Active Implants in MRI:
Implanted Device Industry Perspective

Ross Venook, Ph.D.
Boston Scientific Neuromodulation

Disclosure

- I am an employee of Boston Scientific Neuromodulation Corporation

Outline

- Motivation (for implant manufacturers)
- Types of devices, interactions, and hazards
- Technical example: RF interactions/hazards
- Engineering approaches and perspectives
- Summary and Review Questions

Motivation for Safety of Implantable Devices under MRI

- Increasing patient population with IMDs
  - Passive: joint replacements, stents, heart valves, etc.
  - Active: pacemakers/defibrillators, neurostimulators, drug pumps, etc.

More Patients, Living Longer

- Increasing diagnostic indications for MRI
  - Many IMD patients have MRI on pathway to implant
  - IMD patients may later be indicated for MRI

Increasing Value of MRI Exams

- Scanning patients with IMDs is challenging
  - Scanning an MR Conditional patient can be complex
  - Risk/benefit trade-off not well characterized for most implants and patients

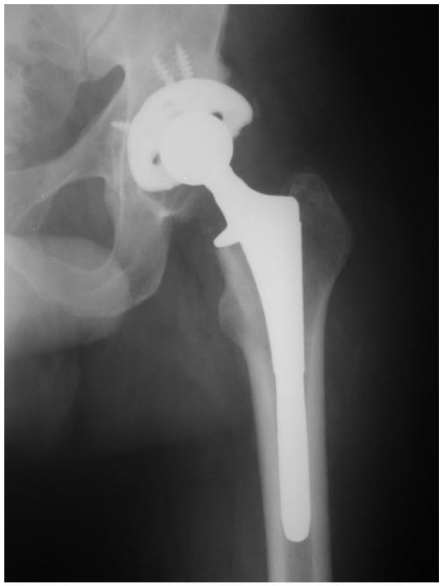
Barriers in Patient Pathway to MRI

Types of implantable devices

- Passive (no powered electronic components)
- Active (with powered electronic components)

Types of implantable devices

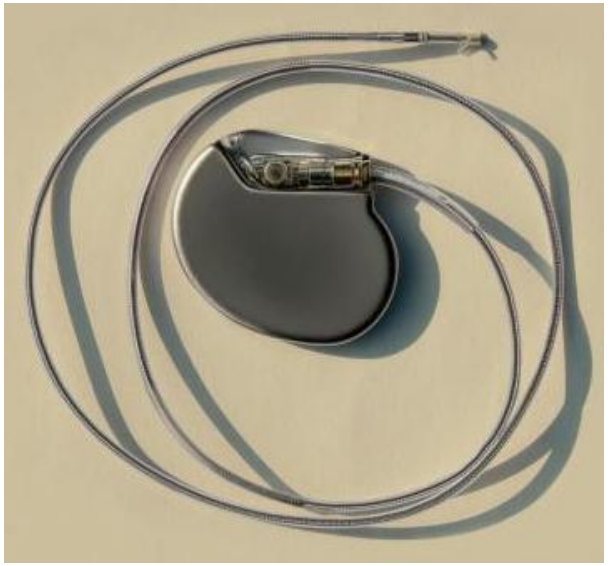
- Passive (no powered electronic components)
  - Orthopedic
    - Hips, knees, rods, screws
  - Cardiovascular
    - Stents, stent-grafts, valves
  - Neurovascular
    - Aneurysm clips, aneurysm coils
  - Interventional
    - Guide wires, catheters
- Active (with powered electronic components)



Types of implantable devices

- Passive (no powered electronic components)

- Active (with powered electronic components)
  - Cardiac stimulators
    - Pacemakers, ICDs
  - Neurostimulators
    - Spinal cord stimulators, deep brain stimulators, cochlear implants, vagus nerve stimulators
  - Drug pumps
    - Insulin, pain
  - Sensors
    - Loop monitor/recorder



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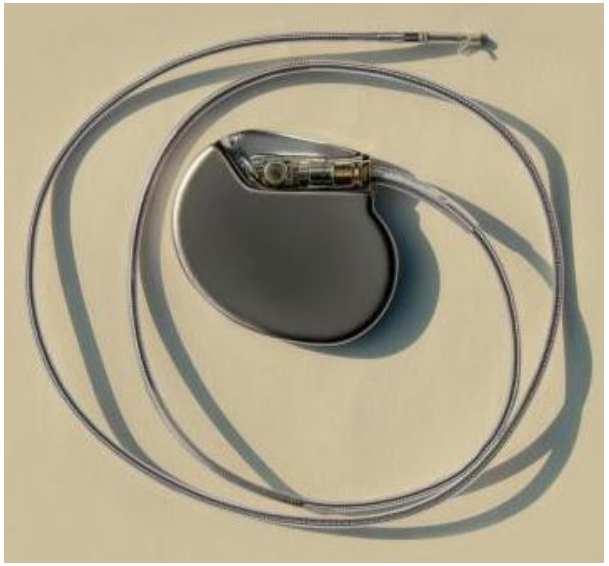

Many active devices now have labeling (!)

Implantable Device Labeling

– Definition of MR **Safe** (ASTM F2503)

"MR Safe—an item that poses no known hazards in all MR environments."

- E.g., plastic bed pan, Petri dish

– Definition of MR **Conditional** (ASTM F2503)

"MR Conditional—an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions of use. Field conditions that define the specified MR environment include field strength, spatial gradient, dB/dt (time rate of change of the magnetic field), radio frequency (RF) fields, and specific absorption rate (SAR). Additional conditions, including specific configurations of the item, may be required."

- E.g., many orthopedic implants, some active implants

– Definition of MR **Unsafe** (ASTM F2503)

"MR Unsafe—an item that is known to pose hazards in all MR environments"

- E.g., ferromagnetic scissors

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AIMD/MR Interactions, by MR Field

Source Field	Interaction Means	Interaction Hazards
B_0	Torque	IPG/Lead twist to align magnetic moment with static field
	Translation	IPG/Lead pulled in response to static field gradient
	Magnetization	Residual magnetization in IPG/lead components alters behavior
	Magnetic Saturation	Saturation of ferrite-core inductors lowers effective inductance
$G_{x,y,z}$	Induced Current in Leads	Unintended tissue stimulation at lead tip(s) High currents injected through header
	EMI	Interference with circuitry, especially telemetry coil and charging coil
	Induced Eddy Currents	Induced eddy currents in metal surfaces (case, ground planes) cause resistive heating
B_1 (RF)	Induced RF Heating	Focused RF tissue heating near device
	EMI	Induced voltages at IPG terminals, rectification, induced stimulation
$B_0 + G_{x,y,z}$	Eddy current torque	Induced eddy currents have magnetic moment that torques to align with large static field
$B_0 + G_{x,y,z} + B_1$	Combined effects	Combination of factors that can affect either the device or MR image quality

AIMD/MR Interactions, by Risk Level

Source Field	Interaction Means	Interaction Hazards
B_0	Torque	IPG/Lead twist to align magnetic moment with static field
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AIMD/MR Potential patient hazards from TS10974 (& Joint Working Group)

Table 1 – Potential patient hazards and corresponding test requirements

General hazards to the patient	Test requirement	Clause
Heat	RF field-induced heating of the AIMD	10
	Gradient field-induced device heating	11
Vibration	Gradient field-induced vibration	12
Force	B_0-induced force	13
Torque	B_0-induced torque	14
Extrinsic electric potential	Gradient field-induced lead voltage	16
Rectification	RF field-induced rectified lead voltage	17
Malfunction	B_0 field-induced device malfunction	18
	RF field-induced device malfunction	19
	Gradient field-induced device malfunction[a]	20

[a] Device malfunction due to eddy current heating of internal components is covered in Clause 11. Device malfunction due to vibration of internal components is covered in Clause 12.

Source: ISO TS10974, Edition 1

Interactions/Patient Effects Summary

- Many different interactions
  - 12-18 distinct interactions
  - Interactions depend on AIMD-specific design, patient-specific variables, scanner variables, etc…
- Many different patient effects
  - Range from negligible to life-threatening
  - Depend on AIMD function

Implant manufacturers need to understand and characterize all potential interactions and effects

Outline

- Motivation
- Types of devices, interactions, and hazards
- Technical example: RF interactions/hazards
- Engineering approaches and perspectives
- Summary and Review Questions

Example: RF Interactions with Devices

- Dominant mechanism of interaction for most implants is between incident **electric fields** and **patient/implant conductive structures**

- Electric fields result from applied B_1 field:

  $B_1 \rightarrow$ Local electric fields in patient $\rightarrow$ …

RF Interactions with Devices: $B_1 \rightarrow$ Local electric fields

- *In vivo* local E field simulation of Duke model in 64MHz RF birdcage coil

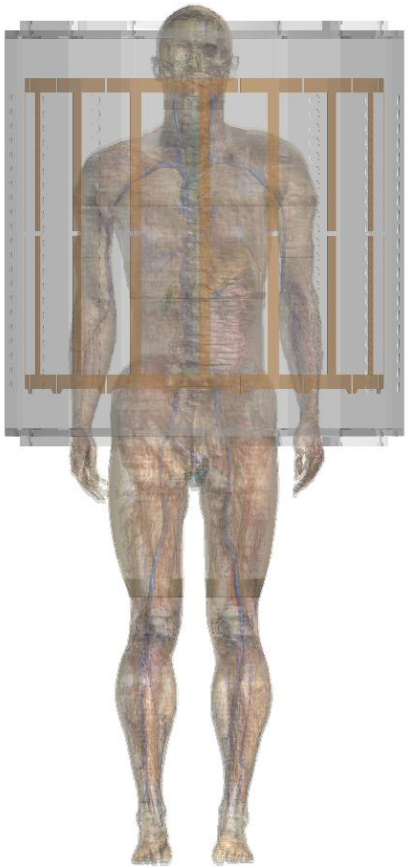


Figure courtesy IT'IS Foundation

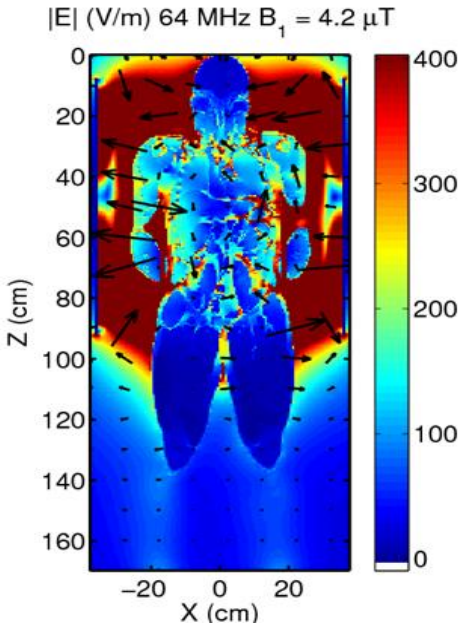
Local E fields vary with:

- Position in bore (landmark)
- Location in body
- Patient size/shape
- MR scanner mode
- Birdcage polarization (CW vs. CCW)
- Frequency
- Coil design
- …

RF Interactions with Devices: $B_1 \rightarrow$ Local electric fields

- *In vivo* local E field simulations of Hugo model
  - Central landmark, Normal Mode (MR Scanner)

1.5T



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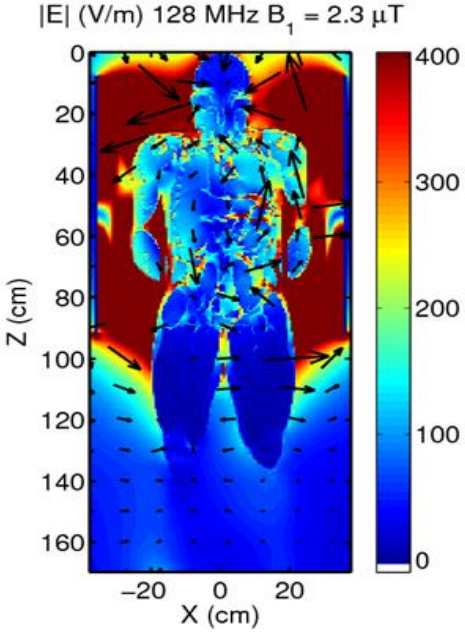

Figure courtesy John Nyenhuis

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- Frequency
- Coil design
- …

RF Interactions with Devices: Overview

Electric fields result from applied B_1 field:

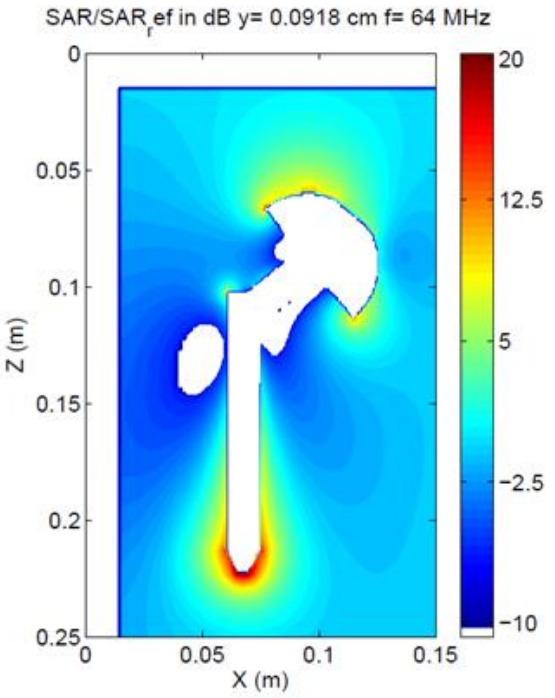
$B_1 \rightarrow$ Local electric fields in patient $\rightarrow$ …

Specific interactions:

- Local power deposition in tissue (RF Heating)
- Induced or injected voltages/currents in device electronics
  - Device malfunction
  - Induced stimulation currents
- MR image artifacts

RF-induced Heating: Mechanism(s) of Induced Power

$B_1 \rightarrow$ Local electric fields $\rightarrow$ *Energy coupling/local SAR deposition* $\rightarrow$ Temperature rise



- E_{tan} coupling of RF along conductors/Local SAR concentration
  - Direct modeling straightforward with simple structures (non-resonant)
  - Transfer function approach empirical
    - Park, et al., *JMRI*, 2007

$$I_{gen} = B\int_0^L S_{gen}(z)\,E_{\tan}(z)\,dz \qquad \Delta T = A\left|\int_0^L S(z)E_{\tan}(z)\,dz\right|^2$$

Figure courtesy John Nyenhuis

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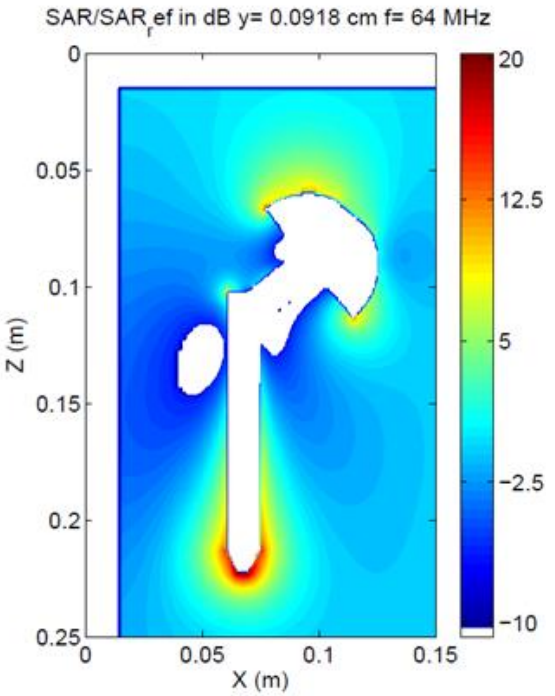
- Temperature rise
  - High SAR concentration at ends/tips of conductive structures
  - *Heat is generated in tissue, not in metal*



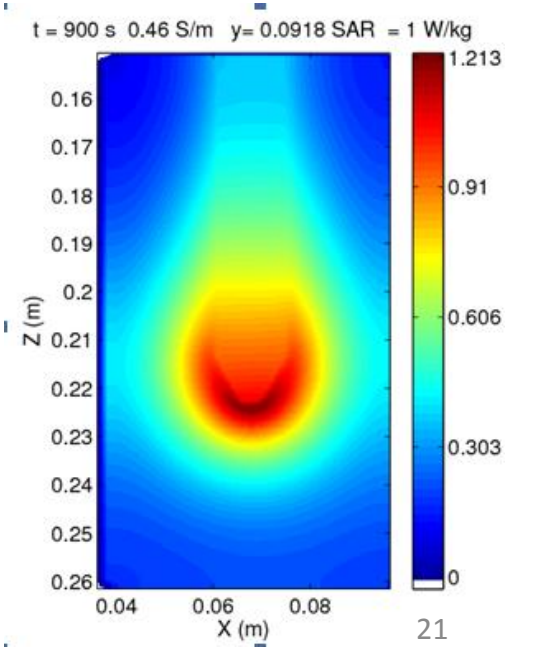
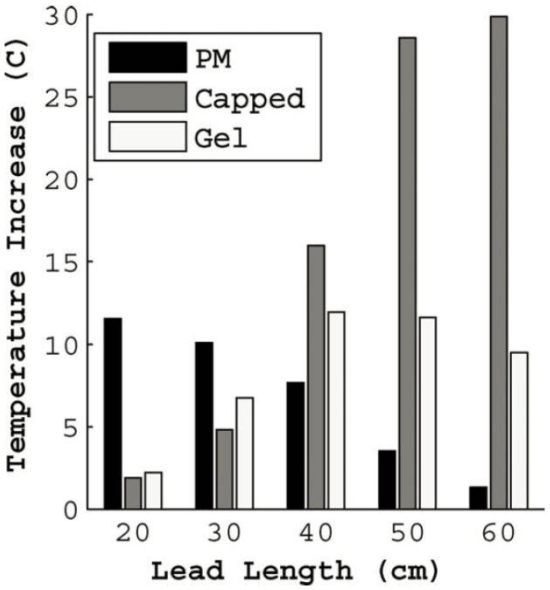


Figure courtesy John Nyenhuis

RF-induced Heating: Device Response Dependencies

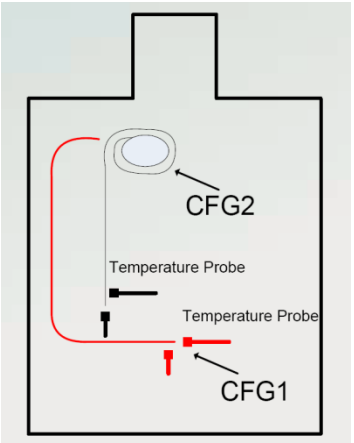
- Resonant structures
  - Equivalent electrical length
- Device configurations
  - Connections
    - E.g., lead terminations
  - Geometries
    - E.g., routing



Source: Langman, et al., JRMI, 2011

ΔT	COA 58cm	COA 46cm	COA 25cm	COA 58cm 1 loop	COR1 58cm	COR2 58cm
Cfg1	0.5 °C	6.2 °C	12.9 °C	45.4 °C	2.6 °C	1.4 °C
Cfg2	6.8 °C	13.8 °C	3.5 °C	NA	23.9 °C	9.9 °C

Source: Moulder, et al., HRS, 2010



RF-induced Device Malfunction*: Mechanisms

$B_1 \rightarrow$ Local electric fields in patient $\rightarrow$

Coupling of fields to device structures $\rightarrow$

Induced voltage/current $\rightarrow$ EMI malfunction

- Injected voltage from leads
  - Conductive structures extending outside of shield can bring energy in via feedthroughs
  - Similar variables and complexity as RF heating (many)

* Active implantable devices only

RF-induced Device Malfunction: Potential Events/Effects

- Potential technical problems and/or patient impacts depend upon:
  - Device therapy type
  - Circuit design and state/mode
  - Patient- and MRI-specific factors

- Example 1: Pacemaker
  - Potential events include*:
    - Interrupted therapy
    - Inappropriate therapy
    - Device damage/replacement
  - Potential effects*:
    - Range from benign to life-threatening

Image Source: http://www.lvhn.org/

*Kalin, R. and M. Stanton (2005). "Current Clinical Issues for MRI Scanning of Pacemaker and Defibrillator Patients." *PACE* 28(4): 326-328.

RF-induced Device Malfunction: Potential Events/Effects

- Potential technical problems and/or patient impacts depend upon:
  - Device therapy type
  - Circuit design and state/mode
  - Patient- and MRI-specific factors

- Example 2: Neurostimulator
  - Potential events include*:
    - Device reset
    - Setting disruption/therapy gap
    - Device damage/explant
  - Potential effects*:
    - Range from benign to moderate

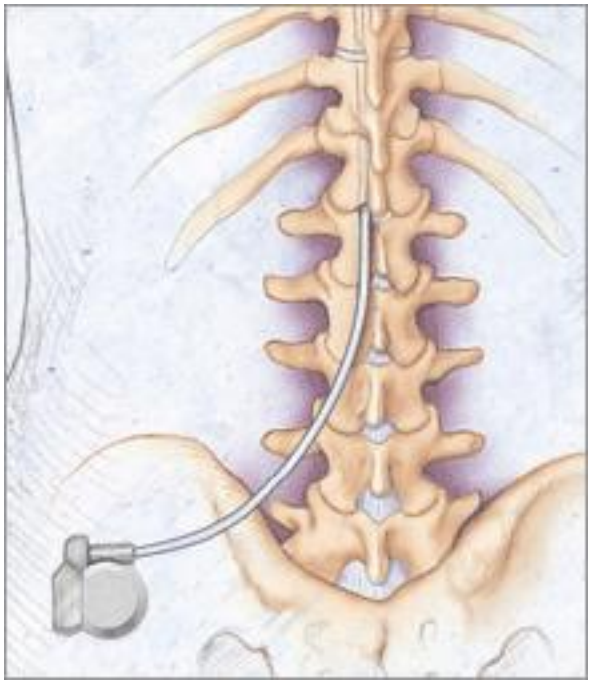


Image Source: http://www.eastbayspine.com/

*De Andres, J., et al. (2007). "Magnetic Resonance Imaging in Patients with Spinal Neurostimulation Systems." Anesthesiology 106(4): 779-786

RF-induced Device Malfunction: Potential Events/Effects

- Potential technical problems and/or patient impacts depend upon:
  - Device therapy type
  - Circuit design and state/mode
  - Patient- and MRI-specific factors

- Example 3: Loop recorder
  - Potential events include:
    - Setting disruption
    - Aberrant recording/diagnosis
    - Device damage/explant
  - Potential effects:
    - Range from benign to moderate

Image Source: http://www.lvhn.org/

RF-induced Artifacts: Mechanisms

- B_1 shielding

  $B_1 \rightarrow$ Conductive surface shields RF $\rightarrow$

  Reduced local flip angle/excitation

- B_1 distortion

  $B_1 \rightarrow$ Local electric fields in patient $\rightarrow$

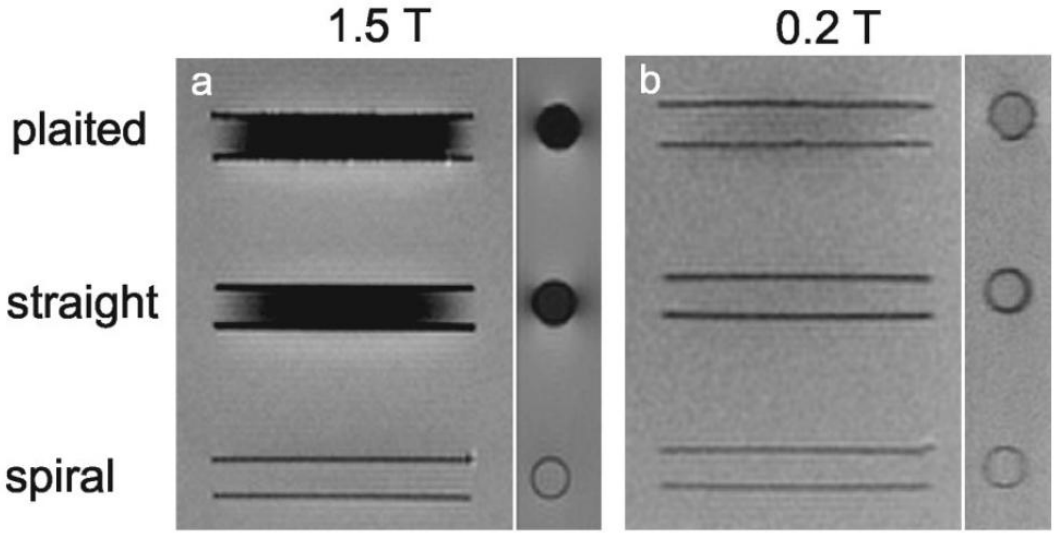
  Coupling of fields to device structures $\rightarrow$

  Induced voltage/current $\rightarrow$ Local Tx/Rx effects

RF-induced Artifacts: Shielding

$B_1 \rightarrow$ Conductive surface shields RF $\rightarrow$

Reduced local flip angle/excitation



Source: Graf, et al., Medical Physics, 2005

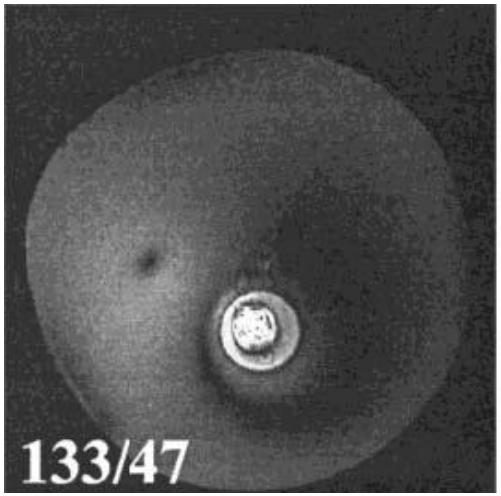
- Depends on conductor size, shape, and material
- Typically benign or dominated by susceptibility artifacts

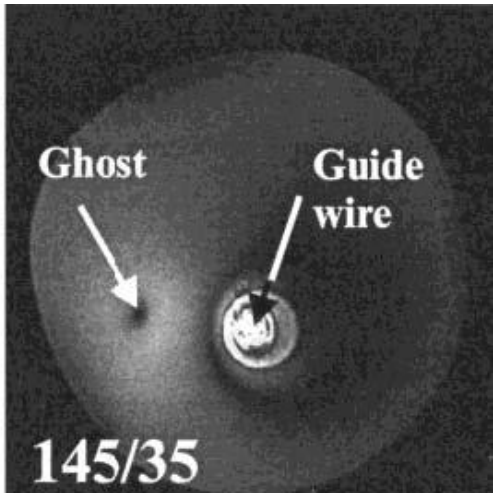
RF-induced Artifacts: B_1 Distortion

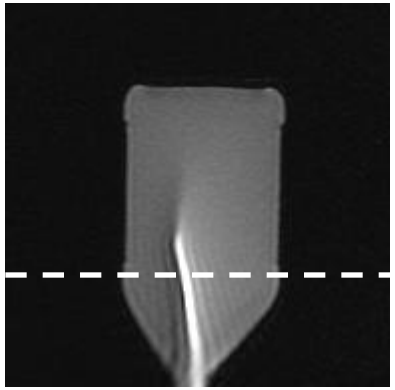
$B_1 \rightarrow$ Local electric fields in patient $\rightarrow$

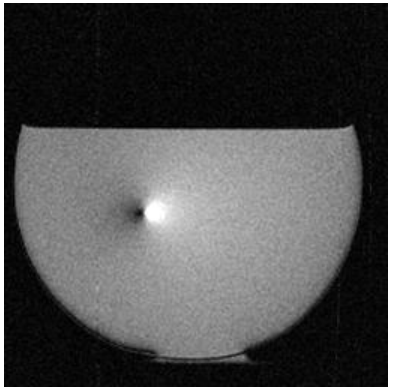
Coupling of fields to device structures $\rightarrow$

Induced voltage/current $\rightarrow$ Local Tx/Rx effects









Source: Nitz, et al. JMRI 2001; 13:105 – 114

- Effects can be complex; distant regions of void/enhancement
- Different character from susceptibility 'arrowhead' artifacts

Device Interactions/Hazard Summary

- Interactions depend significantly on several **device variables**—*no 'rules of thumb'*
  - Length, connectivity/termination, device design, surrounding tissues, device state, implantation geometry
- Interactions depends significantly on **several exposure/patient/MRI variables**—*no 'rules of thumb'*
  - Patient body habitus, orientation/landmark in scanner, scanner field strength (Larmor frequency), scanner mode
- Potential hazards depend significantly on **device and patient specifics**
  - Device type and clinical role
  - Stability/dependence of patient

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Engineering Approaches

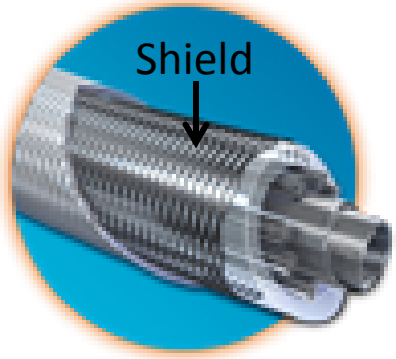
- Device Engineering
  - Leads
  - Electronics
  - Software/firmware
- Safety Evaluation Engineering
  - Exposure and Measurement methods
  - Modeling methods
  - Safety acceptability criteria
- MR Clinical/Workflow Engineering
  - Labeling: Patient screening and scan preparation
  - FPO:B definition and implementation

Device Engineering: Electronics (B_0)

- Removing/reducing ferromagnetic materials
  - Ferrites in inductors
    - E.g., step-up converter, telemetry antenna
  - Ferromagnetic materials in components
    - E.g., Nickel in capacitor plates, Stainless steel grade
- Removing/replacing magnetically activated components
  - E.g., Reed switch -> Hall effect sensor

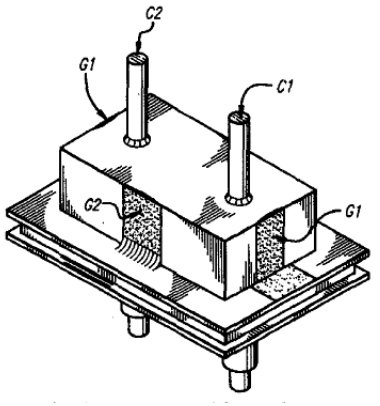
RF Field Mitigation Examples

- Goal: Reduce RF heating and/or RF injection
- Established approaches (on the market)
  - Reduce or block induced current and antenna effects
    - Conductor coiling—tight arrangements, novel arrangements
  - Reduce currents in sensitive locations/components
    - Shield
    - Discrete filter
- Conceivable approaches (future?)
  - 'Fiber optic' lead
  - No lead, microstimulator, etc.



Device Malfunction Mitigation Examples

- Input stage design/filtering
  - E.g., 'EMI filters' are common at pacemaker inputs and can shunt or block aberrant input signals



- Device settings
  - 'MRI Mode' parameter setting
    - E.g., Pacemakers turn off sensing, maintain therapy
    - E.g., Neurostimulators turn off therapy
  - Clinician Programmer or Patient Controller
    - MRI Mode entry/exit, settings
    - Unique use cases

Safety Evaluation Engineering

- Characterization methods
  - Computational/modeling
    - Electromagnetic and Thermal
    - Complex human/animal models
  - Empirical
    - Transfer function-based (Park/Nyenhuis)
- Safety acceptability criteria
  - Power-based vs. Temperature-based
  - Clinical outcome/effects
    - E.g., Pacing Capture Threshold

MR Clinical/Workflow Engineering

- Goals:
  - Patient Safety
    - ‘Nobody gets injured due to inappropriate MRI procedures’
  - Patient Access
    - ‘Patients with MR Conditional devices receive diagnostic benefits of MRI’
- Challenge:
  - Existing ‘No access’ safety methods


provision

M R I Metal Screening

Patient Name: DOB: SS#:

WARNING:

Please indicate if you have any of the following:

Yes No Have you ever been a Welder/Grinder?

Please mark on the figure(s) below the location of any implant or metal inside your body.

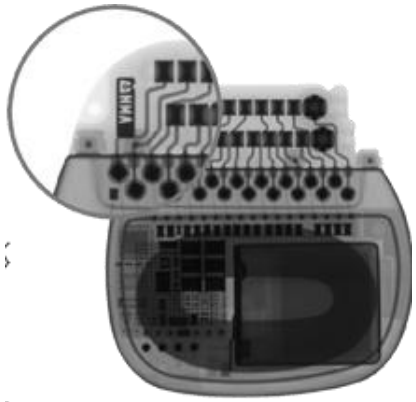
IMPORTANT INSTRUCTIONS

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MR procedure to prevent possible problems or hazards related to acoustic noise.

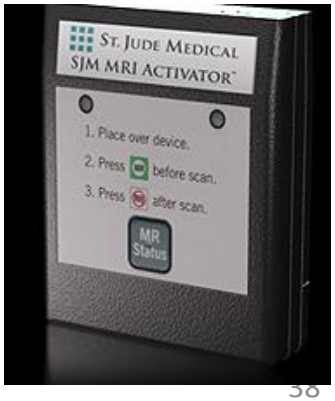
Patient Signature: Date:

AIMD Patient screening and preparation

- 'Positive System Identification' (PSID): Device + components -> Label
  - PSID Technologies
    - Radio-opaque markers = limited role
    - Clinician Programmer/Remote Control info
    - Patient medical history



- Preparation for scan: Evaluate patient and confirm system configuration/settings
  - Patient/AIMD Prep Technologies
    - Clinician Programmer/Remote Control
    - Special-purpose "Activator"



MR Clinical/Workflow Engineering

- MR Scanner settings and usage with IMD patients
  - FPO:B
    - Completing amendment process for IEC 60601-2-33 (3rd Ed.)
    - Need implementation
      - MR manufacturers (scanners) and AIMD manufacturers (labeling)

Physical Parameter	FPO:Basic Limit Value
B_1^+ (peak)	30 µT
B_1^+ (RMS)	3.2 µT (RMS)
d|B|/dt (peak)	100 T/s
d|B|/dt (RMS)	56 T/s (RMS)

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SAMS Question

An article in a reputable journal states: “new pacing systems have been specifically designed for safe use in the MRI environment.”
The pacemakers in the article are most likely to fit which definition:

9%	A. MR Compatible
2%	B. MR Safe
0%	C. MR Unsafe
86%	D. MR Conditional
2%	E. MR Incompatible

An article in a reputable journal states: “new pacing systems have been specifically designed for safe use in the MRI environment.”
The pacemakers in the article are most likely to fit which definition:

~~A. MR Compatible~~ [not a defined term]

~~B. MR Safe~~ [complex devices all have conditions]

~~C. MR Unsafe~~ [not a defined term]

D. MR Conditional

~~E. MR Incompatible~~ [not a defined term]

Reference: ASTM F2503-13, “Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment”, 2013, www.astm.org

SAMS Question

Which type of MRI field poses the greatest risk to a patient with an implanted device?

0% A. Static Field (e.g., 1.5T)

37% B. RF Field (e.g., SAR [W/kg] or B1+rms [uT])

10% C. Spatial Field Gradient (e.g., 720g/cm)

15% D. Time-varying Gradient Field (e.g., 100T/s)

39% E. Devices have different field interactions/risks

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E. Devices have different field interactions/risks

Reference: ISO TS10974: 2012, "Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device"

Implant Manufacturer Perspective: Summary

- Many (12-18) AIMD/MR interactions
  - Safety issues highly AIMD-dependent
- Interactions are complex—no ‘rules of thumb’ (unfortunately)
  - Device-specific experience does not translate to different devices
  - e.g., 1.5T vs. 3T; different pacemakers; intact vs. abandoned leads; etc.
- System design elements
  - AIMD components: Leads, Electronics, SW/FW
  - Workflow and MR system (FPO:B)

Implant Manufacturer Perspective: Summary

- Engineering emphasis on assessing and demonstrating safety is as important as design
- Therapy-based engineering constraints are real
  - MRI-specific changes hard to choose to develop
- MRI safety and access for patients relies on the whole MRI community
  - MR manufacturers; implantable device manufacturers
  - MR Technologists; MR Physicists; Radiologists; hospital admnistrators; referring physicians; etc…
  - Patients

What questions do you have about the implantable device manufacturer perspective?