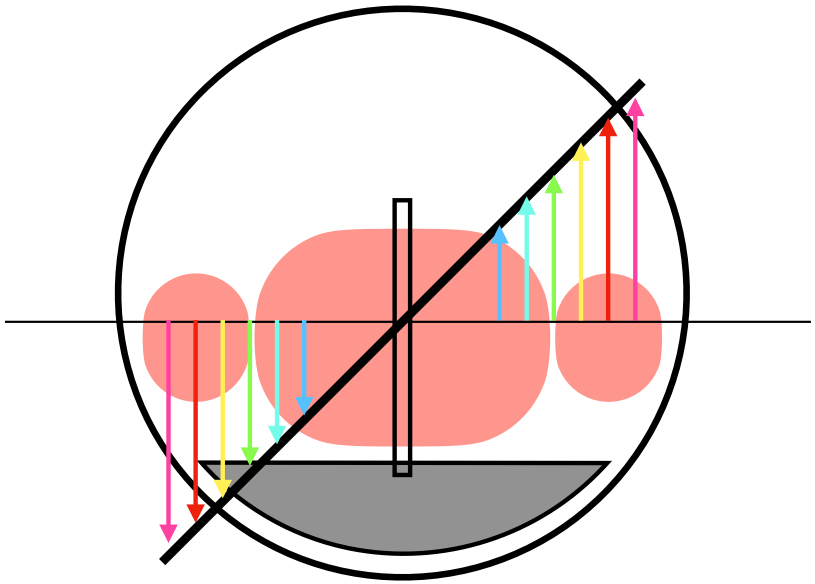
- Because we only want data (signal) from one region (slice) at a time.
- Larmor Frequency



Time-Varying Gradients

When & Where?

- Only during active imaging
- Only in the bore
- But not uniform throughout the bore



Time-Varying Gradients

Modes

Normal Mode

- 80% of Mean Perception Threshold

First Level Controlled Operating Mode*

- 100% of Mean Perception Threshold

Second Level Controlled Operating Mode

- Up To & Including Pain

201.3.208

FIRST LEVEL CONTROLLED OPERATING MODE

mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

Time-Varying Gradients

Amplitude - Slope - Slew

Amplitude

- Single Factor (often mT)
- Max change to field

Slope

- Two-Factor (T/m)
- Change to Field *as a function of distance*
- Steeper Slope = Thinner Slices

Slew

- Three-Factor (T/m/s)
- Captures All 3 Dynamic Elements of TVG

Time-Varying Gradients

Rise-Time & Rate of Change

Also…

Rise-Time

- Single-Factor (ms)
- Speed of Acquisition

Rate

- Two-Factor (T/s)
- Uses Max Values For Amplitude & Rise-Time

Time-Varying Gradients

Plots & Graphs

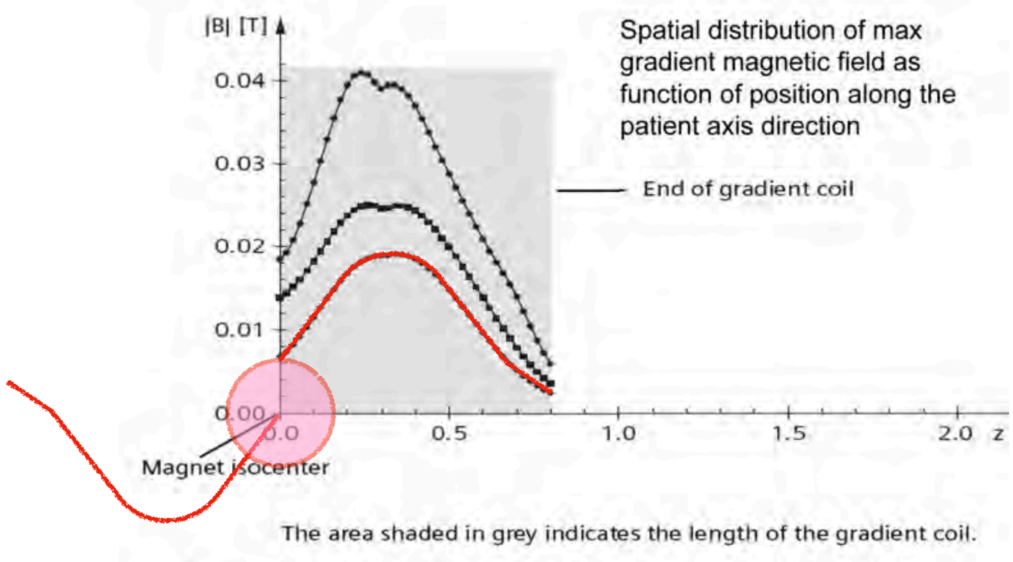
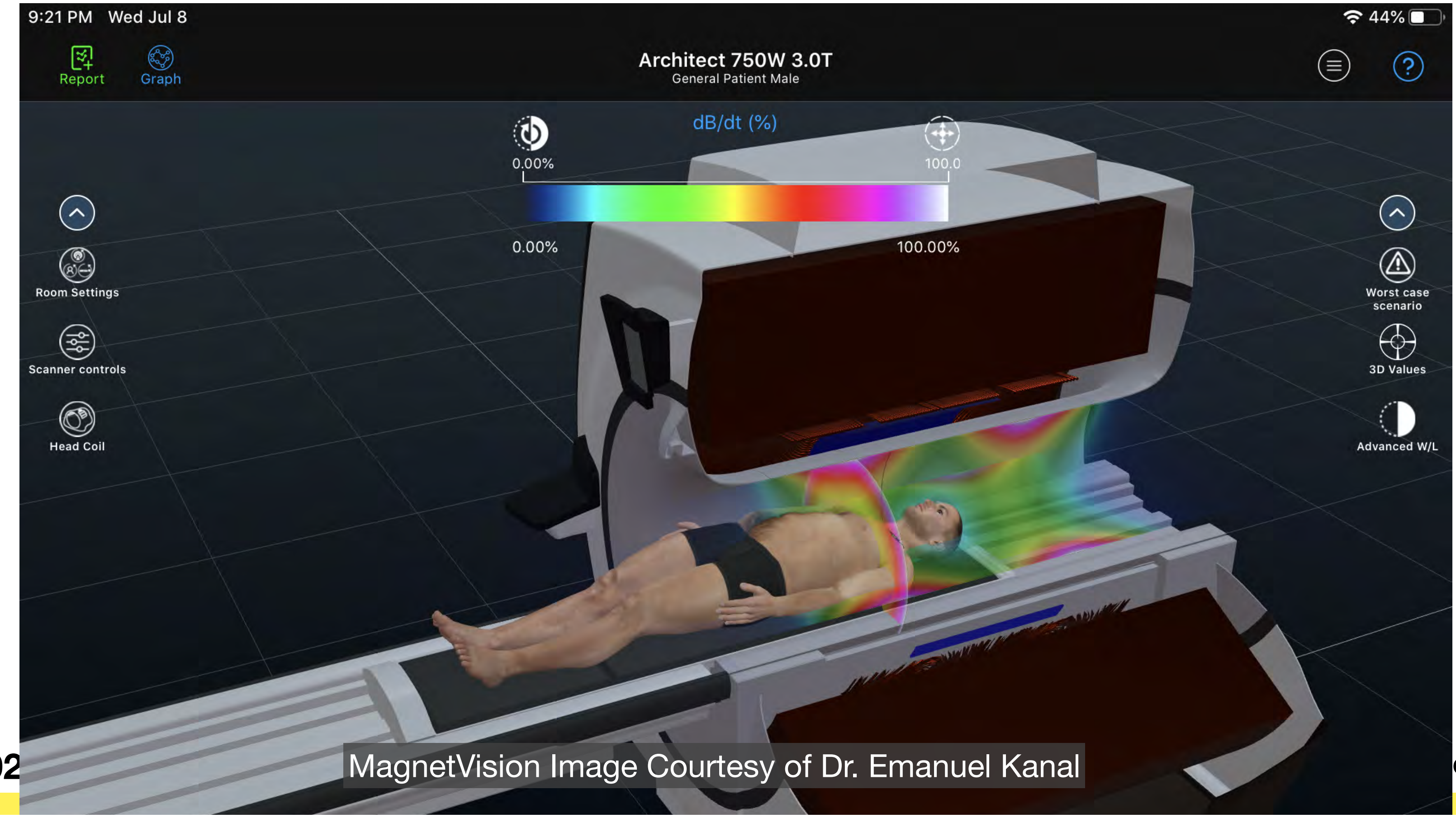


Figure 1: Max gradient magnetic field plots

Time-Varying Gradients

Plots & Graphs



Time-Varying Gradients

Faraday's Law of Induction

Time-Varying Gradients

Faraday's Law of Induction

An electrical conductor exposed to a changing magnetic field will experience an induced electrical voltage.

Time-Varying Gradients

Physical & Physiological Effects

Time-Varying Gradients

Physical Effects

- High-Frequency Vibration
- Induced Voltages

Time-Varying Gradients

High-Frequency Vibration

Time-Varying Gradients

High-Frequency Vibration

- Remember Lenz Effect From Static Field Lecture?
  - Needs *Electrically Conductive Material*
  - Doesn't Have To Be (Ferro)Magnetic

- High-Frequency Vibration Is 'Machine-Gun' Version Of Lenz

Time-Varying Gradients

High-Frequency Vibration

- What Makes TVG-Induced Vibration Stronger?
  - Region of Stronger Gradients
  - Better Electrical Conductor
  - Larger Object

- What Makes Perception Stronger?
  - More Sensitive Nervous Tissues

Time-Varying Gradients

Induced Voltages

Time-Varying Gradients

Induced Voltages

- At TVG Amplitudes & Frequencies, Induced Voltages Are Most Similar to Neuroelectric Signal

- They Do Also Produce Heat, But No Record of Gradient Heat-Caused Injuries

Time-Varying Gradients

Physiological Effects

- Peripheral Nerve Stimulation (PNS)
- Direct Neuromuscular Stimulation
- Heating

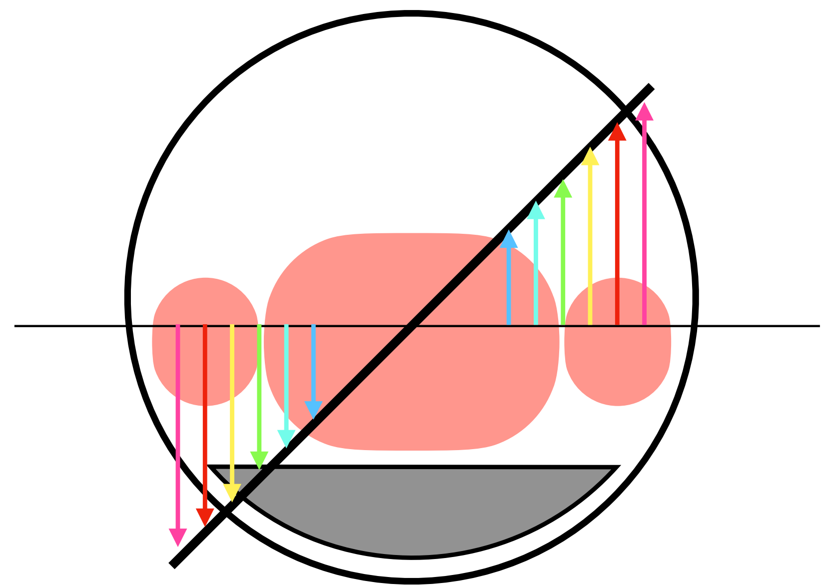
Time-Varying Gradients

Peripheral Nerve Stimulation (PNS)

Time-Varying Gradients

Peripheral Nerve Stimulation (PNS)

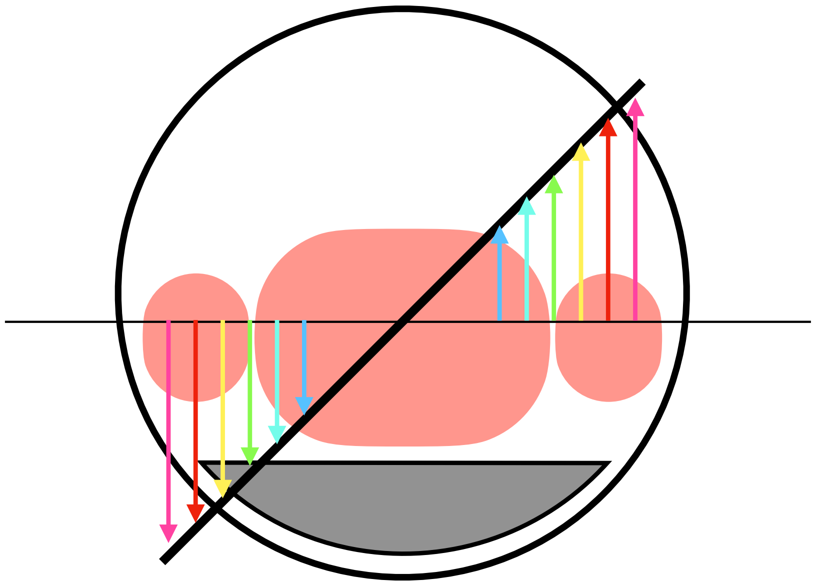
- Why Is It ‘Peripheral’?



Time-Varying Gradients

Peripheral Nerve Stimulation (PNS)

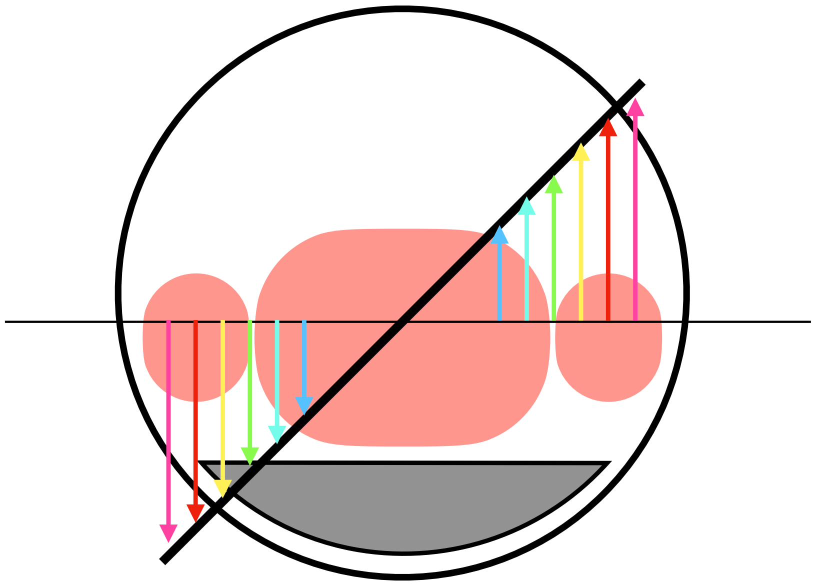
- What Does It Feel Like?
  - Tingling
  - ‘Creepy Crawlies’
  - Buzzing / Shocking
  - Metalic Taste
  - Magnetophosphenes



Time-Varying Gradients

Peripheral Nerve Stimulation (PNS)

- Can Increase All The Way To…
  - Muscle Twitching
  - Pain



Time-Varying Gradients

Direct Neuromuscular Stimulation

"So if gradients can stimulate peripheral nerves, couldn't they also stimulate nerves controlling organs, or even the central nervous system?"

Yes, if MR systems allowed them to go that high. But they don't.

Time-Varying Gradients

Direct Neuromuscular Stimulation

- Different nervous tissues have different tolerances for being activated by time-varying gradient magnetic fields.

Clinical MRI Systems
Can Only Go This Far

  - Sensory Organs
  - Muscles
  - Organ Systems (e.g. Heart, Diaphragm, Lungs, GI)
  - Central Nervous System (e.g. Spine & Brain)

Time-Varying Gradients
Heating

Time-Varying Gradients

Heating

- Can Add Modestly To Heating
- No Documented Patient Injury From Gradient-Induced Heating
- In Some Devices (Large, Flat) There May Be Gradient Limitations

Time-Varying Gradients

The Problem With Leads

- Voxels Of Deposition
- Magnetism & Electricity: Conjoined Twins
- Insulation & ‘Who Is In The Driver’s Seat?’

Time-Varying Gradients

Voxels Of Deposition

- MR System Controls Are Based On Exposure To Human Beings
- What Happens When There's Something Other Than Human Tissues w/in Volume of Deposition?

Time-Varying Gradients

The Conjoined Twin Conundrum

- Enters As Magnetism
- Encounters Good Electrical Conductor
- Switches To Electricity

Time-Varying Gradients

Insulation & ‘Who Is In The Driver’s Seat?’

- Magnetism Passes Through Electrical Insulation
- Enters Lead (Designed To Be Electrically Conductive)
- Electricity In Driver’s Seat
- Can’t Exit Through Insulation

Time-Varying Gradients

Insulation & 'Who Is In The Driver's Seat?'

- Capped Leads May Exacerbate Problem
    - Only Half As Many Ways Out

Time-Varying Gradients

The Problem With Leaded Devices

- False Feedback
- Unintended Stimulation

Time-Varying Gradients

False Feedback

- Devices That Monitor Neuroelectric Signal
  - May Perceive Gradient-Induced Voltages As From Patient
  - May Trigger Inappropriate Delivery of Therapy

Time-Varying Gradients

Unintended Stimulation

- Gradient Energies Delivered To Organ
  - May Deliver Unintended Stimulation

Time-Varying Gradients

How We Manage TVG Risks

- Positionally
- ScanWise

Time-Varying Gradients

How We Manage TVG Risks

- Positionally
  - If The Object Of Concern Is Receiving No Incident Gradient Energy (Consider Electrical Pathways), What Risk Is There

- We Can’t Control Spatial Distribution Of TVG Energies

Time-Varying Gradients

How We Manage TVG Risks

- ScanWise
  - Allows For Control Of Level Of Gradient Output
  - Not Positionally Aware

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

TGilk@GilkRadiologyConsultants.com
@tobiasgilk
www.facebook.com/groups/MRIsafety

Radio Frequency Magnetic Fields:

Effects / Volumes / Forces / Harms

Tobias Gilk - September 22, 2022

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

Radio Frequency Magnetic Fields

- Intro
- Fields / Distributions
- SAR / SED / $B1_{+RMS}$
- Levels & Labeling
- Heating & Burns
- Implant Scenarios
- Q & A

“If you don’t know what you’re exposing a patient (or device) to, you can’t begin to perform an MR risk-assessment.”

— Me

Radio Frequency (RF) Magnetic Fields

Recap & Advance

- When & Where
- Units & Measures
- Plots & Graphs

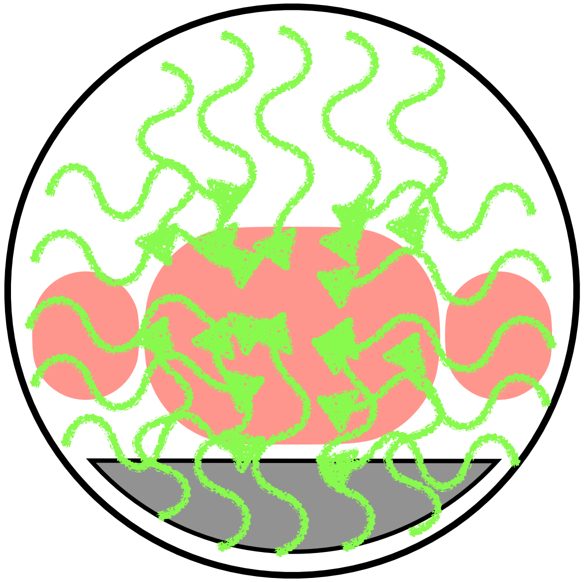
Radio Frequency (RF) Magnetic Fields
What Are They?

- Rapidly fluctuating magnetic field
- Changing 1,000,000s of times per second (Hz)

Radio Frequency (RF) Magnetic Fields

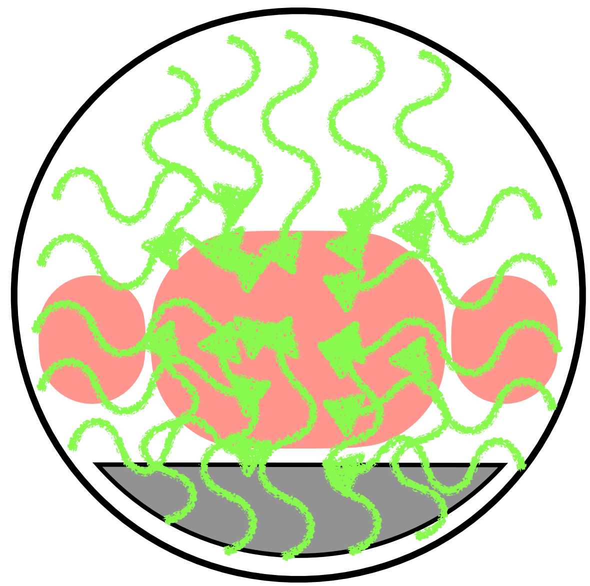
Why?

- Because we need to energize materials, first, to get signal out of them we can read
- Larmor Frequency



Radio Frequency (RF) Magnetic Fields
When & Where?

- Only during active imaging
- Only in the bore
- But not uniform throughout the bore



Radio Frequency (RF) Magnetic Fields
Modes

Normal Mode

- ≦ 2.0 W/kg
  Whole Body Averaged (WBA)
  SAR

First Level Controlled Operating Mode*

- ≦ 4.0 W/kg
  Whole Body
  Averaged (WBA)
  SAR

Second Level Controlled Operating Mode

- Whatever Your System Can Produce

201.3.208
FIRST LEVEL CONTROLLED OPERATING MODE
mode of operation of the MR EQUIPMENT in which one or more outputs reach a value that can cause physiological stress to PATIENTS which needs to be controlled by MEDICAL SUPERVISION

Radio Frequency (RF) Magnetic Fields

Modes

Table 201.105 – SAR limits for volume transmit coils

Averaging time	6 min		
	WHOLE BODY SAR	**PARTIAL BODY SAR**	**HEAD SAR**
Body region →	Whole body	Exposed body part	Head
Operating mode ↓	(W/kg)	(W/kg)	(W/kg)
NORMAL	2	2 – 10 [a]	3,2
FIRST LEVEL CONTROLLED	4	4 – 10 [a]	3,2
SECOND LEVEL CONTROLLED	>4	>(4 –10) [a]	>3,2
MR EXAMINATION specific absorbed energy	The max. energy dose (SAR × examination time) shall be limited, subject to the RISK MANAGEMENT.		
Short duration SAR	The SAR limits over any 10 s period shall not exceed two times the stated values.		

[a] The limit scales dynamically with the ratio "exposed PATIENT mass / PATIENT mass":

NORMAL OPERATING MODE :

PARTIAL BODY SAR = 10 W/kg - (8 W/kg * exposed PATIENT mass / PATIENT mass)

FIRST LEVEL CONTROLLED OPERATING MODE :

PARTIAL BODY SAR = 10 W/kg - (6 W/kg * exposed PATIENT mass / PATIENT mass)

Radio Frequency (RF) Magnetic Fields

Modes

Table 201.106 – SAR limits for local transmit coils

Averaging time	6 min		
	LOCAL SAR		
Body region →	Head	Trunk	Extremities
Operating mode ↓	(W/kg)	(W/kg)	(W/kg)
NORMAL	10 [a]	10	20
FIRST LEVEL CONTROLLED	20 [a]	20	40
SECOND LEVEL CONTROLLED	>20 [a]	>20	>40
Short duration SAR	The SAR limits over any 10 s period shall not exceed two times the stated values		

a NOTE In cases where the orbit is in the field of a small LOCAL RF TRANSMIT COIL, care should be taken to ensure that the temperature rise is limited to 1 °C.

Radio Frequency (RF) Magnetic Fields

SAR - SED - $B1_{+RMS}$

SAR (W/kg)

- Rate of delivered RF energy
- Think of it as the RF speedometer
- Averaged across body mass

SED (kJ/kg)

- Total quantity of delivered RF energy
- Think of it as the RF odometer
- Also averaged across body mass

$B1_{+RMS}$ (μT)

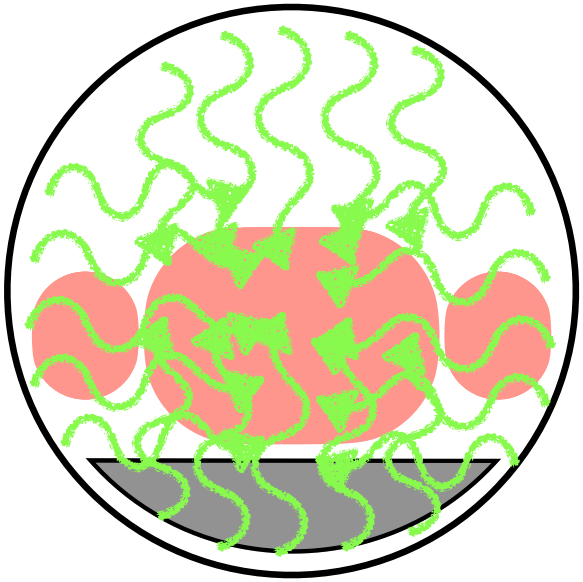
- Total delivered magnetic field energy
- ***Not*** averaged across body mass

Radio Frequency (RF) Magnetic Fields

Quadrature / Circularly Polarized (CP)

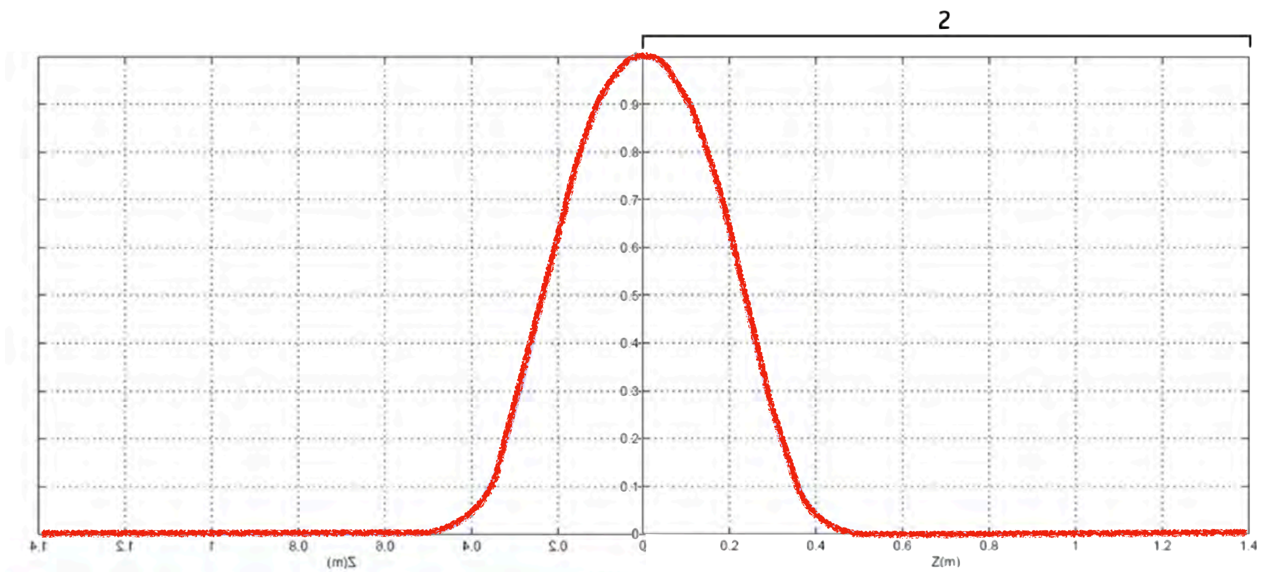
Quadrature = Circularly Polarized

- Method of delivering RF energy by energizing RF transmit coil elements one at a time (typically following a four-step circular path)
- Linearly Polarized or RF Shimming are ***not*** Quadrature or CP



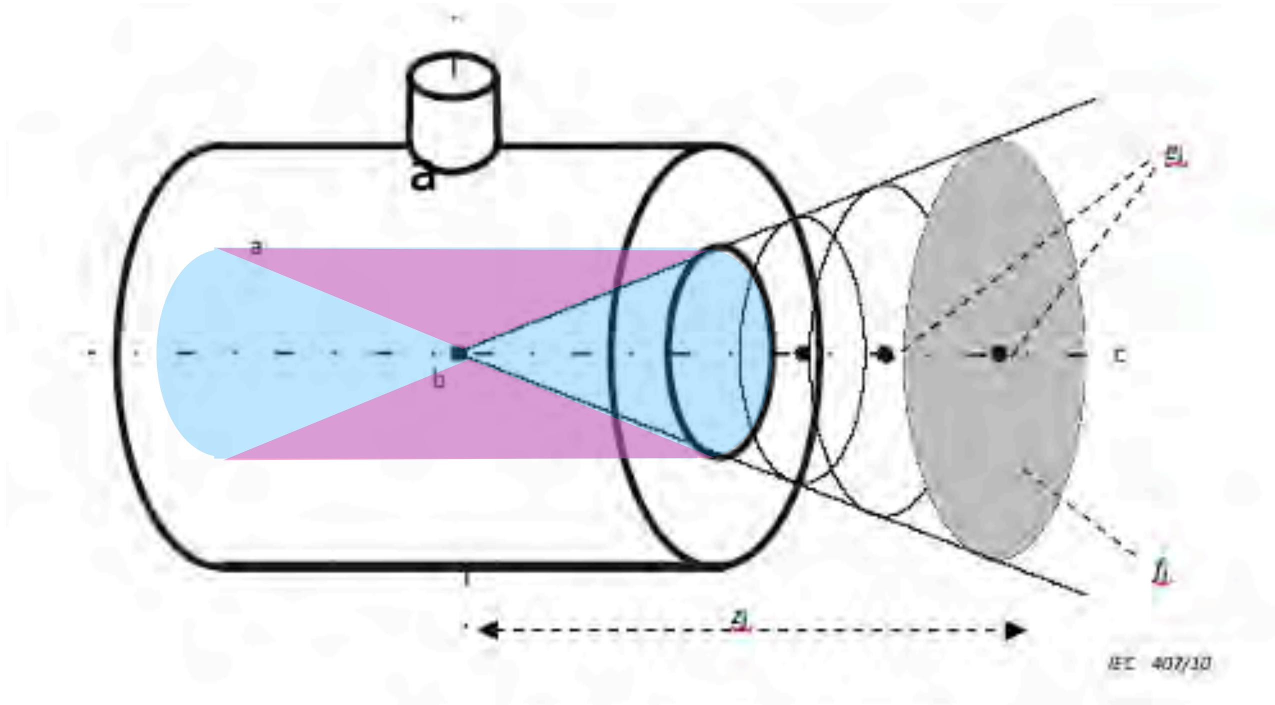
Radio Frequency (RF) Magnetic Fields

Plots & Graphs



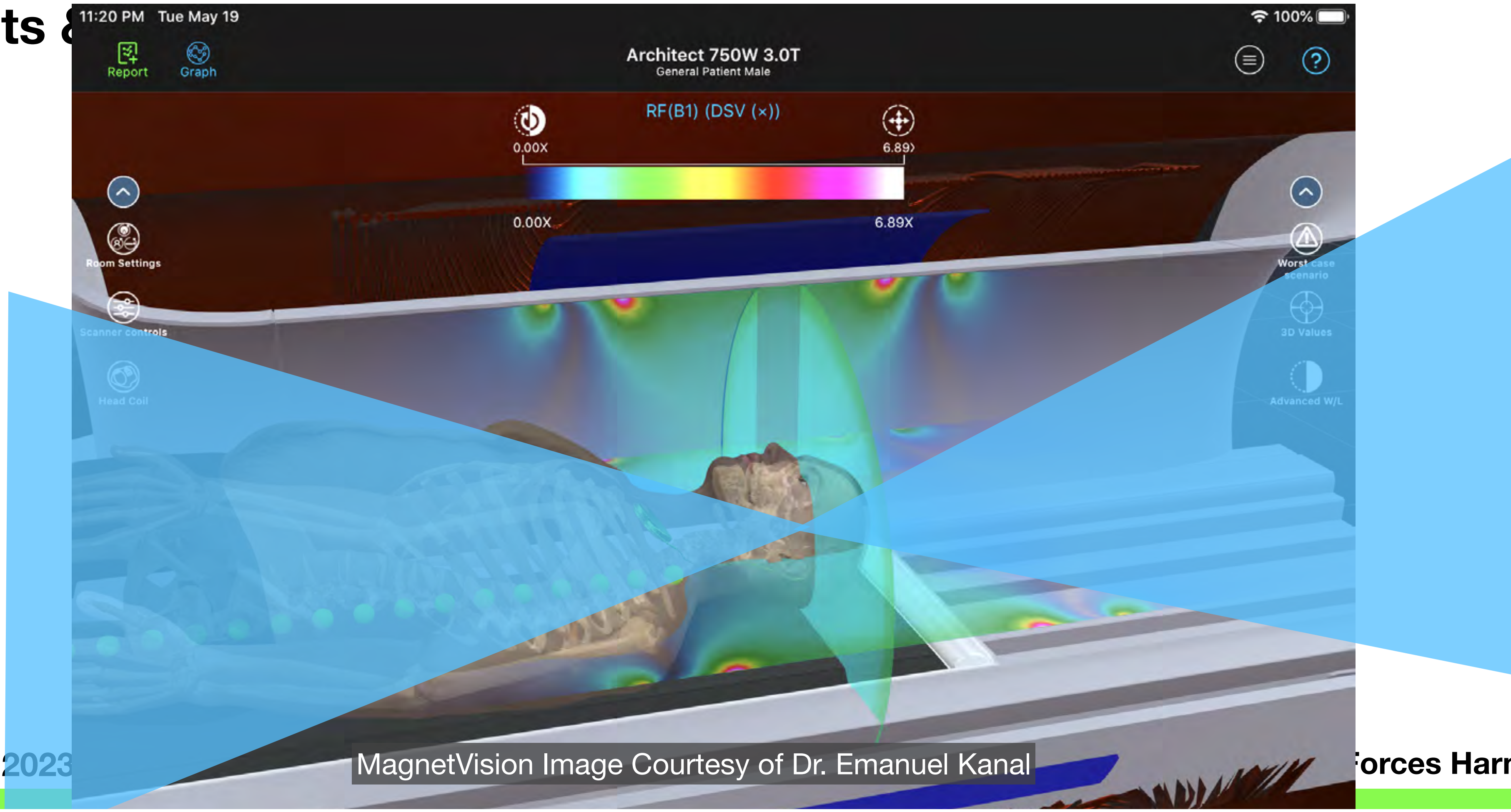
Radio Frequency (RF) Magnetic Fields

Plots & Graphs



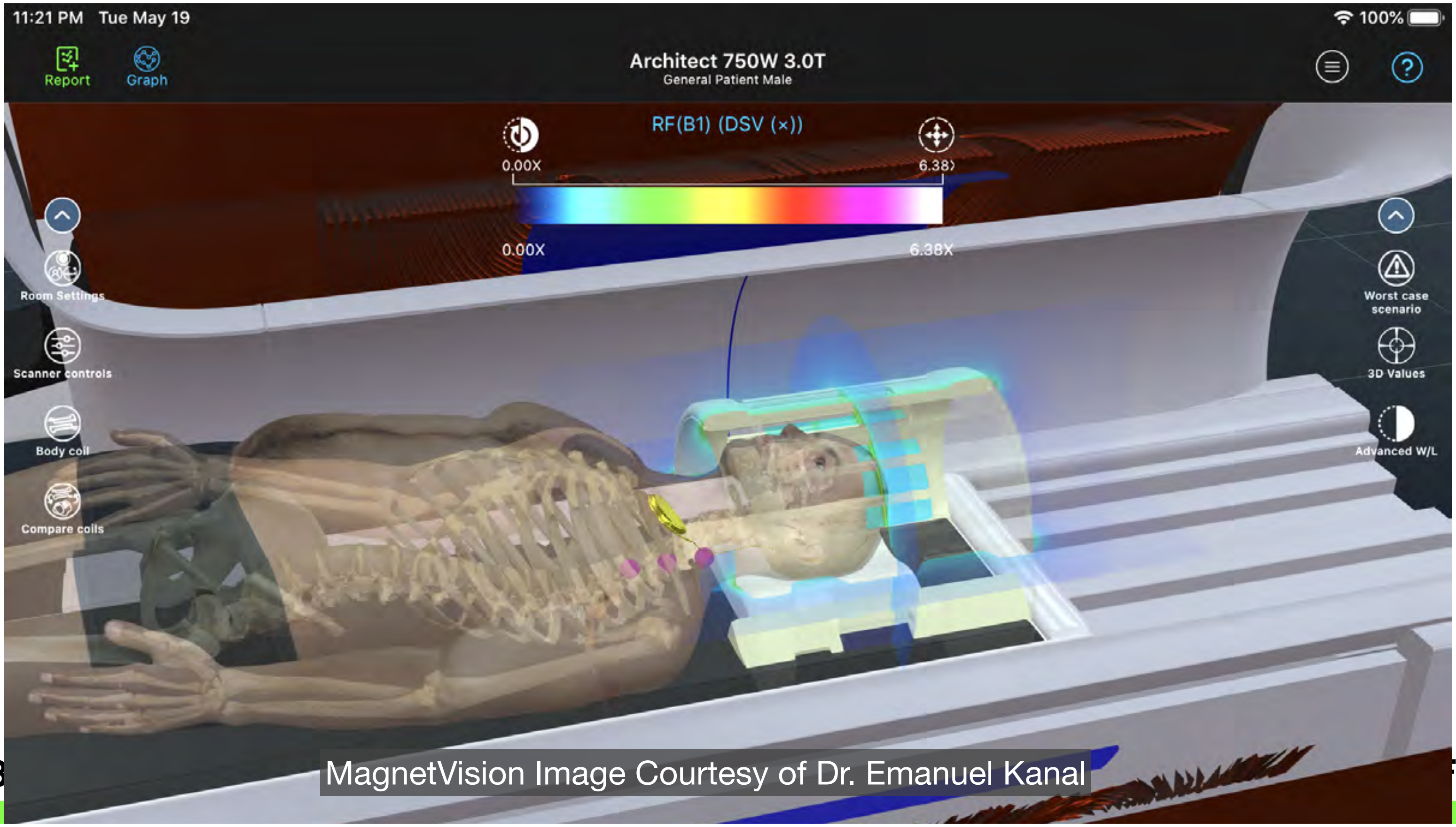
Radio Frequency (RF) Magnetic Fields

Plots &



Radio Frequency (RF) Magnetic Fields

Plots & Graphs



MagnetVision Image Courtesy of Dr. Emanuel Kanal

Radio Frequency (RF) Magnetic Fields

Plots & Graphs

Radio Frequency (RF) Magnetic Fields

Limitations of SAR

Radio Frequency (RF) Magnetic Fields

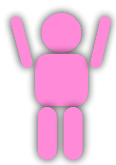
Limitations of SAR

@ 2 W/kg

@ 2 W/kg

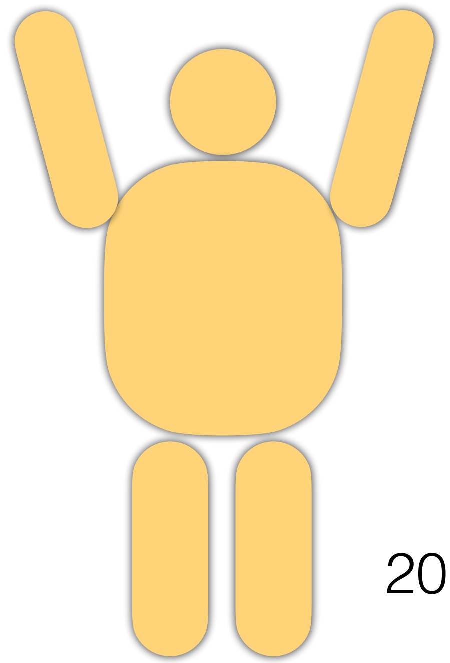
Radio Frequency (RF) Magnetic Fields

Limitations of SAR



5 kg

@ 2 W/kg x 5 kg = 10 W



200 kg

@ 2 W/kg x 200 kg = 400 W

Radio Frequency (RF) Magnetic Fields

Faraday's Law of Induction

Radio Frequency (RF) Magnetic Fields

Faraday's Law of Induction

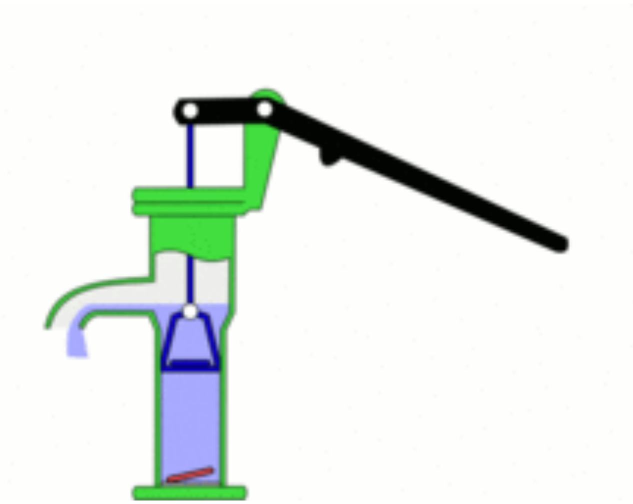
An electrical conductor exposed to a changing magnetic field will experience an induced electrical voltage.

Radio Frequency (RF) Magnetic Fields

Faraday's Law of Induction

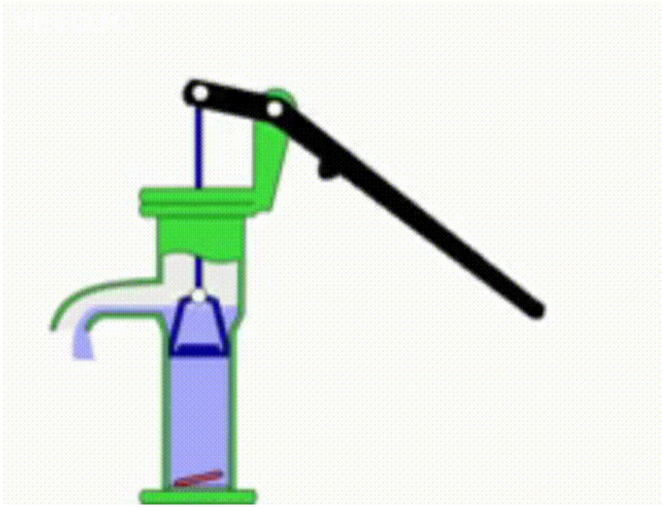
Time-Varying Gradients

1,000's of times per second



RF Magnetic Fields

1,000,000's of times per second



Radio Frequency (RF) Magnetic Fields

Physical & Physiological Effects

Radio Frequency (RF) Magnetic Fields

Physical Effects

- Induced Voltages
- Heating

Radio Frequency (RF) Magnetic Fields
Induced Voltages

- At RF Amplitudes & Frequencies, Induced Voltages Are Mostly ‘Transparent’ (Very Little Direct Physiologic Effect)

- But They Also Produce Heat… Lots Of Heat

Radio Frequency (RF) Magnetic Fields
Burns

There are three most-common ways for RF power to create a burn…

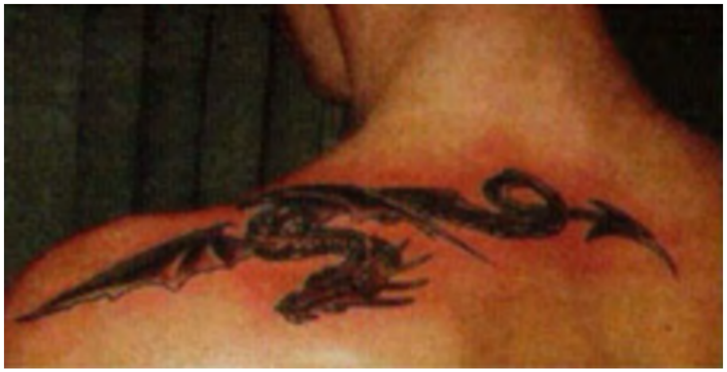
- Near-Field / Proximity Burn
- Large-Calibre Body Loop
- Resonant Circuit

Radio Frequency (RF) Magnetic Fields
Burns

- The Following Images May Be Upsetting

Radio Frequency (RF) Magnetic Fields

Burns (1st & 2nd Degree)



Radio Frequency (RF) Magnetic Fields

Burns (3rd Degree)

Radio Frequency (RF) Magnetic Fields

Burns (4th Degree

Radio Frequency (RF) Magnetic Fields

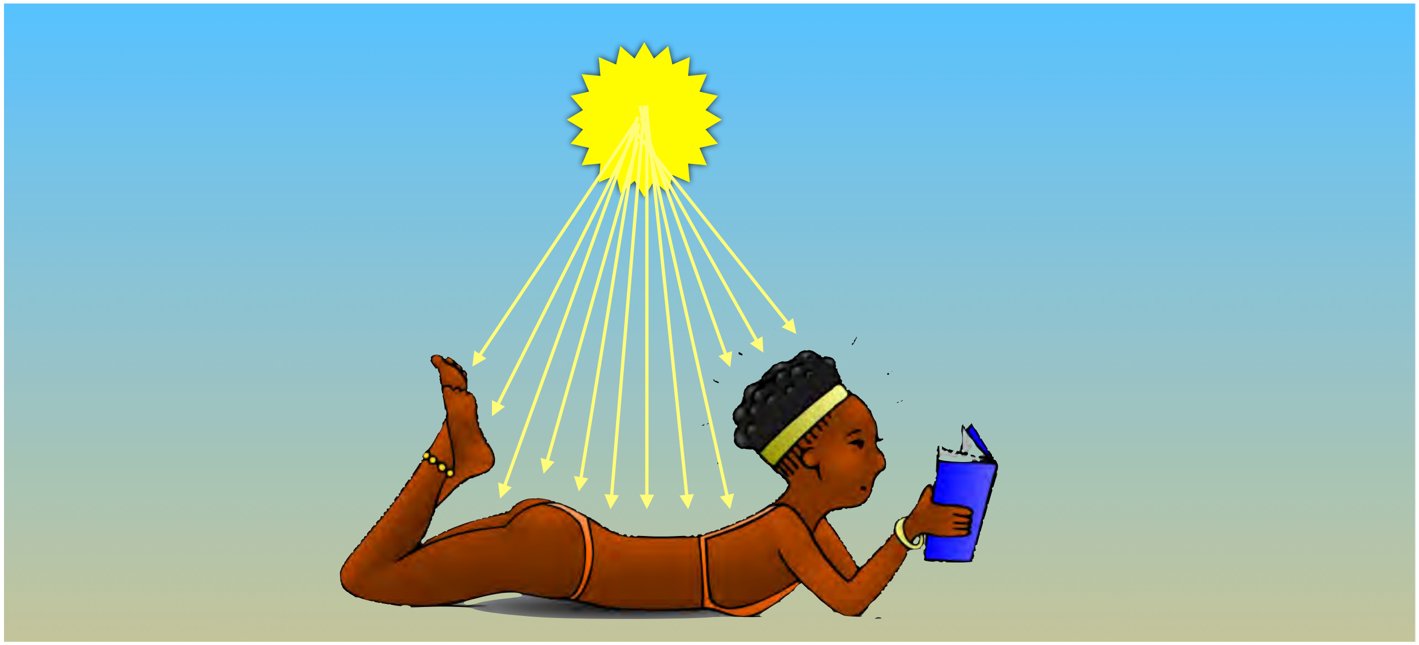
Physical / Physiologic Effects

- Diffuse Thermal Loading
  (What SAR Is Actually Good At…)

- Focal Heating

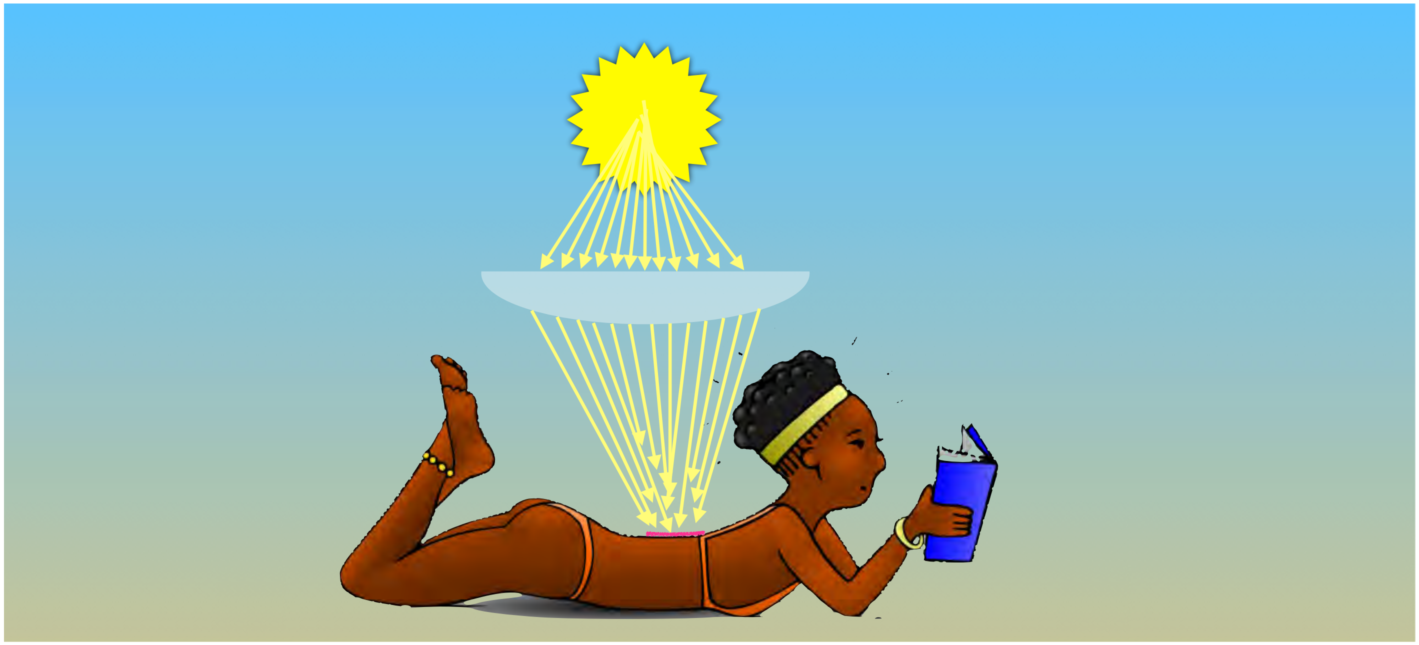
Radio Frequency (RF) Magnetic Fields

Physical / Physiologic Effects



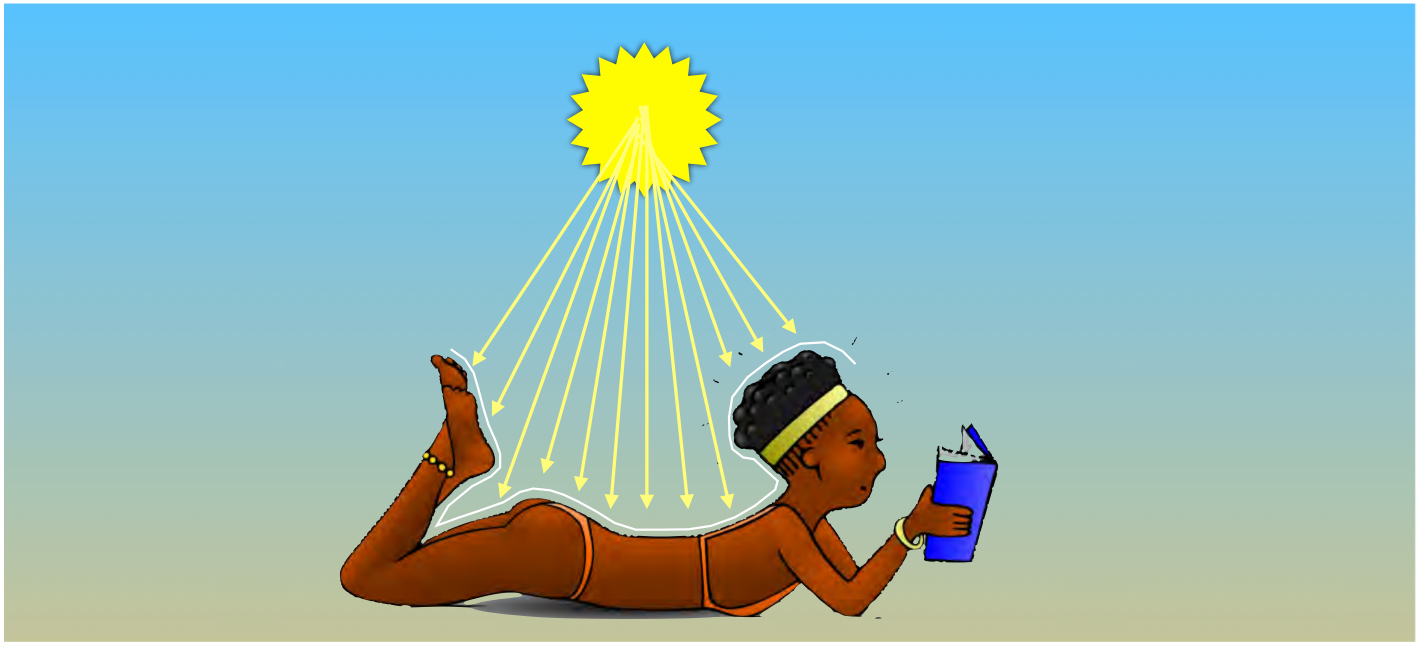
Radio Frequency (RF) Magnetic Fields

Physical / Physiologic Effects



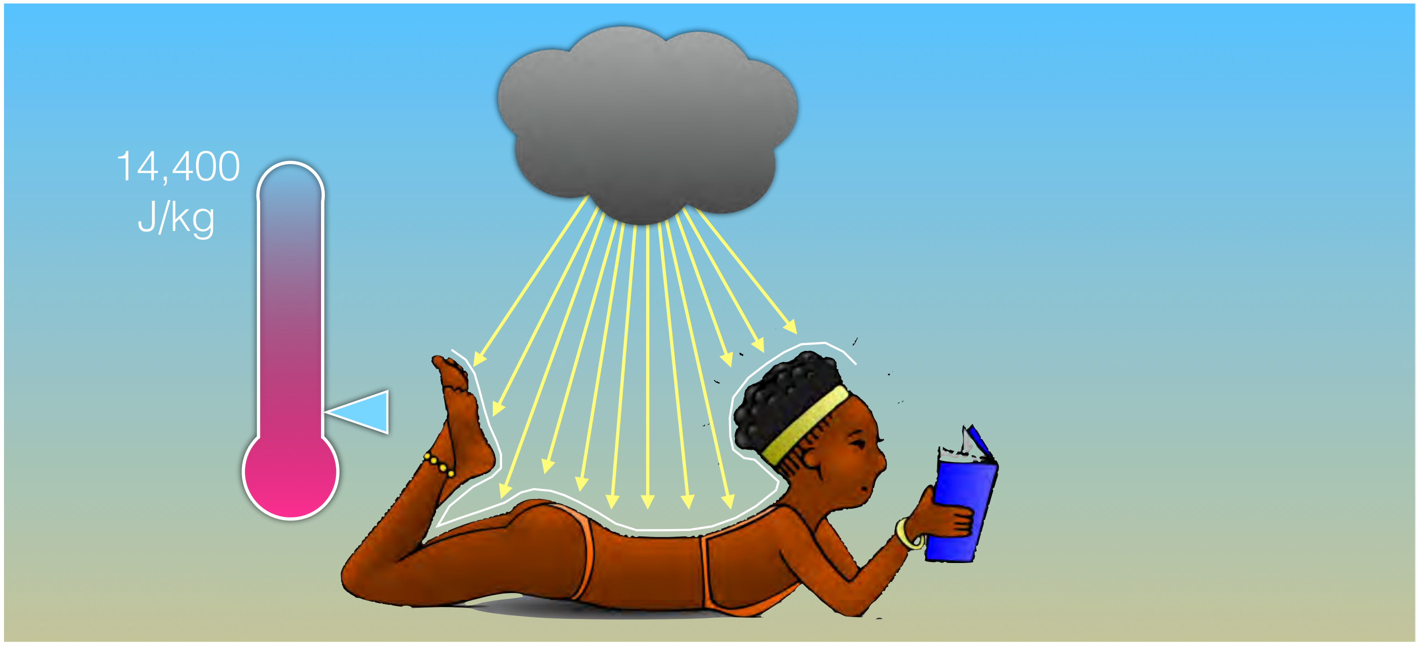
Radio Frequency (RF) Magnetic Fields

Physical / Physiologic Effects



Radio Frequency (RF) Magnetic Fields

Why SED Is Dumb…



Radio Frequency (RF) Magnetic Fields

The Problem With Leads

- Voxels Of Deposition
- Magnetism & Electricity: Conjoined Twins
- Insulation & ‘Who Is In The Driver’s Seat?’

Radio Frequency (RF) Magnetic Fields

Voxels Of Deposition

- MR System Controls Are Based On Exposure To Human Beings
- What Happens When There's Something Other Than Human Tissues w/in Volume of Deposition?

Radio Frequency (RF) Magnetic Fields

The Conjoined Twin Conundrum

- Enters As Magnetism
- Encounters Good Electrical Conductor
- Switches To Electricity

Radio Frequency (RF) Magnetic Fields

Insulation & ‘Who Is In The Driver’s Seat?’

- Magnetism Passes Through Electrical Insulation
- Enters Lead (Designed To Be Electrically Conductive)
- Electricity In Driver’s Seat
- Can’t Exit Through Insulation

Radio Frequency (RF) Magnetic Fields

Insulation & ‘Who Is In The Driver’s Seat?’

- Capped Leads May Exacerbate Problem
  - Only Half As Many Ways Out

Radio Frequency (RF) Magnetic Fields

Current Back To Pulse Generator

- Devices With Leads

Radio Frequency (RF) Magnetic Fields

Current To Organ / Structure

- Devices With Leads

Radio Frequency (RF) Magnetic Fields

"Think Like An Electron"

- Because Of Faraday's Law, RF Energy In Patient Tissues Wants To Behave Like Electricity…
    - ⤴️ Electrical Conductors = ⤴️ Paths (Path of Least Resistance)
    - Path To Form A Circle… I Mean Circuit

Radio Frequency (RF) Magnetic Fields

“Think Like An Electron”

- Large Caliber Body Loops

Radio Frequency (RF) Magnetic Fields

“Think Like An Electron”

- Electrically Conductive Materials

Radio Frequency (RF) Magnetic Fields

"Think Like An Electron"

- Resonant Circuit

Radio Frequency (RF) Magnetic Fields

“Think Like An Electron”

- Resonant Circuit
  - ‘Worst Case’ Lengths For Linear Conductors = 1/2 Wavelength
    - 3.0 T - 12 - 15 cm
    - 1.5 T - 25 - 30 cm
    - 1.0 T - 37 - 45 cm
    - 0.55 T - 67 - 82 cm
    - 0.064 T - 5.75 - 7.0 m

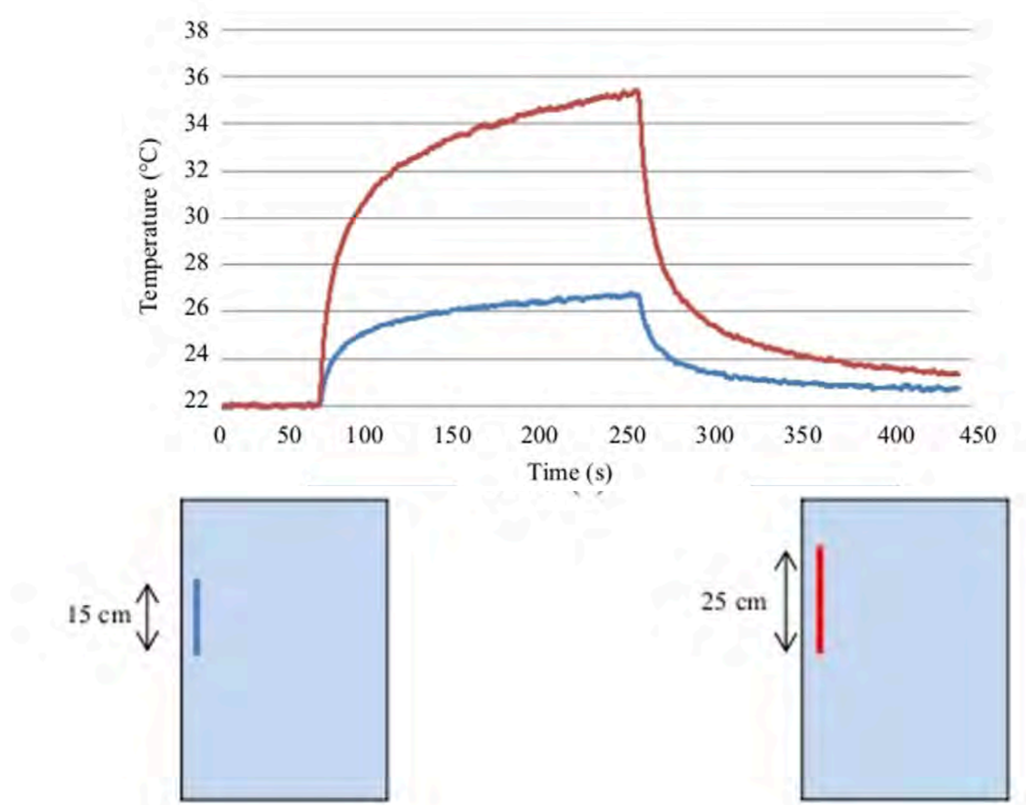
i.e. Siemens Max

i.e. Hyperfine Swoop

Radio Frequency (RF) Magnetic Fields

“Think Like An Electron”

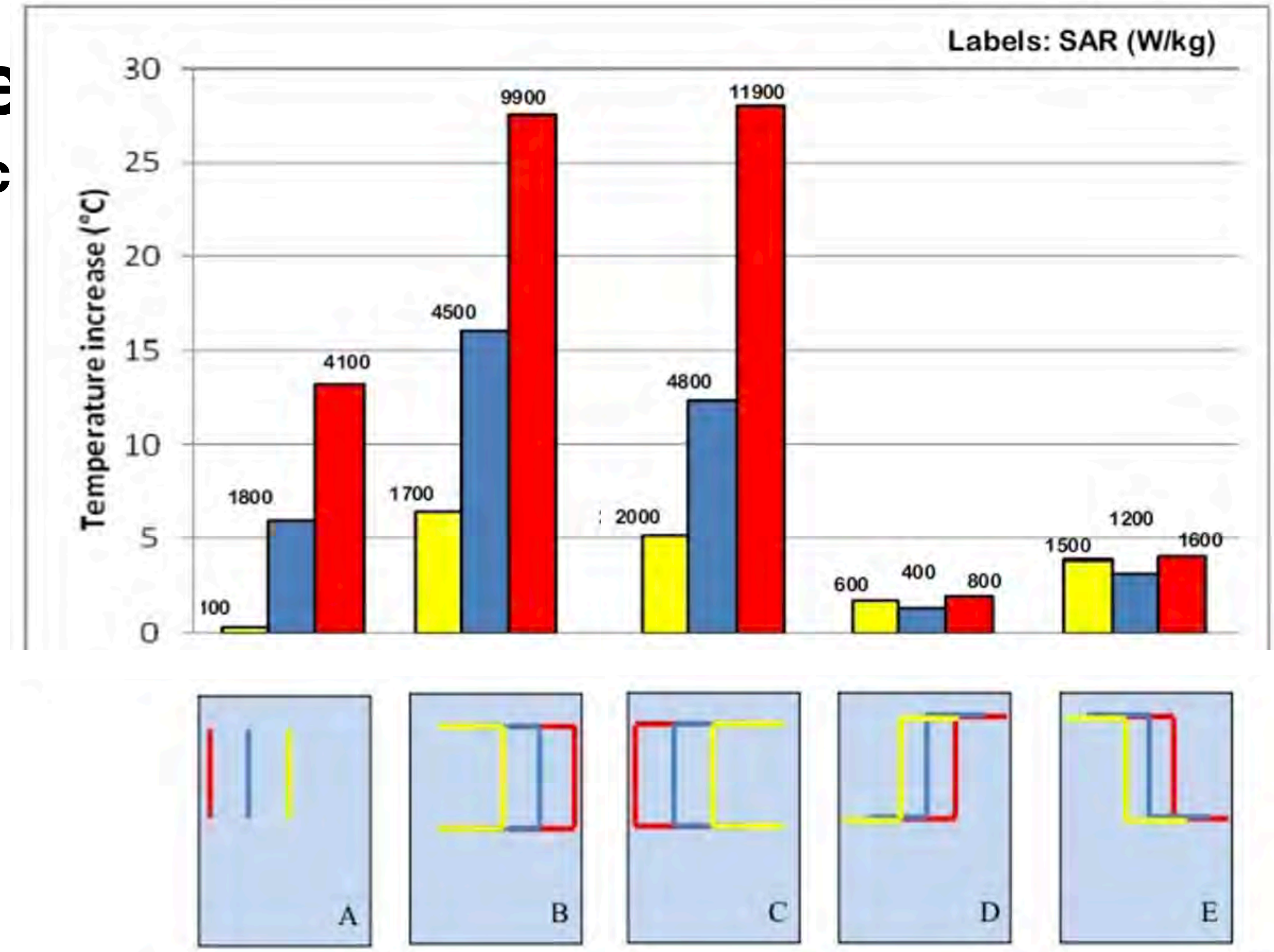
- Resonant Circuit
- 1.5 T



Radio Freque

"Think Like An Elec

- Resonant Circuit



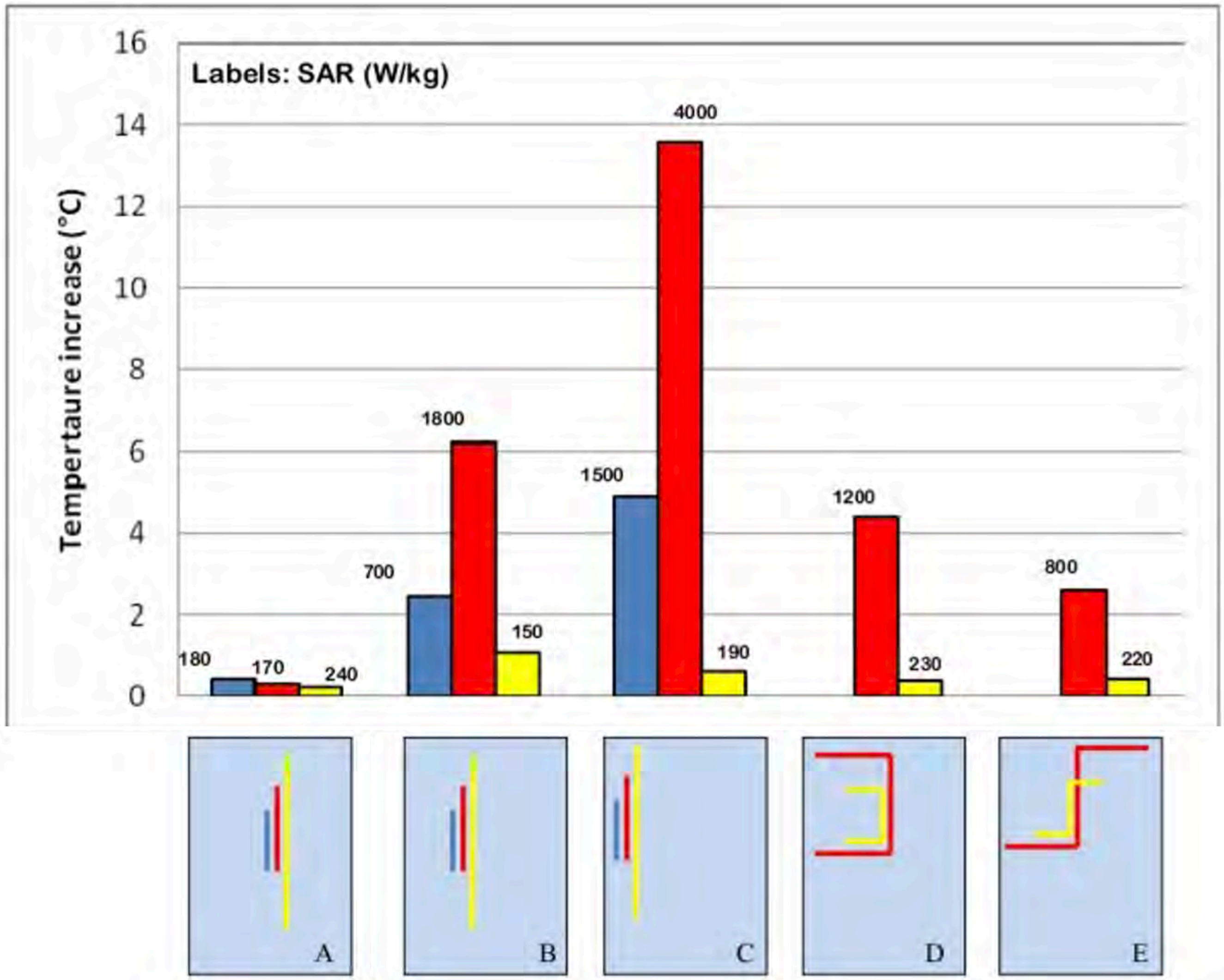
https://link.springer.com/content/pdf/10.1186/1475-925X-7-11.pdf

Radio Freque

"Think Like An Elect

- 1.5 T

15 cm
25 cm
45 cm



Radio Frequency (RF) Magnetic Fields

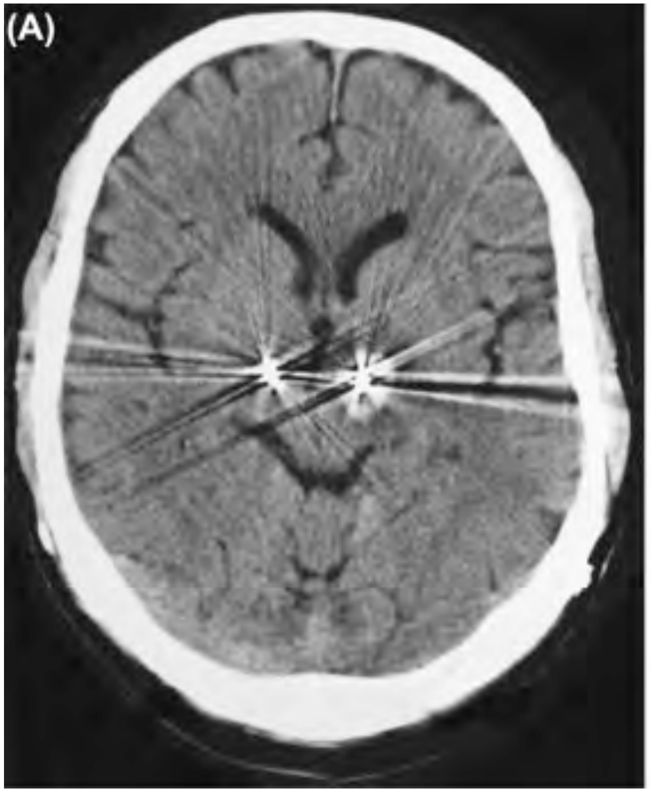
“Think Like An Electron”

- Resonant Circuit
  - ‘Worst Case’ Lengths For Linear Conductors = 1/2 Wavelength
    - 3.0 T - 12 - 15 cm
    - 1.5 T - 25 - 30 cm
    - 1.0 T - 37 - 45 cm
    - 0.55 T - 67 - 82 cm
    - 0.064 T - 5.75 - 7.0 m

Radio Frequency (RF) Magnetic Fields

“Think Like An Electron”

- DBS (bilateral)
- One extended lead
- L-Spine Study



Radio Frequency (RF) Magnetic Fields

How We Manage RF Risks

- Positionally
- “Collimation” (Local T/R Coil Use)
- RF Settings

Radio Frequency (RF) Magnetic Fields

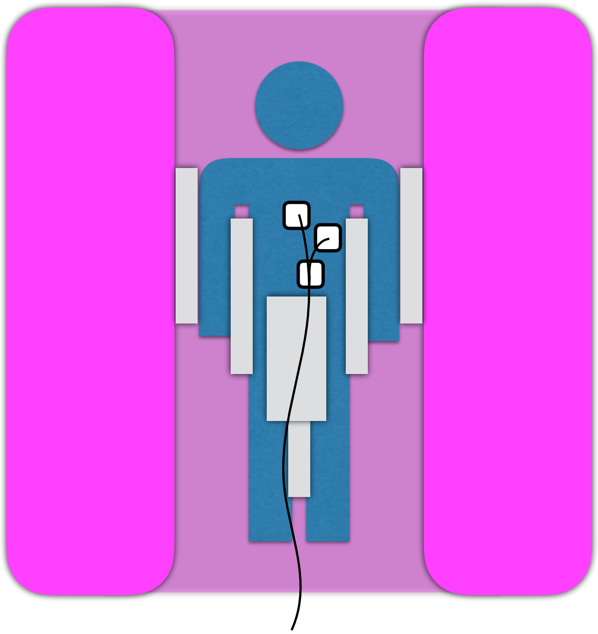
How We Manage RF Risks

- Positionally
  - If The Object Of Concern Is Wholly Outside The RF Body Coil Transmitter & Receiving No Incident RF Energy (Consider Electrical Pathways), What Risk Is There?

Radio Frequency (RF) Magnetic Fields

How We Manage RF Risks

- Padding
  - Patient From Bore Wall (Body Coil)
  - Patient From Own Tissues
  - Patient From Electrical Conductors



Radio Frequency (RF) Magnetic Fields

How We Manage RF Risks

- “Collimation”
  - If You Can Limit The Volume Of RF Irradiation By Using A Local T/R Coil…

Radio Frequency (RF) Magnetic Fields

How We Manage RF Risks

- RF Settings
  - If You Can 'Dial-Back' SAR / B1+RMS To Acceptable Values (For Both Heating Risk & Image Quality…)

Radio Frequency (RF) Magnetic Fields

How We Manage RF Risks

- ScanWise (Philips)
  - Allows For Control Of Level Of RF Output
  - Not Positionally Aware

- MR Output Conditioning (MROC)

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

TGilk@GilkRadiologyConsultants.com
@tobiasgilk
www.facebook.com/groups/MRIsafety

Deciphering
MR Conditional Labeling

Tobias Gilk - Sept 23, 2022

Tobias Gilk,
MRSO, MRSE

- Past Member ACR MRI Safety Committee
- Contributing Author 2007, 2019 & 2020 ACR MRI Safety Guidance
- Founding Board Member / Past Chair ABMRS
- International Trainer on MRI Safety

ABMRS Content Disclosure

This presentation is not sponsored by or affiliated with the American Board of Magnetic Resonance Safety (ABMRS).

As a member of the the Board of the ABMRS, I am prohibited from speaking on specific examination question content, but permitted to provide education on MRI safety concepts and principles.

This presentation is not an exam preparation for any examination.

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

Deciphering MR Conditional Labeling

- Intro
- MR Conditional Labeling / Conditions
- How Devices Are Tested
- Violating MR Conditional Status
- Unlabeled Devices / Foreign Bodies
- “Off-Label” ≠ Unsafe (‘It’s All About Harm’)
- Q & A

What Does “FDA Approved” Mean?

What exactly did the FDA approve?

What Does “FDA Approved” Mean?

What exactly did the FDA approve?

- Drug / device meets minimum criteria for efficacy?
- Drug / device meets minimum criteria for safety?

What Does “FDA Approved” Mean?

What exactly did the FDA approve?

The FDA’s responsibility is to grant and oversee a company’s interstate medical product marketing.

https://www.hudson.org/research/7264-fda-approval-does-not-mean-what-you-think-it-does-

How To Read MR Conditional Labels

What Are “MR Conditional / MR Safe / MR Unsafe”?

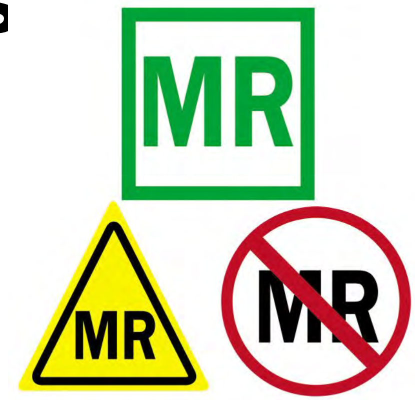
How To Read MR Conditional Labels

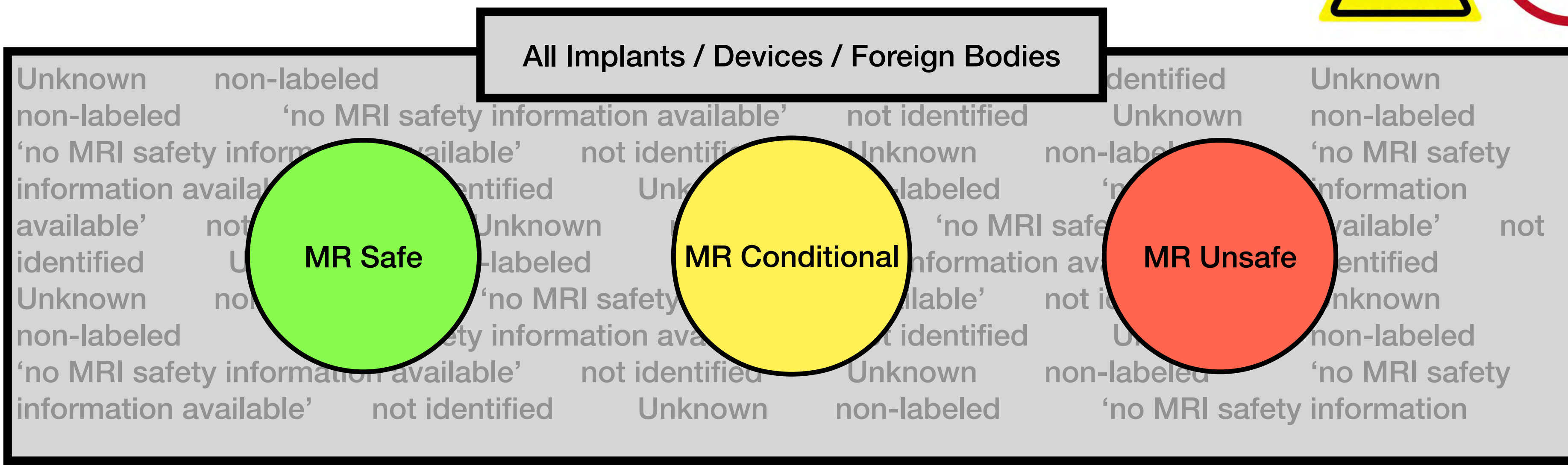
What Are "MR Conditional / MR Safe / MR Unsafe"?

MR safe		The device or implant is completely nonmagnetic, nonelectrically conductive, and nonradiofrequency reactive, therefore eliminating all the primary potential risks during MRI scanning
MR conditional		The device or implant may contain magnetic, electrically conductive, or radiofrequency-reactive components that are safe for operation in proximity to the MRI, provided the conditions for safe operation are defined and observed (both for the MR scanner and the device itself)
MR unsafe		Objects that are significantly ferromagnetic and pose a clear and direct threat to persons and equipment within the magnet room

How To Read MR Conditional Labels

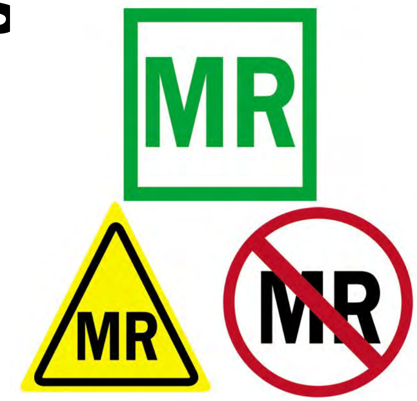
What Are “MR Conditional / MR Safe / MR Unsafe”?

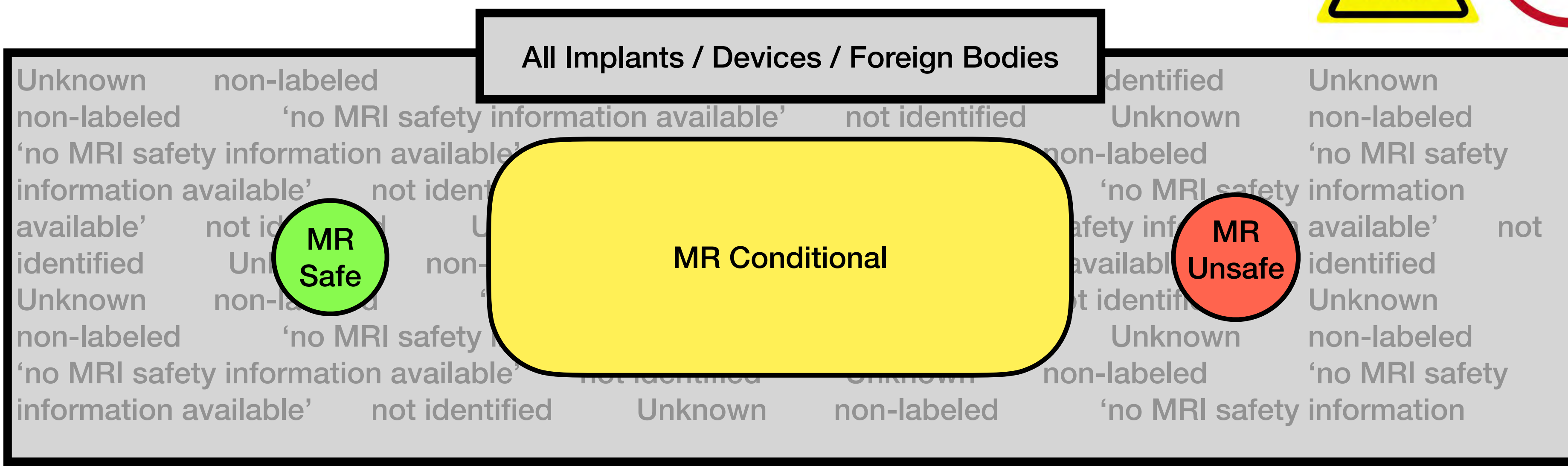


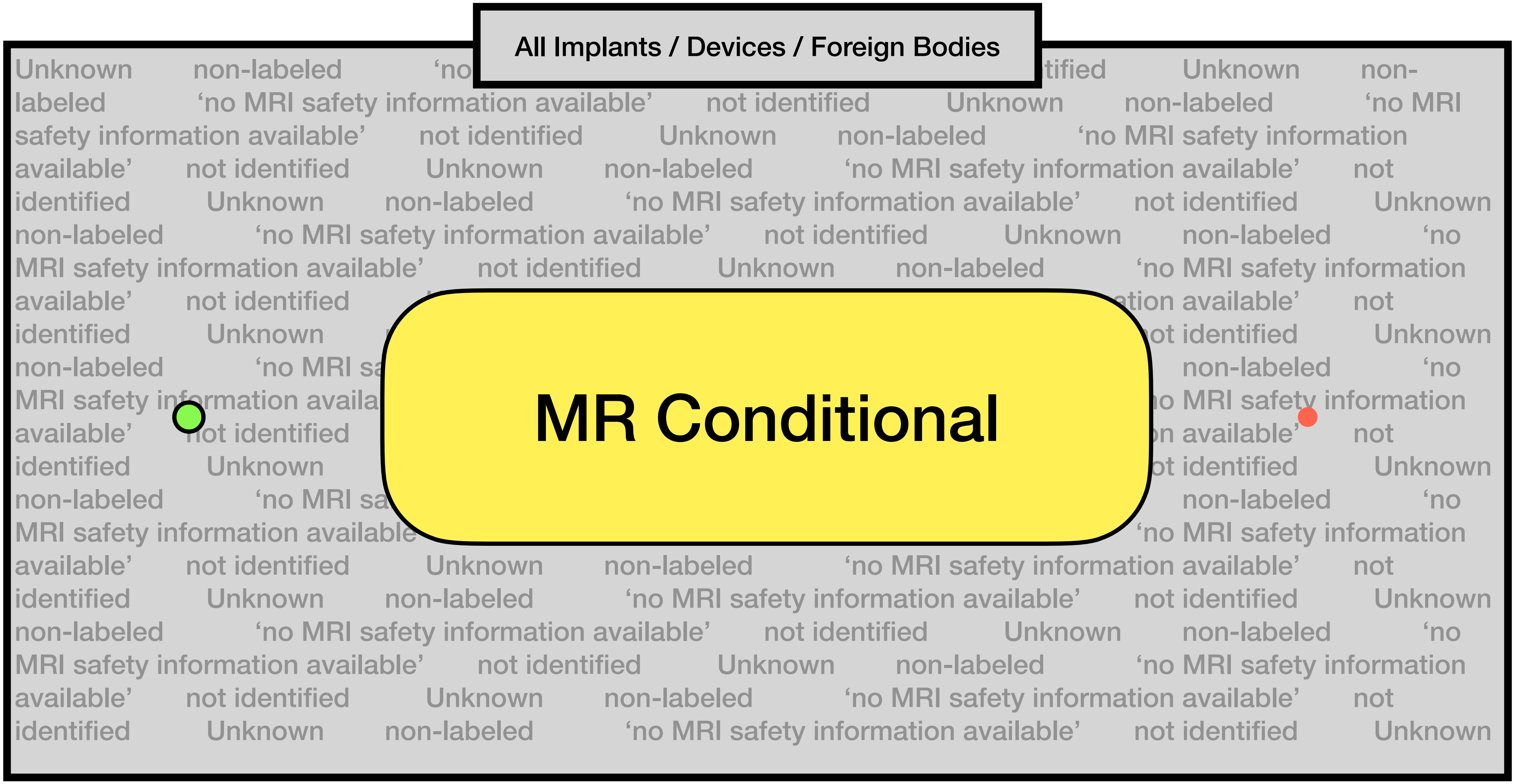


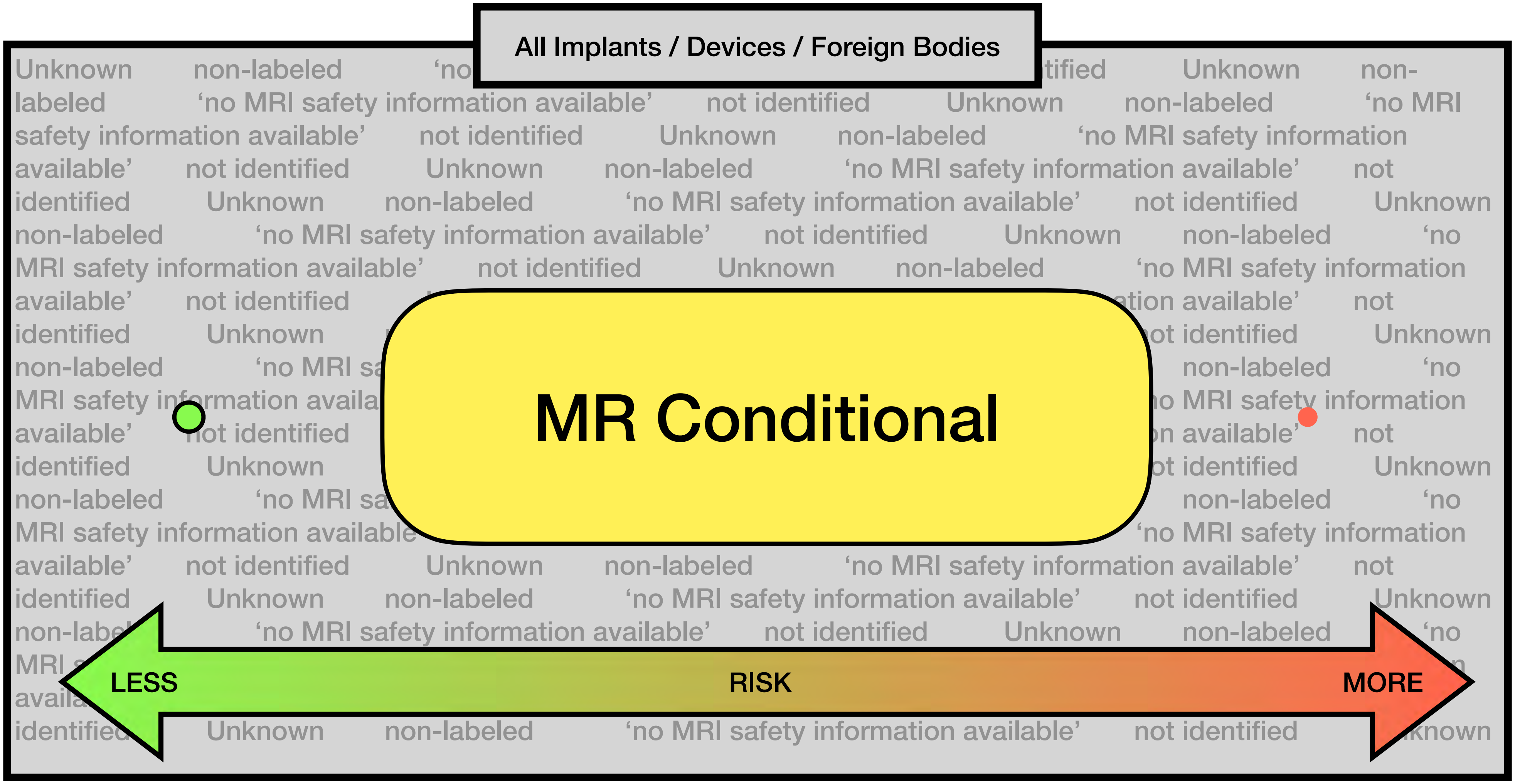
How To Read MR Conditional Labels

What Are "MR Conditional / MR Safe / MR Unsafe"?






All Implants / Devices / Foreign Bodies
MR Conditional
Unknown
non-labeled
‘no MRI safety information available’
not identified


All Implants / Devices / Foreign Bodies
Unknown
non-labeled
‘no MRI safety information available’
not identified
MR Conditional
LESS
RISK
MORE

How To Read MR Conditional Labels

What is ‘Conditionality’?

How To Read MR Conditional Labels

What is ‘Conditionality’?

Manufacturer-Assured Safety When All Stated Conditions Are Met.

How To Read MR Conditional Labels

What is ‘Conditionality’?

- “Up to” vs. “At”
- Electromagnetic Fields
- Assemblies vs. Lone Objects
- Device Functionality

How To Read MR Conditional Labels

What is ‘Conditionality’?

“Up to” vs. “At”

- All MR Conditional Conditions ‘Up To’ For All Risks
  Except Focal Heating (Burns)

- Field Strength In MR Conditional Labeling <u>Two Separate Risks</u>:
  - Torque (‘Up To’)
  - RF Frequency For Resonant Circuit Heating (‘At’)

How To Read MR Conditional Labels

What is ‘Conditionality’?

Electromagnetic Fields

- Most of MR Conditional Labeling Parameters Are Based On Controlling Exposure To Electromagnetic Fields
  - By Position (e.g., ’Center Above / Below’)
  - By Setting (e.g., ’no more than 2 W/kg or 150 T/m/s’)
  - By Coil (e.g., ’T/R knee coil’)

How To Read MR Conditional Labels

What is ‘Conditionality’?

Assemblies vs. Lone Objects

- Many MR Conditional Implants Aren’t Lone Objects, But Rather Assemblies:
    - Plates & Screws
    - Pulse Generator & Lead-Set

- If Assembly Hasn’t Been Tested Together, Shouldn’t Be Labeled.

How To Read MR Conditional Labels

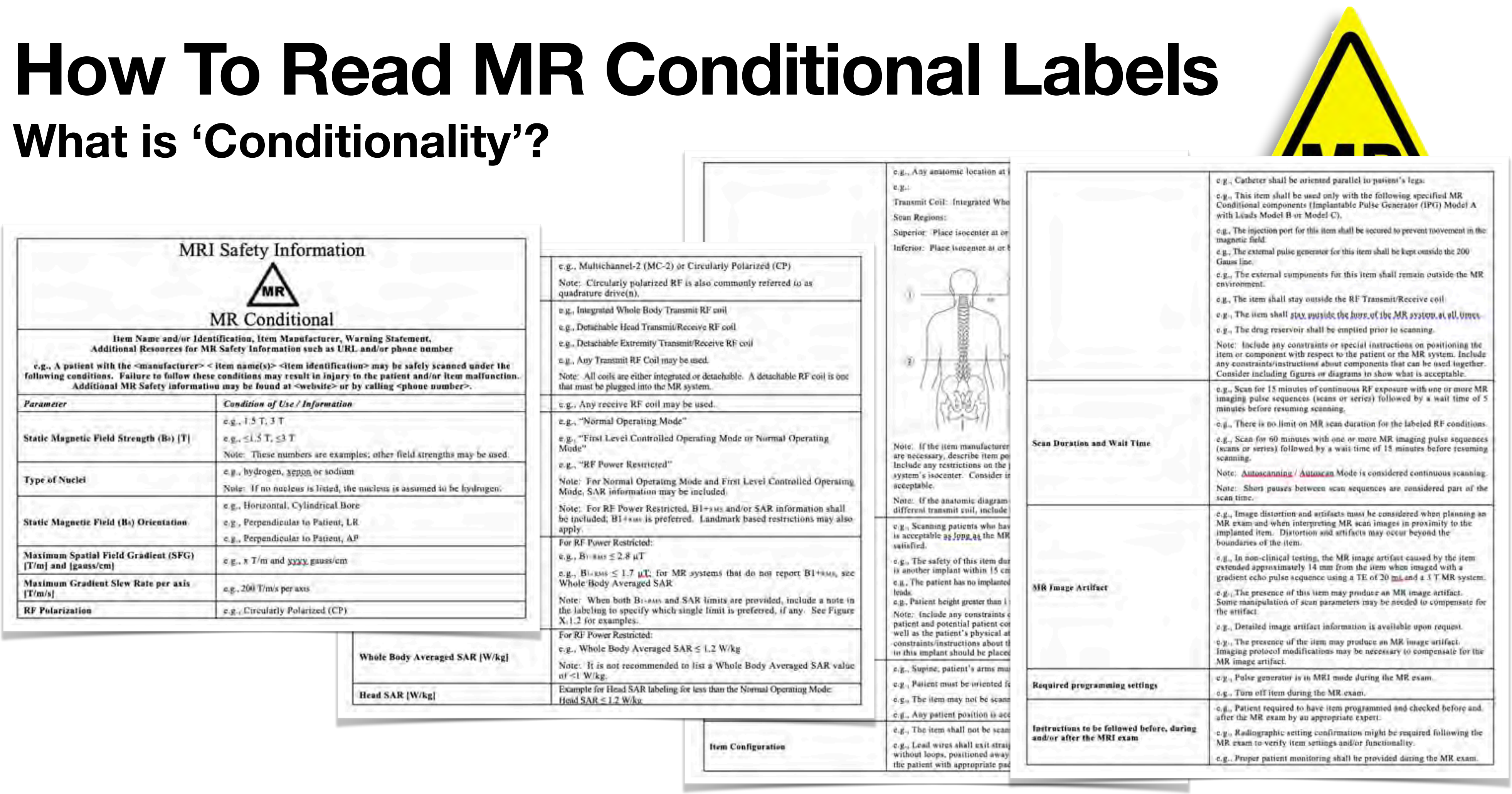
What is ‘Conditionality’?

Device Functionality

- MR May Affect Device Function:
  - Shunt Valve Position
  - Implanted Medication Pumps
  - ‘MR Mode’ For Pacemakers / Neurostimulators
  - ECG Readouts

How To Read MR Conditional Labels

What is ‘Conditionality’?



MRI Safety Information

MR

MR Conditional

Item Name and/or Identification, Item Manufacturer, Warning Statement, Additional Resources for MR Safety Information such as URL and/or phone number

e.g., A patient with the <manufacturer> < item name(s)> <item identification> may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient and/or item malfunction. Additional MR Safety information may be found at <website> or by calling <phone number>.

Parameter	*Condition of Use / Information*
Static Magnetic Field Strength (B_0) [T]	e.g., 1.5 T, 3 T e.g., ≤1.5 T, ≤3 T Note: These numbers are examples; other field strengths may be used.
Type of Nuclei	e.g., hydrogen, xenon or sodium Note: If no nucleus is listed, the nucleus is assumed to be hydrogen.
Static Magnetic Field (B_0) Orientation	e.g., Horizontal, Cylindrical Bore e.g., Perpendicular to Patient, LR e.g., Perpendicular to Patient, AP
Maximum Spatial Field Gradient (SFG) [T/m] and [gauss/cm]	e.g., x T/m and yyyy gauss/cm
Maximum Gradient Slew Rate per axis [T/m/s]	e.g., 200 T/m/s per axis
RF Polarization	e.g., Circularly Polarized (CP)

	e.g., Multichannel-2 (MC-2) or Circularly Polarized (CP) Note: Circularly polarized RF is also commonly referred to as quadrature drive(n).
	e.g., Integrated Whole Body Transmit RF coil e.g., Detachable Head Transmit/Receive RF coil e.g., Detachable Extremity Transmit/Receive RF coil e.g., Any Transmit RF Coil may be used. Note: All coils are either integrated or detachable. A detachable RF coil is one that must be plugged into the MR system.
	e.g., Any receive RF coil may be used.
	e.g., “Normal Operating Mode” e.g., “First Level Controlled Operating Mode or Normal Operating Mode” e.g., “RF Power Restricted” Note: For Normal Operating Mode and First Level Controlled Operating Mode, SAR information may be included. Note: For RF Power Restricted, $B1+_{RMS}$ and/or SAR information shall be included; $B1+_{RMS}$ is preferred. Landmark based restrictions may also apply.
	For RF Power Restricted: e.g., $B_{1+RMS} \leq 2.8\ \mu T$ e.g., $B_{1+RMS} \leq 1.7\ \mu T$; for MR systems that do not report $B1+_{RMS}$, see Whole Body Averaged SAR Note: When both B_{1+RMS} and SAR limits are provided, include a note in the labeling to specify which single limit is preferred, if any. See Figure X.1.2 for examples.
Whole Body Averaged SAR [W/kg]	For RF Power Restricted: e.g., Whole Body Averaged SAR ≤ 1.2 W/kg Note: It is not recommended to list a Whole Body Averaged SAR value of <1 W/kg.
Head SAR [W/kg]	Example for Head SAR labeling for less than the Normal Operating Mode: Head SAR ≤ 1.2 W/kg

	e.g., Catheter shall be oriented parallel to patient’s legs. e.g., This item shall be used only with the following specified MR Conditional components (Implantable Pulse Generator (IPG) Model A with Leads Model B or Model C). e.g., The injection port for this item shall be secured to prevent movement in the magnetic field. e.g., The external pulse generator for this item shall be kept outside the 200 Gauss line. e.g., The external components for this item shall remain outside the MR environment. e.g., The item shall stay outside the RF Transmit/Receive coil. e.g., The item shall stay outside the bore of the MR system at all times. e.g., The drug reservoir shall be emptied prior to scanning. Note: Include any constraints or special instructions on positioning the item or component with respect to the patient or the MR system. Include any constraints/instructions about components that can be used together. Consider including figures or diagrams to show what is acceptable.
Scan Duration and Wait Time	e.g., Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning. e.g., There is no limit on MR scan duration for the labeled RF conditions. e.g., Scan for 60 minutes with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 15 minutes before resuming scanning. Note: Autoscanning / Autoscan Mode is considered continuous scanning. Note: Short pauses between scan sequences are considered part of the scan time.
MR Image Artifact	e.g., Image distortion and artifacts must be considered when planning an MR exam and when interpreting MR scan images in proximity to the implanted item. Distortion and artifacts may occur beyond the boundaries of the item. e.g., In non-clinical testing, the MR image artifact caused by the item extended approximately 14 mm from the item when imaged with a gradient echo pulse sequence using a TE of 20 ms and a 3 T MR system. e.g., The presence of this item may produce an MR image artifact. Some manipulation of scan parameters may be needed to compensate for the artifact. e.g., Detailed image artifact information is available upon request. e.g., The presence of the item may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.
Required programming settings	e.g., Pulse generator is in MRI mode during the MR exam. e.g., Turn off item during the MR exam.
Instructions to be followed before, during and/or after the MRI exam	e.g., Patient required to have item programmed and checked before and after the MR exam by an appropriate expert. e.g., Radiographic setting confirmation might be required following the MR exam to verify item settings and/or functionality. e.g., Proper patient monitoring shall be provided during the MR exam.

How To Read MR Conditional Labels

What is ‘Conditionality’?

MRI Safety Information

MR

MR Conditional

A patient with the BestCompany AlwaysOpenStent may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Additional MR Safety information may be found at www.bestc.com/alwaysopenstent or by calling 1800-XXX-XXXX

Parameter	***Condition of Use / Information***
Static Magnetic Field Strength (B_0)	≤3 T
Static Magnetic Field (B_0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient (SFG)	30 T/m (3000 gauss/cm)
RF Polarization	Circularly Polarized (CP) (i.e., quadrature drive)
RF Transmit Coil	Any Transmit RF Coil may be used.
RF Receive Coil	Any Receive RF coil may be used.
MR System (RF) Operating Modes or Constraints	Normal Operating Mode
Scan Duration and Wait Time	Scan for 15 minutes of continuous RF exposure with one or more MR imaging pulse sequences (scans or series) followed by a wait time of 5 minutes before resuming scanning.
MR Image Artifact	The presence of the AlwaysOpenStent may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

Figure X1.1 Exemplar MR Conditional IFU language for a passive item intended to enter the bore of a MR system.

How To Read MR Conditional Labels

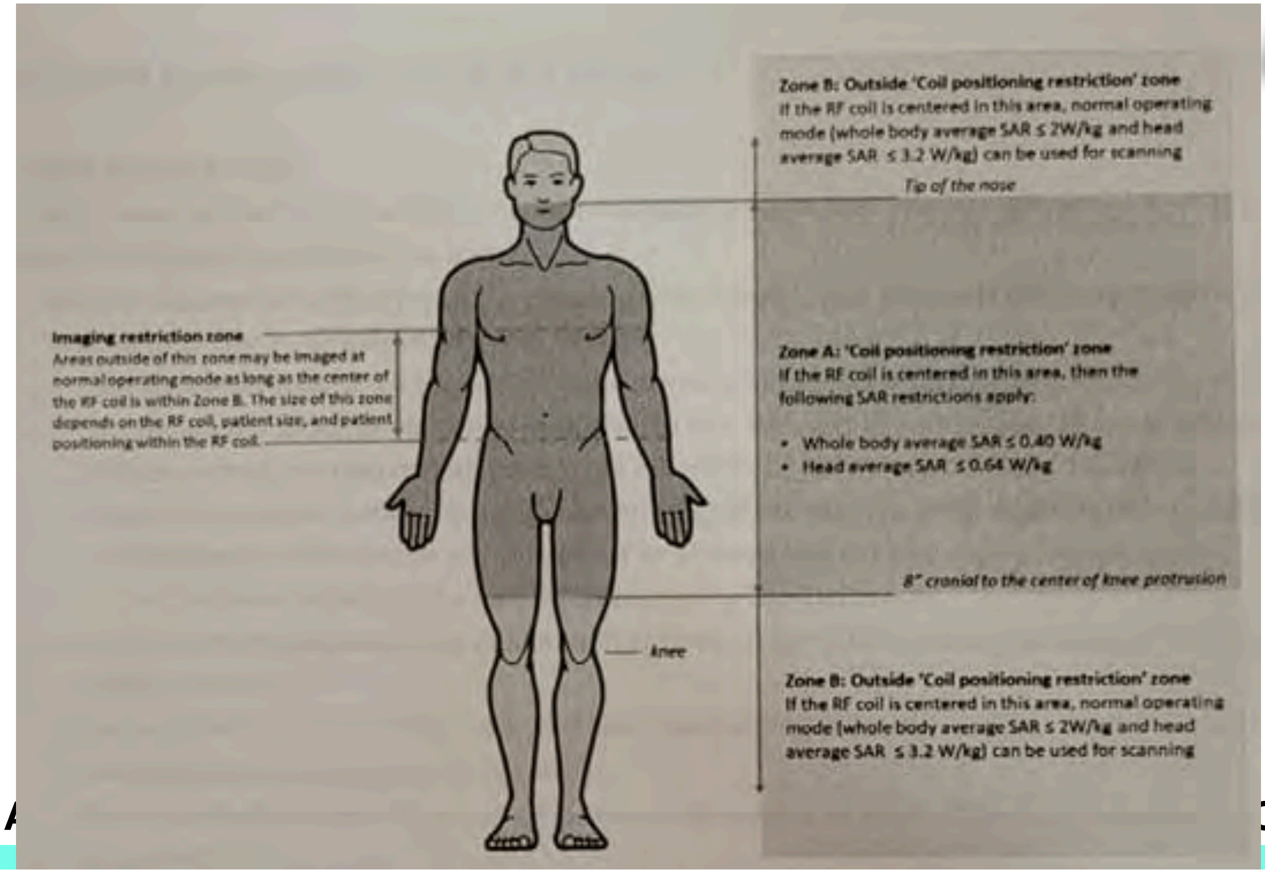
What is 'Conditionality'?

MRI Statement

The MULTI-LINK VISION Coronary Stent has been shown in non-clinical testing to be MRI safe immediately following implantation. **MRI test conditions used to evaluate this stent were: for magnetic field interactions, a static magnetic field strength of 3 tesla with a maximum spatial gradient magnetic field of 3.3 tesla/meter; for MRI-related heating, a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR imaging.** While a single stent produced a temperature rise of less than 0.6°C and should not migrate under these conditions, the response of overlapping stents or stents with fractured struts is unknown. Non-clinical testing has not been performed to rule out the possibility of stent migration at field strengths higher than 3 tesla. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

How To Read MR Conditional Labels

What is ‘Conditionality’?



How To Read MR Conditional Labels

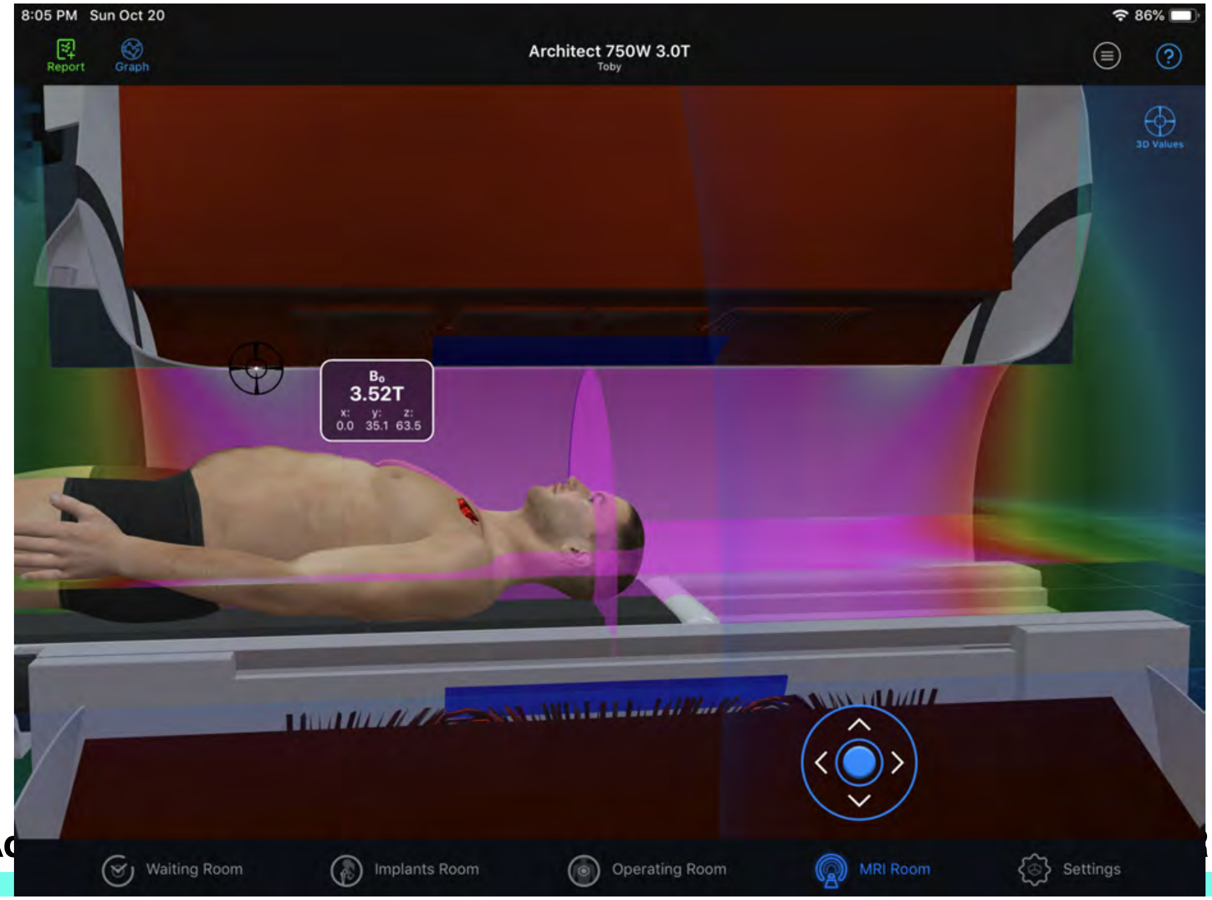
What is ‘Conditionality’?

Static Magnetic Field (1 of 2) - Torque / Rotation

- ‘Up To’ *System Rating* (For Torque)
- What The System Is Sold As (e.g., 1.5T, 3.0T)
- Not The Specific Exposure Of The Device
  (Even If The Exposure Is Greater Than The Listed Value)

How To Read MR Conditional Labels

What is ‘Conditionality’?



How To Read MR Conditional Labels

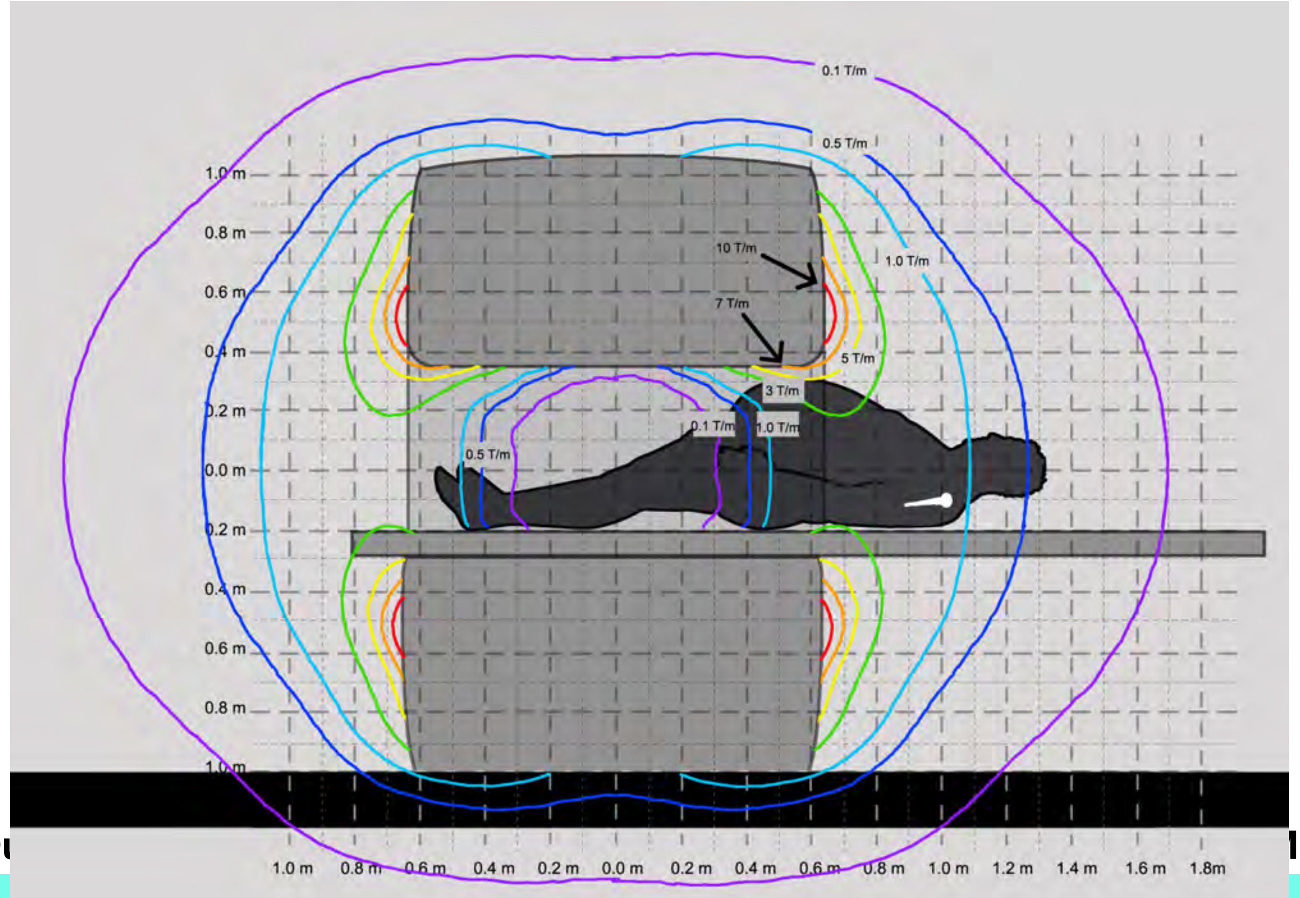
What is ‘Conditionality’?

Spatial Field Gradient - Translation / Attraction

- ‘Up To’ Exposure Value (T/m, G/cm)
- Not System Max. What Device Will Be Exposed To.

How To Read MR Conditional Labels

What is ‘Conditionality’?



How To Read MR Conditional Labels

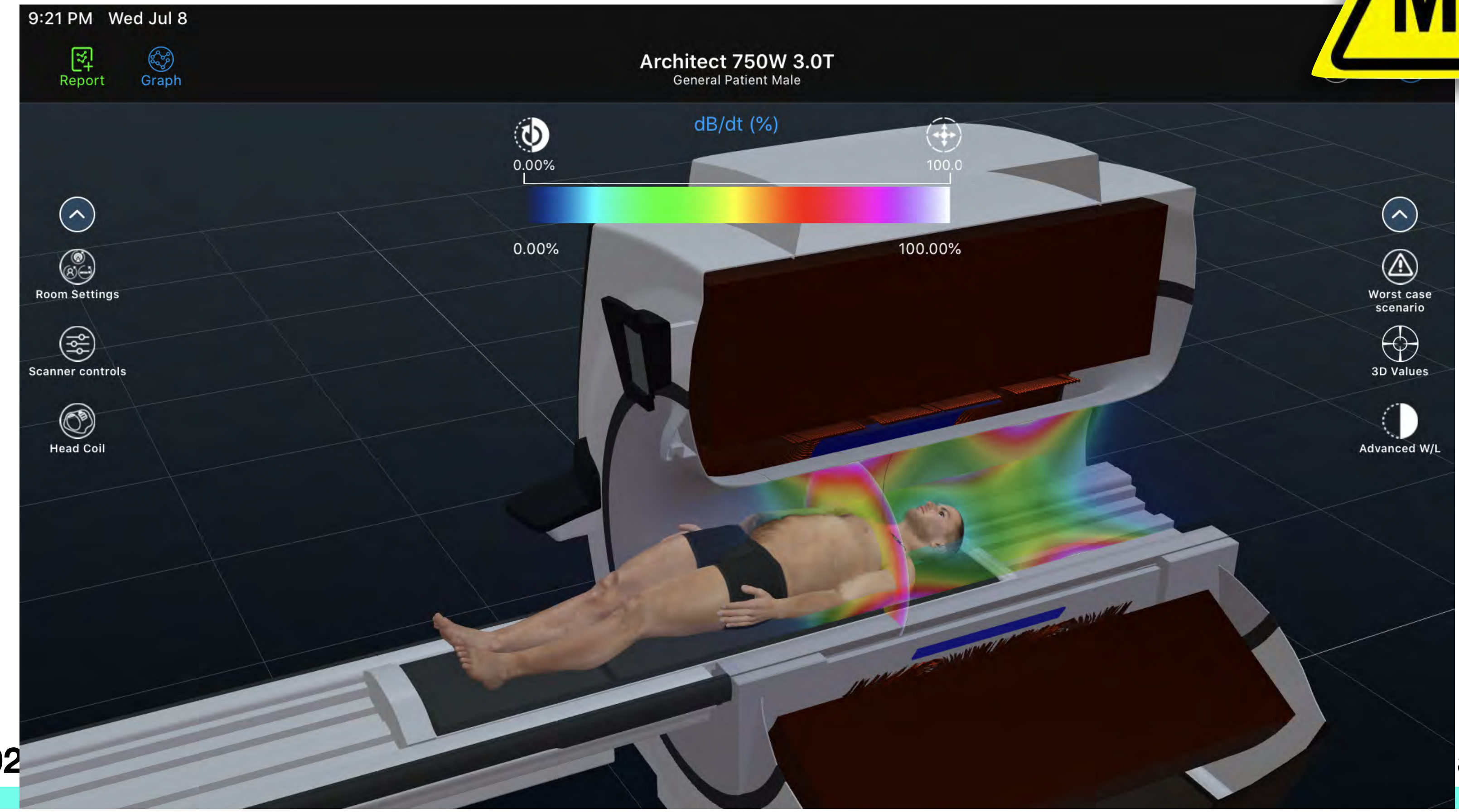
What is 'Conditionality'?

Time-Varying Gradient - Neuromuscular Stim / Device Interference

- 'Up To' Exposure Value (T/m/s)
- Not System Max (If Your System Allows TVG Controls). What Device Will Be Exposed To.
    - May Be Managed By Setting (e.g., 'Slew Rate ≦ 150 T/m/s')
    - May Be Managed By Position (e.g., 'Landmark Above / Below x')
- If System Doesn't Allow TVG Controls…

How To Read MR Conditional Labels

What is ‘Conditionality’?



How To Read MR Conditional Labels

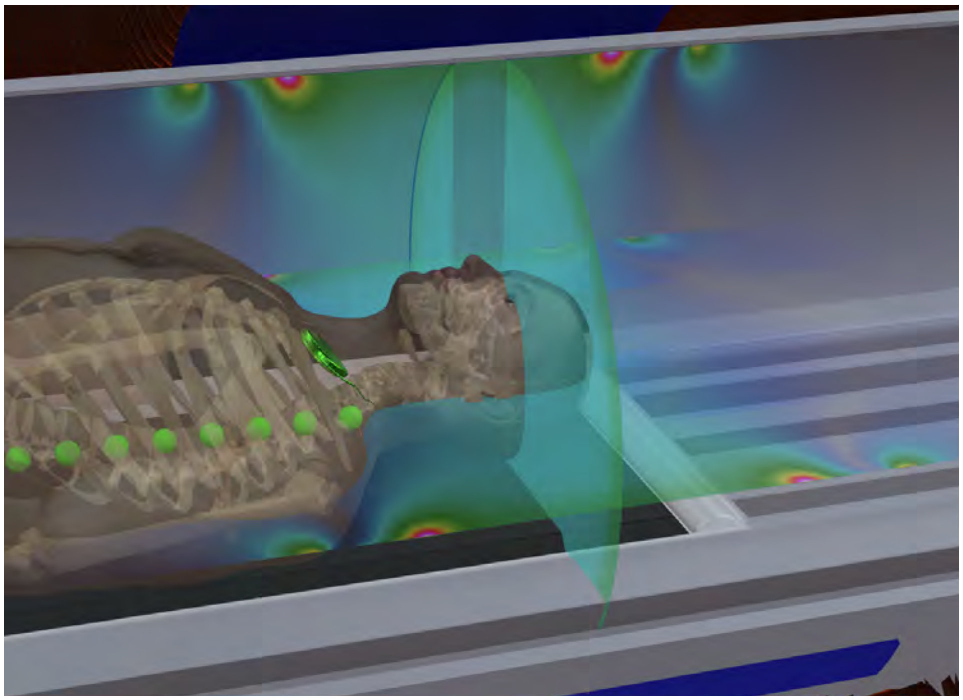
What is ‘Conditionality’?

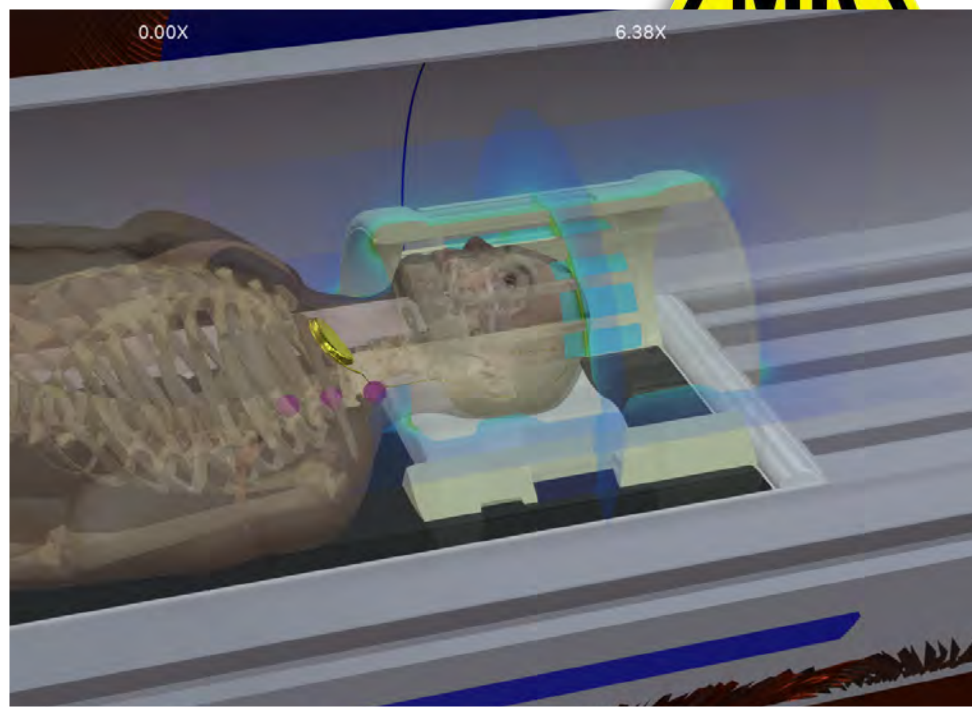
RF Magnetic Fields (1 of 2) - Diffuse Thermal Loading

- ‘Up To’ Pulse Sequence Setting (Whole Body Averaged SAR)
- May Be Managed By:
    - Pulse Sequence Setting
    - Smaller Transmit Volume (Local T/R Coils)

How To Read MR Conditional Labels

What is 'Conditionality'?





How To Read MR Conditional Labels

What is 'Conditionality'?

"What's the center frequency of your MR system?"

How To Read MR Conditional Labels

What is ‘Conditionality’?

RF Magnetic Fields & Static Magnetic Field (2 of 2)
- Focal Heating (Burns) Specifically From Resonant Circuit Effects

- ‘At’ Field Strength (Really Frequency)
- May Be Managed By:
  - Position Within Bore (e.g., ‘Route Cable Along Central Z-Axis’)
  - Position Outside Volume of Deposition (e.g., ‘Above / Below x’)
  - Pulse Sequence (e.g., ‘SAR ≦ 0.5 W/kg’)

How To Read MR Conditional Labels

What is 'Conditionality'?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 µT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

How To Read MR Conditional Labels

What is 'Conditionality'?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 µT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- 'Up To' Highest System Rating For Torque
- *But* 'At' 1.5 or 3.0 T For Resonant Circuit Heating

How To Read MR Conditional Labels

What is ‘Conditionality’?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- ‘Up To’ 9 T/m Device Exposure For Attraction

How To Read MR Conditional Labels

What is ‘Conditionality’?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
B1+RMS	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- ‘Up To’ Normal Mode Console Readout RF Heating
- ‘Up To’ 15 Minutes Per Pulse Sequence (default)

How To Read MR Conditional Labels

What is ‘Conditionality’?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- ‘Up To’ 2 μT Console Readout RF Heating

How To Read MR Conditional Labels

What is ‘Conditionality’?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
“AND” / “OR”	
$B1+_{RMS}$	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- But Which To Use When Both Are Listed?

How To Read MR Conditional Labels

What is 'Conditionality'?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 µT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- 'Up To' 150 T/m/s Console Readout For Stim / Voltage

How To Read MR Conditional Labels

What is 'Conditionality'?

"Just Follow The Label, Right?"

How To Read MR Conditional Labels

What is 'Conditionality'?

Acme Buzz-O-Matic Neurostimulator	
Static Magnetic Field	1.5 or 3.0 Tesla
Spatial Field Gradient	9 T/m (900 G/cm)
SAR	Normal Operating Mode (up to 15 minutes)
$B1+_{RMS}$	2 μT at 1.5 T
Time-Varying Gradient	150 T/m/s (150 mT/m/ms)

- 'Up To' Highest System Rating For Torque
- *But* 'At' 1.5 or 3.0 T For Resonant Circuit Heating
- 'Up To' 9 T/m Device Exposure For Attraction
- 'Up To' Normal Mode Console Readout RF Heating
- 'Up To' 15 Minutes Per Pulse Sequence (default)
- 'Up To' 2 μT Console Readout RF Heating
- 'Up To' 150 T/m/s Console Readout For Stim / Voltage

How MR Conditional Labels Are Written

How Are They Tested?

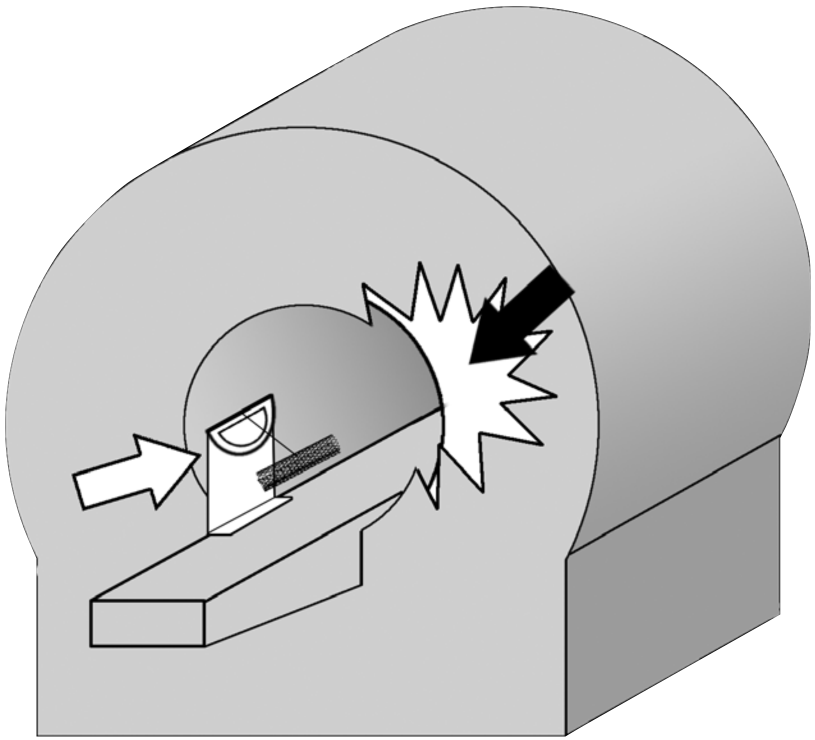
How MR Conditional Labels Are Written

How Are They Tested?

- Manufacturer Defines Test Parameters
- They Then Test (or contract-out testing)
- Manufacturer Reviews Test Data
  (& Decides On Whatever Parameters They Wish For FDA Submittal)
- FDA Reviews
  - Approves, or
  - Requests Supporting Data For Claims, or
  - Rejects

How MR Conditional Labels Are Written

How Are They Tested?



How MR Conditional Labels Are Written

How Are They Tested?

- Testing / Labeling Is ***Not*** Required To Indicate Safe Limits / Thresholds
- Manufacturer's Can Build-In Whatever Safety Margins They Choose To

How MR Conditional Labels Are Written

How Are They Tested?

- I Worked With A Manufacturer On Relabeling Their Device With A Greater Spatial Field Gradient Value (extrapolated).

- When the Manufacturer Sent Me A Courtesy Copy Of Their Draft FDA Application, I Discovered A Math Error. They Were Applying For Labeling ~65% Of What The Calculation Said They Could.

- Attorneys / Risk-Management Said It Wasn't Worth Correcting For The FDA.

How MR Conditional Labels Are Written

What If We Go Beyond / Outside MR Conditional Terms?

How MR Conditional Labels Are Written

What If We Go Beyond / Outside MR Conditional Terms?

- If You Violate Even 1 Of 20 MR Conditional Conditions, That Scan Is 'Off-Label'

But…

- If You Know How To Identify MRI Risks & How To Break-Down MR Conditional Labeling, You Can Make Many Safety Deductions Even If You Go Outside MR Conditional Conditions

What About Devices (FBs) With No Labels?

“This Device Not Tested For MR Safety”

What About Devices (FBs) With No Labels?

"This Device Not Tested For MR Safety"

- Just Because It Hasn't Been Manufacturer Tested Doesn't Mean You Can't Make Safety Assessments
  - Published Studies
  - Exposure Analysis (i.e., 'to what will it be exposed?')
  - Applying Standards (e.g., 'FDA 2 cm standard')
  - Materials Analysis (e.g., 'are the materials ferromagnetic?')

“Off-Label” ≠ Unsafe

It Means No Manufacturer Guidance

“Off-Label” ≠ Unsafe

It Means No Manufacturer Guidance

- When Manufacturer MRI Safety Is ***Not*** Provided, A Site May Operate Under The *Presumption* That Unlabeled / Off-Label Imaging Is Unsafe, But ***MR Unsafe*** Is A Known Condition… Not An Unknown One.

- Yes, Some Off-Label Conditions Are Dangerous, But Just Because It’s Unlabeled / Off-Label Does Not Automatically Mean That All MR Imaging Is Dangerous.

It's All About The Harm

MRI Hippocratic Oath: First *Find* The Harm, Then Avoid It

It's All About The Harm

MRI Hippocratic Oath: First *Find* The Harm, Then Avoid It

- Risk vs. Benefit Requires That You Identify & Characterize The Risks
- In Identifying The Specific Risks, You Also Define What Is In Your Control / Outside Of Your Control To Manage
- If You Can Not Identify Specific Risks / Harms, You're Making Decisions Out Of Ignorance, Not Information

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

What It Means To Go 'Off-Label'

Tobias Gilk - Sept 23, 2023

Outline

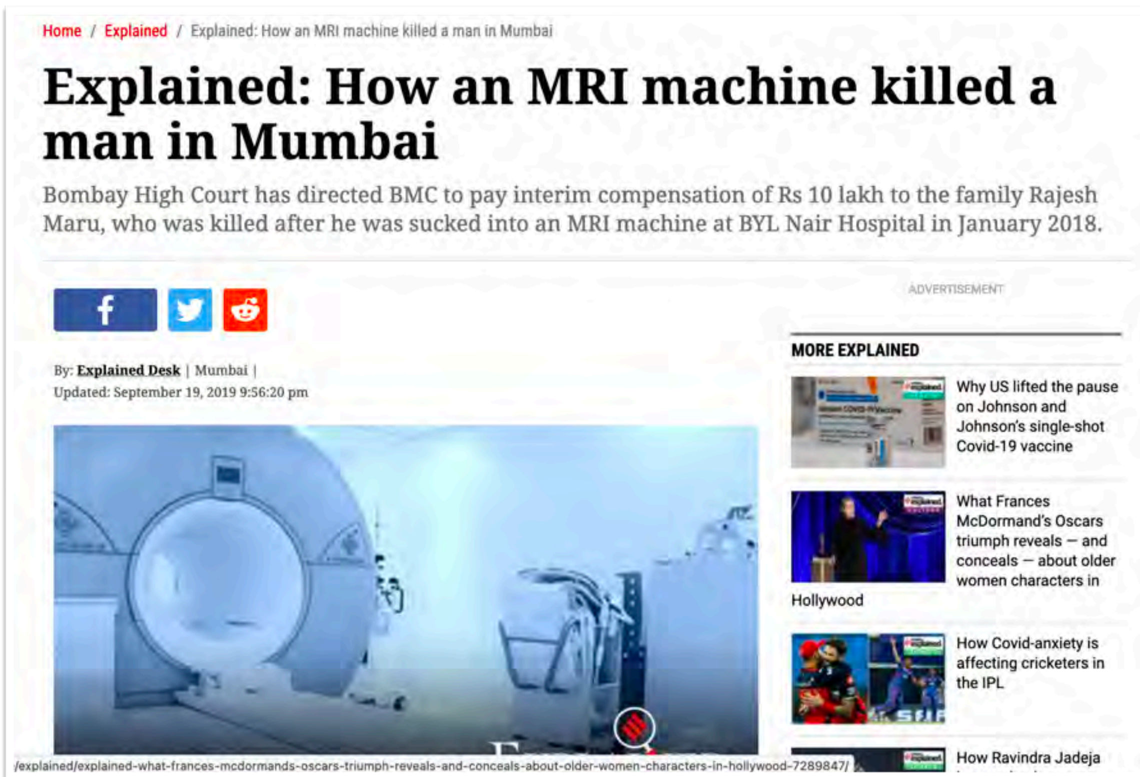
What It Means To Go 'Off-Label'

- Intro
- How Patients Are Harmed In MRI
- 'Off-Label' ≠ Automatically Unsafe
- It's About The Harm
- Tools For Quantifying Risk & Categorizing Devices
- Q & A

How Are Patients Harmed In MRI?

How Are Patients Harmed In MRI?

How Are Patients Harmed In MRI?


Home / Explained / Explained: How an MRI machine killed a man in Mumbai

Explained: How an MRI machine killed a man in Mumbai

Bombay High Court has directed BMC to pay interim compensation of Rs 10 lakh to the family Rajesh Maru, who was killed after he was sucked into an MRI machine at BYL Nair Hospital in January 2018.

ADVERTISEMENT

By: **Explained Desk** | Mumbai |
Updated: September 19, 2019 9:56:20 pm

MORE EXPLAINED

Why US lifted the pause on Johnson and Johnson's single-shot Covid-19 vaccine

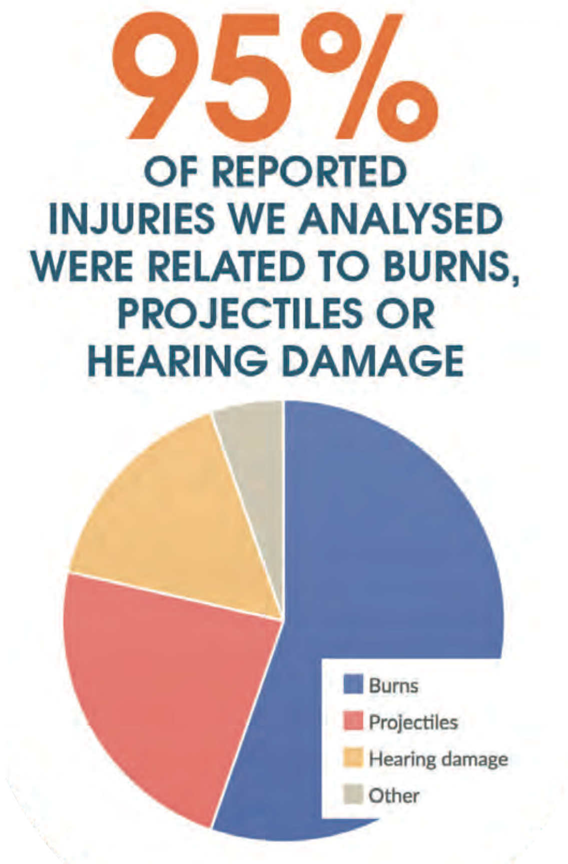
What Frances McDormand's Oscars triumph reveals — and conceals — about older women characters in Hollywood

How Covid-anxiety is affecting cricketers in the IPL

How Ravindra Jadeja

/explained/explained-what-frances-mcdormands-oscars-triumph-reveals-and-conceals-about-older-women-characters-in-hollywood-7289847/

How Are Patients Harmed In MRI?



However…

Internal (Implant-Related) Injuries Are <u>*NOT*</u> Well Quantified.

How Are Patients Harmed In MRI?

MAUDE Adverse Event Report: MRI

FDA Home · Medical Devices · Databases

CDRH SuperSearch

510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

MRI Back to Search Results

Device Problem Improper or Incorrect Procedure or Method (2017)
Patient Problems Death (1802); Hemorrhage, Subarachnoid (1893)
Event Date 08/12/2016
Event Type Death
Event Description
My father had an mri of the spine ordered at (b)(6) center. He has a history of a craniotomy for aneurysm clipping in 1982, and should not have an mri due to the risk of migration of clips and possible bleeding. Md well aware of his history, and ordered mri anyway. During the mri, my father became unresponsive and was posturing. A f/u ct scan of the brain showed a massive subarachnoid hemorrhage. He passed away about 15 hours later. After the mri and hemorrhage event, md came to speak to my mother, and informed her that they had made a mistake, and that the mri should never have been ordered, and likely caused the massive brain hemorrhage. I am concerned that they ordered this test, being well aware of the fact that my father had aneurysm clips in his brain, as this was documented in his admitting h&p, by the very md that ordered the mri. Please investigate.

Search Alerts/Recalls

How Are Patients Harmed In MRI?

A woman dies after a resonance 'blows' her morphine pump

The patient had the device for the administration of this opiate four years before because of her back pains

How Are Patients Harmed In MRI?

How Are Patients Harmed In MRI?

- Implant & Device Adverse Events Can Be Some Of The Most Dangerous!
- While Very Rare, The Poor Quantification (And Reluctance To Discuss Them) Leads Us To Mis-Estimate Risk.

How Are Patients Harmed In MRI?

“Cowboys” and “Ghosts”

Allows Everything
In MRI b/c
“Risks Are Overblown”

Prohibits Everything
In MRI b/c
“It Could Kill The Patient”

‘Off-Label’ ≠ Automatically Unsafe

‘Off-Label’ ≠ Automatically Unsafe
MR Unsafe

Known to pose hazards in all MRI environments

MR Unsafe - an item that is known to pose hazards in all MRI environments. MR Unsafe items include magnetic items such as a pair of ferromagnetic scissors.

‘Off-Label’ ≠ Automatically Unsafe

MR Unsafe

- Labeled “MR Unsafe” Is An Affirmative Condition…

  “Known to pose (unacceptable) hazards in MR environment”

- If You Only *Presume* The Hazard, That Doesn’t Make A Device “Unsafe Equivalent”

‘Off-Label’ ≠ Automatically Unsafe

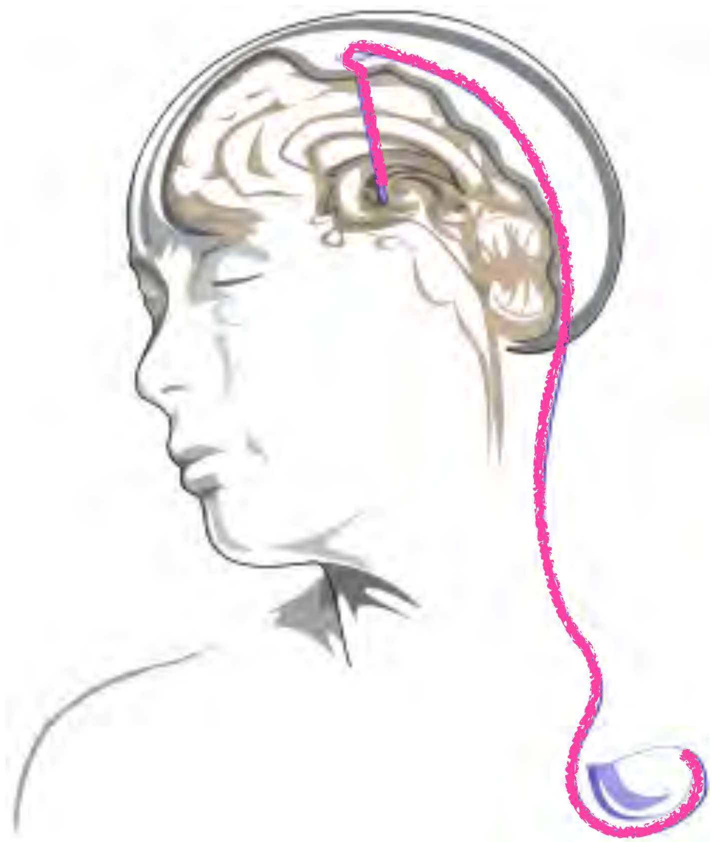
- Outside of MR Conditional Conditions or “off-label” means device manufacturer does not promise safety.

‘Off-Label’ ≠ Automatically Unsafe

- Sites may elect to presume “off-label” is unsafe (unless / until further information is developed), but this is operational.

‘Off-Label’ ≠ Automatically Unsafe

- Presumption is based on ignorance, not informed risk-assessment.



It’s About Harm

It’s About Harm

- If you can’t identify the specific harms at risk, you can’t mitigate them.

It's About Harm

Static Magnetic Field Harms

- Twisting (B0)
- Pulling (SFG)
- Device Functional Interference

It's About Harm

Time-Varying Gradient Harms

- Neuromuscular Stimulation
- Vibration
- "False Feedback" (for active, sensing devices)
- Heating (often not clinically significant)

It’s About Harm

Radio Frequency (RF) Magnetic Field Harms

- Diffuse Thermal Loading (typically managed by MRI scanner)
- Focal Heating

Tools For Quantifying Risk & Categorizing Devices

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

Field Strength: For Torque: All lesser values included

For RF Heating: May be introducing greater risks

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

Spatial Gradient: For Translation / Attraction: All lesser values included

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

Time-Varying Gradient:	For Stimulation & Vibration: All lesser values included

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

RF SAR / B1+: For Heating: All lesser values included

Tools For Quantifying Risk & Categorizing Devices

Working From MR Conditional Labeling

If you're going 'off-label' for…

Patient Position: Changing position may change exposures & may significantly change risk profile.

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

What Are Categorical Safety Statements?

- When An Entire Category Of Implants Have…
  - Similar shapes / sizes
  - Similar material composition

We can begin to identify safety profile by class / category.

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

When Do Categories NOT Work?

- When Implants Within A Category Have…
  - Very different sizes / shapes
  - Different material composition

For example, coronary stents vs. femoral stents

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

- Dr. Kanal Statements On Coronary Stents
- Dr. Shellock Statements On
  - Coronary Stents
  - Annuloplasty Rings
  - Artificial Heart Valves

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

Guidelines for the Management of Patients with Coronary Artery Stents Referred for MRI Procedures

Frank G. Shellock, Ph.D., FACR, FISMRM, FACC
Adjunct Clinical Professor of Radiology and Medicine
Keck School of Medicine, University of Southern California
www.MRIsafety.com

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

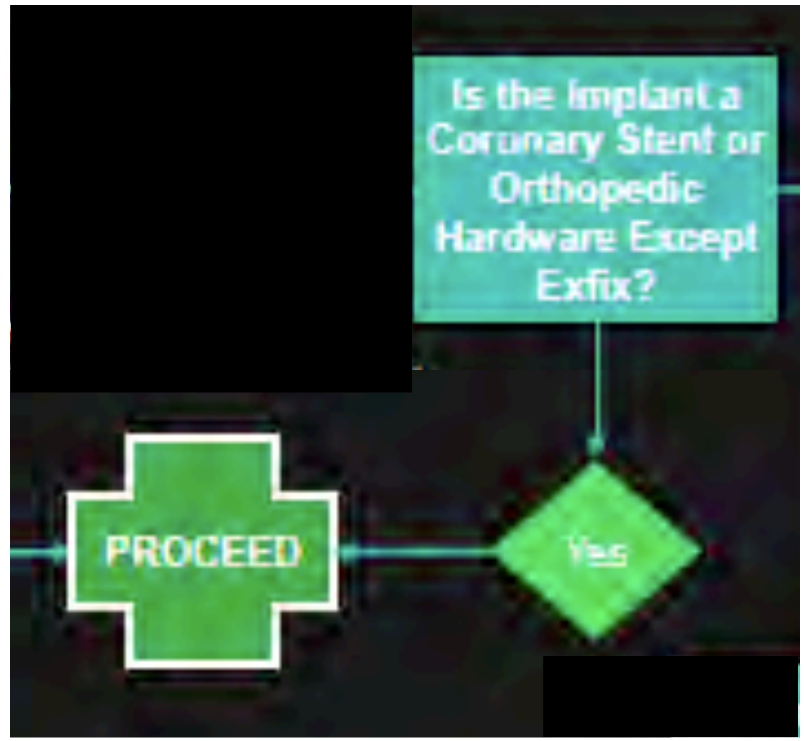
MRI labeling information exists for many coronary artery stents (3, 22). By following the pertinent MRI labeling information (i.e., presented in the Instructions for Use, Patient Identification Card, etc.), patients with coronary artery stents have safely undergone MRI examinations, including those performed at 1.5- and 3-Tesla. Importantly, there has never been an adverse event reported in association with performing MRI in patients with these particular implants.

Tools For Quantifying Risk & Categorizing Devices

Categorical Safety Statements

- I have worked with some radiologists who make site safety statements about passive orthopedic implants.

- Categorical safety statements are at the discretion / authority of the supervising physician (radiologist).



Tools For Quantifying Risk & Categorizing Devices

Exposure Analysis

- It *WILL* be exposed to static magnetic fields
  - Field Strength of Exposure (Torque)
  - Spatial Field Gradient of Exposure (Translation)
- To What Degree will it be exposed to Time-Varying Gradients?
- To What Degree will it be exposed to RF Magnetic Fields?

Tools For Quantifying Risk & Categorizing Devices

Exposure Analysis

C. Heating

The radiofrequency (RF) and time-varying gradient fields (dB/dt) of the MR system can induce heating of the tissue adjacent to the medical device and/or heating of the medical device itself. This hazard should be addressed for all medical devices anticipated to enter the bore of the MR system.

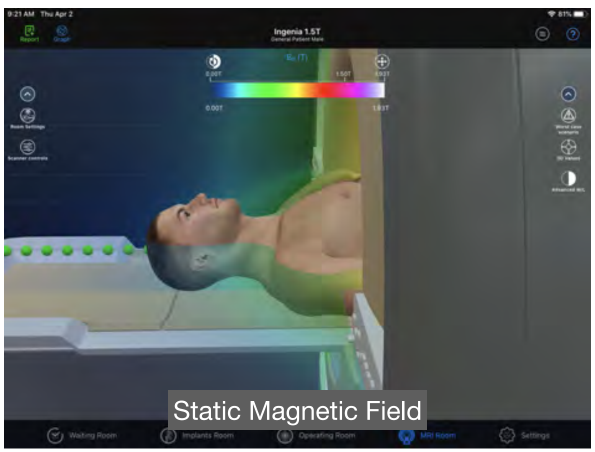
"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"
US FDA (2021)

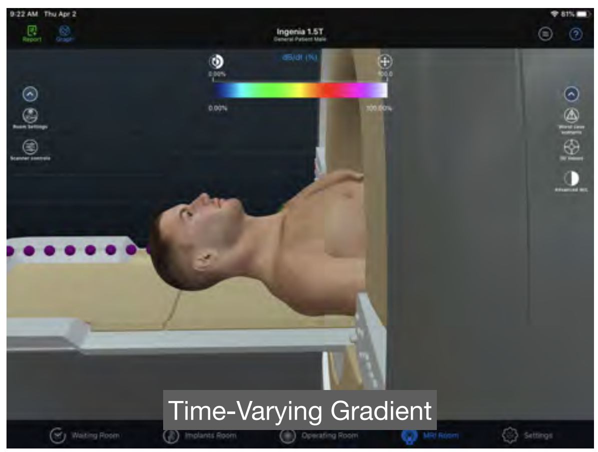
Tools For Quantifying Risk & Categorizing Devices

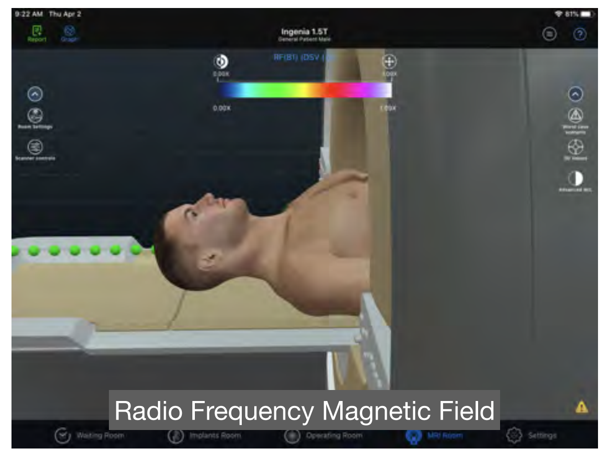
Exposure Analysis

In other words…

- If it's wholly outside the bore, it will not be exposed to meaningful RF, nor meaningful time-varying gradient energies.







Tools For Quantifying Risk & Categorizing Devices

Materials Analysis - Static Magnetic Field

- These Are Some Nominally Non-Magnetic Materials
  - 316L Stainless Steel
  - Nitinol
  - Phynox
  - Elgiloy
  - Titanium (CP)

Tools For Quantifying Risk & Categorizing Devices

Materials Analysis - Time Varying Gradients & RF

- These Are Some Nominally Non-Electrically Conductive Materials
  - Silicone
  - PEEK

- Greater Risks From Insulated Electrical Conductors

Tools For Quantifying Risk & Categorizing Devices

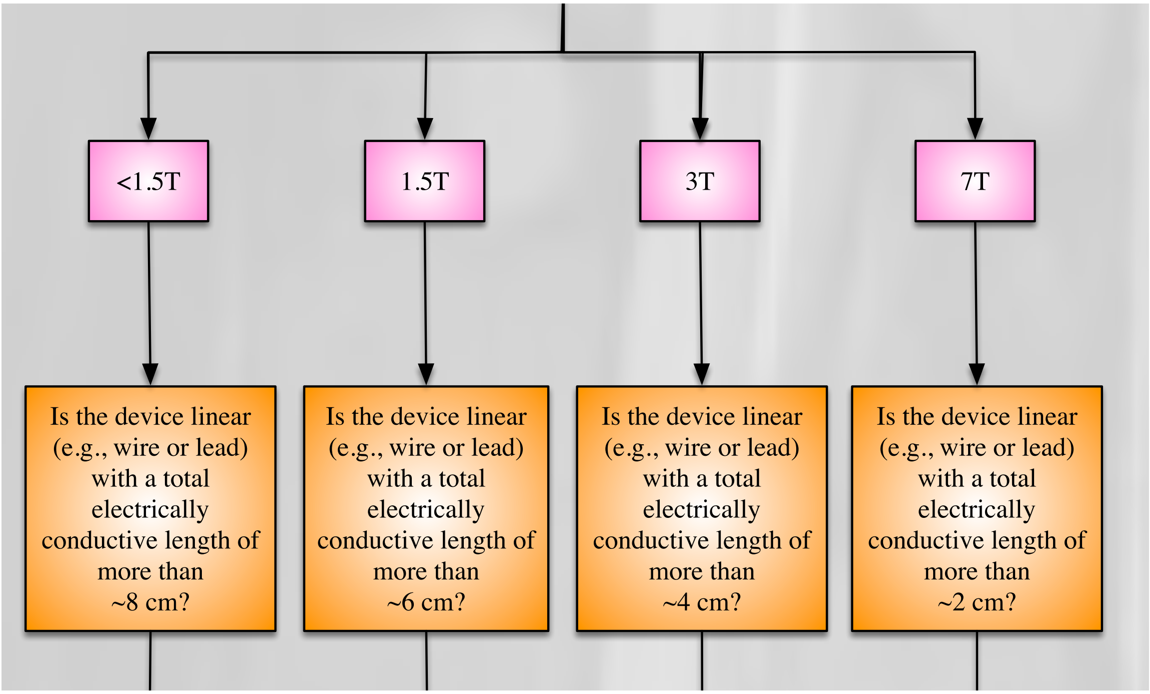
Size Analysis

A passive implant with dimensions of less than 2 cm in all directions and at least 3 cm away from another passive implant does not need to be tested with respect to RF induced heating at 3.0 T or less, as it is expected to generate a temperature increase of less than 2 °C in Normal Operating Mode, over the course of 1 hour of exposure. This test exclusion is not valid (i)

"Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment"
US FDA (2021)

Tools For Quantifying Risk & Categorizing Devices

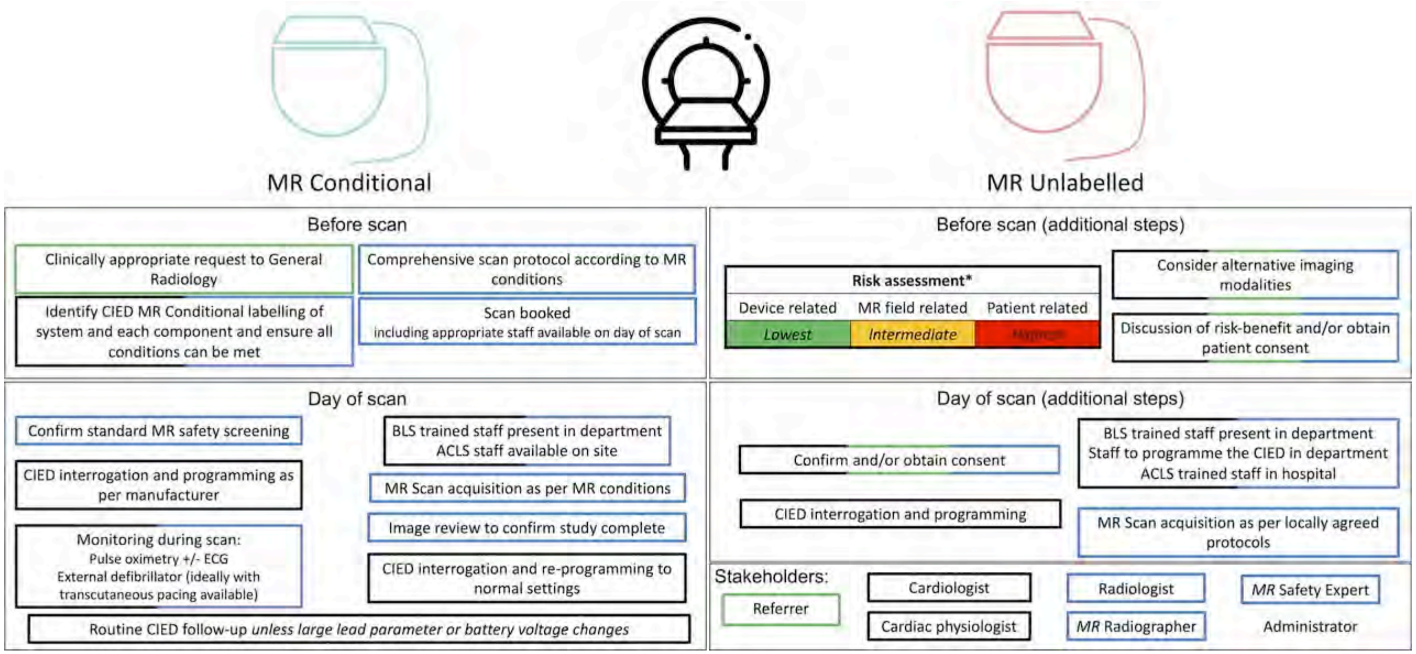
Size Analysis



“MR Safety Implant Decision Tree Diagram v. 1.6”
Dr. Emanuel Kanal

Tools For Quantifying Risk & Categorizing Devices

Literature



Joint British Society consensus recommendations for magnetic resonance imaging for patients with cardiac implantable electronic devices
https://heart.bmj.com/content/early/2022/09/14/heartjnl-2022-320810

“I Can’t Go Off-Label”

“I Can’t Go Off-Label”

But You Already Do… All The Time.

- GBCA Contrast Studies
  - Brain & Spine
  - Arterial / Vascular / Run-Off
  - Arthrogram
  - Breast
  - Pediatric Populations

“I Can’t Go Off-Label”

But You Already Do… All The Time.

- GBCA Contrast Studies

Off-Label Use of MRI Contrast Agents

In the past, radiologists often used GBCM in an off-label fashion (e.g., off-label higher doses or off- label indications). By definition, such usage is not approved by the FDA. However, physicians have some latitude in off-label GBCM use as guided by clinical circumstances as long as they can justify such usage in individual cases.

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

“I Can’t Go Off-Label”

But You Already Do… All The Time.

How did you decide to use contrast off-label?

- Reviewed literature?
- Consulted with peer experts?
- Consulted with certified MRI safety professionals?

Going ‘Off-Label’ Can Be Best Practice

Going ‘Off-Label’ Can Be Best Practice

- IV Valium & Status Epillepticus

Clinical Decision-Making To Go ‘Off-Label’

Clinical Decision-Making To Go ‘Off-Label’

- Risk v. Benefit

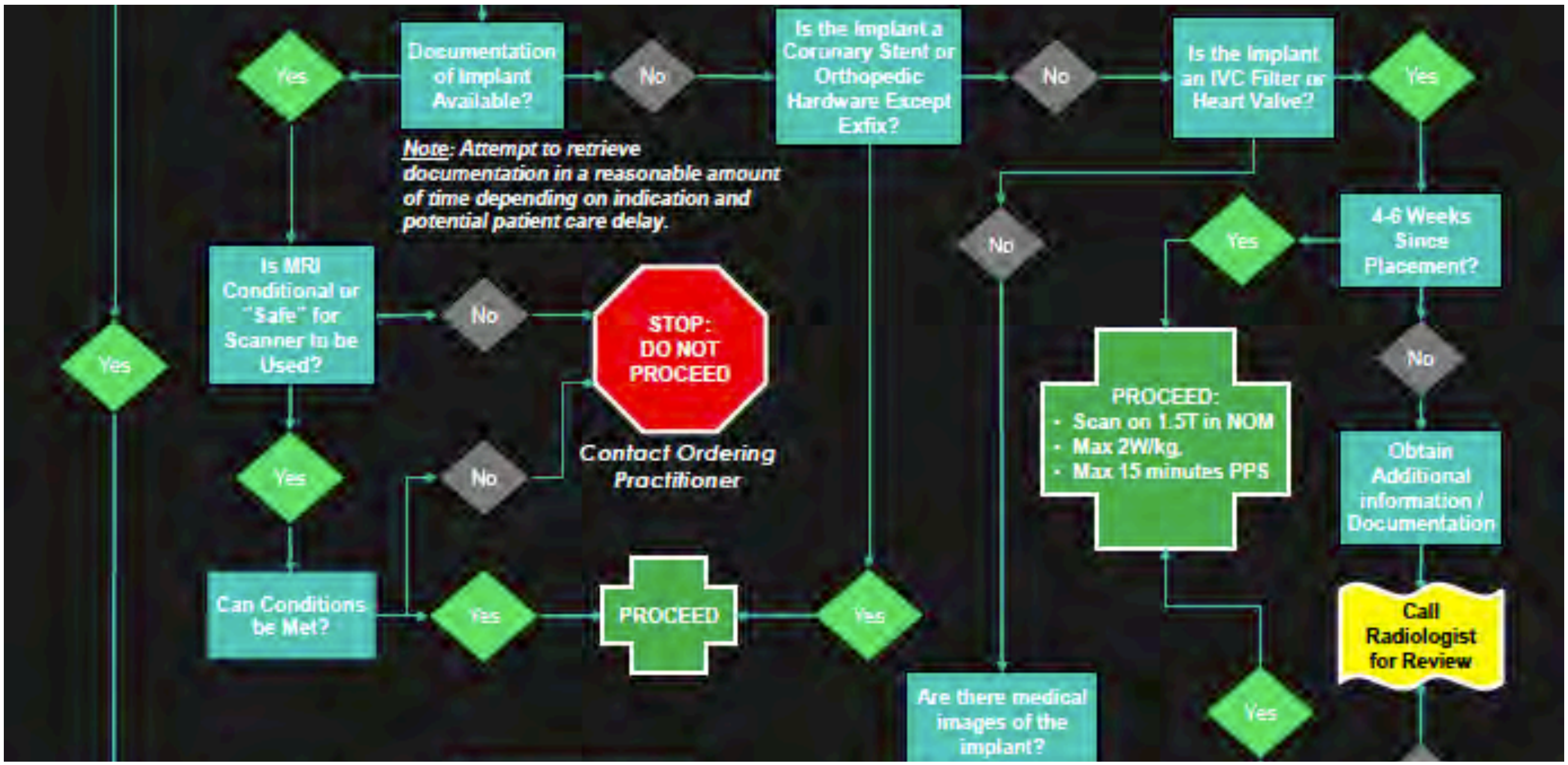
Risk

- Can be informed / quantified by anyone

Benefit

- To be determined by exam-supervising physician

Clinical Decision-Making To Go 'Off-Label'



Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

Gadolinium-Based Contrast Agents

(GBCA)

Tobias Gilk - Sept 23, 2023

Outline

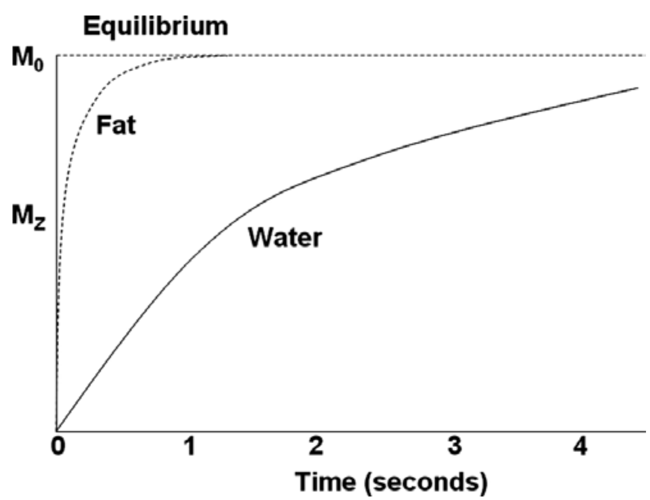
Gadolinium-Based Contrast Agents (GBCAs)

- Intro
- How GBCAs work
- Chelate Structures & Bonds
- NSF, Toxicity, Retention
- GBCAs in Pregnant / Pediatric Populations
- Q & A

How GBCAs Work

How GBCAs Work

- GBCAs change the relaxivity properties of water molecules near contrast molecules.
- Greater separation, over time, between water and other signal.



Chelate Structures & Bonds

Chelate Structures & Bonds

We Don’t Inject Gadolinium…

- Raw Gadolinium is a heavy metal & highly toxic
- We pair the Gd ion with another molecule to make it biologically inert
- Different chelates / ligands give the GBCA different attributes
  - Relaxivity
  - Stability

Chelate Structures & Bonds

Bonds

- Ionic
- Non-Ionic

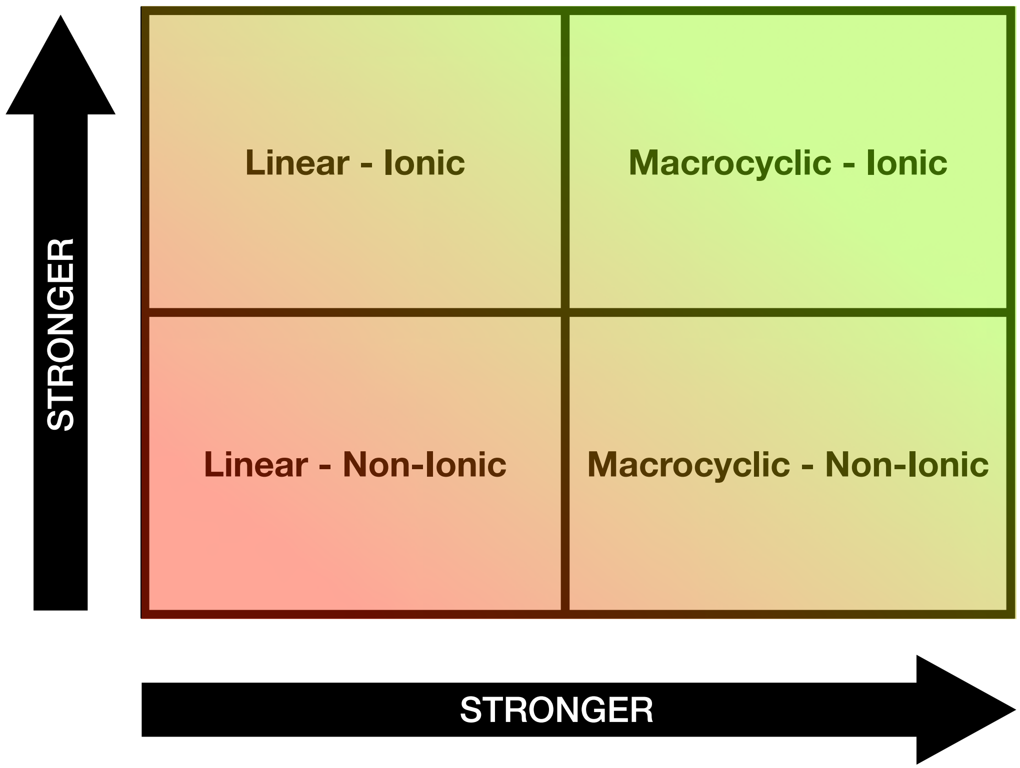
Chelate Structures & Bonds

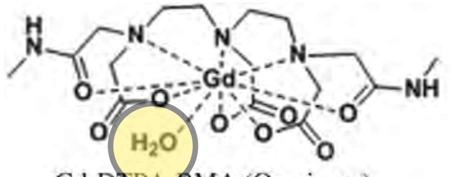
Structure

- Linear
- Macrocyclic

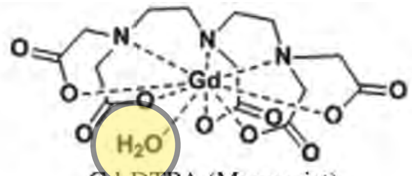
Chelate Structures & Bonds

Stability

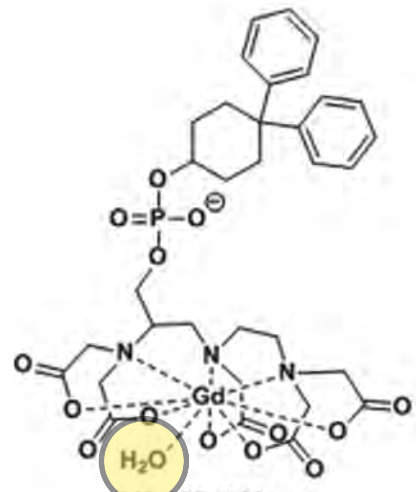




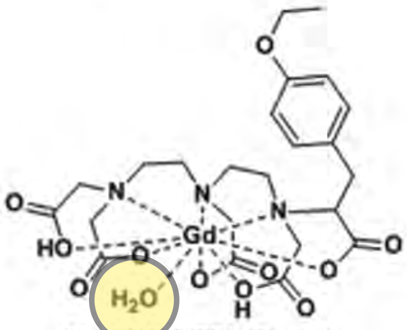
Gd-DTPA-BMA (Omniscan)
Gadodiamide
linear, charge-neutral



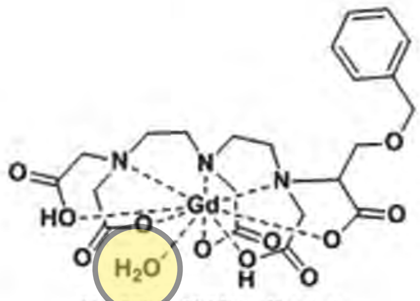
Gd-DTPA (Magnevist)
Gadopentetate dimeglumine
linear, charged



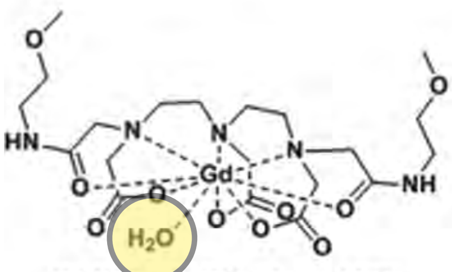
MS-325 (Ablavar)
Gadofosveset
linear, charged



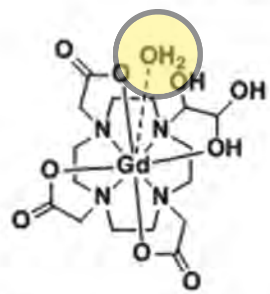
Gd-EOB-DTPA (Eovist)
Gadoxetic acid
linear, charged



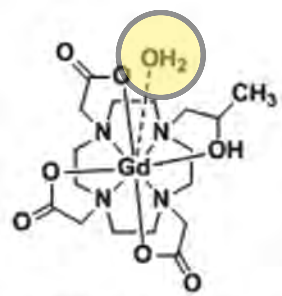
Gd-EOB-DTPA (Eovist)
Gadoxetic acid
linear, charged



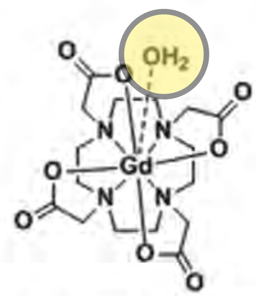
Gd-DTPA-BMEA (OptiMARK)
Gadoversetamide
linear, charge-neutral



Gd-DO3A-butrol (Gadovist)
Gadobutrol
cyclic, charge-neutral



Gd-HPDO3A (ProHance)
Gadoteridol
cyclic, charge-neutral



Gd-DOTA (Dotarem)
Gadoterate meglumine
cyclic, charged

Chelate Structures & Bonds

New US FDA-Approved Agents September, 2022

Guerbet gets FDA approval for Elucirem lower-dose MRI contrast
By Brian Casey, AuntMinnie.com staff writer

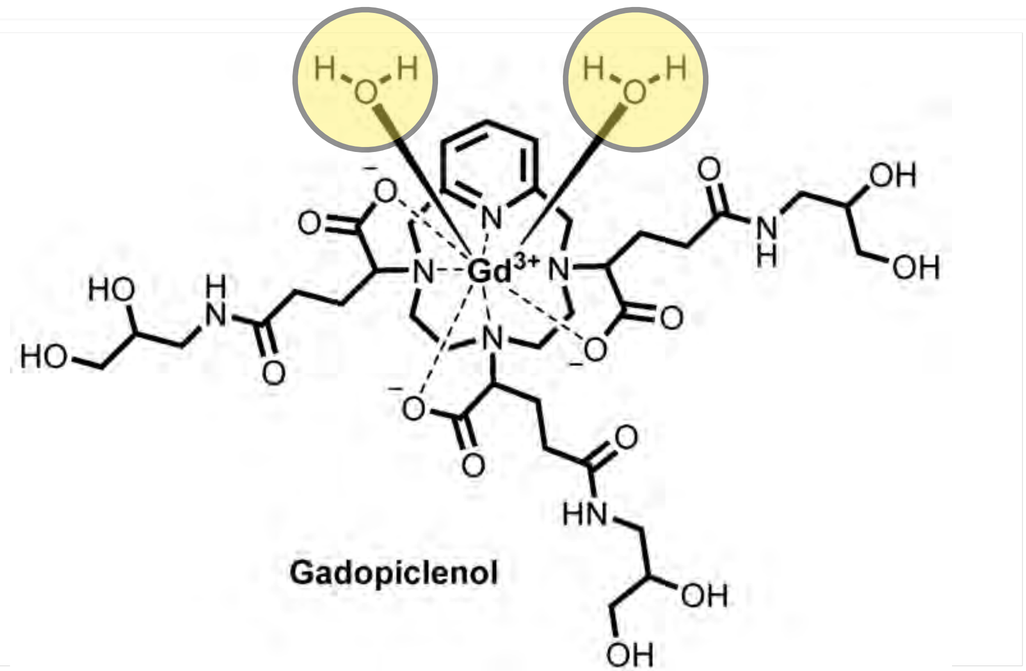
September 22, 2022 -- Contrast agent developer Guerbet has received approval from the U.S. Food and Drug Administration (FDA) for Elucirem (gadopiclenol), a new MRI contrast agent the company is developing in collaboration with Bracco.

Elucirem is a high-relaxivity macrocyclic gadolinium-based contrast agent (GBCA) that was developed with the goal of allowing radiology practices to use half the gadolinium dose of existing GBCAs. The product is designed to address ongoing concerns about gadolinium exposure in patients and has been designed with two sites for water molecule exchange to increase relaxivity and contrast, according to Guerbet.

Indications for the agent include detection and visualization of lesions with abnormal vascularity in

Chelate Structures & Bonds

New US FDA-Approved Agents September, 2022



Gadopiclenol

Chelate Structures & Bonds

What Do GBCAs Do?

It increases visual contrast.

… computers can detect contrast at lower levels than the human eye, so does our future suggest AI-enhanced contrast displays with markedly lower doses?

NSF, Toxicity, Retention

NSF, Toxicity, Retention

Nephrogenic Systemic Fibrosis

In 2005 - 2006 we 'discovered' Nephrogenic Systemic Fibrosis.

A syndrome of symptoms linked to patients who had received GBCAs.

Symptoms included painful hardening of skin and organs.

Was originally believed to only occur in patients with very poor renal function. Though we have a small number of NSF cases without clear evidence of poor renal function.

NSF, Toxicity, Retention

Nephrogenic Systemic Fibrosis

In 2007 the US FDA started grouping agents based on NSF association

Group 1		Group 2		Group 3	
~~Magnevist~~	~~(L-I)~~	Gadovist	(M-NI)	Ablavar	(L-I)
~~Omniscan~~	~~(L-NI)~~	Multihance	(L-I)	Eovist / Primavist	(L-I)
~~Optimark~~	~~(L-NI)~~	Prohance	(M-NI)		
		Dotarem / Clarisan	(M-I)		
		Elucerim / Vueway	(M-NI)		

NSF, Toxicity, Retention

Sub-NSF Toxicity

> "Lead is a potent neurotoxin, affecting the way our kids learn and behave. There is no safe level of lead for children."
>
> — Dr. Sean Palfrey, Medical Director, Boston Lead Poisoning Prevention Clinic

NSF, Toxicity, Retention

Sub-NSF Toxicity

- In 2016 Semelka et al describe ‘Gadolinium Deposition Disease’

Magnetic Resonance Imaging 34 (2016) 1383–1390

Contents lists available at ScienceDirect

Magnetic Resonance Imaging

journal homepage: www.mrijournal.com

ELSEVIER

Future Directions

Gadolinium deposition disease: Initial description of a disease that has been around for a while

CrossMark

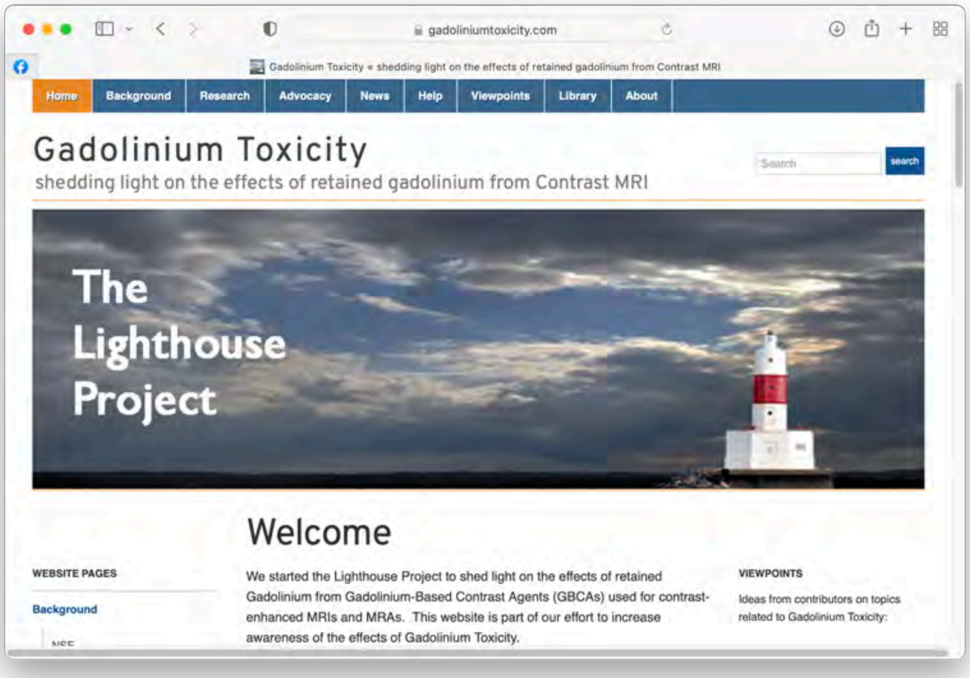
Richard C. Semelka [a,*], Joana Ramalho [a,b], Ami Vakharia [a], Mamdoh AlObaidy [a,c], Lauren M. Burke [a], Michael Jay [d], Miguel Ramalho [a,e]

https://mriquestions.com/uploads/3/4/5/7/34572113/gd_emelka_jrmi.pdf

NSF, Toxicity, Retention

Sub-NSF Toxicity

- GDD / Gadolinium Toxicity is not formally recognized as a disease.



NSF, Toxicity, Retention

Benign GBCA Retention

We used to think *all* GBCA was excreted.

It's not.

Some GBCA <u>from every agent</u> may be retained, indefinitely…

producing enhancement in regions where it collects.

NSF, Toxicity, Retention

Benign GBCA Retention

Recently, residual gadolinium has been found within the brain tissue of patients who received multiple doses of GBCAs over their lifetimes. For reasons that remain unclear, gadolinium deposition appears to occur preferentially in certain specific areas of the brain, even in the absence of clinically evident disease and in the setting of an intact blood brain barrier. Such deposition is not expected, and led the FDA to publish a Safety Alert in July of 2015 indicating that they were actively investigating the risk and clinical significance of these gadolinium deposits. To date, no adverse health effects have been uncovered, but the radiology community has initiated a rigorous investigation.

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

NSF, Toxicity, Retention

Benign GBCA Retention

Since small quantities of GBCA will remain / reside in patients, stability of the the agent is of significant importance.

Nonionic Linear GBCAs:

Optimark [21 (19–22) %, 0.44 (0.40–0.51) %/d) and Omniscan [20 (17–20) %, 0.16 (0.15–0.17) %/d].

Ionic Linear GBCAs:

Magnevist [1.9 (1.2–2.0) %, 0.16 (0.12–0.36) %/d], Multihance [1.9 (1.3–2.1) %, 0.18 (0.13–0.38) %/d], Vasovist [1.8 (1.4–1.9) %, 0.12 (0.11–0.18) %/d], and Primovist [1.1 (0.76–1.2) %, 0.07 (0.05–0.08) %/d].

Macrocyclic GBCAs:

Gadovist, Prohance, and Dotarem (all < limit of quantification of 0.1%, <0.007%/d).

Stability of Gadolinium-Based Magnetic Resonance Imaging Contrast Agents in Human Serum at 37°C

Frenzel et al

https://journals.lww.com/investigativeradiology/Abstract/2008/12000/Stability_of_Gadolinium_Based_Magnetic_Resonance.1.aspx

NSF, Toxicity, Retention

Renal Function Testing

Assessment of Risk (See Table 1 for the classification of GBCAs)

Group II agents

Based on the most recent scientific and clinical evidence [32-39] the ACR Committee on Drugs and Contrast Media considers the risk of NSF among patients exposed to standard or lower than standard doses of group II GBCAs is sufficiently low or possibly nonexistent such that assessment of renal function with a questionnaire or laboratory testing is optional prior to intravenous administration. As in all instances, group II GBCAs should only be administered if they are deemed necessary by the supervising radiologist, and the lowest dose needed for diagnosis should be used as deemed necessary by the supervising radiologist.[1]

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

NSF, Toxicity, Retention

Renal Function Testing

Assessment of Risk (See Table 1 for the classification of GBCAs)

Group II agents

Based on the most recent scientific and clinical evidence [32-39] the ACR Committee on Drugs and Contrast Media considers the risk of NSF among patients exposed to standard or lower than standard doses of group II GBCAs is sufficiently low or possibly nonexistent such that assessment of renal function with a questionnaire or laboratory testing is optional prior to intravenous administration. As in all instances, group II GBCAs should only be administered if they are deemed necessary by the supervising radiologist, and the lowest dose needed for diagnosis should be used as deemed necessary by the supervising radiologist.[1]

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

NSF, T

Renal Fu

WARNING: NEPHROGENIC SYSTEMIC FIBROSIS (NSF)

Gadolinium-based contrast agents (GBCAs) increase the risk for NSF among patients with impaired elimination of the drugs. Avoid use of GBCAs in these patients unless the diagnostic information is essential and not available with non-contrasted MRI or other modalities. NSF may result in fatal or debilitating fibrosis affecting the skin, muscle and internal organs.

- The risk for NSF appears highest among patients with:
    - Chronic, severe kidney disease (GFR < 30 ml/min/1.73m2), or
    - Acute kidney injury.
- Screen patients for acute kidney injury and other conditions that may reduce renal function. For patients at risk for chronically reduced renal function (e.g. age > 60 years, hypertension, diabetes), estimate the glomerular filtration rate (GFR) through laboratory testing.
- For patients at highest risk for NSF, do not exceed the recommended DOTAREM dose and allow a sufficient period of time for elimination of the drug from the body prior to any re-administration.

https://www.guerbet.com/en-us/products-solutions/contrast-agents/dotarem-gadoterate-meglumine-injection

GBCAs In Pregnant / Pediatric Populations

GBCAs In Pregnant / Pediatric Populations

Pregnant Patients

- Gadolinium Based Contrast Agents cross the placenta
- Once fetal kidneys are functional, GBCA will deposit in amniotic fluid

GBCAs In Pregnant / Pediatric Populations

Pregnant Patients

RESULTS Of 1 424 105 deliveries (48% girls; mean gestational age, 39 weeks), the overall rate of MRI was 3.97 per 1000 pregnancies. Comparing first-trimester MRI (n = 1737) to no MRI (n = 1 418 451), there were 19 stillbirths or deaths vs 9844 in the unexposed cohort (adjusted relative risk [RR], 1.68; 95% CI, 0.97 to 2.90) for an adjusted risk difference of 4.7 per 1000 person-years (95% CI, −1.6 to 11.0). The risk was also not significantly higher for congenital anomalies, neoplasm, or vision or hearing loss. Comparing gadolinium MRI (n = 397) with no MRI (n = 1 418 451), the hazard ratio for NSF-like outcomes was not statistically significant. The broader outcome of any rheumatological, inflammatory, or infiltrative skin condition occurred in 123 vs 384 180 births (adjusted HR, 1.36; 95% CI, 1.09 to 1.69) for an adjusted risk difference of 45.3 per 1000 person-years (95% CI, 11.3 to 86.8). Stillbirths and neonatal deaths occurred among 7 MRI-exposed vs 9844 unexposed pregnancies (adjusted RR, 3.70; 95% CI, 1.55 to 8.85) for an adjusted risk difference of 47.5 per 1000 pregnancies (95% CI, 9.7 to 138.2).

Association Between MRI Exposure During Pregnancy and Fetal and Childhood Outcomes
Ray et al
https://jamanetwork.com/journals/jama/article-abstract/2547756

GBCAs In Pregnant / Pediatric Populations

Pregnant Patients

CONCLUSIONS AND RELEVANCE Exposure to MRI during the first trimester of pregnancy compared with nonexposure was not associated with increased risk of harm to the fetus or in early childhood. Gadolinium MRI at any time during pregnancy was associated with an increased risk of a broad set of rheumatological, inflammatory, or infiltrative skin conditions and for stillbirth or neonatal death. The study may not have been able to detect rare adverse outcomes.

Association Between MRI Exposure During Pregnancy and Fetal and Childhood Outcomes
Ray et al
https://jamanetwork.com/journals/jama/article-abstract/2547756

GBCAs In Pregnant / Pediatric Populations

Pregnant Patients

Gadolinium Pregnancy Screening Statement

It has been shown that some gadolinium-based contrast agents (GBCAs) pass the placental barrier into the fetal circulation of nonhuman primates [1]. While multiple small sample size studies have not shown convincing evidence of adverse effects from fetal exposure to GBCAs [2,3], a 2016 retrospective study cited an increased risk of stillbirth/neonatal death as well as increased risk of rheumatologic, inflammatory, or infiltrative skin conditions in the offspring after GBCA exposure during pregnancy [4]. While, questions have been raised regarding study methodology, and these results have not been independently confirmed, both uncertainty and an abundance of caution in general about the effect of GBCA exposure and retention on the developing fetus has led to statements in the ACR Manual on Contrast Media [5] and the ACR Manual on MR Safety [6] recommending avoidance of routine administration of GBCAs to pregnant patients. A decision to administer GBCAs to a pregnant woman should only be made when there is the potential for significant clinical benefit that outweighs the unknown risk of fetal exposure and should be the product of discussion that involves the referring provider and patient.

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

GBCAs In Pregnant / Pediatric Populations

Breastfeeding Patients

Less than 0.04% of the intravascular dose given to the mother is excreted into the breast milk in the first 24 hours [4-6]. Because less than 1% of the contrast medium ingested by the infant is absorbed from its gastrointestinal tract [6,7], the expected systemic dose absorbed by the infant from the breast milk is less than 0.0004% of the intravascular dose given to the mother. This ingested amount is far less than the permissible dose for intravenous use in neonates. The likelihood of an adverse effect from such a minute fraction of gadolinium chelate absorbed from breast milk is remote [2]). However, the potential risks to the infant include direct toxicity (including toxicity from free gadolinium, because it is unknown how much, if any, of the gadolinium in breast milk is in the unchelated form) and allergic sensitization or reaction. These are theoretical concerns but none of these complications have been reported [5]. As in the case with iodinated contrast medium, the taste of the milk may be altered if it contains a gadolinium-based contrast medium [2].

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

GBCAs In Pregnant / Pediatric Populations

Breastfeeding Patients

Recommendation

Because of the very small percentage of gadolinium-based contrast medium that is excreted into the breast milk and absorbed by the infant's gut, we believe that the available data suggest that it is safe for the mother and infant to continue breast-feeding after receiving such an agent [6].

https://www.acr.org/-/media/ACR/Files/Clinical-Resources/Contrast_Media.pdf

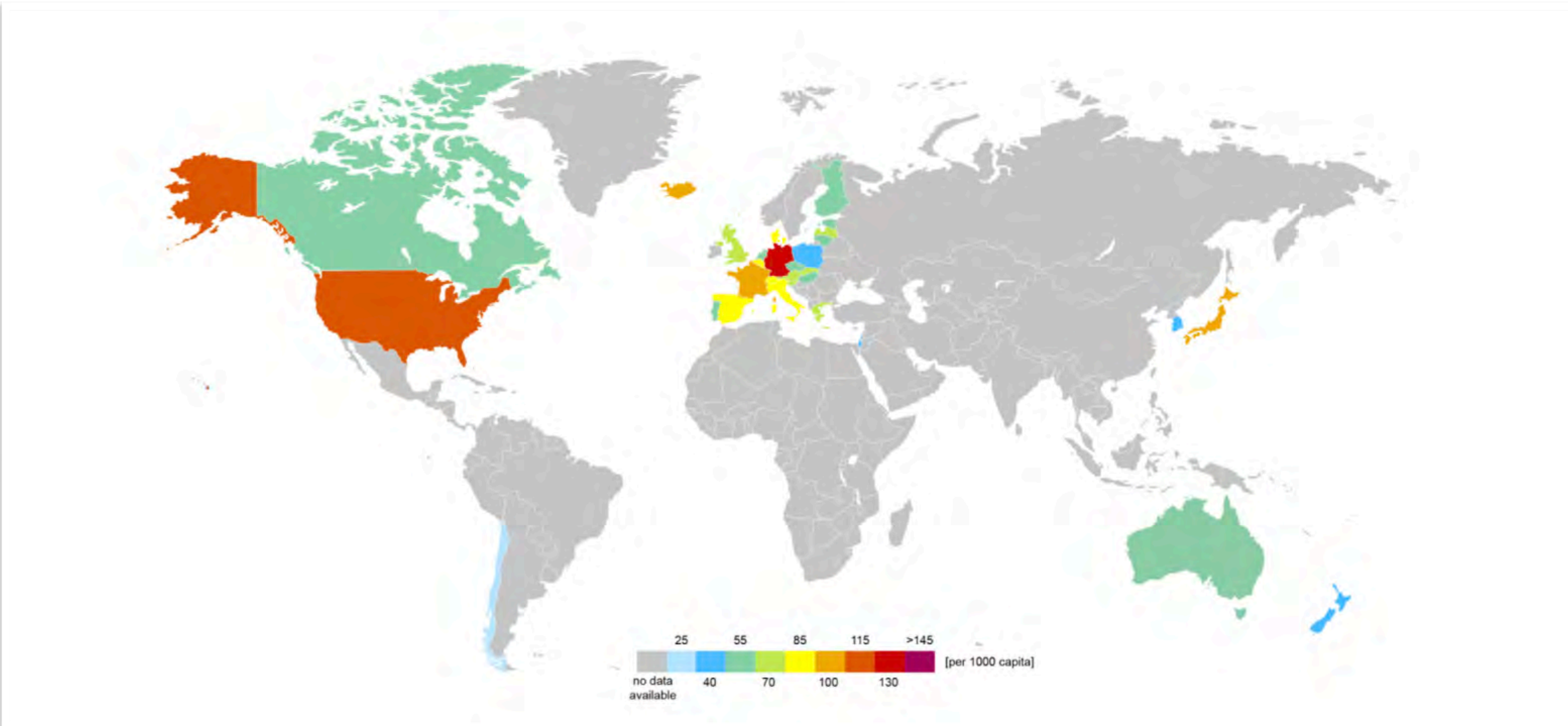
GBCAs In Pregnant / Pediatric Populations

Pediatric Patients

- The ACR & US FDA offer no specific guidance on GBCAs in pediatric populations.
- They defer to GBCA Manufacturer IFU

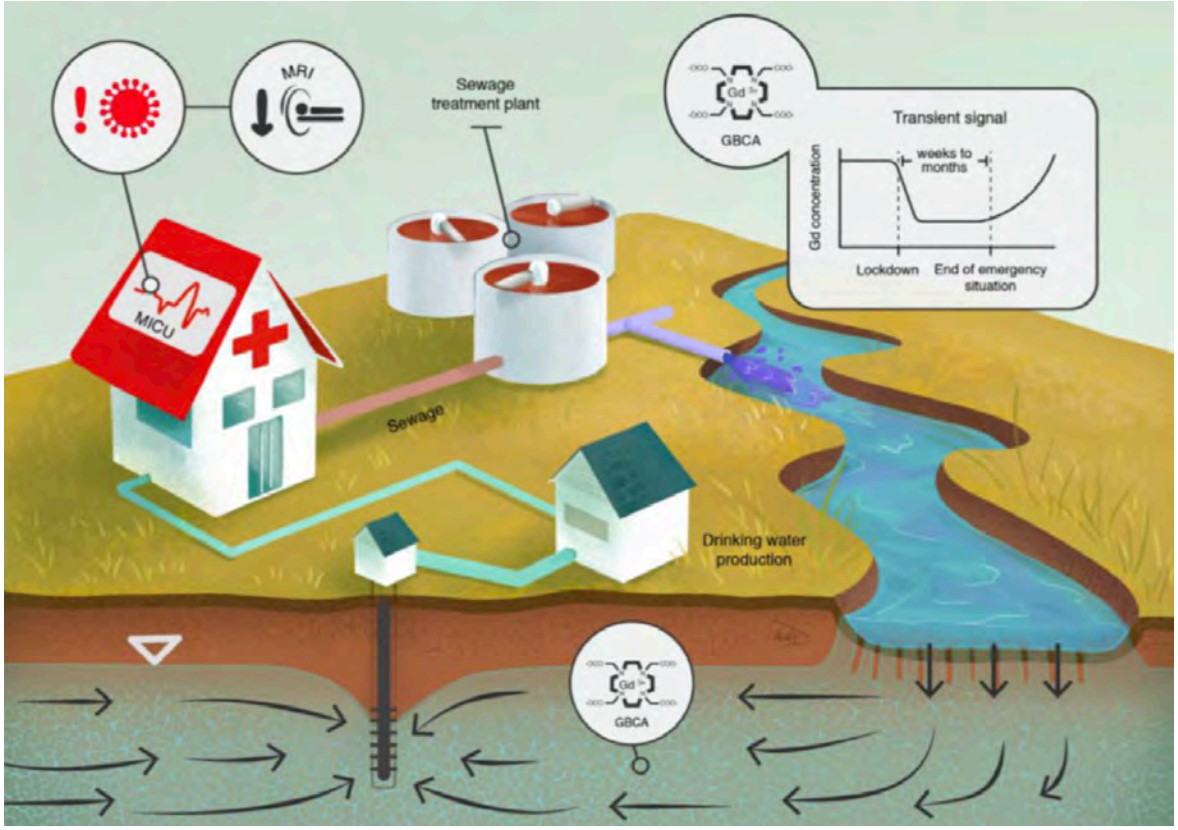
Anthropogenic Gadolinium Exposure

Anthropogenic Gadolinium Exposure



https://reader.elsevier.com/reader/sd/pii/S0043135420305030

Anthropogenic Gadolinium Exposure



https://reader.elsevier.com/reader/sd/pii/S0043135420305030

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

TGilk@GilkRadiologyConsultants.com
@tobiasgilk
www.facebook.com/groups/MRIsafety

MRI: Pregnancy, & Pediatrics

Tobias Gilk - Sept 23, 2023

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

MRI: Pregnancy & Pediatrics

- Intro
- Pregnancy Risks To MRI Patients
- Pregnancy Risks To Healthcare Workers
- Pediatric Population MRI Risks
- Pediatric Population MRI Safety Advantages
- Q & A

Pregnancy Risks To MRI Patients

Pregnancy Risks To MRI Patients
Non Contrast

MRI is

- Non carcinogenic
- Non mutinogenic
- Produces no lasting physiologic effects of any kind

Pregnancy Risks To MRI Patients
Non Contrast

Patient pregnancies: The vast majority of data today has failed to show that exposure to MR has deleterious effects on the developing fetus. Nevertheless, if pregnancy is established, the decision to proceed with a noncontrast MR study at 1.5 T should be based on the medical benefits weighed against unknown potential risk.

https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Pregnancy Risks To MRI Patients

Non Contrast

It’s worth noting that ACR Guidance on MRI for pregnant patients…

- ***Used to*** contain addition concern regarding imaging in 1st trimester
- First trimester concerns were removed from guidance because:
  - Majority of MRI studies of pregnant patients occur in 1st trimester (often before the patient is aware of the pregnancy)
  - No evidence in literature / research of any increased risk in 1st trimester

Pregnancy Risks To MRI Patients

Non Contrast

So if there are no known adverse effects…

- There is no ethical way to perform randomized controlled trials on pregnant patients
- There are small, individualized studies that appear to show small risks, in narrow timeframes within pregnancy… but without confirmed results

Pregnancy Risks To MRI Patients

Non Contrast

So we reduce even *possible* risks…

- Is MRI the best non-ionizing modality to obtain the diagnosis?
- Is the exam timely?
  - Will the clinical information inform care *during* the pregnancy?
- Reduce field strength exposure (if there's not a clear benefit from higher fields).
- Reduce energies (scan in Normal Mode)

Pregnancy Risks To MRI Patients

Non Contrast - Consent?

Do you obtain ‘informed consent’ to provide MRI for pregnant patients?

Informed Consent

- What are the identified additional / peculiar risks of a study
- What are the alternative options (pros & cons)
- What are the risks of not having the study
- Opportunity to discuss risks : benefits with physician

Pregnancy Risks To Healthcare Workers

Pregnancy Risks To Healthcare Workers

Health care practitioner pregnancies: Pregnant health care practitioners are permitted to work in and around the MR environment throughout all stages of their pregnancy.[24] Acceptable activities include, but are not limited to, positioning patients, scanning, archiving, injecting contrast, and entering the MR system room in response to an emergency. Although permitted to work in and around the MR environment, pregnant health care practitioners are requested not to remain within the MR scanner bore or Zone IV during actual data acquisition or scanning. These recommendations are based on the preponderance of data on 3-T magnetic fields. There is a paucity of data available to date regarding human pregnancy exposures to 7-T magnetic fields.

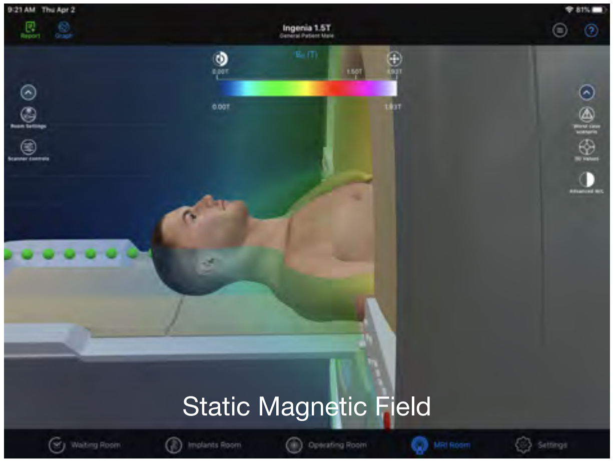
https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

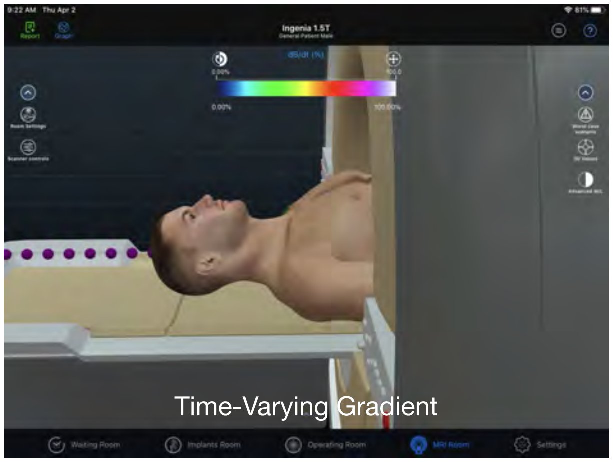
Pregnancy Risks To Healthcare Workers

Using our ‘exposure model’ of MRI risk, if the pregnant healthcare worker can be in the MRI scanner room *-except when active imaging-* what field exposures does this guidance feel are not meaningful concerns?

- Static Magnetic Fields
- Time-Varying Gradients
- RF Fields

Pregnancy Risks To Healthcare Workers





Pregnancy Risks To Healthcare Workers

Survey of reproductive health among female MR workers

Epidemiologic data were obtained to evaluate potential risks from exposure to the static and time-varying magnetic fields used in magnetic resonance (MR) imaging. A questionnaire sent to women workers in more than 90% of clinical MR facilities in the United States addressed menstrual-reproductive experiences, work activities, and potential confounders (eg, age, smoking, alcohol use). In 1,915 completed questionnaires, 1,421 pregnancies were reported: 280 occurred in an MR worker (technologist or nurse), 894 in an employee in another job, 54 in a student, and 193 in homemakers. Comparing MR-worker pregnancies with those occurring in employees at other jobs, a relative risk ratio of 1.27 (95% confidence interval [CI], 0.92-1.77) was found for spontaneous abortions; for conception taking more than 12 months, 0.90 (CI, 0.54-1.51); for delivery before 39 weeks, 1.19 (CI, 0.76-1.88); for birth weight below 5.5 lb (2.5 kg), 1.01 (CI, 0.50-2.04); and for male gender of the offspring, 0.99 (CI, 0.80-1.22). Adjustment for maternal age, smoking, and alcohol use also failed to markedly change any of the associations. These results suggest that there is not a substantial increase in these common adverse reproductive outcomes.

https://pubs.rsna.org/doi/10.1148/radiology.187.2.8475280

Pediatric Population MRI Risks

Pediatric Population MRI Risks

Pediatric MR Safety Concerns

Sedation and monitoring issues: Children form the largest group requiring sedation for MRI. Sedation may not always be required: for example, if an ultrafast MR examination may be diagnostic. When necessary, sedation protocols may vary from institution to institution according to procedures performed (diagnostic vs interventional), the complexity of the patient population (healthy preschoolers vs premature infants), the method of sedation (mild sedation vs general anesthesia), and the qualifications of the sedation provider.

https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Pediatric Population MRI Risks

Sedation / Anesthesia Guidance

PRACTICE PARAMETERS

Practice Advisory on Anesthetic Care for Magnetic Resonance Imaging

An Updated Report by the American Society of Anesthesiologists Task Force on Anesthetic Care for Magnetic Resonance Imaging

http://www.asahq.org/~/media/sites/asahq/files/public/resources/standards-guidelines/practice-advisory-on-anesthetic-care-for-magnetic-resonance-imaging.pdf

Pediatric Population MRI Risks

Sedation / Anesthesia Guidance

Do you feel that anesthesia (or other allied clinical services) are among the biggest risks in your MRI suites?

Pediatric Population MRI Risks

For the neonatal and the young pediatric population, special attention is needed in monitoring body temperature for both hypo- and hyperthermia, in addition to other vital signs. Temperature monitoring equipment that is approved for use in the MR suite is readily available. Commercially available, neonatal isolation transport units and other warming devices intended to be used in the MR environment are also available.

https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Pediatric Population MRI Risks

Screening Issues

Pediatric/minor patients: Children may not be reliable historians and, especially for older children and teenagers, should be questioned twice by Level 2 Personnel: once in the presence of parents or guardians and once separately to maximize the possibility that all potential dangers are disclosed. Therefore, it is recommended that they be gowned before entering Zone IV to help ensure that no metallic objects, toys, or other unacceptable items inadvertently find their way into Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent potential risks and should be discouraged from entering Zone IV.

https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Pediatric Population MRI Risks

Screening Issues

Companions in Zones III or IV: Those deemed appropriate to accompany or remain with the patient should be screened using the same criteria as anyone else entering Zone IV.

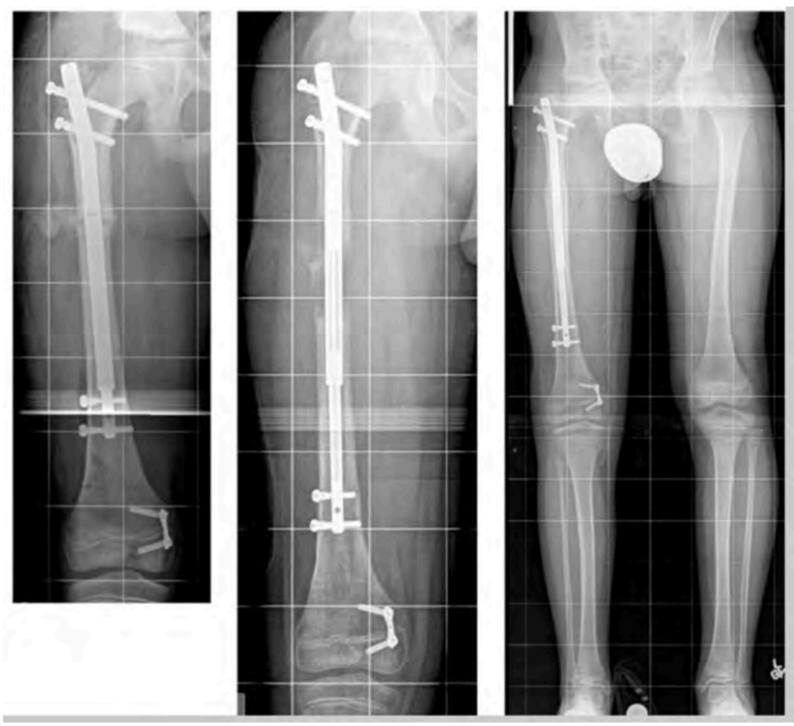
In general, it would be prudent to limit accompanying companions to a single individual. Only a qualified, responsible Level 2 MR Physician should make screening criteria exceptions.

Hearing protection and MR Safe/MR Conditional seating are recommended for accompanying companions within the MR scan room.

https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Pediatric Population MRI Risks

Pediatric - Specific Implants / Devices



PRECISE Telescoping Intramedullary Rod System

MAGEC Telescoping Spinal Implant

Pediatric Population MRI Safety Advantages

Pediatric Population MRI Safety Advantages

Smaller habitus

- Likely naturally further away from both RF and gradient transmitters
- Smaller mass means less total absorbed energies

Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

Pediatric Population MRI Safety Advantages

Newborns / Neonates

- Can’t vaso-constrict
- Shed heat, uncontrollably
- Less likely to have ‘overheating’ concerns

Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

Physical Environment MRI Safety

Tobias Gilk - Sept 24, 2023

Tobias Gilk,
MRSO, MRSE

- Past Member ACR MRI Safety Committee
- Contributing Author 2007, 2019 & 2020 ACR MRI Safety Guidance
- Founding Board Member / Past Chair ABMRS
- International Trainer on MRI Safety

ABMRS Content Disclosure

This presentation is not sponsored by or affiliated with the American Board of Magnetic Resonance Safety (ABMRS).

As a member of the the Board of the ABMRS, I am prohibited from speaking on specific examination question content, but permitted to provide education on MRI safety concepts and principles.

This presentation is not an exam preparation for any examination.

Rules of the Road

- Everything on the screen is for you (you can copy or take photos).
- If you have questions, ask!
- If you disagree, please speak up.

Outline

Physical Environment MRI Safety

- Intro
- Magnetic Field Reach
- Zones
- Cryogen Safety
- Novel MRI Systems
- Q & A

Magnetic Field Reach

Magnetic Field Reach

Static Field

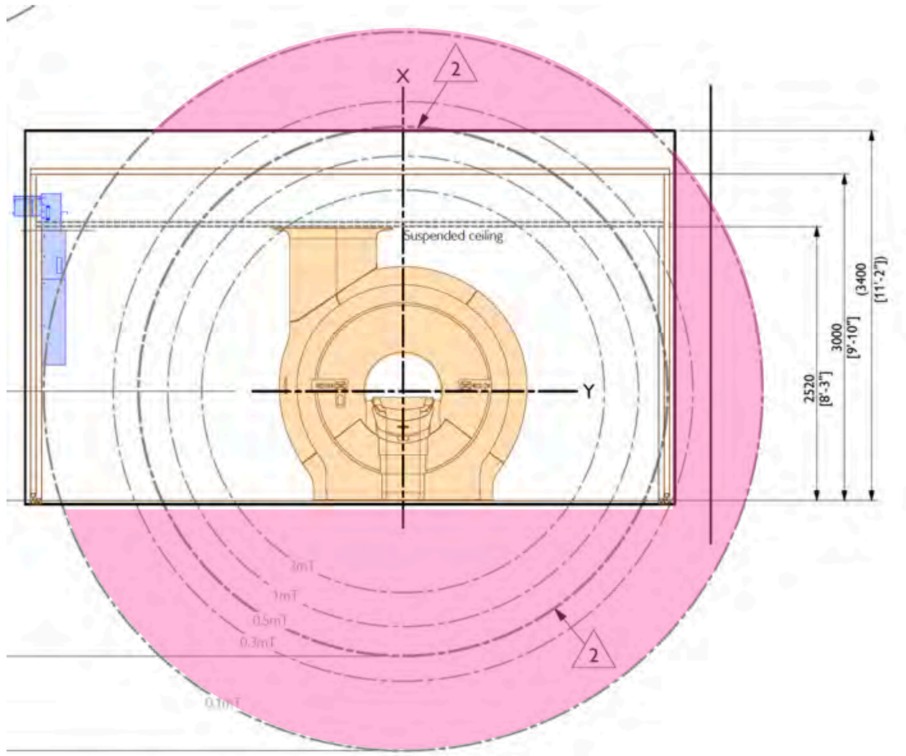
- In Construction, many construction materials do not contain magnetic fields.

- Steel structures will interact with magnetic fringe field, reshaping it.

- Steel structures can become magnetized, or ‘magnetically contaminated’, which can affect future functions in the space.

Magnetic Field Reach

Static Field



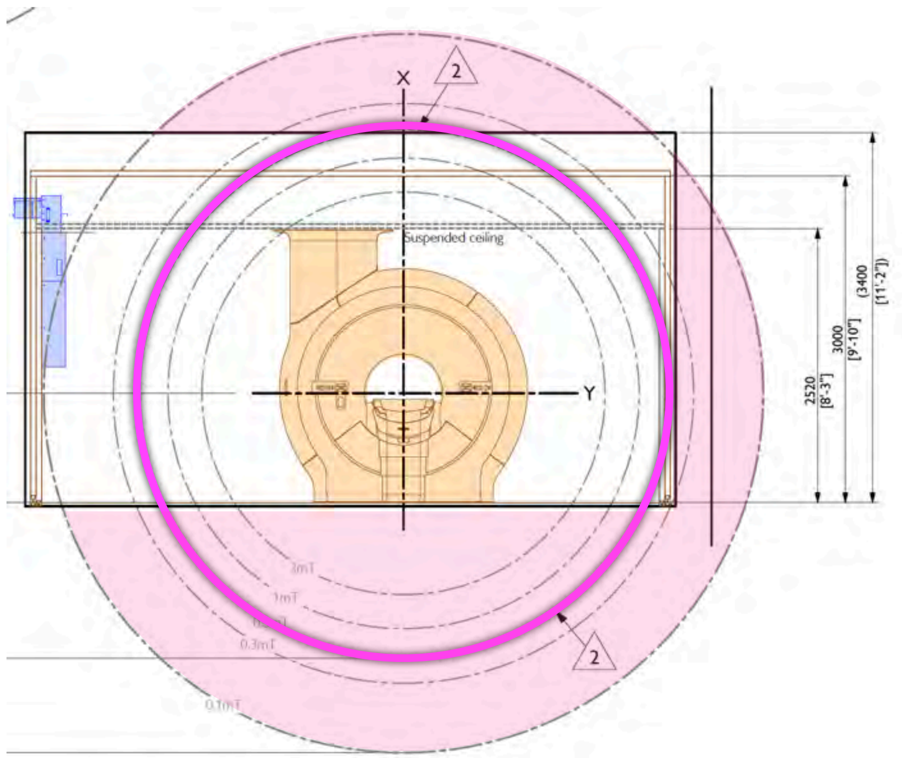
Magnetic Field Reach

9 Gauss (0.9 mT) is the new 5 Gauss (0.5 mT)

- Last month the IEC changed the standard for static field safety for unscreened persons from 5 Gauss (0.5 mT) to 9 Gauss (0.9 mT)
- IEC governs *manufacture* of MRI equipment, but this change has obvious implications for all existing MRIs
- US FDA does not have independent safety standard… they reference IEC
- I understand EU regulation references ICNIRP, so perhaps more steps

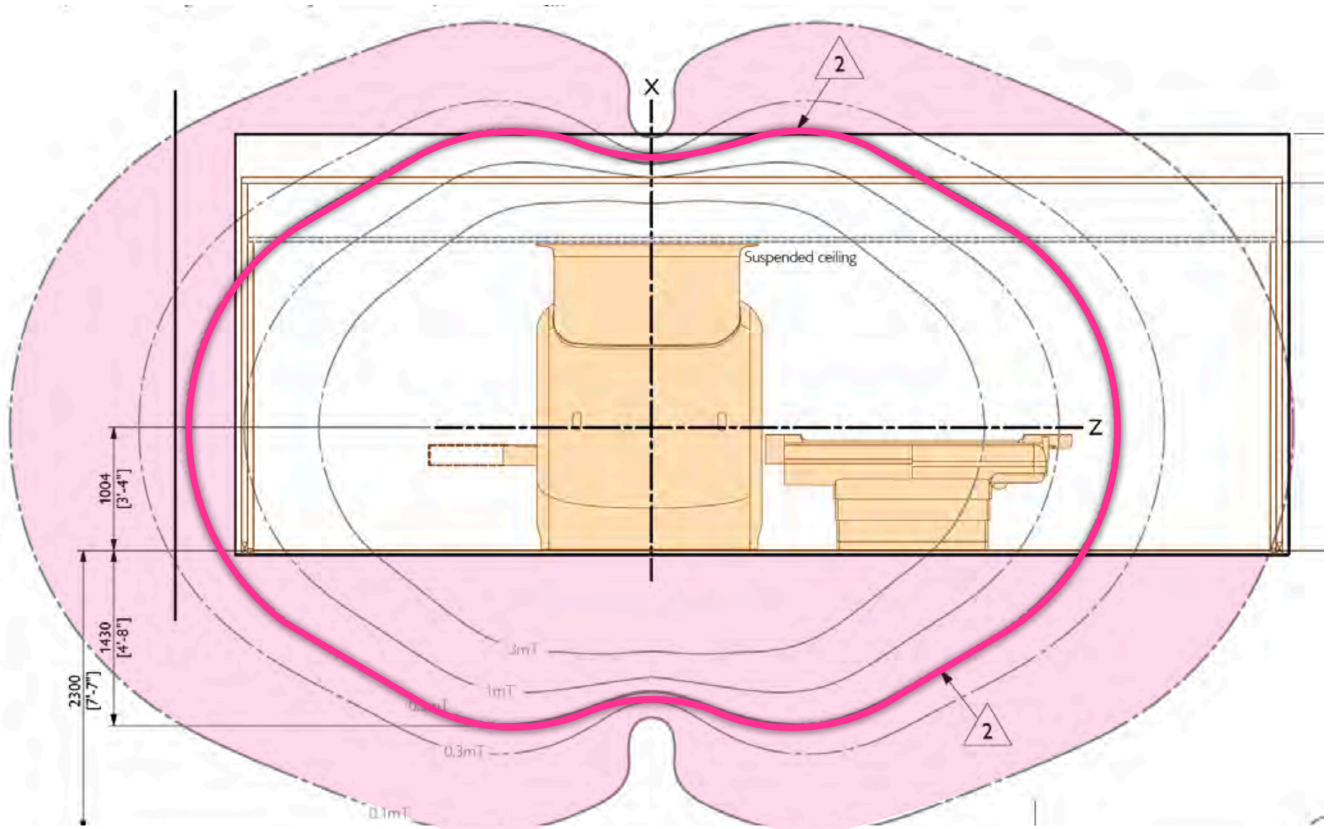
Magnetic Field Reach

9 Gauss (0.9 mT) is the new 5 Gauss (0.5 mT)



Magnetic Field Reach

9 Gauss (0.9 mT) is the new 5 Gauss (0.5 mT)



Zones

Zones

What They Are

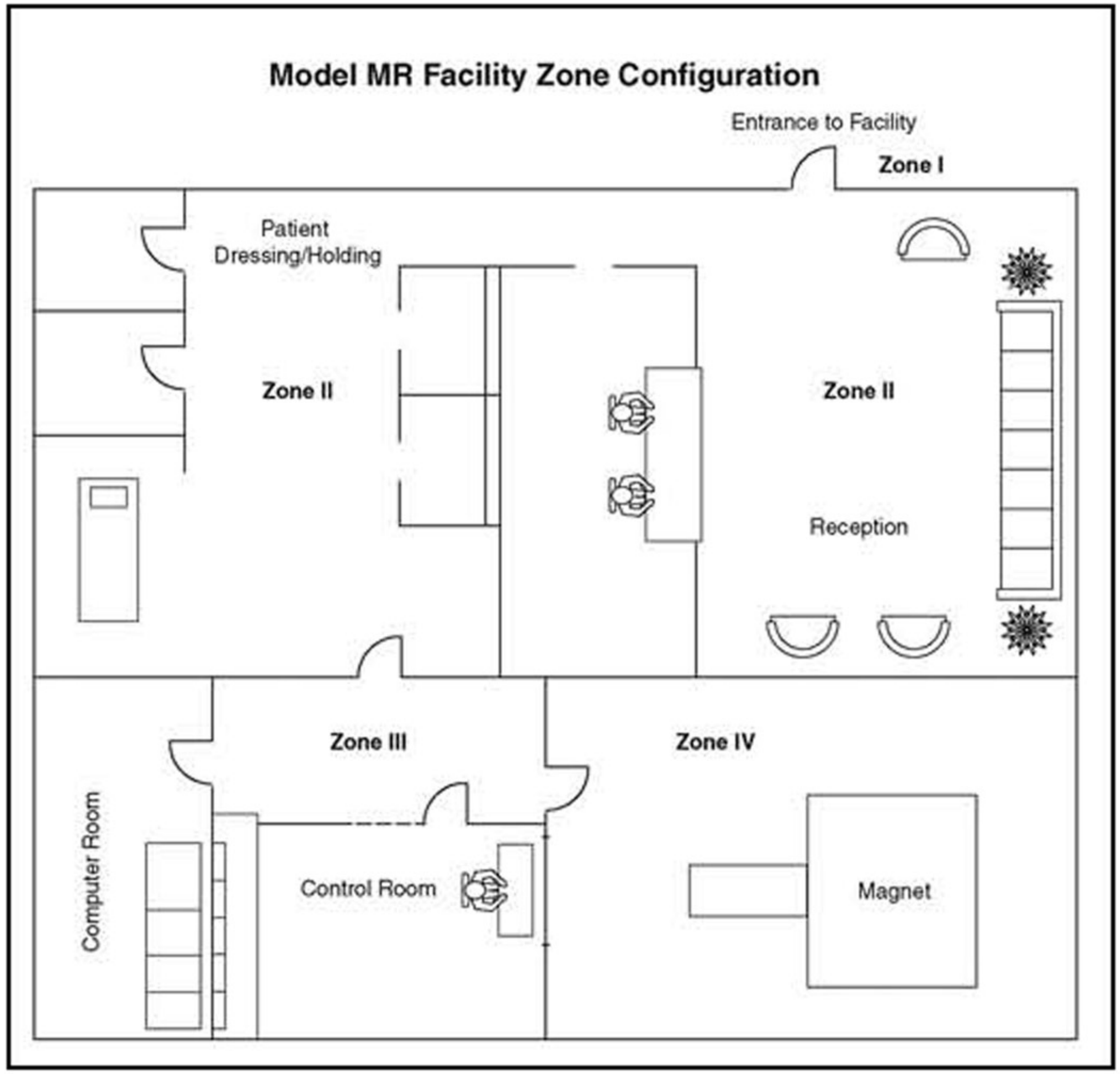
- Zones are MRI-specific hazard areas, going sequentially from ‘No Risk’ to ‘Maximum Risk’

  - Zone 1 - No MRI Function. No MRI-specific Risk.
  - Zone 2 - MRI Function. No MRI-specific Risk.
  - Zone 3 - MRI Function. Moderate MRI-specific Risks.
  - Zone 4 - MRI Scanner Room. Extreme Possible MRI-Specific Risks

Zones

What They Are

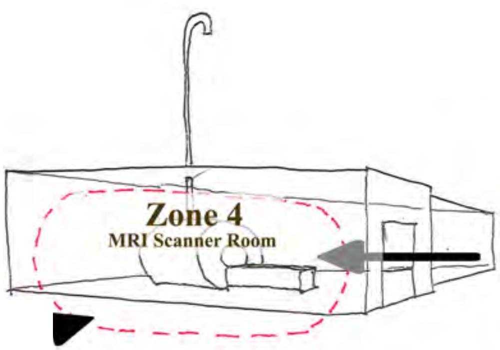
- Zones often shown on floor plan, associated with rooms
- Zone 4 is the only zone defined as a specific room



Zones

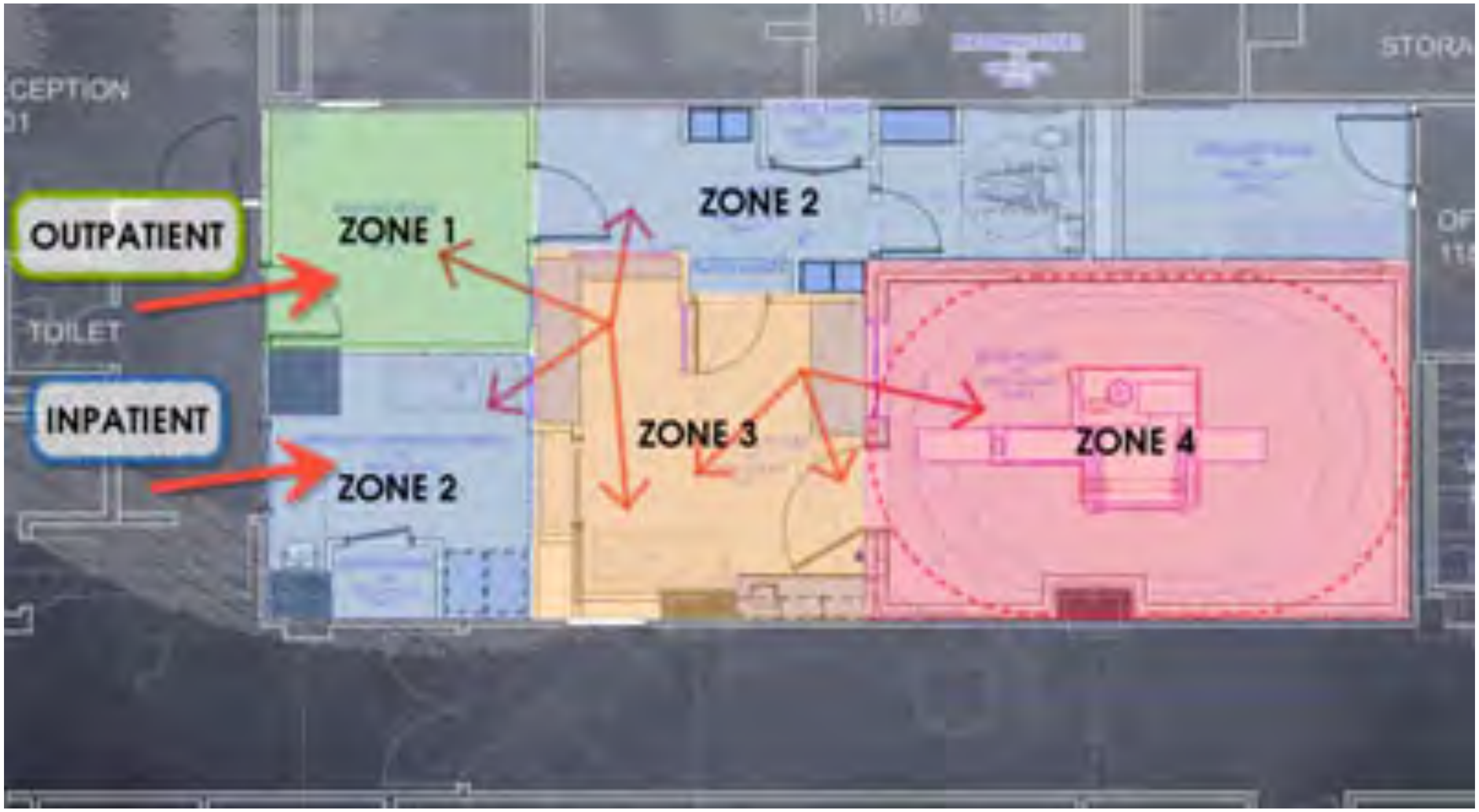
What They Are

- MRI Hazard Designations



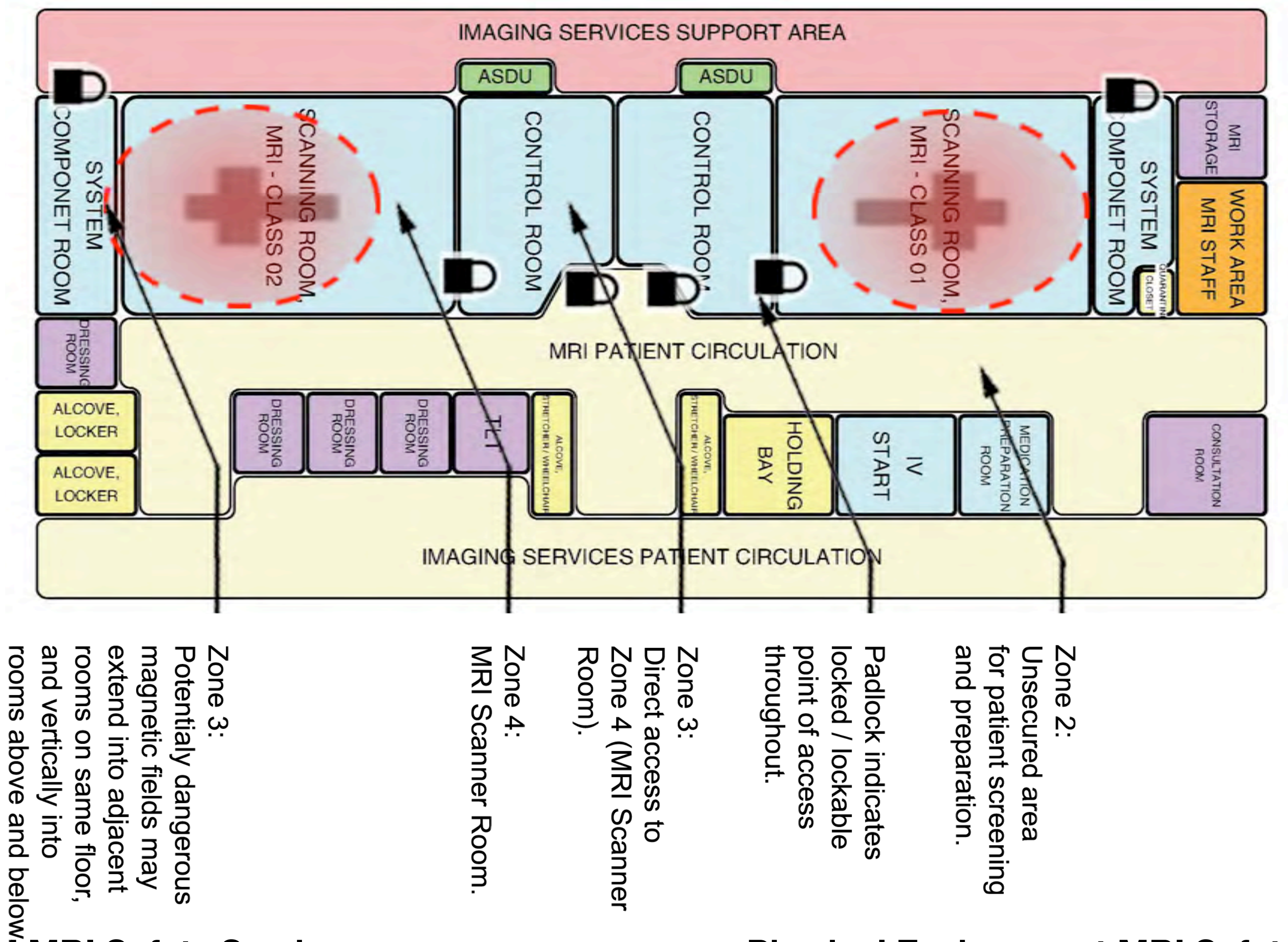
Zones

What They Are



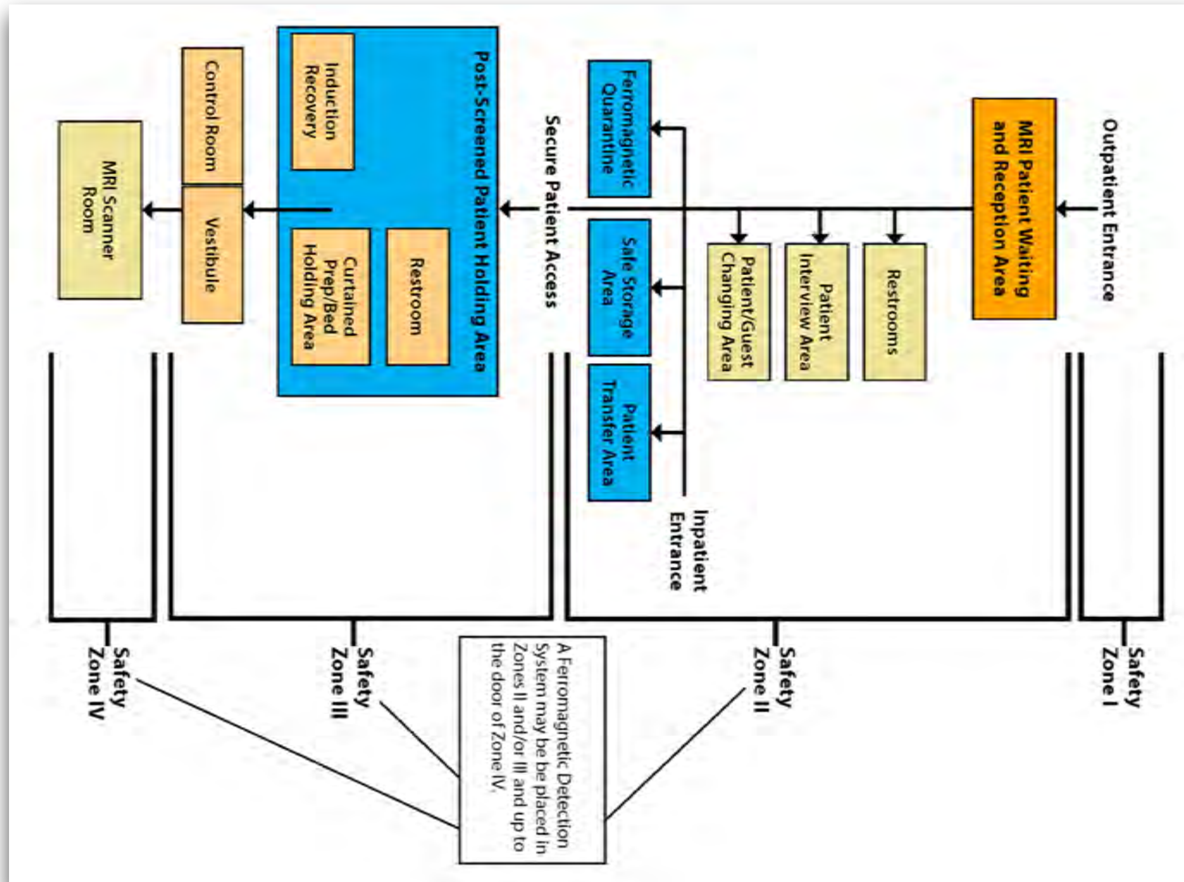
Zones

What They Are



Zones

What They Are



Zones
Signage

Zones
Signage

Zones

Signage

Zones
Signage

Zones

Door to Zone 4

- Door to Zone 4 is the *absolute last chance* to catch hazard items


MRI
IN USE
DANGER!
MRI
ZONE IV
Screened MRI Patients Under Constant Direct
Supervision of Trained MRI Personnel Only
MAGNETOM
3T

Zones

Door to Zone 4

FULL STOP/FINAL CHECK

A "full stop and final check" performed by the MRI technologist is recommended to confirm the satisfactory completion of MR safety screening for the patient, support equipment, and personnel immediately prior to crossing from Zone III to Zone IV. The purpose of this final check is to confirm the patient's identification, ensure that all screening has been appropriately performed, and ensure that there has been no change in patient and/or equipment status while in Zone III.

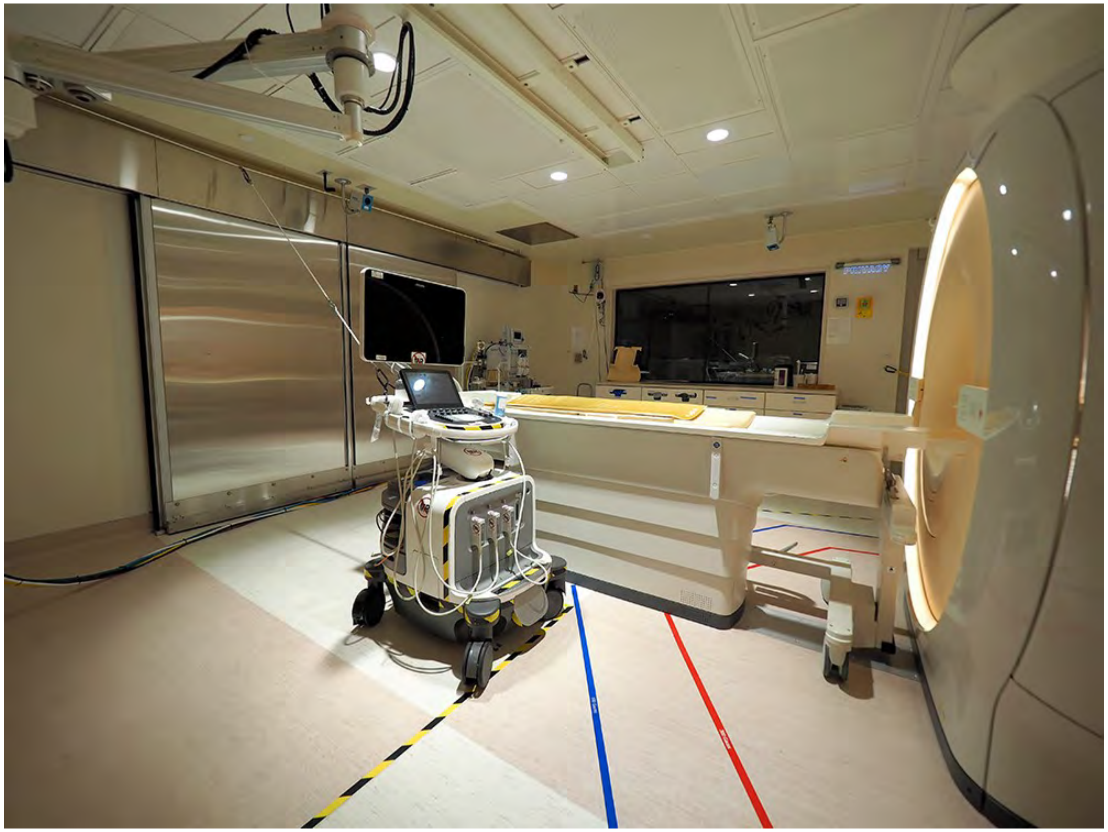
https://www.acr.org/-/media/ACR/Files/Radiology-Safety/MR-Safety/Manual-on-MR-Safety.pdf

Zones
Tethers

When supporting the use of non-MR Conditional portable equipment outside the MRI Scanner Room (Zone 4), such as horizontal patient transfer devices, infusion pumps, or patient monitors, planners shall provide anchoring tether-points to allow each individual portable piece of non-MR Conditional equipment to be tethered to prevent its inadvertent introduction into the MRI Scanner Room.

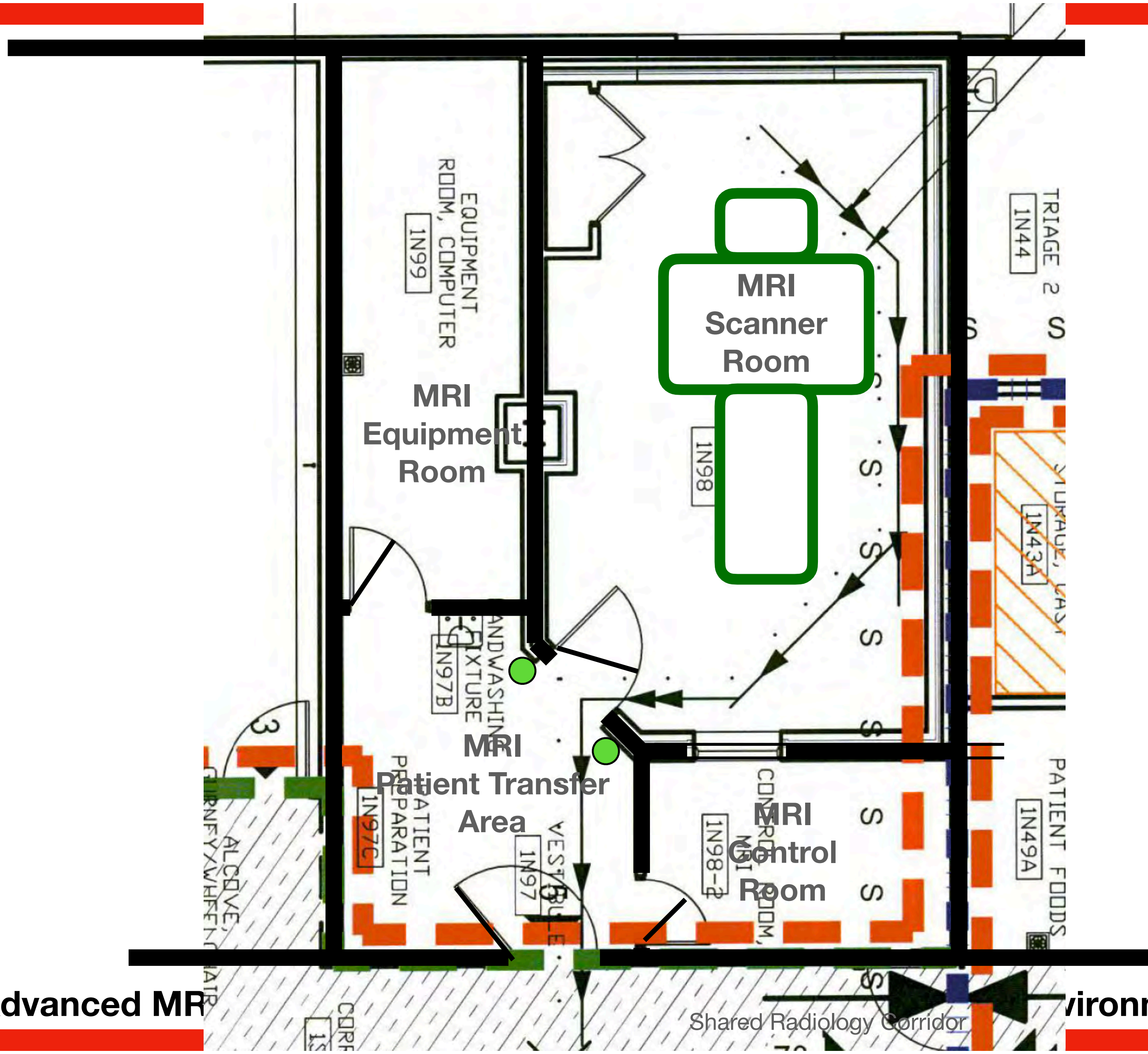
Zones

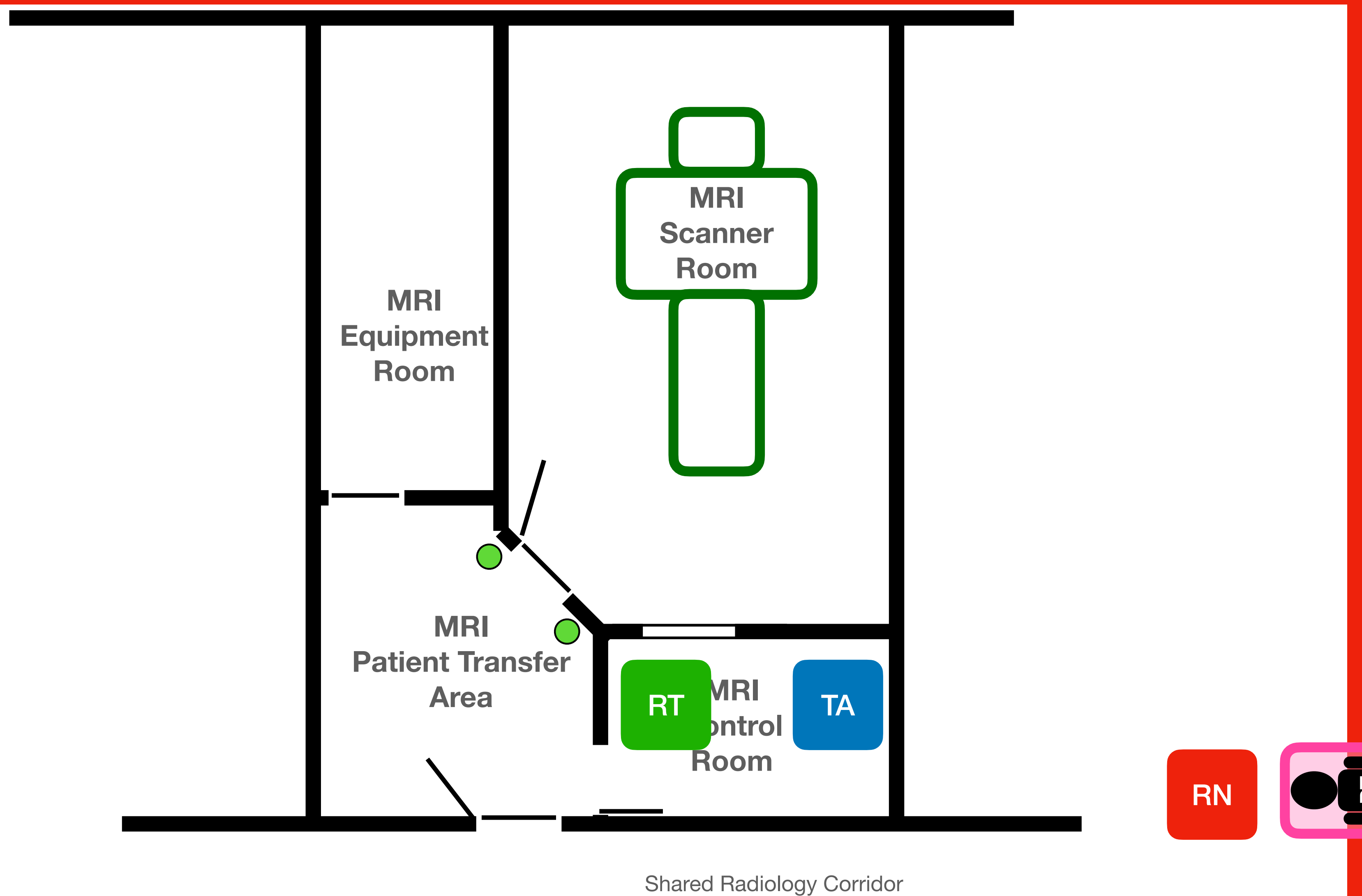
Tethers

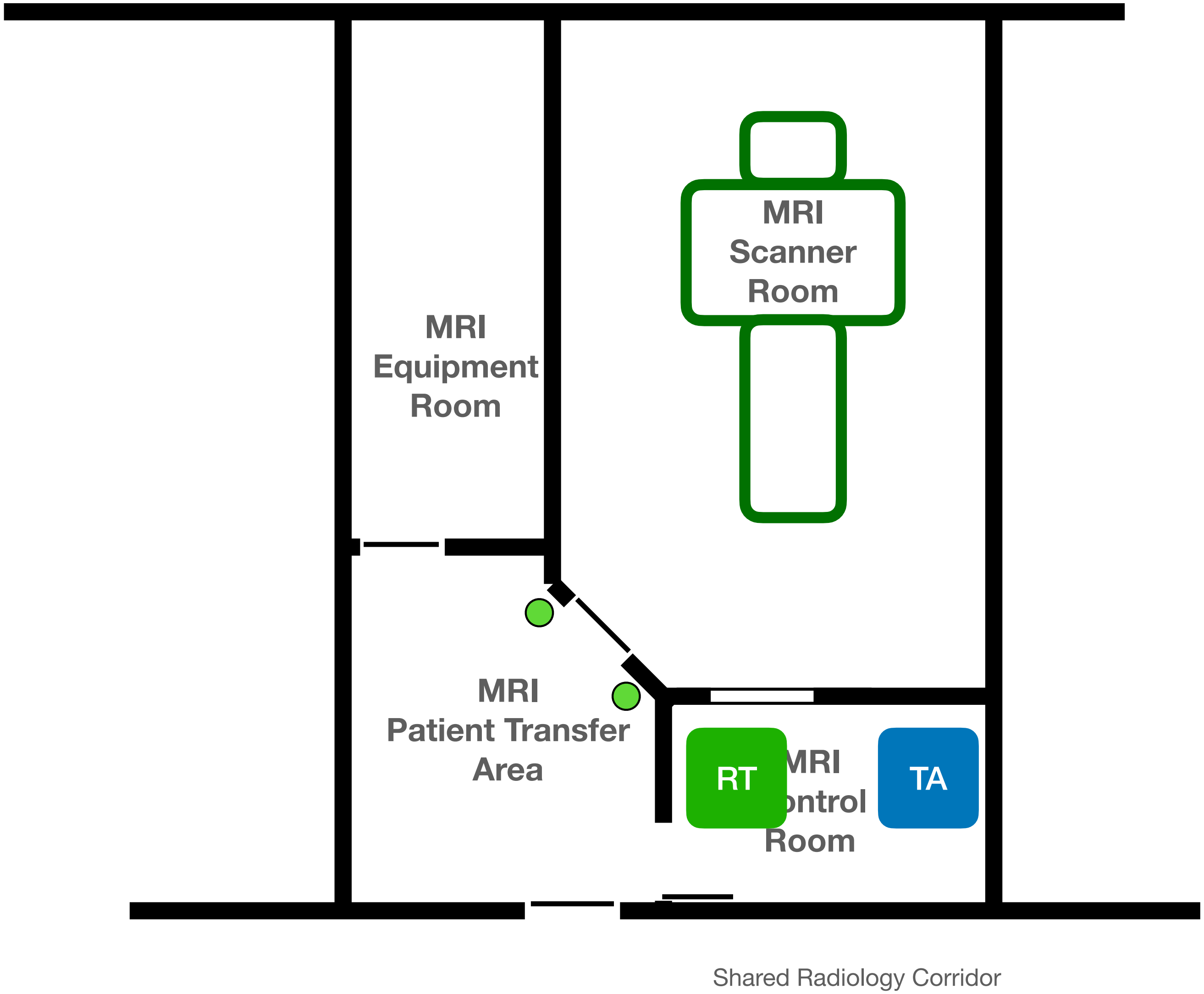


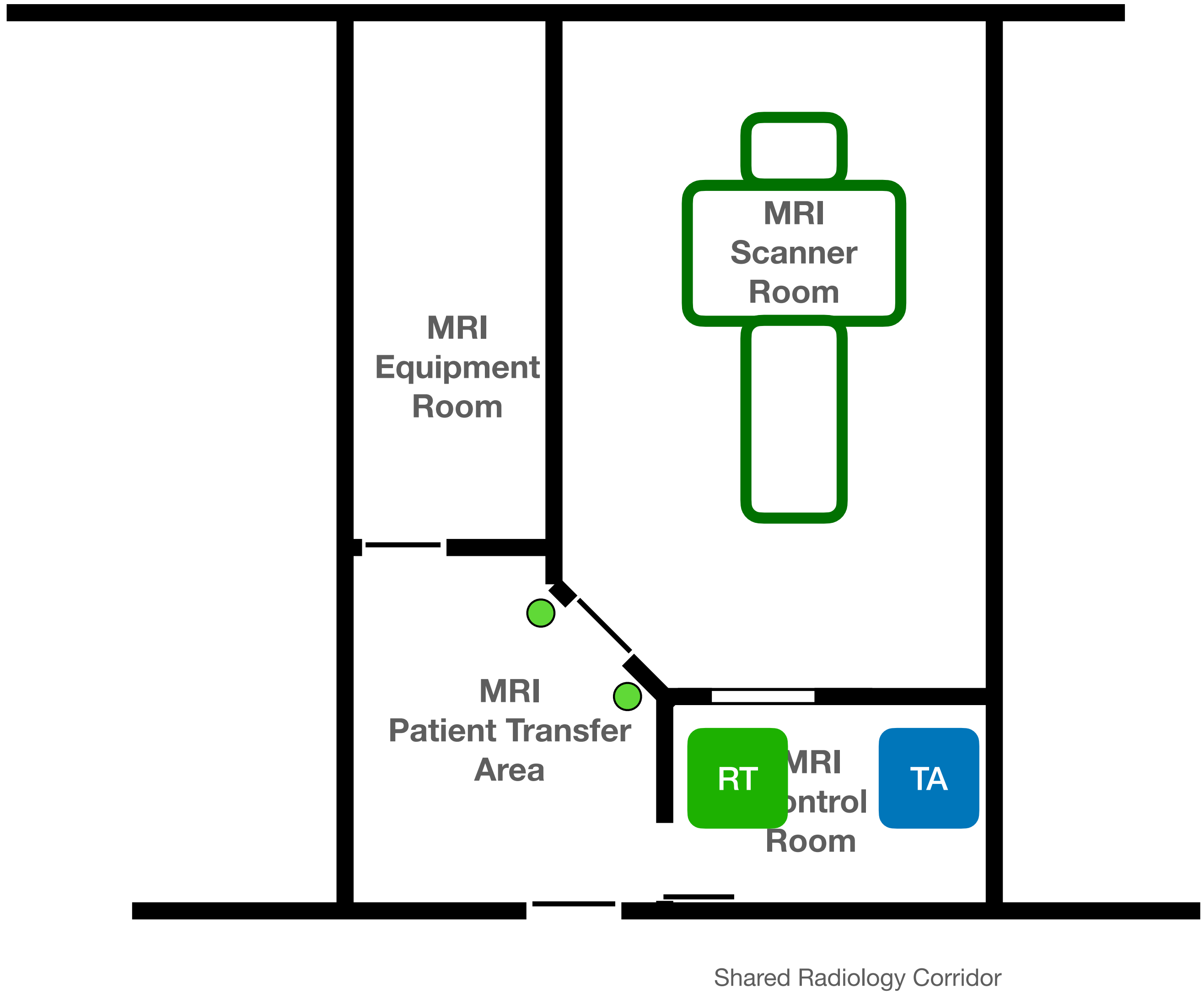
Designs That Make MRI Less Safe

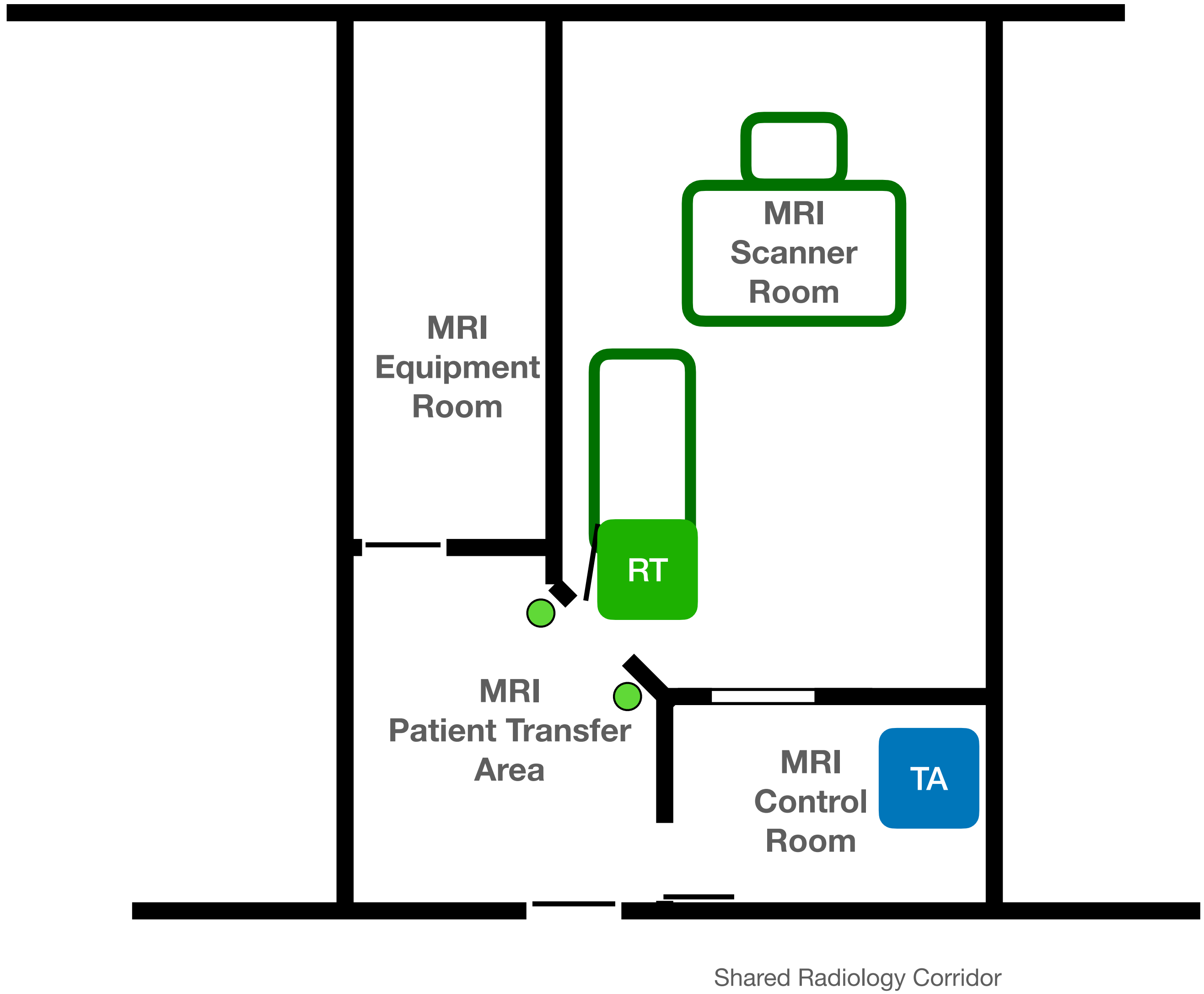
Designs That Make MRI Less Safe

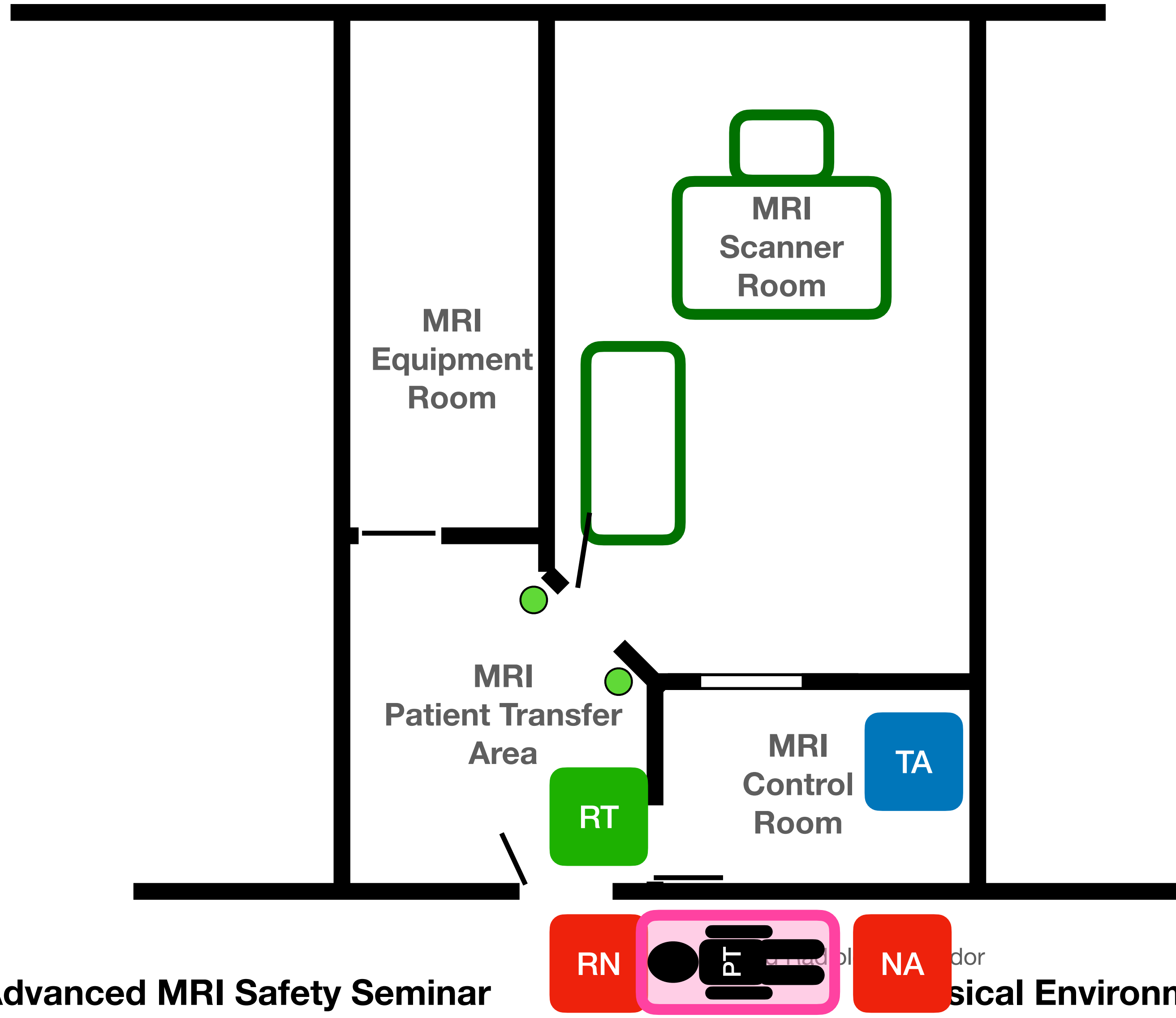

MRI
Scanner
Room
MRI
Equipment
Room
MRI
Patient Transfer
Area
MRI
Control
Room
Shared Radiology Corridor
EQUIPMENT
ROOM, COMPUTER
1N99
1N98
TRIAGE 2
1N44
1N43A
PATIENT FOODS
1N49A
HANDWASHING
FIXTURE
1N97B
PATIENT
PREPARATION
1N97C
VESTIBULE
1N97
CONTROL ROOM,
1N98-2
ALCOVE,

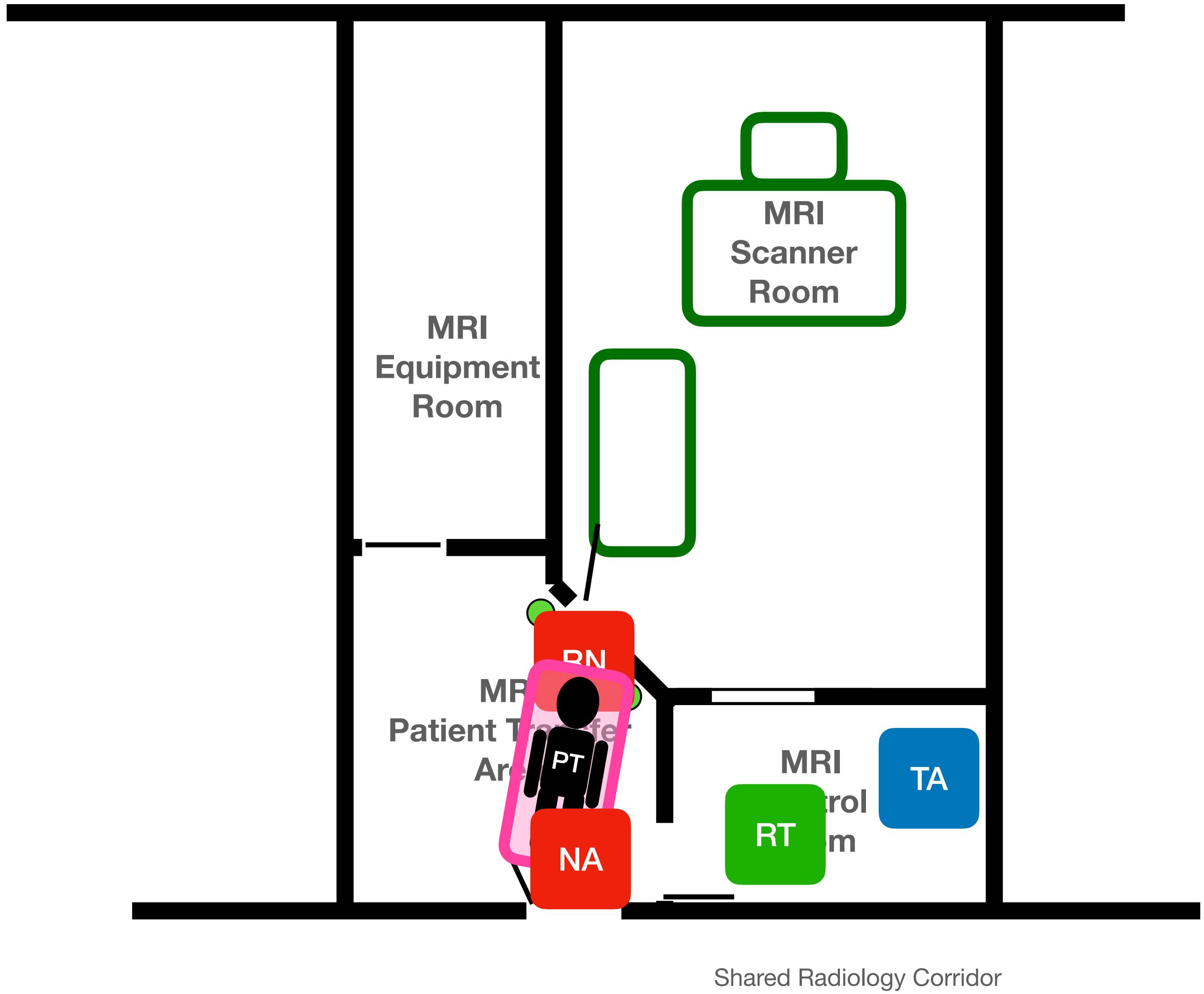

MRI Scanner Room
MRI Equipment Room
MRI Patient Transfer Area
RT
MRI Control Room
TA
RN
Shared Radiology Corridor

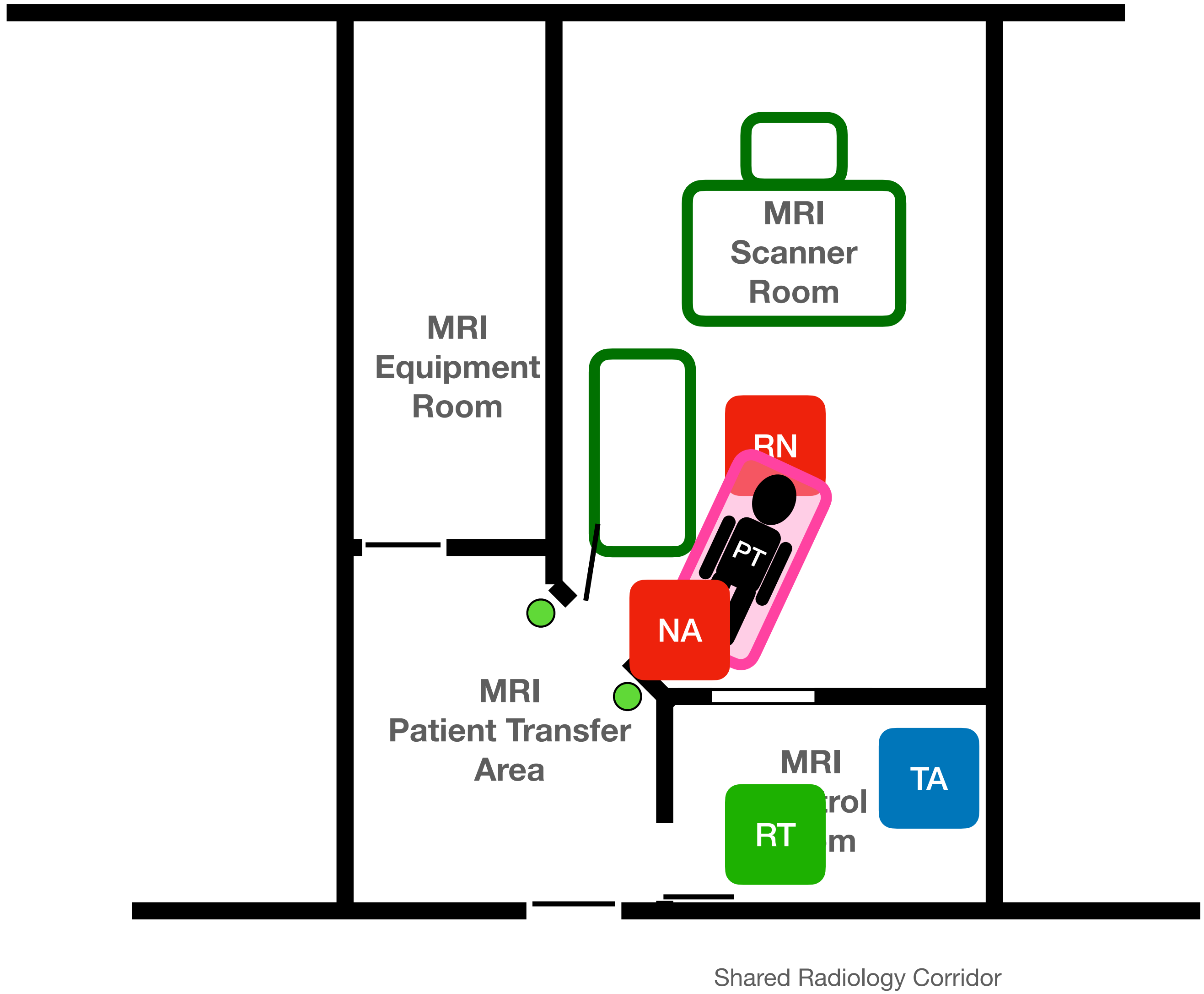

MRI
Equipment
Room
MRI
Scanner
Room
MRI
Patient Transfer
Area
RT
MRI
ontrol
Room
TA
Shared Radiology Corridor

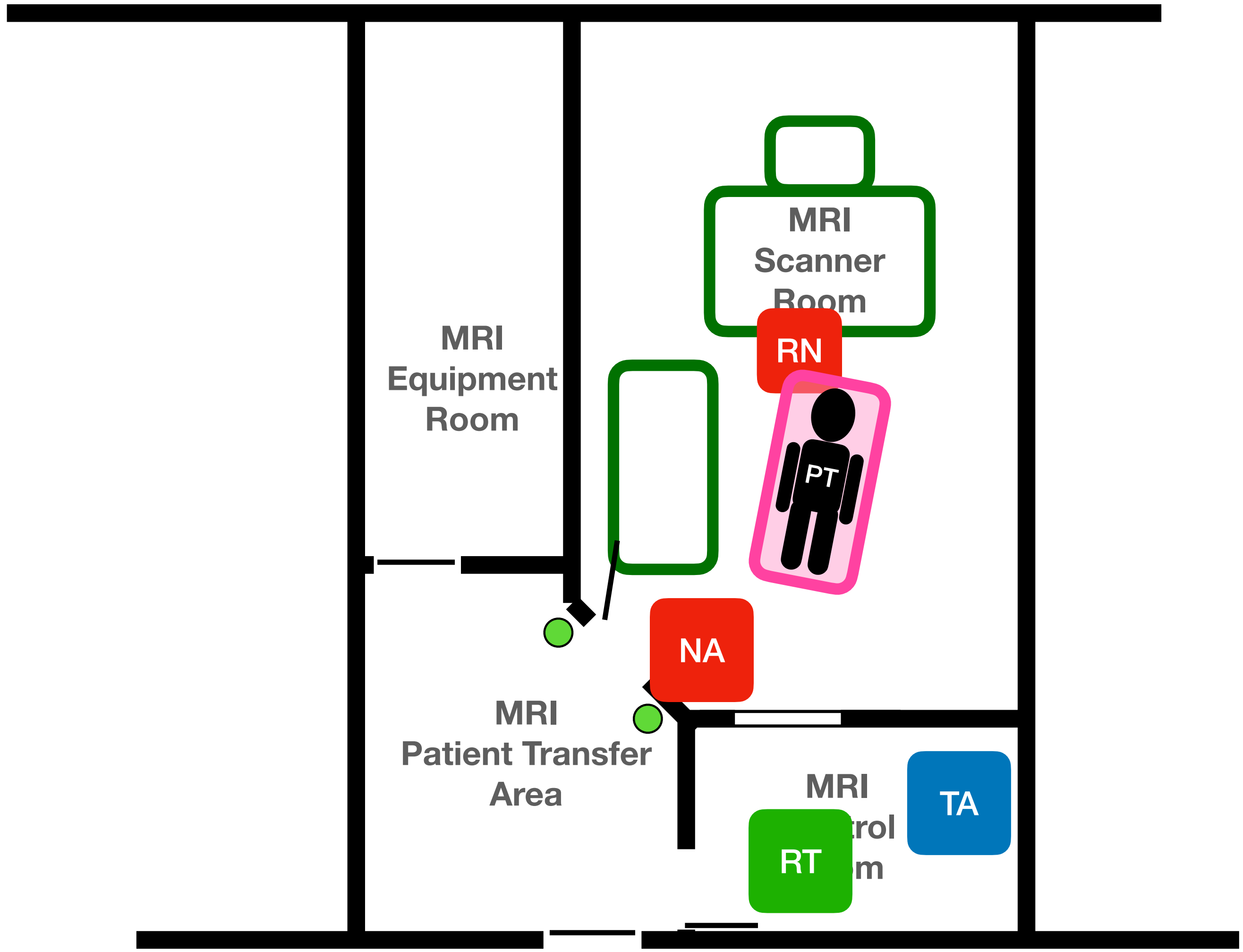

MRI Scanner Room
MRI Equipment Room
MRI Patient Transfer Area
RT
MRI
ontrol
Room
TA
Shared Radiology Corridor


MRI Scanner Room
MRI Equipment Room
RT
MRI Patient Transfer Area
MRI Control Room
TA
Shared Radiology Corridor


MRI
Equipment
Room
MRI
Scanner
Room
MRI
Patient Transfer
Area
MRI
Control
Room
RT
TA
RN
PT
NA


MRI
Scanner
Room
MRI
Equipment
Room
RN
MRI
Patient Transfer
Area
PT
NA
MRI
Control
Room
TA
RT
Shared Radiology Corridor


MRI
Scanner
Room
MRI
Equipment
Room
RN
PT
NA
MRI
Patient Transfer
Area
MRI
trol
m
TA
RT
Shared Radiology Corridor


MRI
Scanner
Room
RN
PT
MRI
Equipment
Room
NA
MRI
Patient Transfer
Area
MRI
trol
m
TA
RT
Shared Radiology Corridor

Cryogen Safety

Cryogen Safety
Cryogens and Superconductivity

- MRIs Are Electromagnets
  - Superconductivity reduces electrical consumption
    (reduces operational cost)
  - Superconductivity only available at super-cold temperatures
  - Liquid Helium boiling temperature -269° C

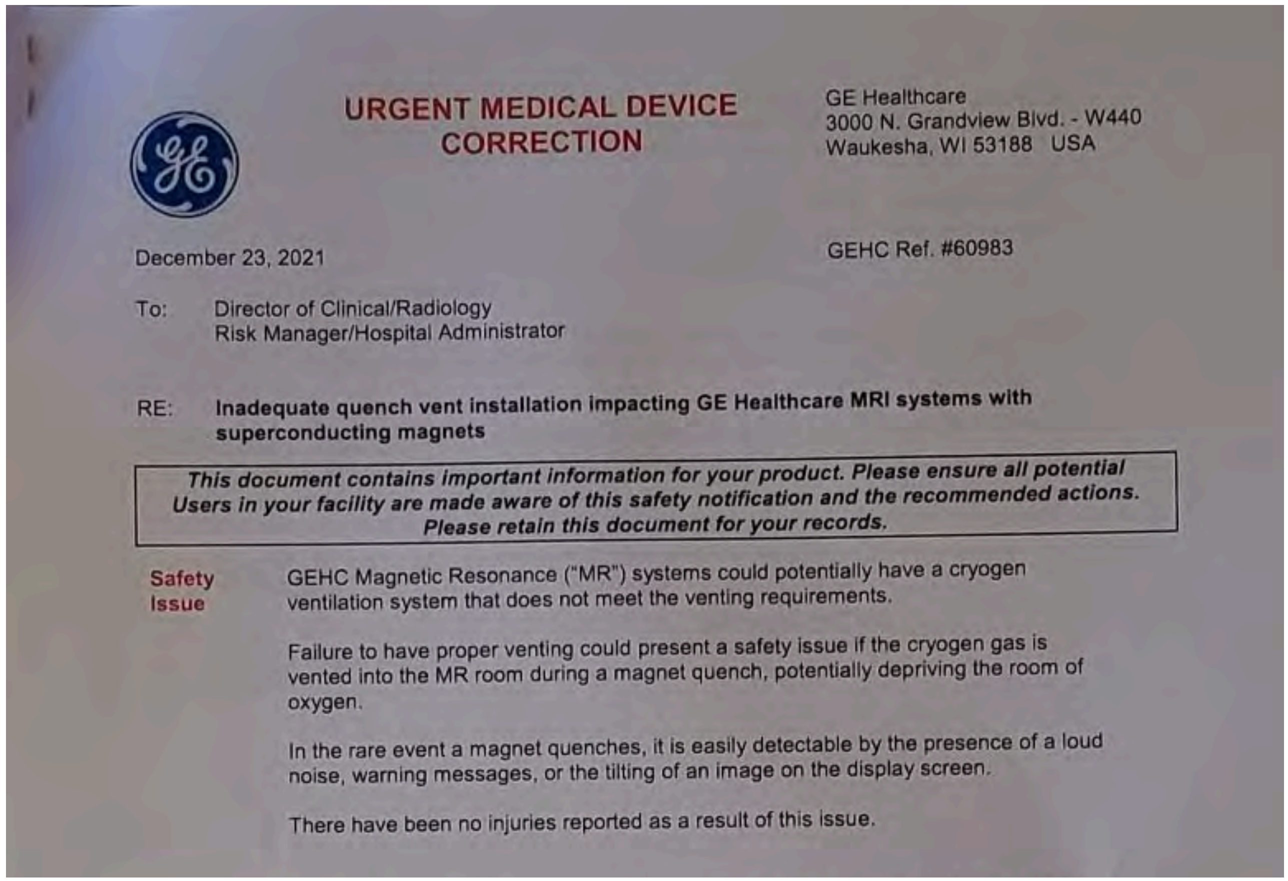
Cryogen Safety
Quench vs. EPO

- Superconducting MRI Systems Typically Have 2 Emergency Features…
  - Emergency Power Off (EPO)
  - Quench Button

Cryogen Safety

- A Large Majority of MRI Systems Are Superconducting & Require Cryogens
- A Few Newer Superconducting Magnets Do <u>NOT</u> Require Quench Pipes
- The Following Relates To Systems <u>WITH</u> Quench Pipes

Cryogen Safety



URGENT MEDICAL DEVICE CORRECTION

GE Healthcare
3000 N. Grandview Blvd. - W440
Waukesha, WI 53188 USA

December 23, 2021

GEHC Ref. #60983

To: Director of Clinical/Radiology
Risk Manager/Hospital Administrator

RE: **Inadequate quench vent installation impacting GE Healthcare MRI systems with superconducting magnets**

This document contains important information for your product. Please ensure all potential Users in your facility are made aware of this safety notification and the recommended actions. Please retain this document for your records.

Safety Issue

GEHC Magnetic Resonance ("MR") systems could potentially have a cryogen ventilation system that does not meet the venting requirements.

Failure to have proper venting could present a safety issue if the cryogen gas is vented into the MR room during a magnet quench, potentially depriving the room of oxygen.

In the rare event a magnet quenches, it is easily detectable by the presence of a loud noise, warning messages, or the tilting of an image on the display screen.

There have been no injuries reported as a result of this issue.

Cryogen Safety

Cryogen Safety

Cryogen Safety

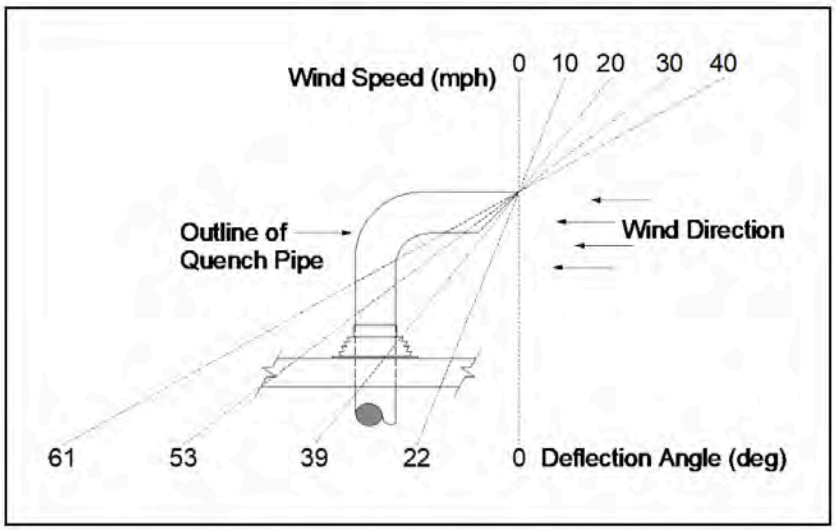


Figure 2.7.3.3-1: Diagrammatic illustration of how wind-driven rain can defeat a 90° quench pipe discharge with 45° chamfered end. (Image used with permission from RAD-Planning)

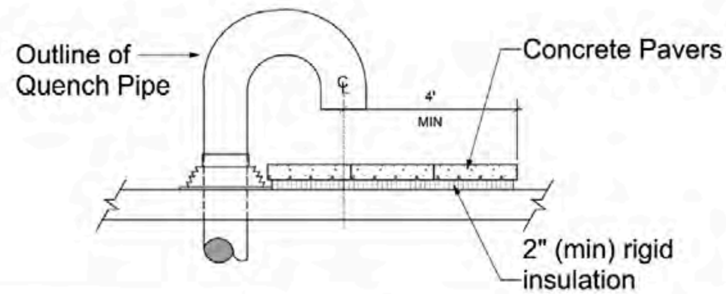


Figure 2.7.3.3-4: Diagrammatic illustration of a sacrificial roof protection assembly. (Image used with permission from RAD-Planning)

Cryogen Safety

Cryogen Safety

Cryogen Safety
Magnet Room Door Swing

- I was one of the loudest voices demanding out-swinging MRI room doors (in the 90's / early 00's)
- This was when most RF doors were 'finger' or 'friction-fit' doors
- Hospital design standards increased requirements for latching doors
- MRI manufacturers began recommending / requiring passive pressure relief systems

Cryogen Safety

Magnet Room Door Swing

Although it can provide a degree of redundancy, it should be noted that, even with an exhaust fan, designing the door to Zone IV to swing outward is not, by itself, an appropriate means of pressure relief. In a severe positive-pressure situation, unlatching an outward-swinging door might permit the door to burst open with tremendous pressure, potentially injuring person(s) opening the door. If employed as the only means of pressure equalization, an outward-swinging door may actually introduce new hazards to any person attempting to open the door to a pressurized magnet room from the outside.

https://www.cfm.va.gov/til/dGuide/dgImaging.pdf

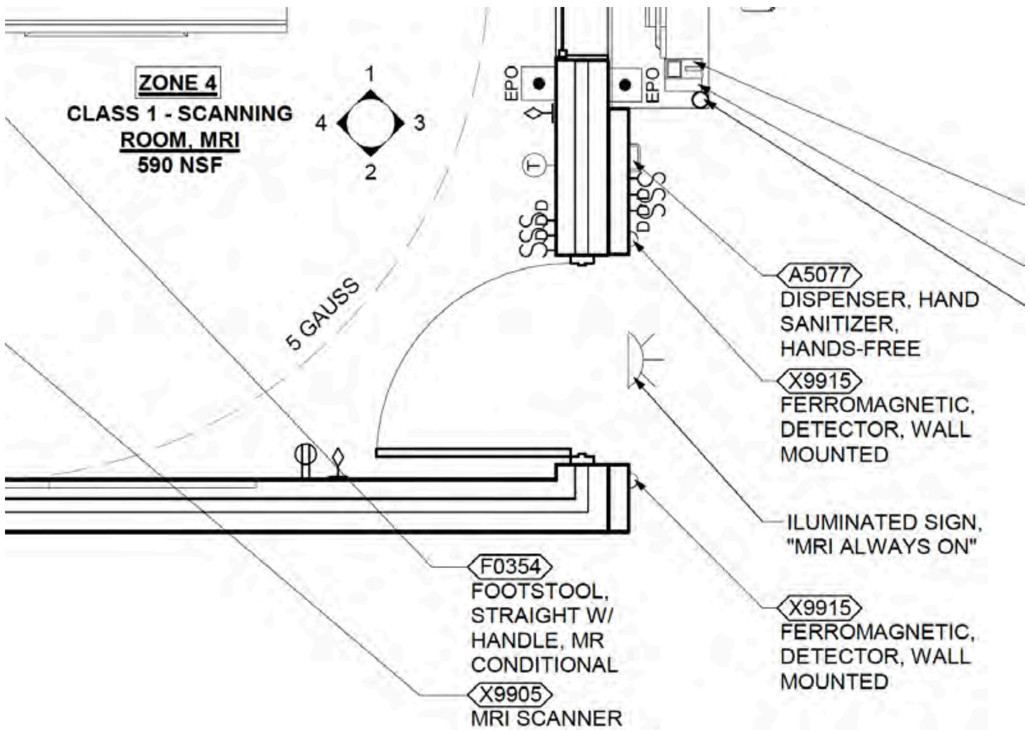
Cryogen Safety
Magnet Room Door Swing

Once provided with appropriate pressure equalization and emergency exhaust, magnet room door-swing direction and design should be left to the discretion of a facility and their design professionals.

https://www.cfm.va.gov/til/dGuide/dgImaging.pdf

Cryogen Safety

Magnet Room Door Swing



Cryogen Safety

If Your Magnet Has A Quench Pipe…

… The scanner room should also have

- An Exhaust Fan
- An Overpressure Relief

Novel MRI Systems

Novel MRI Systems

Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

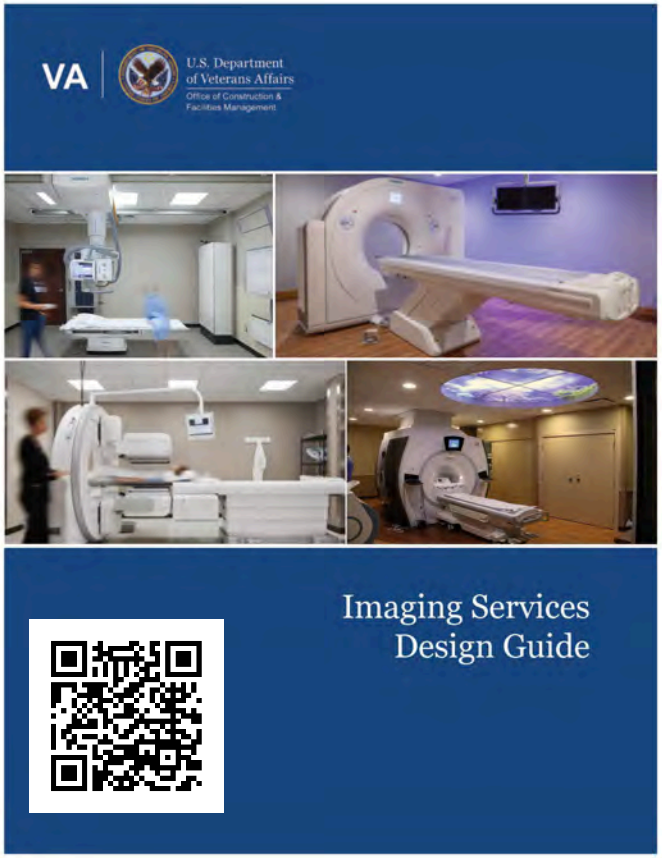
Novel MRI Systems

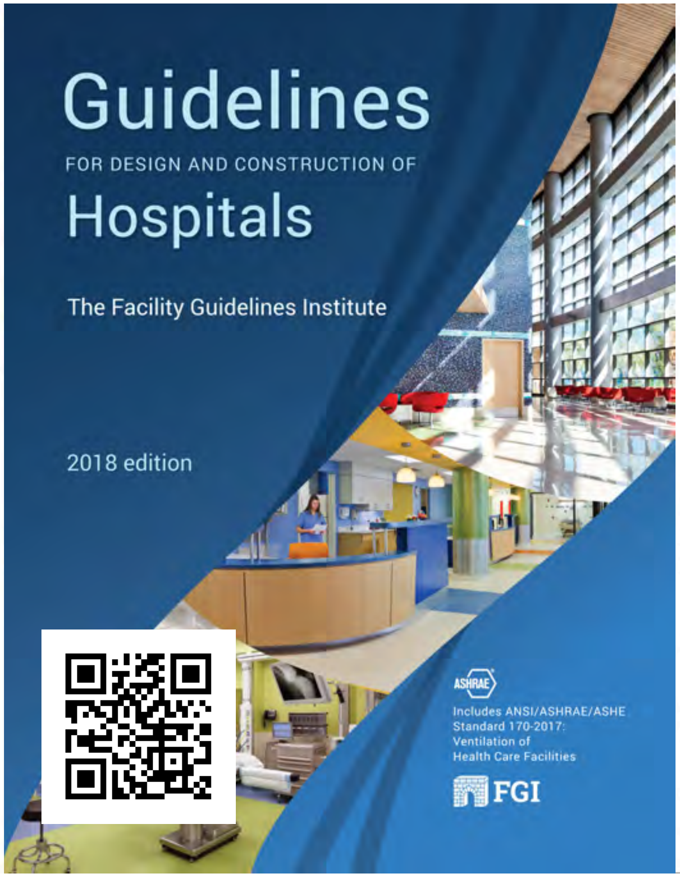
Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

Resources

Resources





MR Imaging Safety
Siting and Zoning Considerations

Tobias Benjamin Gilk, MArch, MRSO (MRSC), MRSE (MRSC)[a,b,*]

KEYWORDS

• MR imaging • Safety • Zones • Standards • Practice • Physical environment • Construction • Renovation

KEY POINTS

- In the past 20 years, MR imaging seems to have steadily produced increasing risk of harm. By contrast, safety initiatives have substantially reduced risk of harm from ionizing radiation usage in diagnostic settings.
- MR imaging safety, as an initiative, has suffered from the absence of formal standards of training or implementation.
- Physical environment MR safety (PEMS) has a significant potentiating capability for clinical and operational safety practices, when effectively integrated. When executed poorly, PEMS initiatives can actively undermine clinical and operational safety practices.
- Although several PEMS initiatives are only practical as a part of a major capital project, many PEMS improvements can be implemented without meaningful interruption to MR imaging patient care services.

INTRODUCTION/BACKGROUND

MR imaging safety, as a discipline, has been poorly formed in practice. With neither radiologists nor MR imaging technologists having formal curriculum in MR imaging safety as a part of their professional education, and with scant licensure or accreditation standard requirements for MR imaging safety that directly combat the sources of MR imaging harm, the structure and practice of MR imaging safety has developed in an alarmingly ad hoc manner, particularly when contrasted with contemporary practices for ionizing radiation safety. In this regard, MR imaging safety has become a victim of its own marketing.

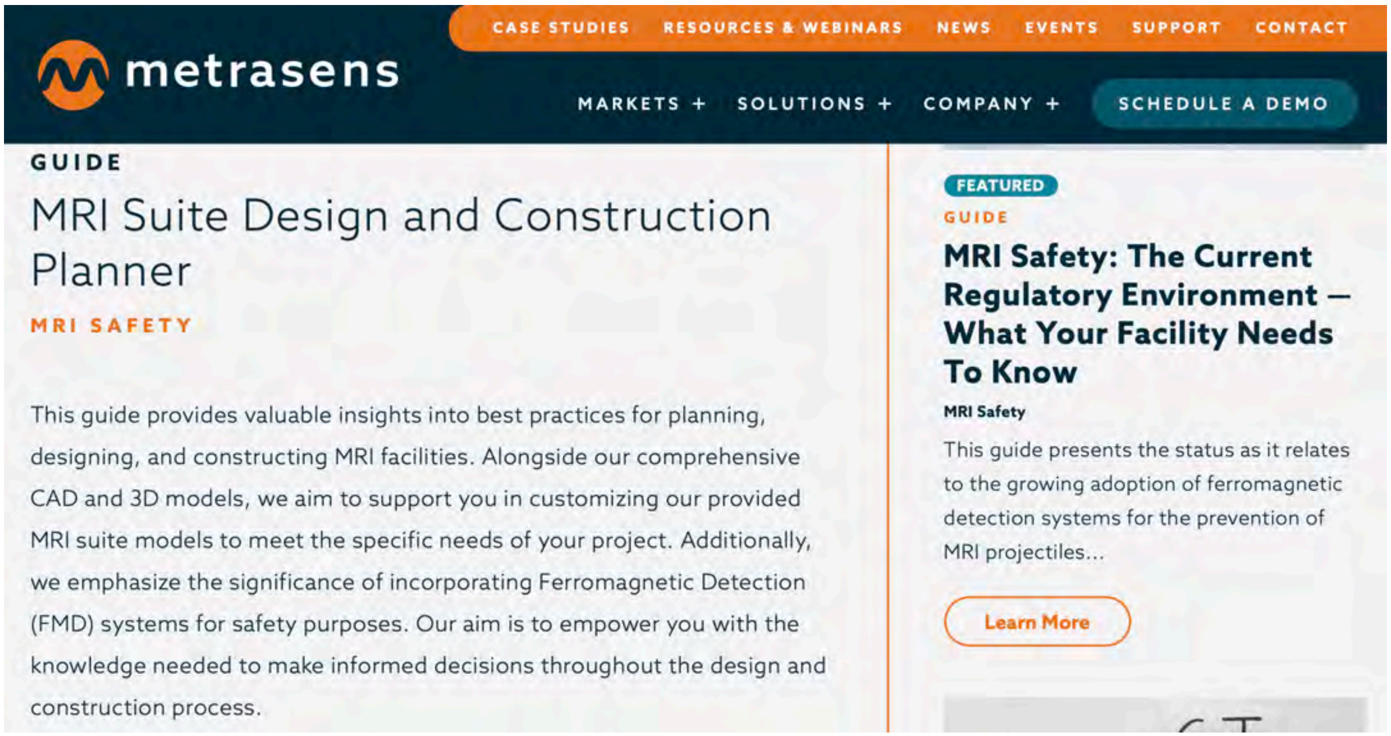
In the past decade, alone, the stochastic risk from diagnostic exposure to ionizing radiation has fallen significantly due to concerted safety efforts on multiple fronts, although very small numbers of deterministic radiation burns continue to occur. It seems that the improvements in radiograph-based imaging technology coupled with practice changes inspired by programs such as "Image Gently" and "Image Wisely" have made marked improvements in the safety of diagnostic modalities that use ionizing radiation.

By contrast, technological improvements in MR imaging over the past 20 years have largely increased risk concerns (eg, more powerful magnetic fields, greater radiofrequency (RF) power, increased slew rates), and there have been no comparable p… imaging to id… report the ad… timeframe, M… report rates to… tion (FDA) hav… of examinatio… suggest that, … are injuring m… we were 20 y…

When we ac… individual prac…

[a] Radiology-Planning, Kansas City, MO, USA; [b] Gilk Radiology Consultants, PO Box 26466, Overland Park, KS 66225, USA

Resources



metrasens
CASE STUDIES
RESOURCES & WEBINARS
NEWS
EVENTS
SUPPORT
CONTACT
MARKETS +
SOLUTIONS +
COMPANY +
SCHEDULE A DEMO
GUIDE
MRI Suite Design and Construction Planner
MRI SAFETY
This guide provides valuable insights into best practices for planning, designing, and constructing MRI facilities. Alongside our comprehensive CAD and 3D models, we aim to support you in customizing our provided MRI suite models to meet the specific needs of your project. Additionally, we emphasize the significance of incorporating Ferromagnetic Detection (FMD) systems for safety purposes. Our aim is to empower you with the knowledge needed to make informed decisions throughout the design and construction process.
FEATURED
GUIDE
MRI Safety: The Current Regulatory Environment — What Your Facility Needs To Know
MRI Safety
This guide presents the status as it relates to the growing adoption of ferromagnetic detection systems for the prevention of MRI projectiles...
Learn More

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

MRI Safety Standards

Tobias Gilk - Sept 24, 2023

Outline

MRI Safety Standards

- Intro
- MRI Machine Safety Standards
- Physical Environment & Clinical Practice MRI Safety Standards
- Ionizing vs. MRI Safety Accreditation
- Organizational Structure For MRI Safety
- Q & A

MRI Machine Safety Standards

IEC 60601-2-33

MRI Machine Safety Standards

IEC 60601-2-33

- International Electrotechnical Commission (IEC)
  - Establishes standards for electrical products (including medical)
  - 2022 published ed. 4.0 of MRI safety standard (for manufacturers)

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis

Physical & Clinical MRI Safety Standards

Physical & Clinical MRI Safety Standards

Physical Environment

Design Standards

- FGI Guidelines (USA)
- VA MRI Safety Directive (USA)

Best Practices

- MRI Facility Safety Design Guidelines (appendix 2 in ACR 2020 Manual on MR Safety)
- VA Imaging Services Design Guide
- Metrasens MRI Planning Guide
- MHRA MRI Safety Guidelines

Physical & Clinical MRI Safety Standards

Clinical Care

Clinical Care Standards

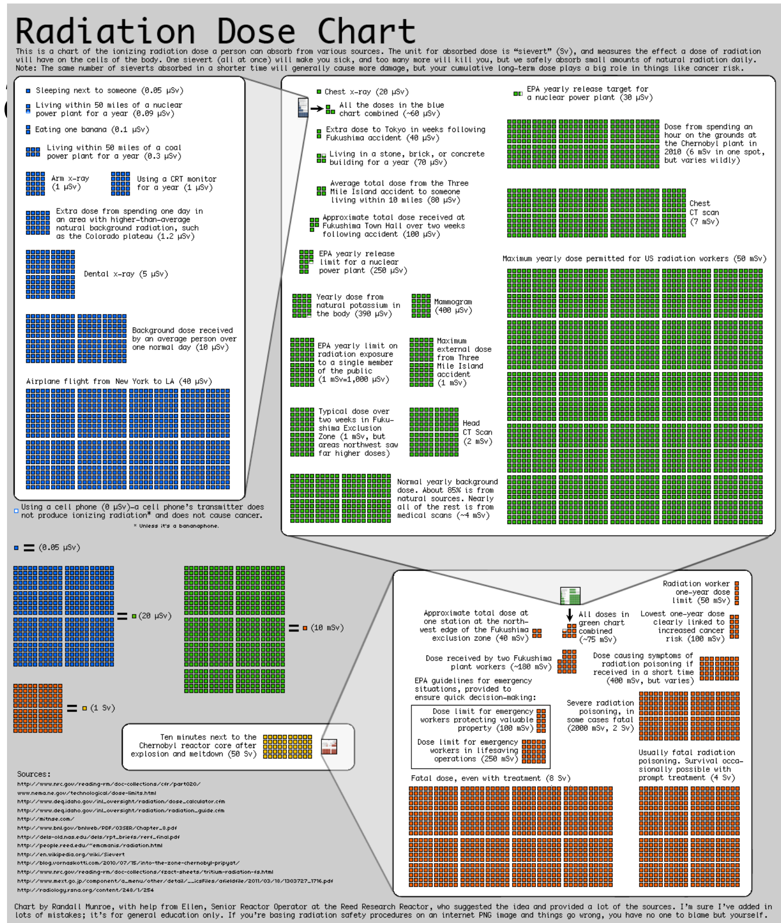
- ACR 2020 Manual on MR Safety

Best Practices

- ACR 2020 Manual on MR Safety
- MHRA MRI Safety Guidelines

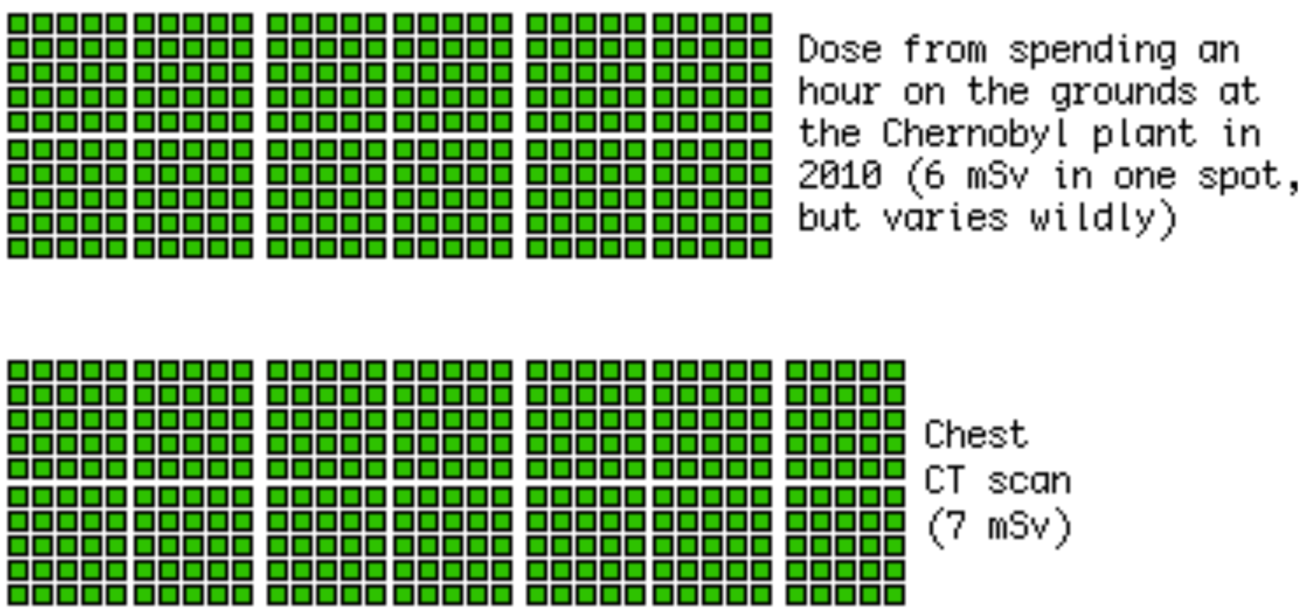
Ionizing Radiation vs. MRI

Ionizing Radi



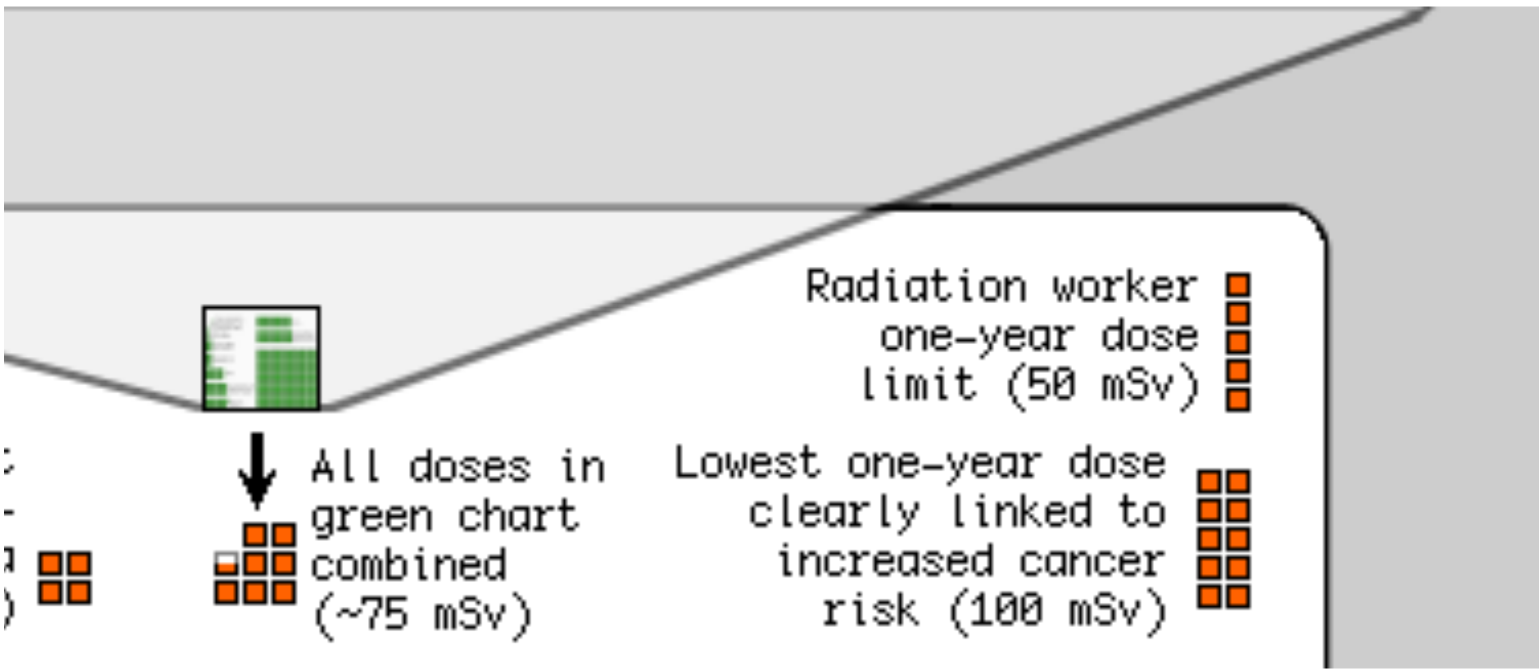
https://xkcd.com/radiation/

Ionizing Radiation vs. MRI



https://xkcd.com/radiation/

Ionizing Radiation vs. MRI



https://xkcd.com/radiation/

Ionizing Radiation vs. MRI

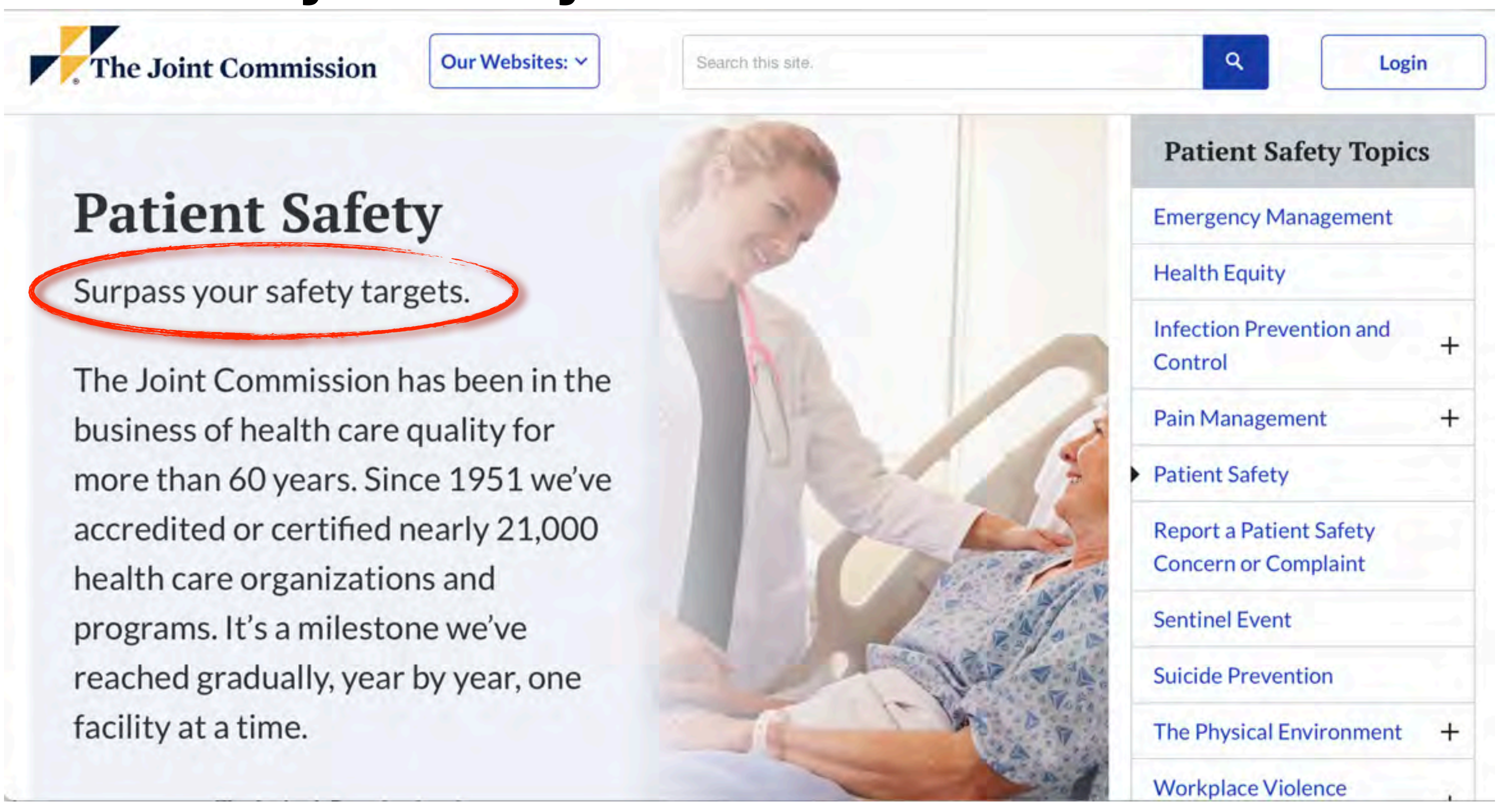
Risk = Likelihood x Consequence

LIKELIHOOD	insignificant	minor	moderate	major	critical
almost certain	Moderate	Major	[illegible]	[illegible]	[illegible]
likely	Moderate	Major	Major	[illegible]	[illegible]
possible	Moderate	Moderate	Major	Major	[illegible]
unlikely	Minor	Moderate	Moderate	Major	[illegible]
rare	Minor	Minor	Moderate	Moderate	Major
	CONSEQUENCE				

MRI Safety In Accreditation

MRI Safety In Accreditation

Promise of Quality & Safety



MRI Safety In Accreditation

Promise of Quality & Safety

Contact:
Name
Title
Phone Number
E-mail

For Immediate Release

(Facility Name Here) Earns ACR Accreditation

(City, State) — (Facility Name), has been awarded a three-year term of accreditation in magnetic resonance imaging (MRI) as the result of a recent review by the American College of Radiology (ACR). MRI is a noninvasive medical test that utilizes magnetic fields to produce anatomical images of internal body parts to help physicians diagnose and treat medical conditions.

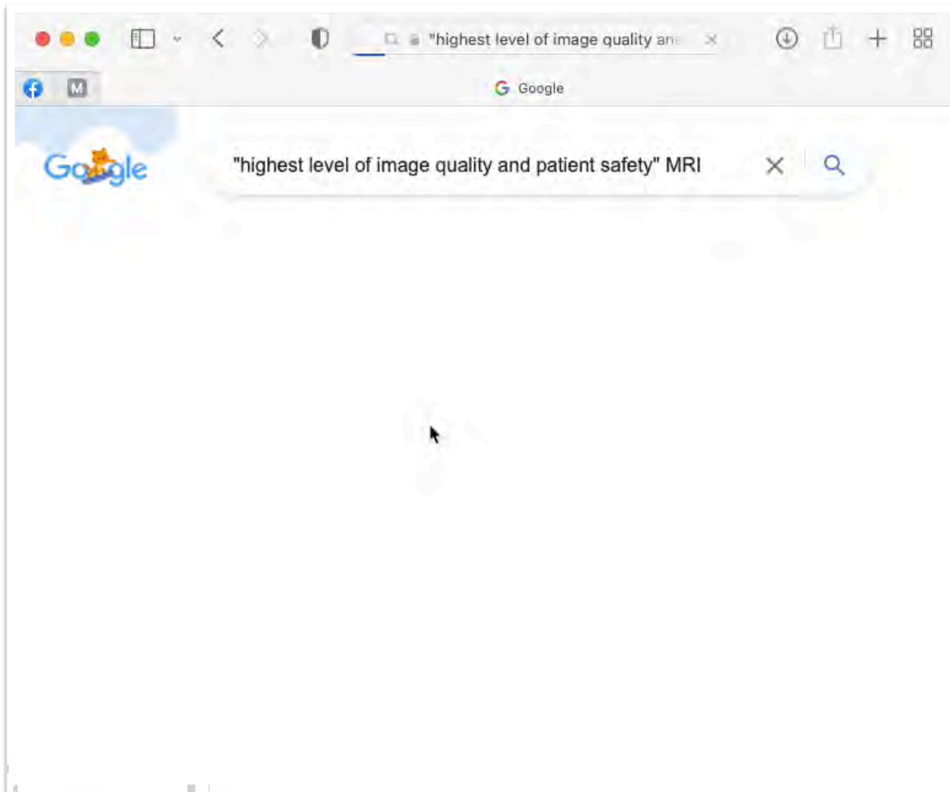
The ACR gold seal of accreditation represents the highest level of image quality and patient safety. It is awarded only to facilities meeting ACR Practice Guidelines and Technical Standards after a peer-review evaluation by board-certified physicians and medical physicists who are experts in the field. Image quality, personnel qualifications, adequacy of facility equipment, quality control procedures, and quality assurance programs are assessed. The findings are reported to the ACR Committee on Accreditation, which subsequently provides the practice with a comprehensive report they can use for continuous practice improvement.

The ACR is a national professional organization serving more than 34,000 diagnostic/interventional radiologists, radiation oncologists, nuclear medicine physicians, and medical physicists with programs focusing on the practice of medical imaging and radiation oncology and the delivery of comprehensive health care services.

###

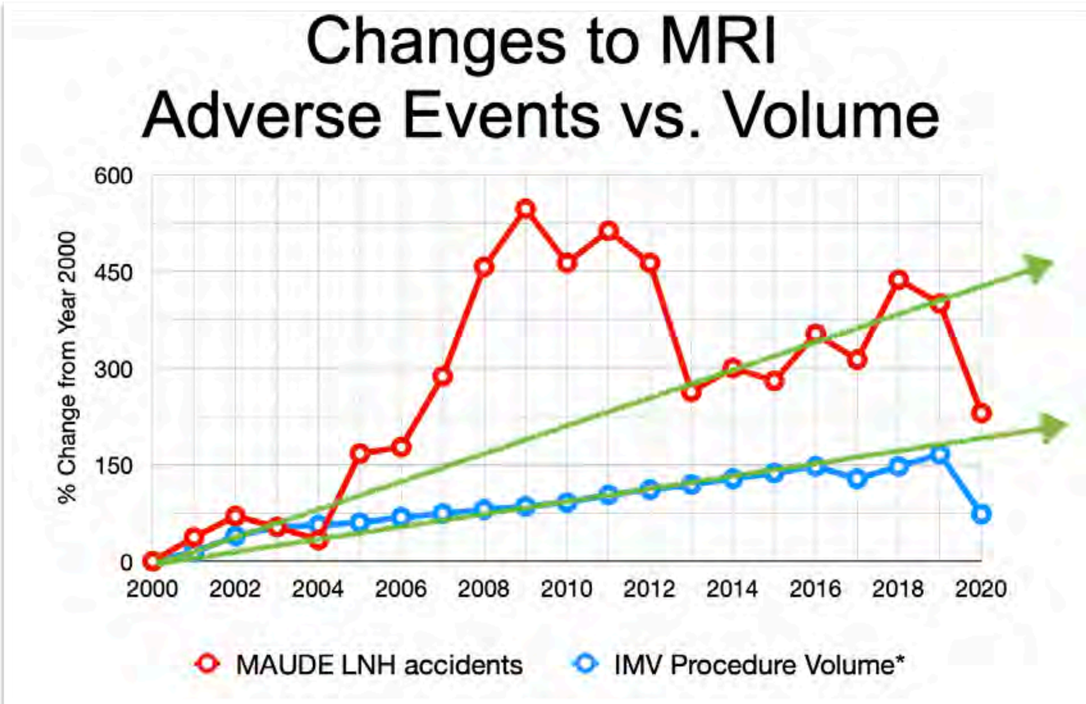
MRI Safety In Accreditation

Promise of Quality & Safety



MRI Safety In Accreditation

Promise of Quality & Safety



https://gilkradiologyconsultants.com/blog/the-mri-accident-chart-2000-2020/

MRI Safety In Accreditation

Joint Commission International (JCI)

Radiology and Diagnostic Imaging Services

Standard AOP.6
Radiology and diagnostic imaging services are available to meet patient needs, and all such services meet applicable local and national standards, laws, and regulations.

Standard AOP.6.1
A qualified individual(s) is responsible for managing the radiology and diagnostic imaging services.

Standard AOP.6.2
Individuals with proper qualifications and experience perform diagnostic imaging studies, interpret the results, and report the results.

Standard AOP.6.3
Radiation safety program is in place, followed, and documented, and compliance with the facility management and infection control programs is maintained.

Standard AOP.6.4
Radiology and diagnostic imaging study results are available in a timely way as defined by the hospital.

Standard AOP.6.5
All equipment and medical technology used to conduct radiology and diagnostic imaging studies is regularly inspected, maintained, and calibrated, and appropriate records are maintained for these activities.

Standard AOP.6.6
X-ray film and other supplies are regularly available.

Standard AOP.6.7
Quality control procedures are in place, followed, and documented.

Standard AOP.6.8
The hospital regularly reviews quality control results for all outside sources of diagnostic services.

MRI Safety In Accreditation

Joint Commission (USA)

Environment of Care (EC)

Standard EC.02.01.01
The organization manages safety and security risks.

Elements of Performance for EC.02.01.01

A 14. The organization manages magnetic resonance imaging (MRI) safety risks associated with the following:

- Patients who may experience claustrophobia, anxiety, or emotional distress
- Patients who may require urgent or emergent medical care
- Patients with medical implants, devices, or imbedded metallic foreign objects (such as shrapnel)
- Ferromagnetic objects entering the MRI environment
- Acoustic noise

A 16. The organization manages magnetic resonance imaging (MRI) safety risks by doing the following: ⚠

- Restricting access of everyone not trained in MRI safety or screened by staff trained in MRI safety from the scanner room and the area that immediately precedes the entrance to the MRI scanner room.
- Making sure that these restricted areas are controlled by and under the direct supervision of staff trained in MRI safety.
- Posting signage at the entrance to the MRI scanner room that conveys that potentially dangerous magnetic fields are present in the room. Signage should also indicate that the magnet is always on except in cases where the MRI system, by its design, can have its magnetic field routinely turned on and off by the operator.

C 25. Ⓓ The [critical access] hospital verifies and documents that technologists who perform magnetic resonance imaging (MRI) examinations participate in ongoing education that includes annual training on safe MRI practices in the MRI environment, including the following: Ⓜ

- Patient screening criteria that address ferromagnetic items, electrically conductive items, medical implants and devices, and risk for Nephrogenic Systemic Fibrosis (NSF)
- Proper patient and equipment positioning activities to avoid thermal injuries
- Equipment and supplies that have been determined to be acceptable for use in the MRI environment (MR safe or MR conditional) *
- MRI safety response procedures for patients who require urgent or emergent medical care
- MRI system emergency shutdown procedures, such as MRI system quench and cryogen safety procedures
- Patient hearing protection
- Management of patients with claustrophobia, anxiety, or emotional distress

* Terminology for defining the safety of items in the magnetic resonance environment is provided in ASTM F2503 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (http://www.astm.org).

MRI Safety In Accreditation

CBAHI

CBAHI

STANDARDS

RD.1 Qualified radiologist is responsible for managing the radiology department.

RD.2 The radiology department has adequate qualified staff.

RD.2.1 The radiology department has adequate staff, including:

RD.2.1.3 Radiation safety officer and supervisor (for radiotherapy nuclear medicine and diagnostics).

RD.3 The radiology department has policies and procedures that guide all radiological activities.

RD.3.1 The radiology department has policies and procedures to address all important radiological investigations and procedures, including:

RD.3.1.4 Magnetic Resonance Imaging.

RD.4 Requests for radiological investigations utilize a standardized method throughout the hospital.

RD.5 The radiology department implements a policy and procedure that defines the process and time limits of results reporting for all radiological studies.

RD.6 The radiology department implements a policy and procedure for reporting of critical results.

RD.7 Previous radiological studies can always be accessed.

RD.7.1 There is a master X-ray jacket or an access to all archived previous radiological studies (Picture Archiving and Communication System-PACS) for every patient.

RD.8 The radiology department has a documented and implemented safety plan.

RD.8.1 There is a safety plan that indicates the periodic inspection, maintenance, and calibration of all equipment.

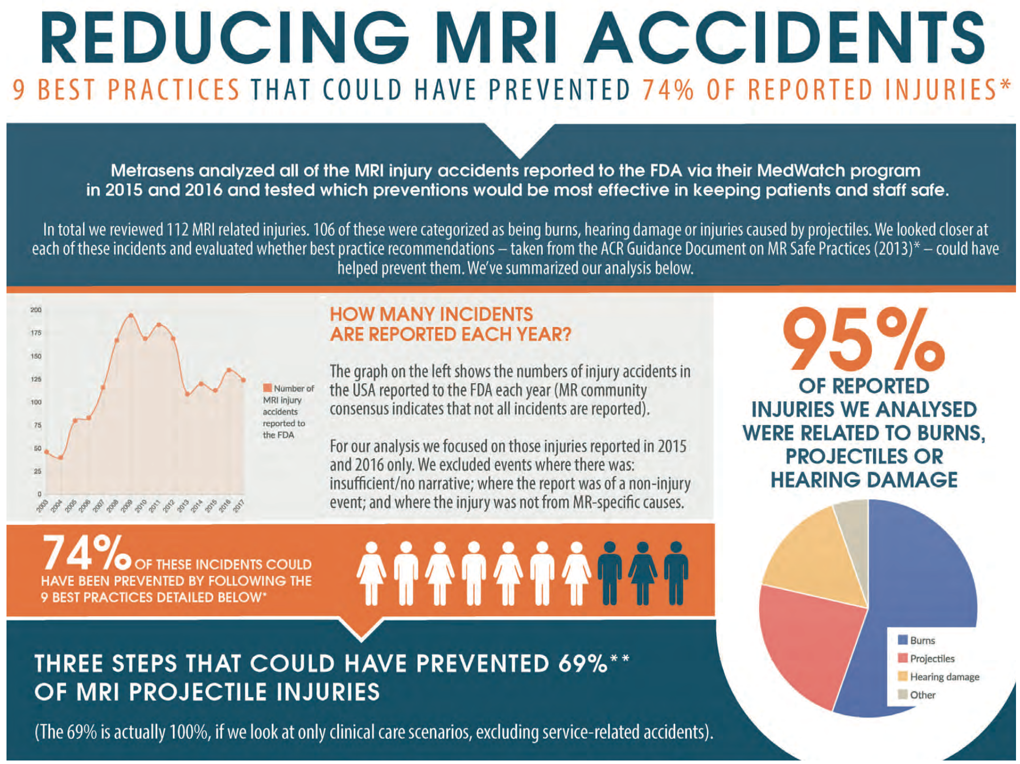
RD.8.2 The safety plan involves the management of radioactive materials used for therapeutic and diagnostic purposes, particularly with regard to handling, storing, and transportation.

RD.8.3 The safety plan involves posting of safety warnings on the doors.

RD.9 The radiology department has a documented and implemented protocol for interventional radiological procedures.

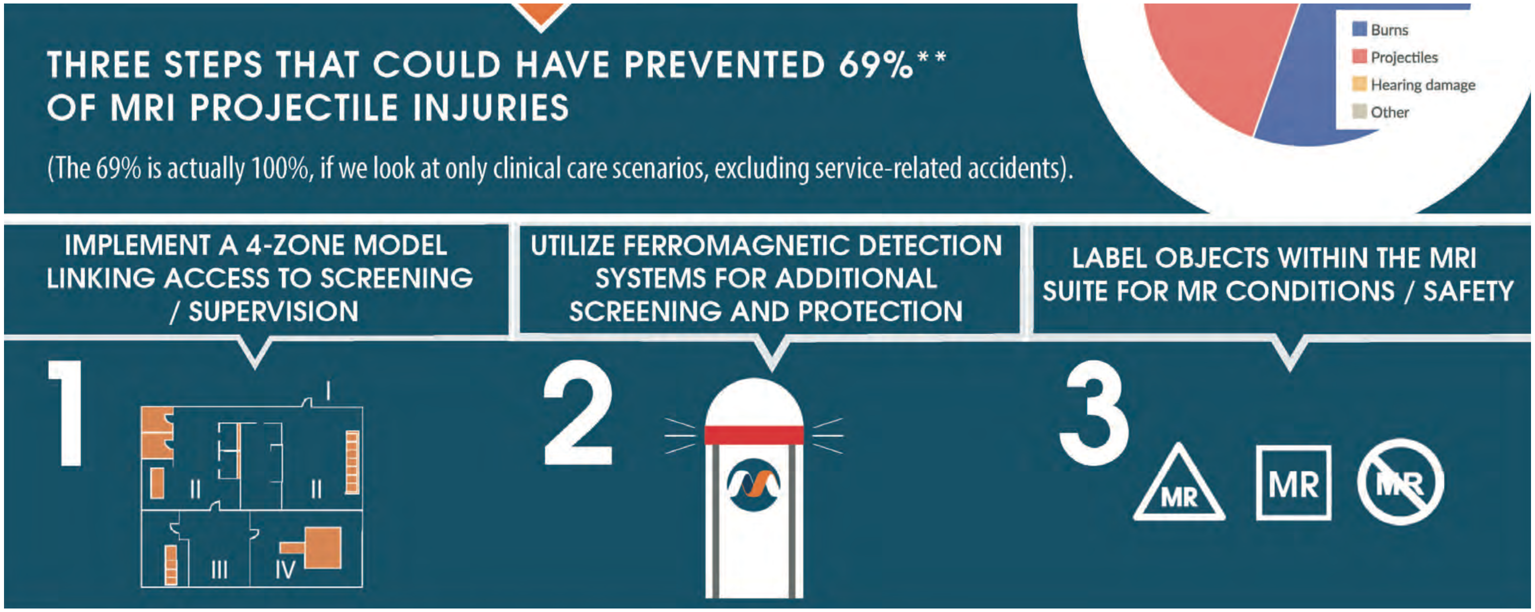
RD.10 The radiology department ensures the safety of diagnostic imaging equipment.

MRI Safety In Accreditation



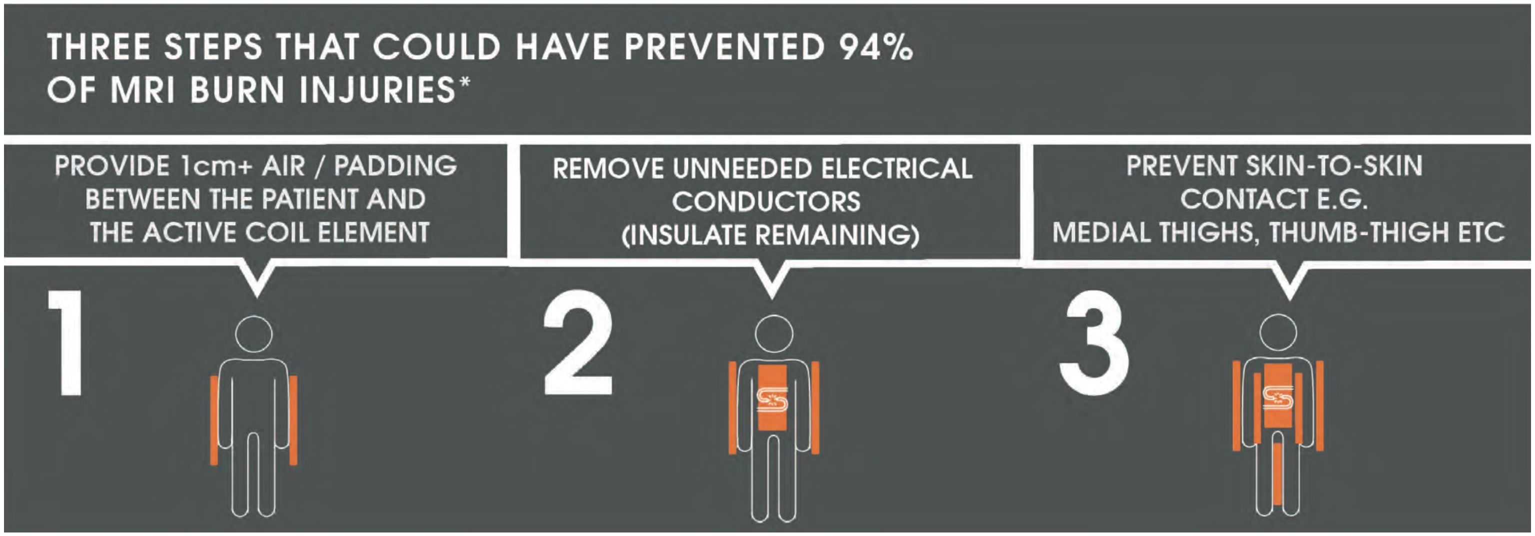
https://www.metrasens.com/resource/reducing-mri-accidents/

MRI Safety In Accreditation



https://www.metrasens.com/resource/reducing-mri-accidents/

MRI Safety In Accreditation



https://www.metrasens.com/resource/reducing-mri-accidents/

MRI Safety In Accreditation

https://www.metrasens.com/resource/reducing-mri-accidents/

MRI Safety In Accreditation

https://www.metrasens.com/resource/reducing-mri-accidents/

MRI Safety In Accreditation

Projectile Safety

	Require 4-Zones	Require FMD	Req. Device Labeling
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

Projectile Safety

	Require 4-Zones	Require FMD	Req. Device Labeling
Joint Commission (H)	[kinda]	✗	✗
DNV Healthcare (H)	✗	✗	✗
ACR (OP)	[kinda]	✗	✗
IAC (OP)	✗	✗	✗

MRI Safety In Accreditation

RF Burn Protections

	Require Padding	Remove Conductors	Prevent Skin-to-Skin
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

RF Burn Protections

	Require Padding	Remove Conductors	Prevent Skin-to-Skin
Joint Commission (H)	[kinda]	❌	[kinda]
DNV Healthcare (H)	❌	❌	❌
ACR (OP)	❌	❌	❌
IAC (OP)	❌	❌	❌

MRI Safety In Accreditation

Hearing Protection

	Require Protection	Verify Fit & Function	Provide Alt. Means
Joint Commission (H)			
DNV Healthcare (H)			
ACR (OP)			
IAC (OP)			

MRI Safety In Accreditation

Hearing Protection

	Require Protection	Verify Fit & Function	Provide Alt. Means
Joint Commission (H)	[kinda]	❌	❌
DNV Healthcare (H)	❌	❌	❌
ACR (OP)	❌	❌	❌
IAC (OP)	❌	❌	❌

MRI Safety In Accreditation

- The prior ‘scorecards’ don’t even touch on requirements managing complex device patients

MRI Safety In Accreditation

Change Is Coming

MRI Safety Program Assessment Checklist

Site: ____________________

The site's written MRI safety policy addresses the following:	Yes/No/NA
1. Designated MR medical director	
2. Site access restrictions (MR zones)	
3. Documented MR Safety education/training for all personnel	
4. Patient and non-MR personnel screening	
5. Pediatric patients	
6. Magnet quench	
7. Cryogen safety	
8. Acoustic noise	
9. Pregnant patients and staff	
10. Contrast agent safety	
11. Sedations	
12. Thermal burns	
13. Emergency code procedures	
14. Device and object screening	
15. Designation of MR safe/MR conditional status	
16. Reporting of MR safety incidents or adverse incidents	
17. Patient communication	
18. Infection control and medical waste	

ACR criteria for compliance:	Yes/No/NA
1. Written policies are present and readily available to facility staff.	
2. Written policies are reviewed and updated on a regular basis.	
3. Facility has appropriate MR safety warning signage and methods of controlled access.	
Overall Pass/Fail	

MRI Safety In Accreditation

Change Is Coming

وزارة الصحة
Ministry of Health

Appendix One

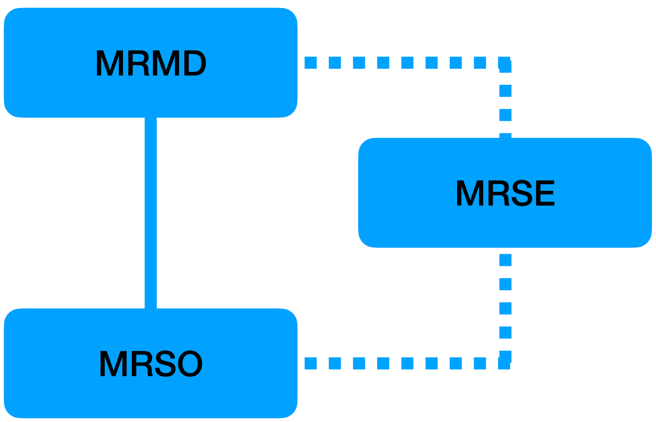
Magnetic Resonance (MR) Safety Checklist

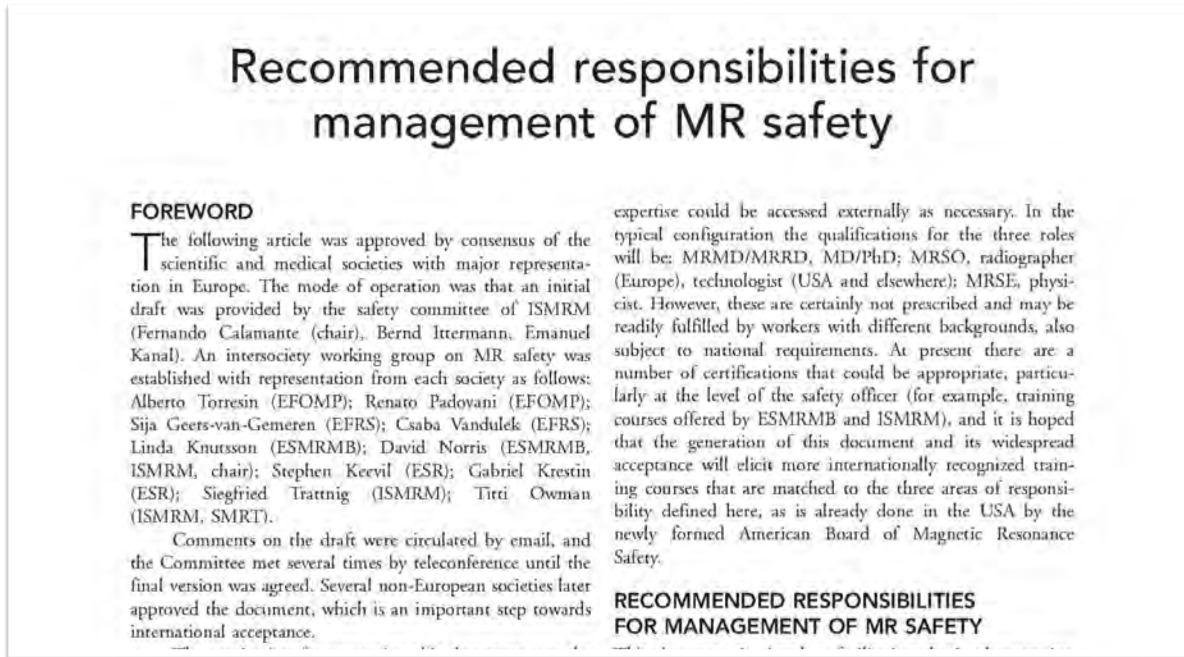
Hospital Name: .... **Region/Governance Name:** .... **Date**: .../.../......

Code	D♦	Criteria	Best Practices		Means of Verification	Is It Applicable		Score ♣	Remarks
						No	Yes		
MRS-1	S	Supervision of MR unit	MRS-1-1	There is a policy and procedure (PP) to assign the MR supervisor	Review PP				
			MRS-1-2	The responsibilities involve implementing MR policies and procedures					
			MRS-1-3	The responsibilities updating MR policies and procedures					
			MRS-1-4	The responsibilities involve provision of MR safety training					
			MRS-1-5	The responsibilities involve quality monitoring and improvement					
MRS-2	P	Implement the PP for MR supervisor	MRS-2-1	The PP for supervisor of MR unit is implemented.	Review documents/ interview				
MRS-3	S	Staff training on MR safety	MRS-3-1	There is a PP to ensure staff training on MR safety.	Review PP				
			MRS-3-2	This PP defines training required for staff in					

Organizational Structure For MRI Safety

Organizational Structure For MRI Safety





Recommended responsibilities for management of MR safety

FOREWORD

The following article was approved by consensus of the scientific and medical societies with major representation in Europe. The mode of operation was that an initial draft was provided by the safety committee of ISMRM (Fernando Calamante (chair), Bernd Ittermann, Emanuel Kanal). An intersociety working group on MR safety was established with representation from each society as follows: Alberto Torresin (EFOMP); Renato Padovani (EFOMP); Sija Geers-van-Gemeren (EFRS); Csaba Vandulek (EFRS); Linda Knutsson (ESMRMB); David Norris (ESMRMB, ISMRM, chair); Stephen Keevil (ESR); Gabriel Krestin (ESR); Siegfried Trattnig (ISMRM); Titti Owman (ISMRM, SMRT).

Comments on the draft were circulated by email, and the Committee met several times by teleconference until the final version was agreed. Several non-European societies later approved the document, which is an important step towards international acceptance.

expertise could be accessed externally as necessary. In the typical configuration the qualifications for the three roles will be: MRMD/MRRD, MD/PhD; MRSO, radiographer (Europe), technologist (USA and elsewhere); MRSE, physicist. However, these are certainly not prescribed and may be readily fulfilled by workers with different backgrounds, also subject to national requirements. At present there are a number of certifications that could be appropriate, particularly at the level of the safety officer (for example, training courses offered by ESMRMB and ISMRM), and it is hoped that the generation of this document and its widespread acceptance will elicit more internationally recognized training courses that are matched to the three areas of responsibility defined here, as is already done in the USA by the newly formed American Board of Magnetic Resonance Safety.

RECOMMENDED RESPONSIBILITIES FOR MANAGEMENT OF MR SAFETY

https://onlinelibrary.wiley.com/doi/full/10.1002/jmri.25282

Pediatric Population MRI Safety Benefits

- TEXT
- TEXT

Training Levels

Training Levels

- **Key Elements of MRI Safety Training**

Topic	Level 1 MRI Personnel	Level 2 MRI Personnel
Ferromagnetic Projectile risks	✓	✓
General Magnetic Field Safety- "Magnet is <u>Always</u> On"	✓	✓
Importance of Maintaining Zone III and IV doorway protection and vigilance	✓	✓
Emergency procedures and responsibilities in the MRI environment, including when and how to quench	✓	✓
Importance of MR Safety screening prior to entering Zone III and Zone IV	✓	✓
Understanding the roles of MRMD, MRSO, MRSE and how to contact these personnel	✓	✓
Understanding the importance of safety events and near miss reporting, and the site-specific mechanisms of doing this	✓	✓
Procedures to secure potentially unsafe equipment in Zone III (tether; locked storage, etc.)	✓	✓
Appropriate precautions/procedures for operation in alternative MR environments (e.g., PET/MR; intraoperative/interventional, 7T, etc.)	✓	✓
Elements of MR Safety screening prior to entering Zone III and Zone IV, including proper use of ferromagnetic detection equipment		✓
RF-related safety		✓
Time-Varying magnetic fields-PNS and acoustic noise		✓
Cryogen and quench safety		✓
Implanted device safety		✓
Contrast agent safety		✓
Proper use and function of all safety switches		✓
Static magnetic field safety- spatial gradients and Lenz forces		✓
Thermal burn prevention		✓
Procedures to ensure ability to communicate with the patient/research participant when scanning		✓
Factors related to scanning of unique patients (pregnant, pediatric, claustrophobic, high BMI, prisoners/detainees, parolees, etc.)		✓

Table 1. Key elements of MRI safety training.

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

MRI Safety: Implant & Device Scenarios

Tobias Gilk - Sept 24, 2023

Outline

MRI Safety Scenarios

We're going to decide on:

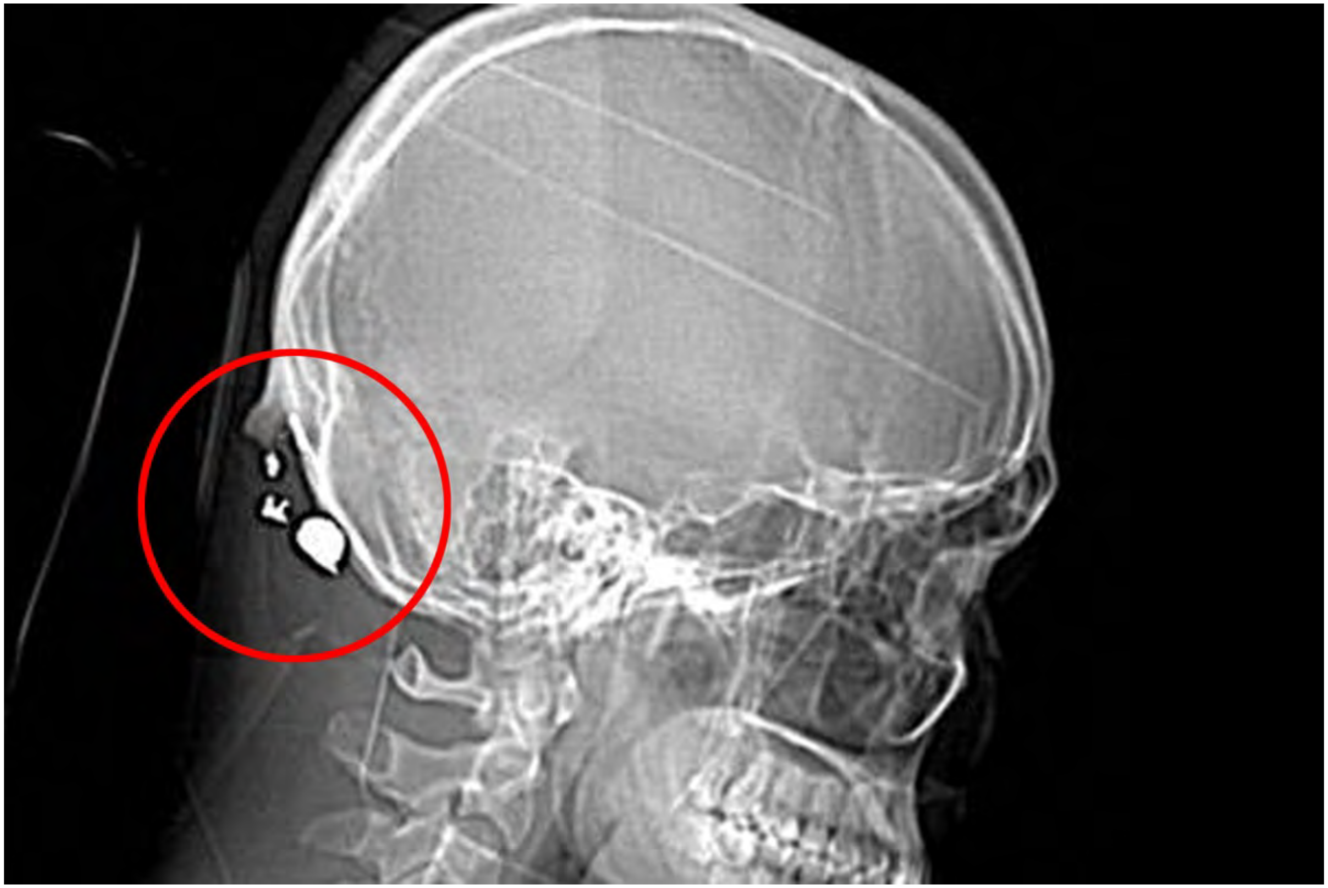
- MRI Scanner
- Patient Description
- Desired Study

I'm going to give you:

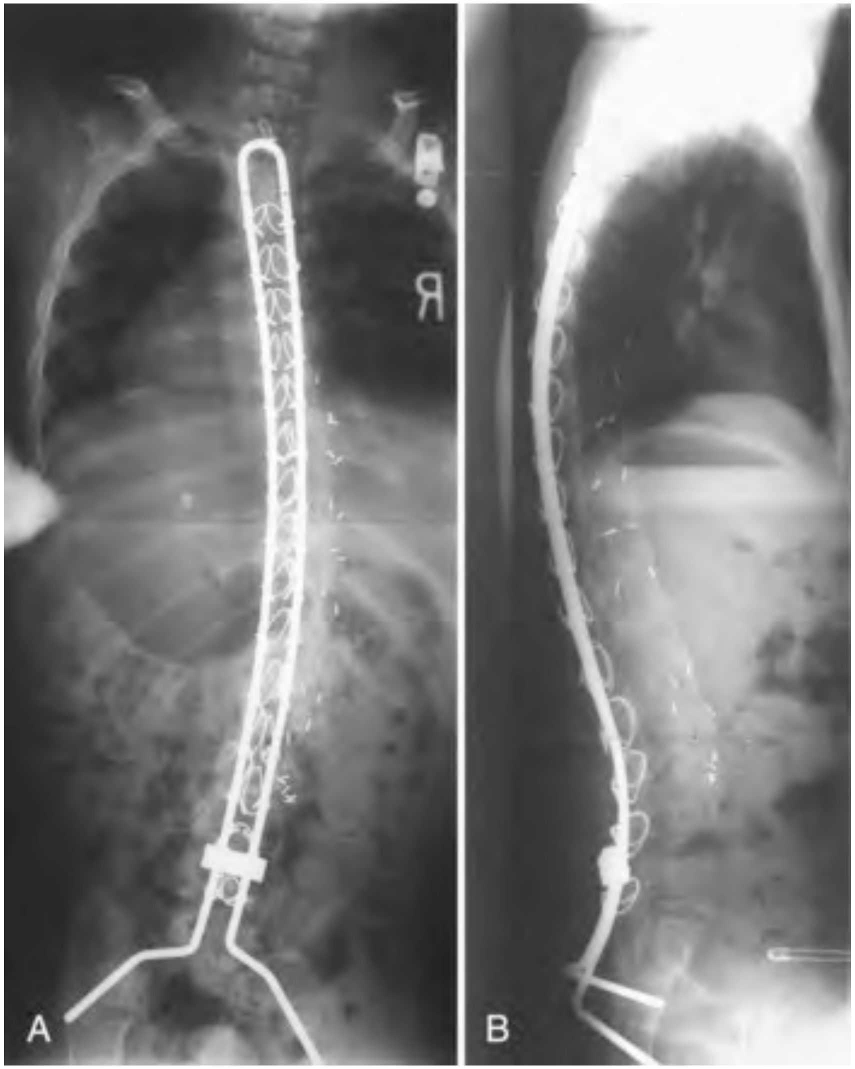
- An Implant / Device / Foreign Body

Scenarios

Scenarios



Scenarios

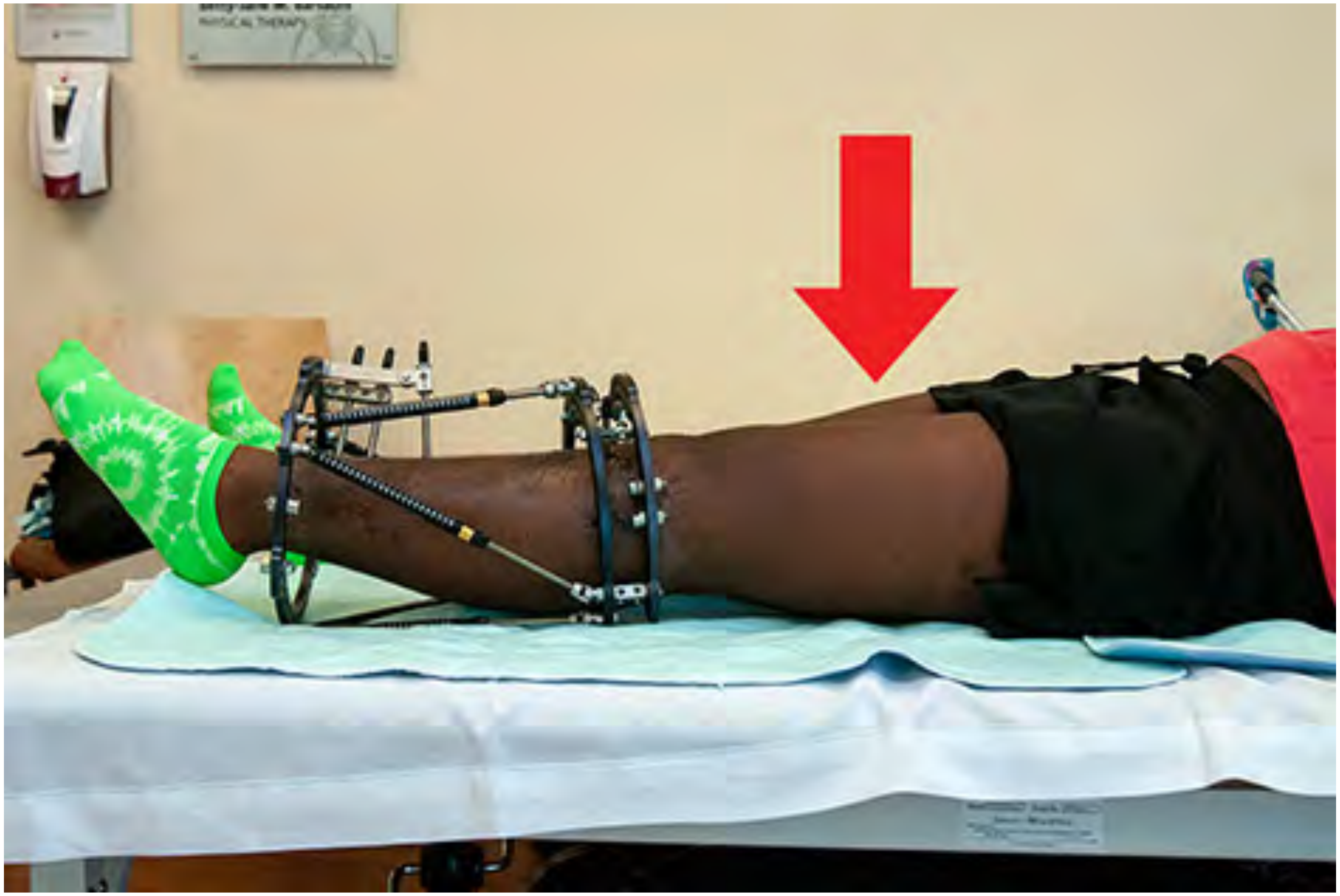


Scenarios

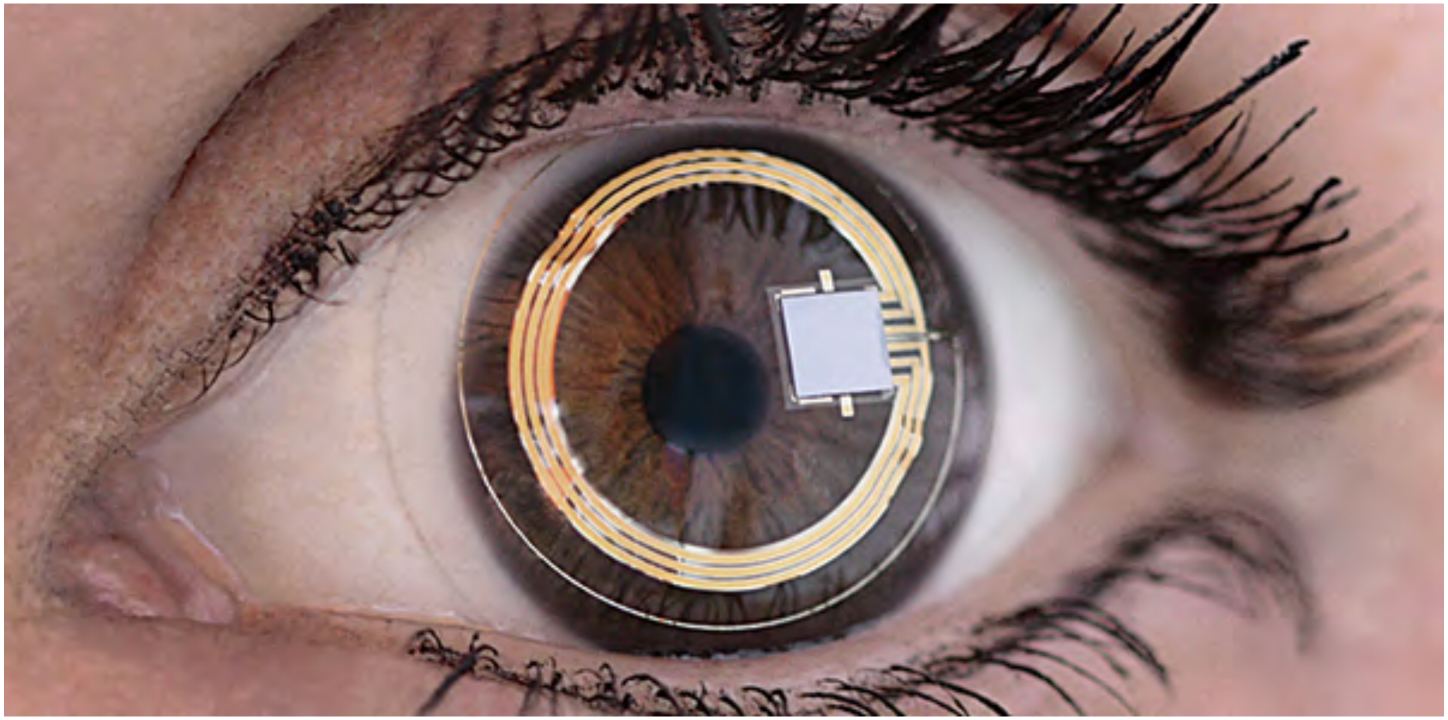
Scenarios

Scenarios

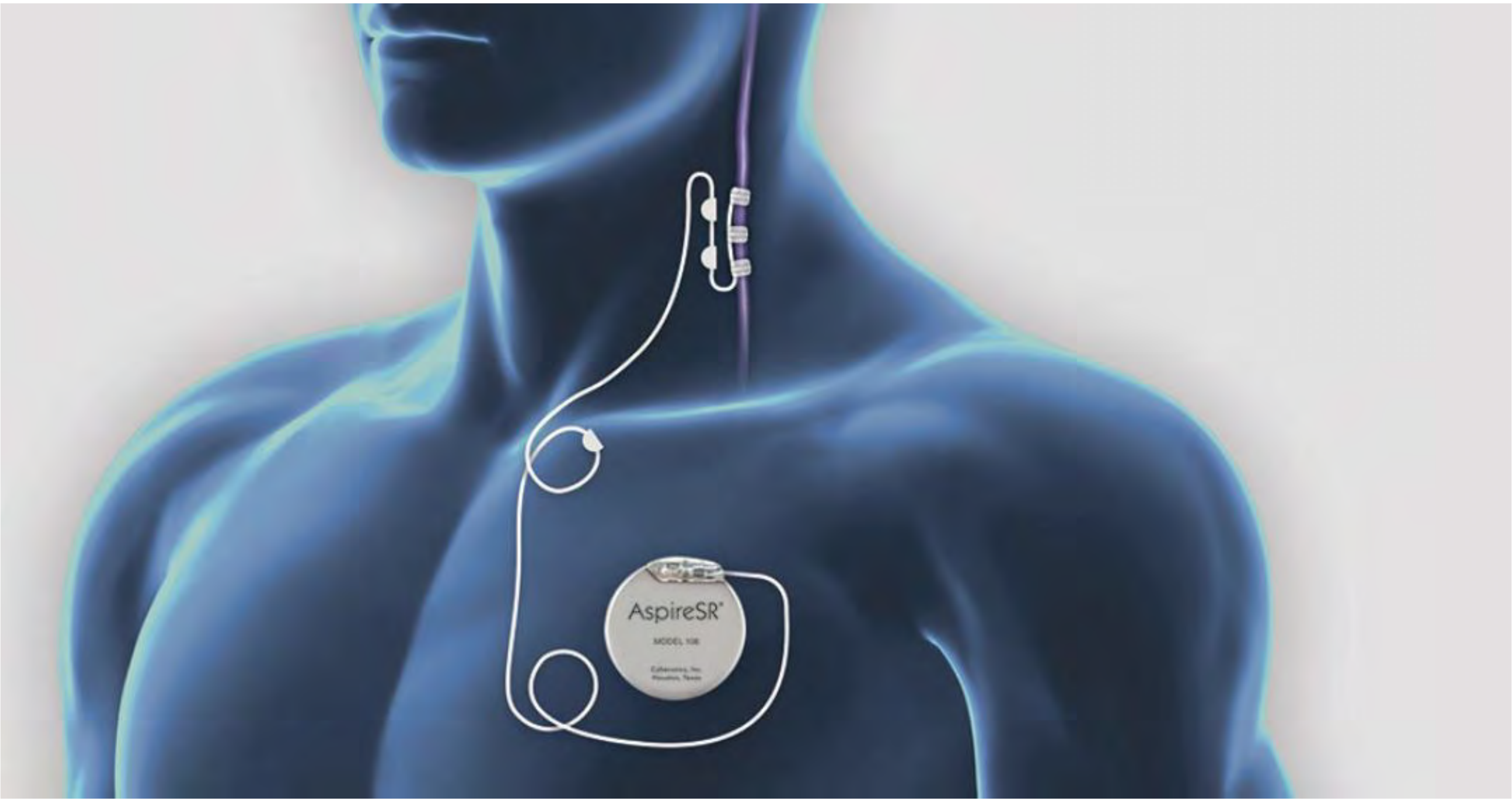
Scenarios



Scenarios



Scenarios



Scenarios

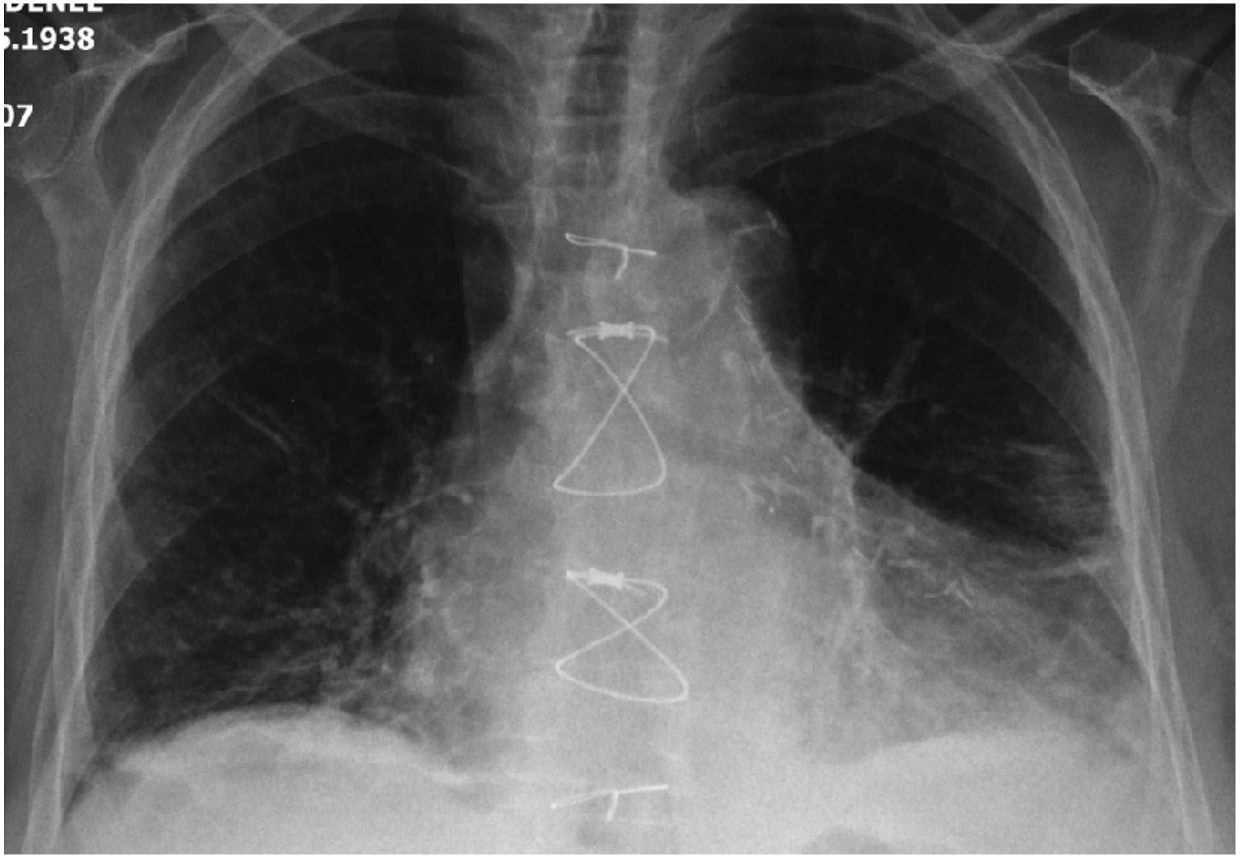
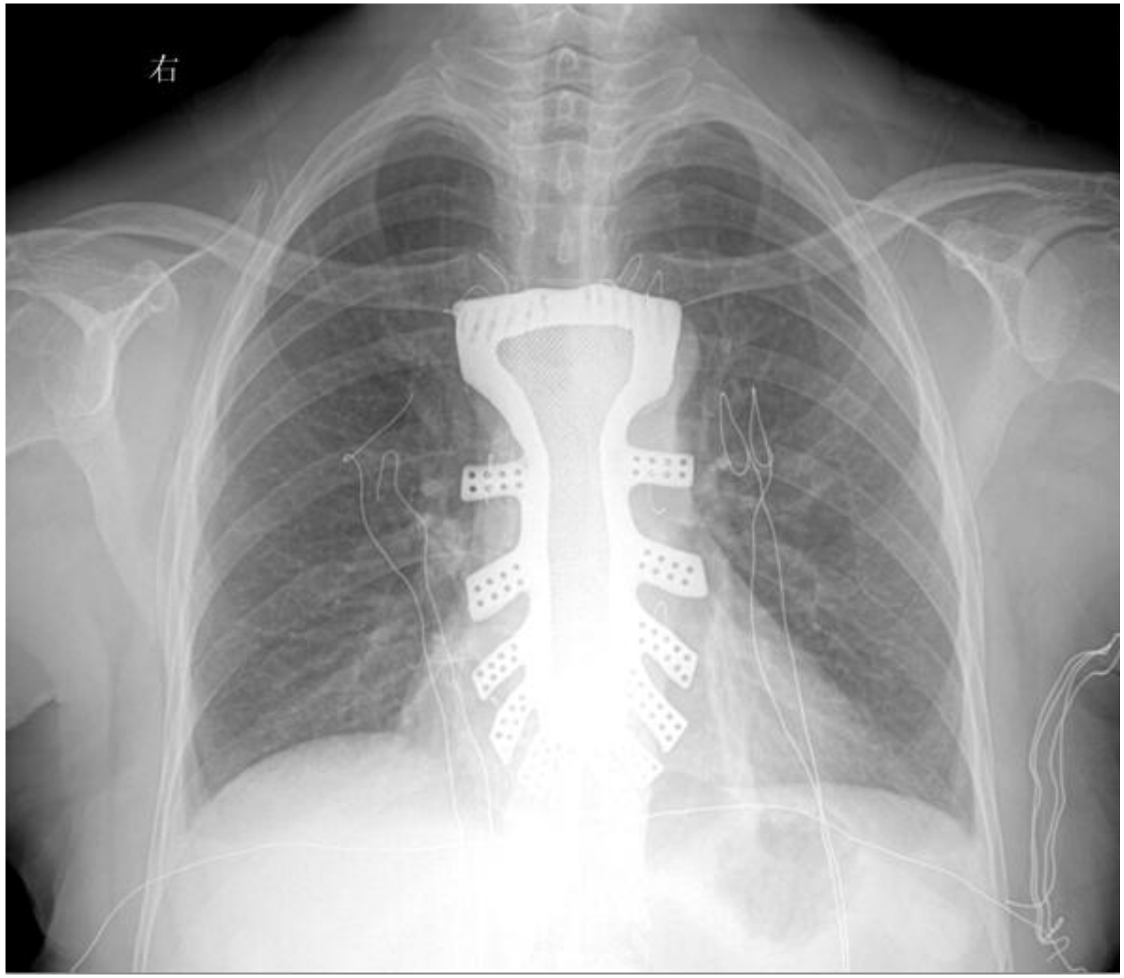


Figure 1. X-Ray of a patient closed with sternal cable system.

Scenarios

Scenarios

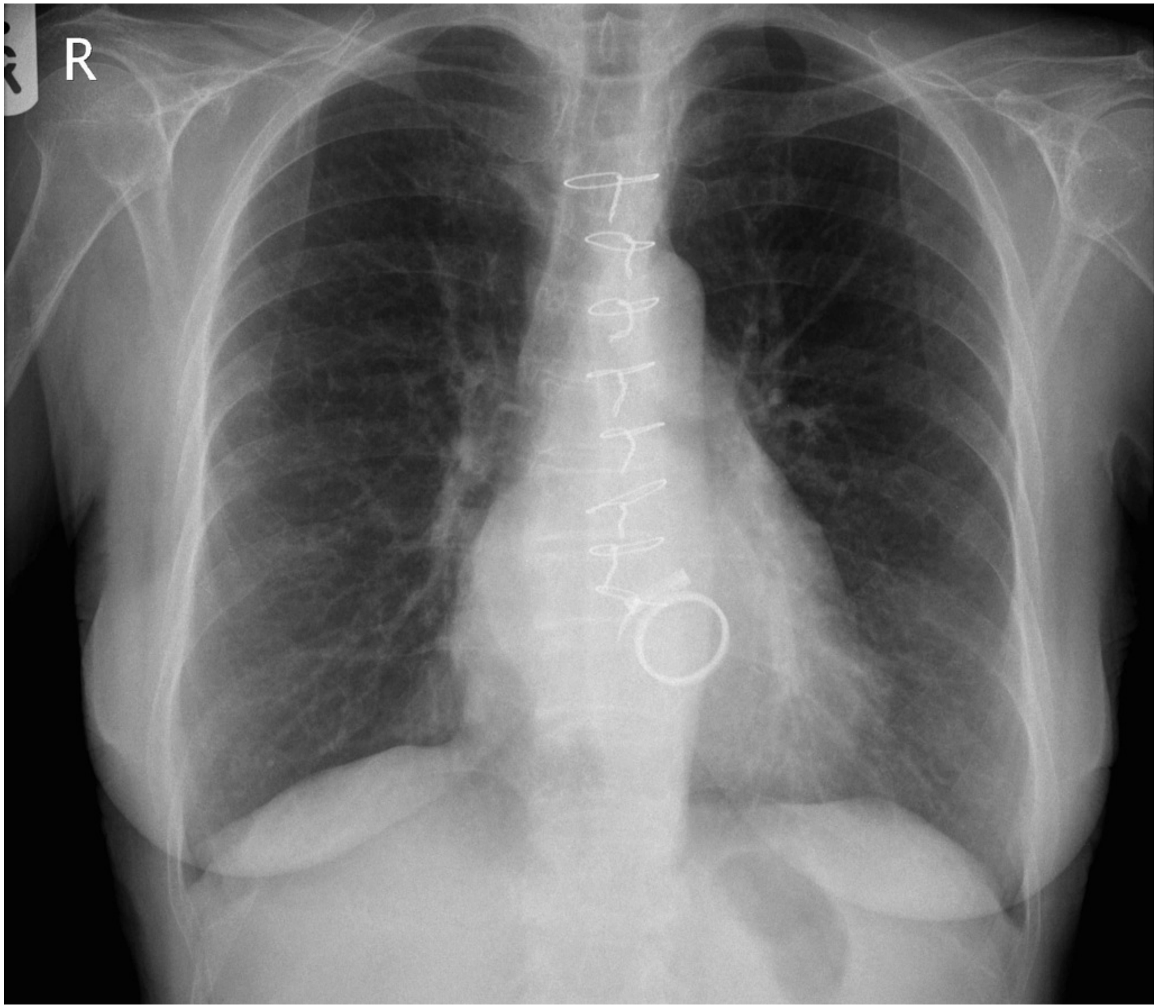


Scenarios

Scenarios

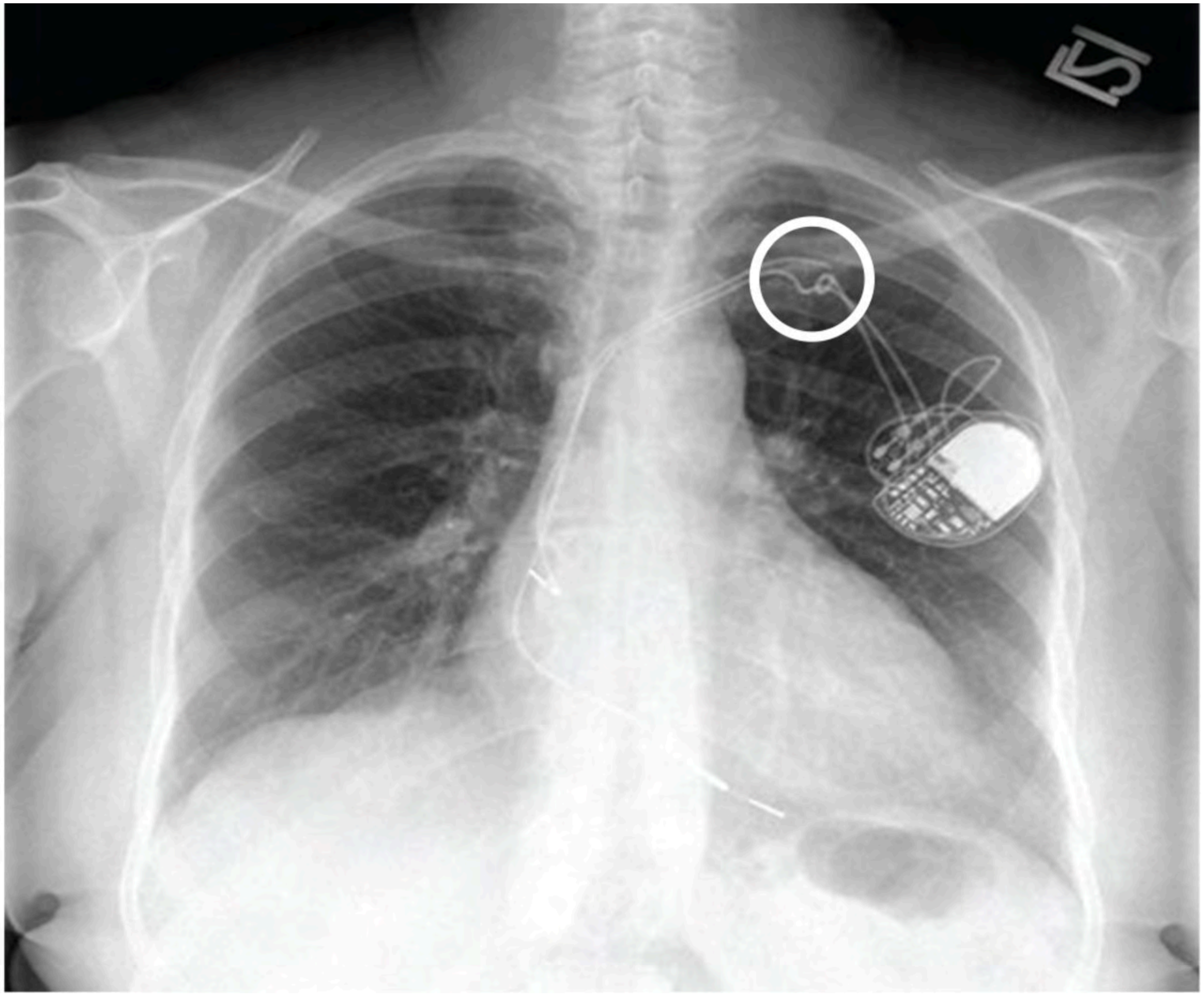
Scenarios

Scenarios

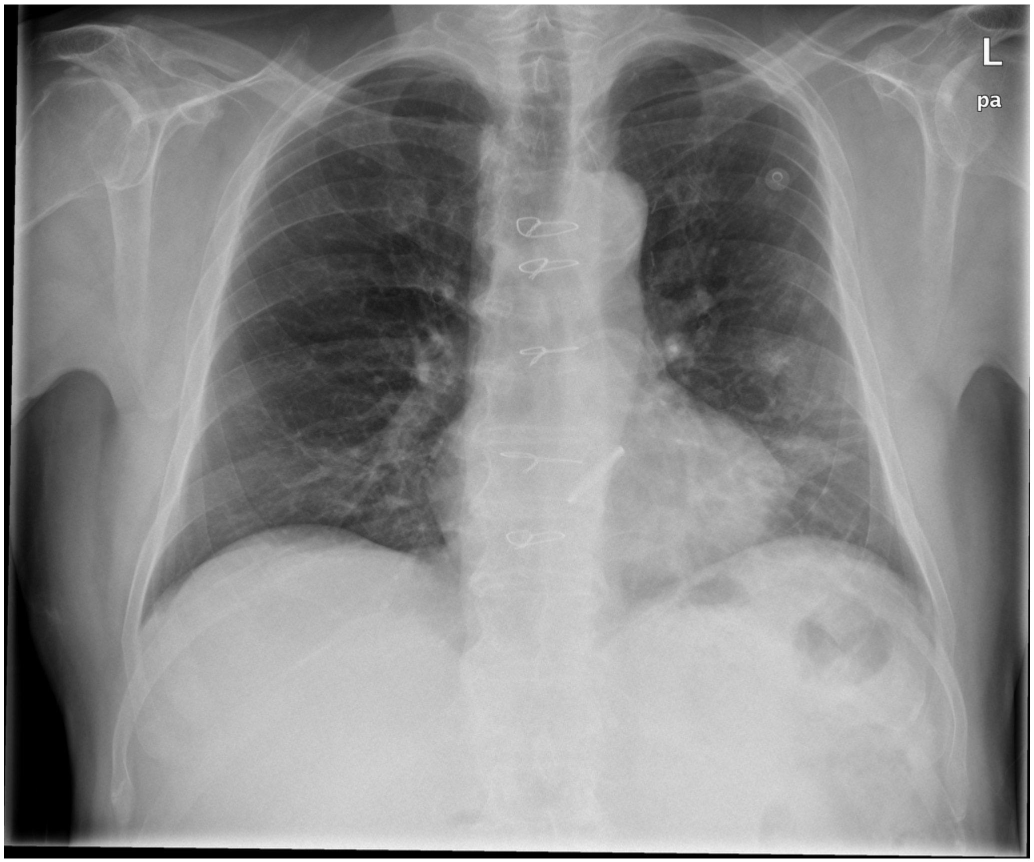


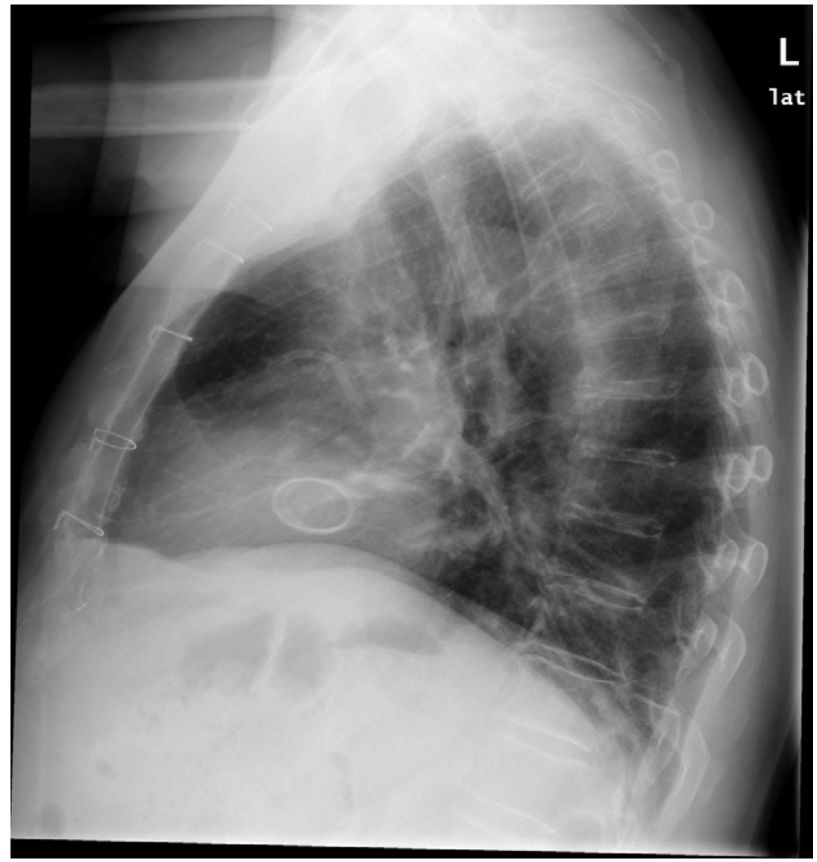
Scenarios

Scenarios



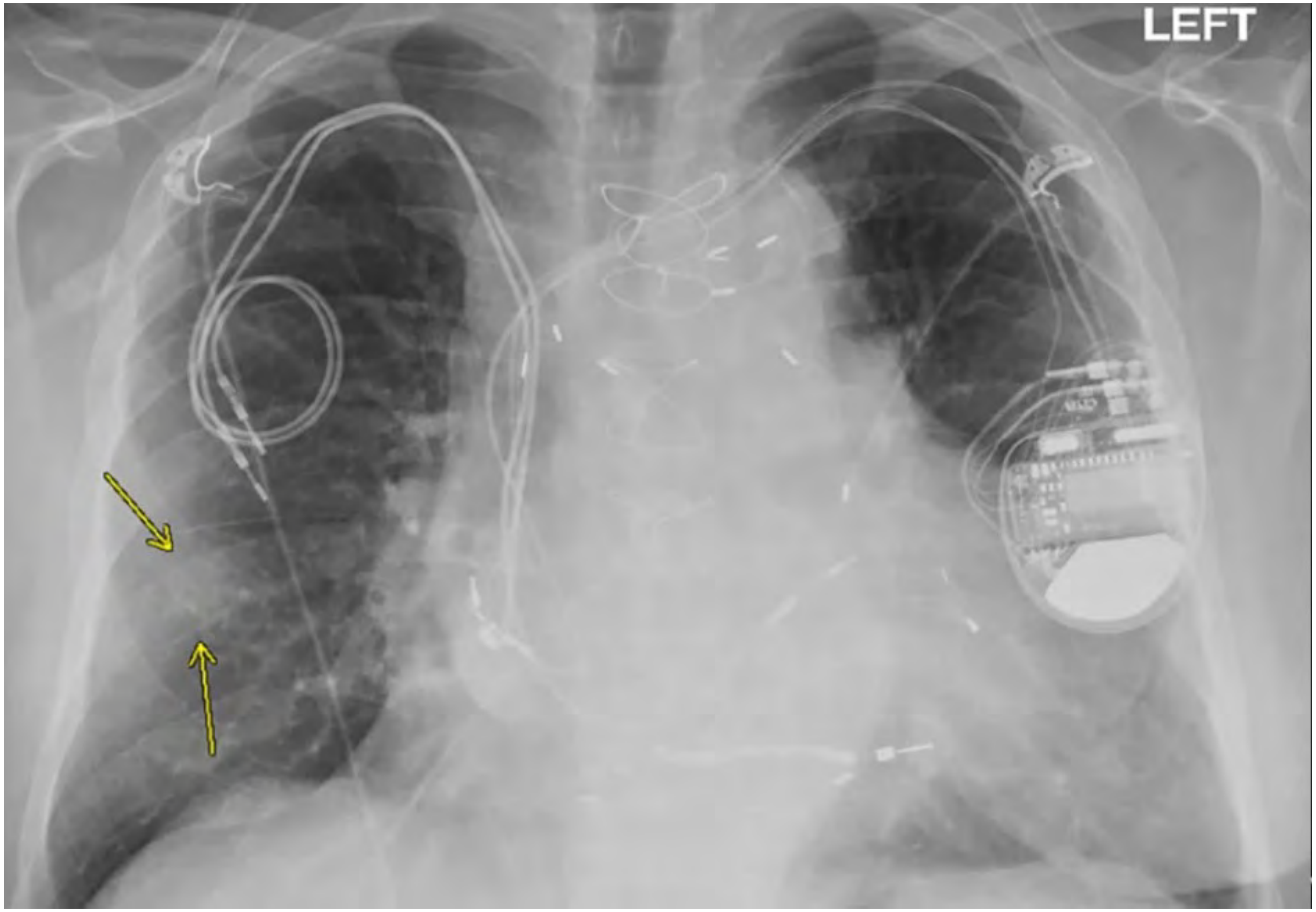
Scenarios





Scenarios

Scenarios



Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety

Operational MRI Safety Structures

Tobias Gilk - Sept 24, 2023

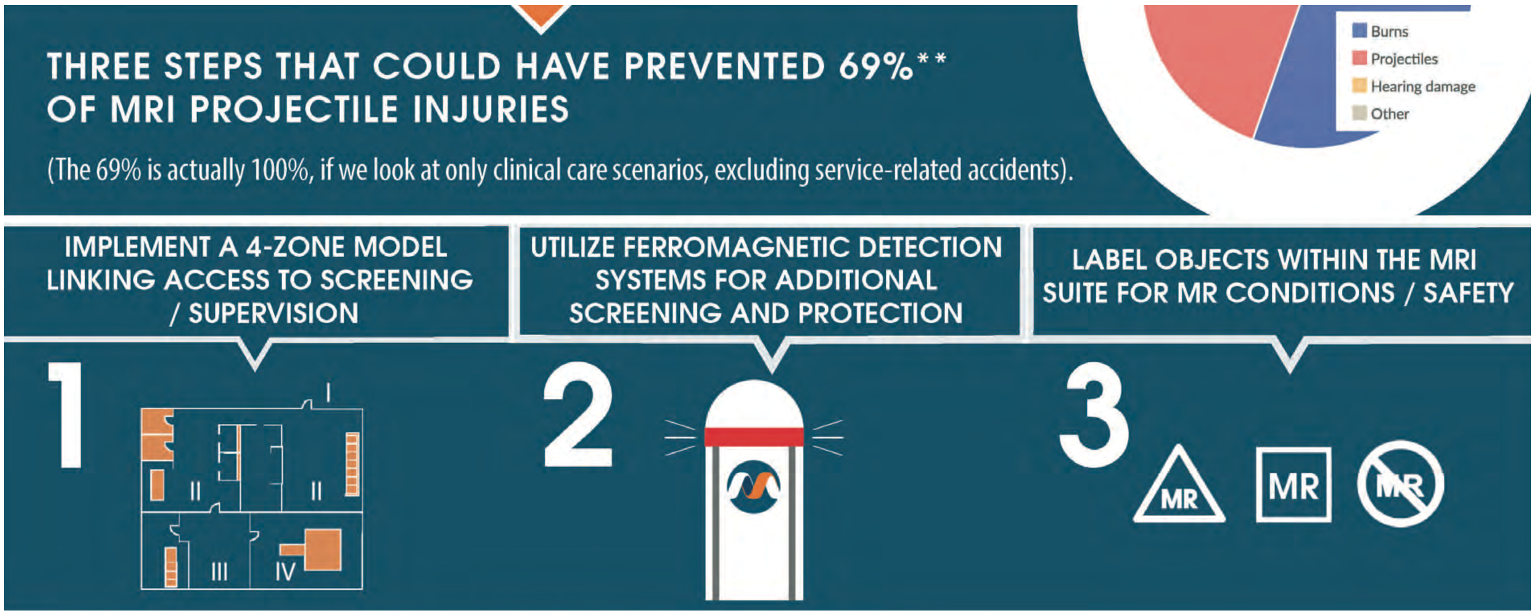
Outline

Operational MRI Safety Structures

- Intro
- Injury-Reducing ‘Low-Hanging Fruit’
- Policies
- Training
- Culture
- Q & A

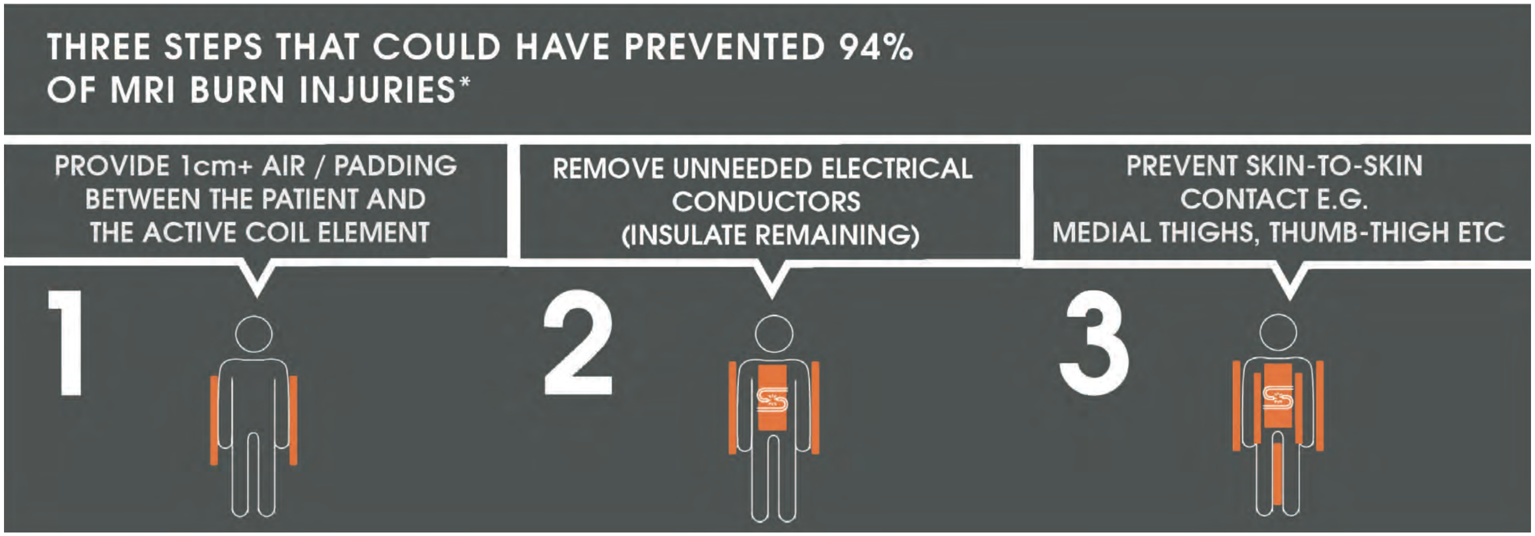
Injury-Reducing ‘Low-Hanging Fruit’

Injury-Reducing 'Low-Hanging Fruit'



https://www.metrasens.com/mri-safety/mri-safety-infographic/

Injury-Reducing 'Low-Hanging Fruit'



https://www.metrasens.com/mri-safety/mri-safety-infographic/

Injury-Reducing 'Low-Hanging Fruit'

https://www.metrasens.com/mri-safety/mri-safety-infographic/

Injury-Reducing 'Low-Hanging Fruit'

Expert Panel on MRI Safety Best Practices

- MRMD / MRSO / MRSE
- Obtain Device Documentation
- Review MRI Site Planning w/ Expert
- Report Near-Miss Events to MRMD
- Documented Annual MRI Safety Training
- +1 Staffing Model
- Supervision By Level 2-Trained Person At All Times
- Use Ferromagnetic Detectors
- Gown All Patients To Skin
- Full-Stop / Final Check
- Pad Patients Per OEM Specifications

“MRI Safety Is Everyone’s Responsibility”

"MRI Safety Is Everyone's Responsibility"

No, It's Not!

“MRI Safety Is Everyone’s Responsibility”

MRI Safety Responsibilities & Authorities Need To Be Clearly Defined & Assigned

“MRI Safety Is Everyone’s Responsibility”

“Everyone’s Responsibility” = “Group Project”

“MRI Safety Is Everyone’s Responsibility”

Kitty Genovese

"MRI Safety Is Everyone's Responsibility"

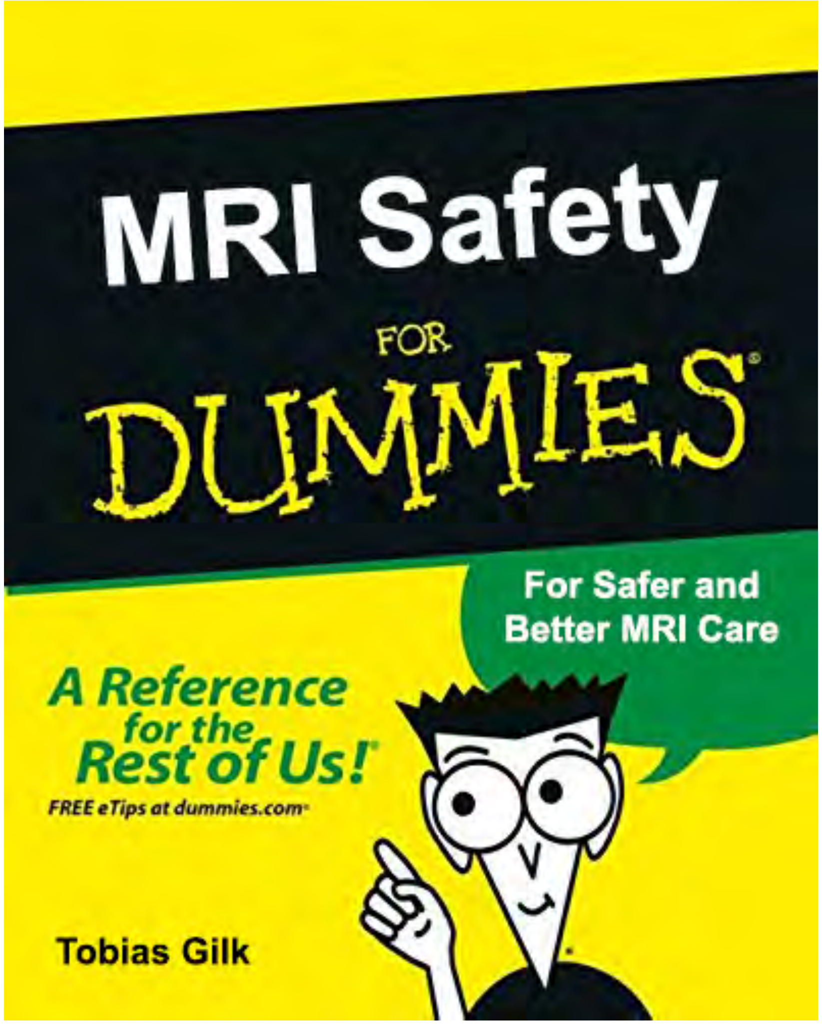
Everyone has a role in MRI safety, but specific responsibilities need to be clearly defined & communicated.

Policies

Policies

Test your policies…

Could a new radiographer safely complete an MRI exam by *only following the direction in your written policies*?



Policies

Test your policies…

Could a new radiographer safely complete an MRI exam by *only following the direction in your written policies*?

GILK RADIOLOGY CONSULTANTS

Gilk Radiology Consultants
PO Box 26466
Overland Park, KS
66225
USA
913-515-8449

Gilk Radiology Consultants
MRI Safety Policies & Procedures Checklist

1.0 MR Safety Policy Structure

MRI Safety Practices Review
Annual Review of Policies, Procedures, Practices
Annual (Re-)Endorsement of Clinical P&P by MR Clinical Head and / or MRMD
Annual (Re-)Endorsement of Operational P&P by MR Administrator
P&P Review Trigger Criteria (e.g., new clinical practice, or change to MR equipment)
Culture (protection of staff based on adhering to policies)

2.0 MRI Physical Environment Safety

Zones and Access Controls
- Four Zone Concept
- Controlled Access Areas
  - General Restriction
  - MRI Scanner Room (Zone IV) Restriction

Who is permitted within the MRI Controlled Access area(s) (Zones 3 and 4)
- Patients
- Visitors
- Associates
- MR Departmental Staff

Who is permitted within the MRI scanner room(s) (Zone 4)
Not During MR Scanning / During MR Scanning (Screening / Protection Required)
- Patients
- Visitors
- Clinical Associates (e.g., anesthesia)
- Non-clinical Associates (e.g., maintenance)
- MR Departmental Staff

3.0 MRI Safety Training & Staff Standards

Safety Training Levels
- Level 1 Safety Training
  - Allowed Access / Restrictions
  - Different Training for different needs (e.g., 1a, 1b, 1c, 1d...)
- Level 2 Safety Training
  - Allowed Access
  - Situational Authority
  - Different Training for different needs (e.g 2a, 2b...)

Safety Training Content / Frequency
- Level 1 (Associates)
  - Annual (Documented)
  - Training / Competency content by need / purpose
- Joint Commission Required Training
  - Annual (Documented)
- Level 2 (MR Staff)

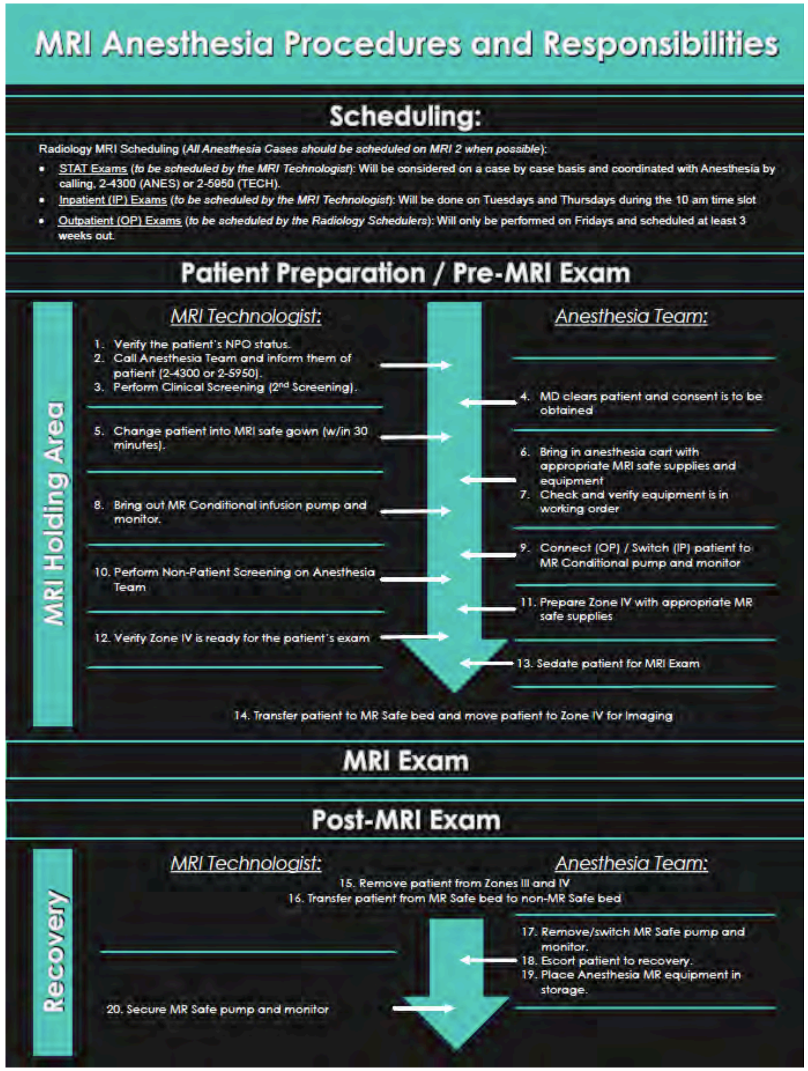
Policies

In My Experience…

… Many hospitals develop ‘standard operating procedures’ but never write them down.

This can lead to tremendous variation in delivery of care.

Policies



MRI Anesthesia Procedures and Responsibilities

Scheduling:

Radiology MRI Scheduling (*All Anesthesia Cases should be scheduled on MRI 2 when possible*):

- STAT Exams (*to be scheduled by the MRI Technologist*): Will be considered on a case by case basis and coordinated with Anesthesia by calling, 2-4300 (ANES) or 2-5950 (TECH).
- Inpatient (IP) Exams (*to be scheduled by the MRI Technologist*): Will be done on Tuesdays and Thursdays during the 10 am time slot
- Outpatient (OP) Exams (*to be scheduled by the Radiology Schedulers*): Will only be performed on Fridays and scheduled at least 3 weeks out.

Patient Preparation / Pre-MRI Exam

MRI Holding Area

MRI Technologist:

1. Verify the patient's NPO status.
2. Call Anesthesia Team and inform them of patient (2-4300 or 2-5950).
3. Perform Clinical Screening (2nd Screening).

5. Change patient into MRI safe gown (w/in 30 minutes).

8. Bring out MR Conditional infusion pump and monitor.

10. Perform Non-Patient Screening on Anesthesia Team

12. Verify Zone IV is ready for the patient's exam

Anesthesia Team:

4. MD clears patient and consent is to be obtained

6. Bring in anesthesia cart with appropriate MRI safe supplies and equipment
7. Check and verify equipment is in working order

9. Connect (OP) / Switch (IP) patient to MR Conditional pump and monitor

11. Prepare Zone IV with appropriate MR safe supplies

13. Sedate patient for MRI Exam

14. Transfer patient to MR Safe bed and move patient to Zone IV for Imaging

MRI Exam

Post-MRI Exam

Recovery

MRI Technologist:

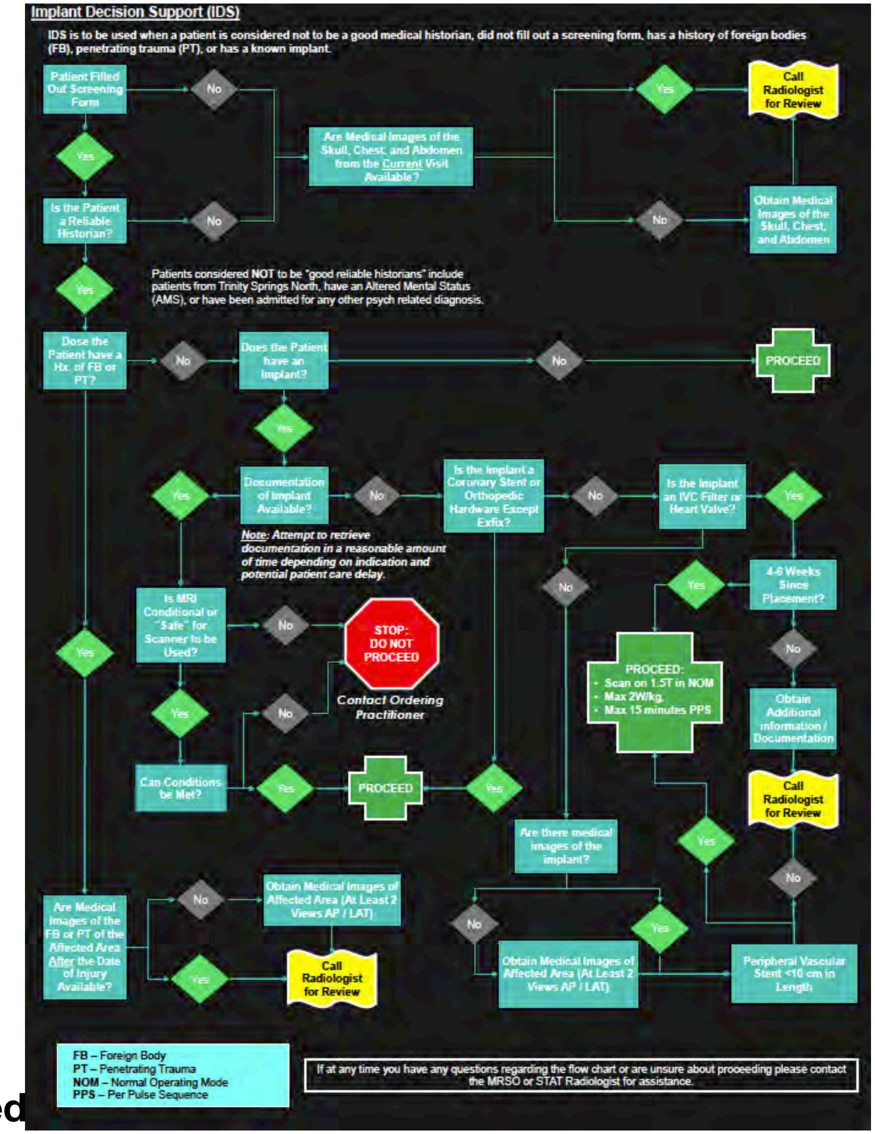
Anesthesia Team:

15. Remove patient from Zones III and IV
16. Transfer patient from MR Safe bed to non-MR Safe bed

17. Remove/switch MR Safe pump and monitor.
18. Escort patient to recovery.
19. Place Anesthesia MR equipment in storage.

20. Secure MR Safe pump and monitor

Policies



Implant Decision Support (IDS)
IDS is to be used when a patient is considered not to be a good medical historian, did not fill out a screening form, has a history of foreign bodies (FB), penetrating trauma (PT), or has a known implant.
Patient Filled Out Screening Form
No
Yes
Is the Patient a Reliable Historian?
No
Yes
Are Medical Images of the Skull, Chest, and Abdomen from the Current Visit Available?
Yes
Call Radiologist for Review
No
Obtain Medical Images of the Skull, Chest, and Abdomen
Patients considered NOT to be "good reliable historians" include patients from Trinity Springs North, have an Altered Mental Status (AMS), or have been admitted for any other psych related diagnosis.
Dose the Patient have a Hx. of FB or PT?
No
Does the Patient have an Implant?
No
PROCEED
Yes
Documentation of Implant Available?
Yes
No
Is the Implant a Coronary Stent or Orthopedic Hardware Except Exfix?
No
Is the Implant an IVC Filter or Heart Valve?
Yes
Note: Attempt to retrieve documentation in a reasonable amount of time depending on indication and potential patient care delay.
No
Yes
4-6 Weeks Since Placement?
Is MRI Conditional or "Safe" for Scanner to be Used?
No
STOP: DO NOT PROCEED
Contact Ordering Practitioner
Yes
PROCEED:
• Scan on 1.5T in NOM
• Max 2W/kg
• Max 15 minutes PPS
No
Obtain Additional information / Documentation
Yes
No
Can Conditions be Met?
Yes
PROCEED
Yes
Call Radiologist for Review
Are there medical images of the implant?
Yes
No
Are Medical Images of the FB or PT of the Affected Area After the Date of Injury Available?
No
Obtain Medical Images of Affected Area (At Least 2 Views AP / LAT)
Yes
Call Radiologist for Review
No
Yes
Obtain Medical Images of Affected Area (At Least 2 Views AP / LAT)
Peripheral Vascular Stent <10 cm in Length
FB – Foreign Body
PT – Penetrating Trauma
NOM – Normal Operating Mode
PPS – Per Pulse Sequence
If at any time you have any questions regarding the flow chart or are unsure about proceeding please contact the MRSO or STAT Radiologist for assistance.

Training

Training

ACR Manual Describes Two Levels of MRI Safety Training

- Level 1 & Level 2

Code Team
Aides / Porters
Engineering
Cleaning Staff
Vendor Reps
EP
Anesthesia
Radiographers
Radiologists
Radiology Nurses
Respiratory
Cardiology
ICU Nursing
Administration
Security
CRNAs

Training

In My Opinion, Most Hospitals Need 4 (or more) Levels of MRI Safety Training:

- Level 0 (General Hospital Staff Orientation to MRI Safety)
  - Don't Go To MRI (unless you have a specific reason to)
  - It Is Always A Dangerous Place (24 / 7 / 365)
  - If You Do Have To Go, Follow MRI Staff Directions

Training

In My Opinion, Most Hospitals Need 4 (or more) Levels of MRI Safety Training:

- Level 1 (MRI Support Staff)
  - static magnetic field forces and risks (torque and translation)
  - quench risks
  - authority to act within the controlled access areas
  - implications of clinical and physical MRI safety screenings
  - emergency response / code events
  - MRI safety labeling and terminology

Training

In My Opinion, Most Hospitals Need 4 (or more) Levels of MRI Safety Training:

- Level 2 (non-radiographer / technologist)
  - time-varying gradient and RF fields / forces / and risks
  - physiological effects of MRI's electromagnetic fields
  - detailed understanding of MR safety labeling and terminology
  - detailed understanding of both clinical and physical screening processes
  - detailed understanding of emergency response policies and practices
  - detailed understanding of the site quench policy
  - detailed understanding of the chain-of-command with respect to MRI safety decisions.

Training

In My Opinion, Most Hospitals Need 4 (or more) Levels of MRI Safety Training:

- Level 2 (radiographer / technologist)
  - In addition to the fundamental elements of Level 2 MRI Safety Training, MRI radiographers must also receive competency training on the safe operation of the MRI equipment in order to be able to safely and effectively deliver MRI patient care.

Training

- The MRMD can / should tailor educational content / competency requirements for site needs (even if that means making more / fewer levels)

Culture

Culture

"It is easier to bend steel than to twist arms."

— John Gosbee, MD, PhD

Culture

Set up structures & practices that reinforce the culture you want to have…

- ‘Good Catch’ Rewards
- Thank People for Identifying Problems
- Reward People for Identifying Solutions
- Collaborate With Other Parts of Care Team
- Develop Documented Policies
- Make Sure Policies Are Being Followed

Q&A

Thank You

Tobias Gilk, MRSO, MRSE

- TGilk@GilkRadiologyConsultants.com
- @tobiasgilk
- www.facebook.com/groups/MRIsafety