ISMRM-AAPM Joint Symposia: MR Safety for Experts

Intraoperative & Interventional MRI Safety Considerations

R. Jason Stafford
Department Of Imaging Physics
The University of Texas
MD Anderson Cancer Center

Why MRI for Image-Guided Intervention?

- US
- CT/Fluoroscopy
- MRI

Radio-opaque marker placement in liver @ 1.5T

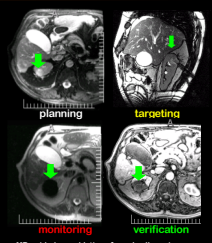
Biopsy @ 1.5T: Extremity

Non-invasive
Non-ionizing
Near real-time
Arbitrary 3D oblique plane orientation
Multiple *soft tissue contrast* mechanisms for
- anatomy
- function
- metabolism
- temperature

What types of procedures?
Intraoperative & endoscopic
Implant/device placement
Biopsy & aspiration
Local drug & cell delivery
Vascular
Ablation (radiation, chemical, thermal)

Why MRI for Image-Guided Intervention?

- Imaging for
  - planning
  - targeting
  - monitoring/control
  - verification
- Synergy with biological and physical modeling & simulation
- Endgame
  - 'close the loop'
  - increase procedure safety + efficacy
  - facilitate minimally invasive approaches previously not considered possible or safe



MR-guided cryoablation of renal cell carcinoma illustrating ability to visualize, target , monitor progress of therapy and verify damage via post-treatment perfusion changes.

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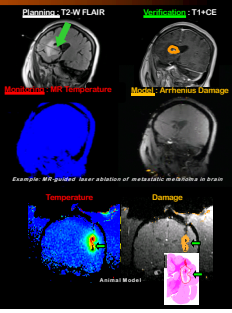
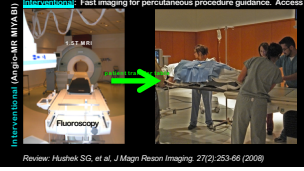


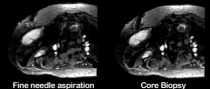
A Carpentier, RJ McNichols, RJ Stafford, et al, Neurosurgery 2008

Intraoperative vs Interventional paradigms

Intraoperative: Extended anatomic imaging for stereotactic approaches. Geometric accuracy is critical.

Interventional: Fast imaging for percutaneous procedure guidance. Access to patient in magnet is helpful.

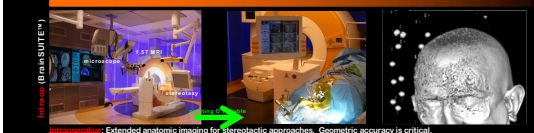




MR-guided biopsy of mixoid sarcoma: bSSFP + FS provides real-time imaging with T2-like contrast.

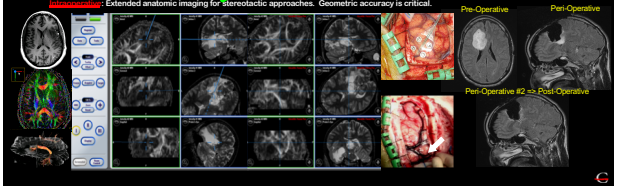
Review: Hushek SG, et al, J Magn Reson Imaging. 27(2):253-66 (2008)

Intraoperative vs Interventional paradigms



Procedures:
- Craniotomy
- Laser Ablation
- Biopsy

Intraoperative: Extended anatomic imaging for stereotactic approaches. Geometric accuracy is critical.



Intraoperative vs Interventional paradigms

Biopsies: renal, liver, MSK, prostate and breast

Cryoablation: renal, liver, bone

Interventional: Fast imaging for percutaneous procedure guidance. Access to patient in magnet is limited.

Intraoperative (Angio-MR MYVAB)

Fluoroscopy

Fine needle aspiration

Core Biopsy

MR-guided biopsy of mixoid sarcoma: bSSFP + FS provides real-time imaging with T2-like contrast.

Review: Hushek SG, et al, J Magn Reson Imaging. 27(2):253-66 (2008)

JOURNAL OF MAGNETIC RESONANCE IMAGING 37:501–530 (2013)

Special Communication

ACR Guidance Document on MR Safe Practices: 2013

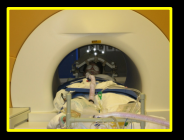
Expert Panel on MR Safety: Emanuel Kanal, MD,[1*] A. James Barkovich, MD,[2] Charlotte Bell, MD,[3] James P. Borgstede, MD,[4] William G. Bradley Jr, MD, PhD,[5] Jerry W. Froelich, MD,[6] J. Rod Gimbel, MD,[7] John W. Gosbee, MD,[8] Ellisa Kuhni-Kaminski, RT,[1] Paul A. Larson, MD,[9] James W. Lester Jr, MD,[10] John Nyenhuis, PhD,[11] Daniel Joe Schaefer, PhD,[12] Elizabeth A. Sebek, RN, BSN,[1] Jeffrey Weinreb, MD,[13] Bruce L. Wilkoff, MD,[14] Terry O. Woods, PhD,[15] Leonard Lucey, JD,[16] and Dina Hernandez, BSRT[16]

The principles behind these MR Safe Practice Guidelines are specifically intended to apply not only to diagnostic settings but also to patient, research subject, and health care personnel safety for all MRI settings, including those designed for clinical diagnostic imaging, research, interventional, and intraoperative MR applications.

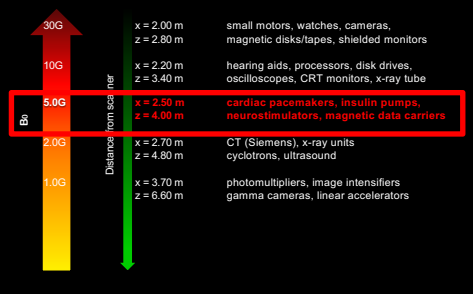
Note: Guidance specific to safe practices in the iMRI/ioMRI environment not explicitly addressed

MR safety considerations begin during siting of the suite

- Suites increasingly embedded in departments outside diagnostic radiology (OR, IR, Cath lab, etc)
- Zoning & access considerations for patients and staff
  - Fringe field considerations
  - Multi-room design? Where will procedures be performed?
  - Appropriate training & credentialing
- In-room workflow + instrumentation + storage
- Anesthesia + patient management workflow
- Ancillary equipment in Zone IV
  - Procedure mix? Multi-modal? Integrated therapy devices?
- Emergent procedure considerations



Ancillary equipment and room integration fringe field considerations

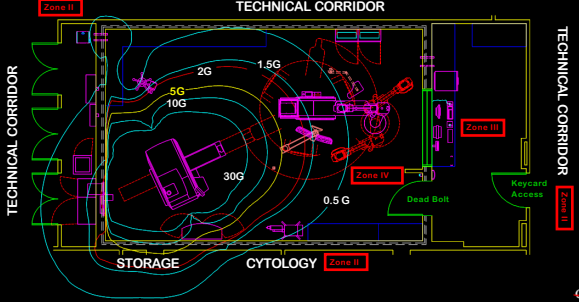


Ancillary equipment and room integration considerations

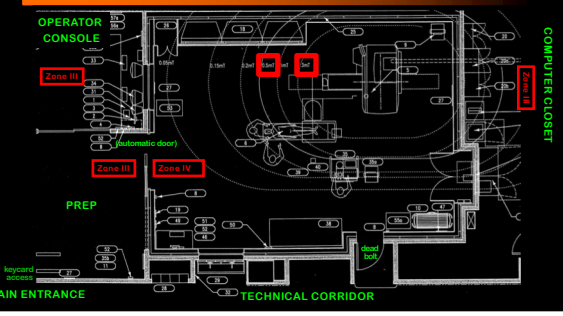
Need to address securing equipment in room, demarking regions of use and procedures for when used, power management issues and assessing MR conditional status.

ASTM F2503-05 Standard Practice for *Marking Medical Devices and Other Items for Safety* in the Magnetic Resonance Environment

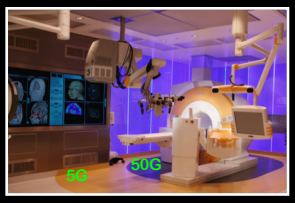
Hybrid single-room interventional MRI (iMRI) + fluoroscopy suite



Hybrid single-room intraoperative MRI (ioMRI) suite



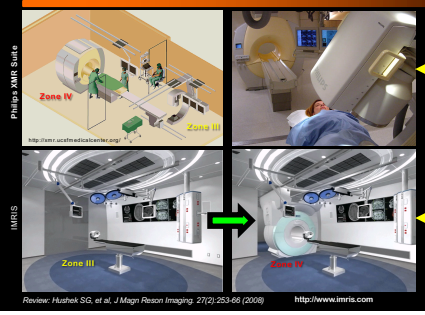
Ancillary equipment and integration considerations: single room?



Most integrated equipment cannot be on during procedure. Equipment power procedures needed.

- Siemens Espree 1.5T Magnet
- VectorVision Sky and VectorVision Software Cranial
- Zeiss NC4 Multivision with advanced integration
- OR Table with integrated headclamp and coil
- Automatic Image Registration
- BrainSUITE Data Billboard
- Digital Data Management and OR Device and Room Control System
- BrainSUITE RF Shielded OR Cabin
- Telemedicine

Hybrid MR Suites: Single vs Multi-Room solutions



move patient

Some safety concerns can be addressed via use of a multi-room option.

move magnet

Review: Hushek SG, et al, J Magn Reson Imaging. 27(2):253-66 (2008)

http://www.imris.com

Patient transfer from procedure arena to MRI arena

- Remove surgical instruments/sharps/sponges from table + count
- Remove ground patches, leads and/or electrodes from patient/arena
- Remove MR unsafe navigation instruments
- Prepare patient drapes
  - remove metal clips, wire edges, drain plugs
  - secured & clear for transfer
- Prepare and manage sterile field and wound for transfer/imaging
- Anesthesia team
  - remove laryngoscope handles, blades, stylets, nerve stimulator + count
  - prepare IV, air, catheter and monitoring lines
  - patient management devices: warmers, compression boots, etc
  - position/secure infusion pumps
  - patient positioning and padding (longer OR procedure times)
- Patient Hearing Protection
- Position patient and RF coils for imaging
- Management/removal of conducting wires and skin-to-skin contacts
- Personnel MRI safety check (i.e., ferromagnetic objects, hearing protection, etc)
- Ferromagnetic screening (if available)
- MR time out, visual checks and audibles + assess room readiness

(Procedure specific CHECKLISTS strongly encouraged)

Anesthetized patients in hybrid suites: concerns

- Careful patient screening for appropriateness of procedure
  - MRI compatible equipment, procedure times & limitations
  - Isolation of patient
- Patient inability to report sensations or pain during procedure
- Patient setup and positioning for MR
  - RF coils & conductors needed for monitoring
- Rapid removal of patient from Zone IV in case of an emergency
  - Isolation of suite and location

- From an MR vendor safety manual:

WARNING

Exposure to RF electromagnetic fields in the *First Level Controlled Operating Mode*

Patient burns

- Do not examine patients with restricted thermoregulatory capability (e.g. small children, elderly, sick, or medicated patients).
- Do not examine patients unable to communicate potential overheating effects (e.g. small children, seriously ill, paralyzed, unconscious, sedated, or handicapped patients).
- Carefully monitor the patient during the MR examination.
- Ensure that patients wear light clothing (e.g. light pyjamas or nightgown).
- Remove all additional insulation, e.g. blankets or covers.

Journal of Clinical Anesthesia 54 (2019) 89–101

MRI environment and medical devices

1 W/kg → ~1°C/hr
15 min @ 4 W/kg → ~1°C

Source	Primary Safety Concern(s)
Static Magnetic Field (B_0) - Spatial field gradient (∇B_0)	Translation projectile "missile" hazards Transient bioeffects at high fields
Radiofrequency Field (B_1+) - Specific Absorption Rate (SAR) - Specific Energy Deposition (SED) - Exposure time and/or temperature	Local tissue and whole body heating
Pulsed Gradient Magnetic Field (G) - Slew rate (T/m/s) - Max dB/dt (T/s)	Peripheral nerve stimulation Acoustic noise

MRI environment and medical devices

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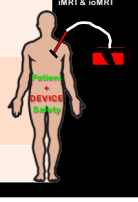
Static Magnetic Field (B_0) - Spatial field gradient (∇B_0)	Translation projectile "missile" hazards Transient bioeffects at high fields
Medical devices on/in patient:	**Displacement** **Disruption** **Damage**
Radiofrequency Field (B_1+) - ~~Specific Absorption Rate (SAR) $B_1^2{}_{rms}$~~ - Specific Energy Deposition (SED) - Exposure time and/or temperature	Local tissue and whole body heating
Medical devices on/in patient:	**Heating** **Unintended stimulation** **Disruption** **Damage**
Pulsed Gradient Magnetic Field (G) - Slew rate (T/m/s) - Max dB/dt (T/s)	Peripheral nerve stimulation Acoustic noise
Medical devices on/in patient:	**Heating** **Unintended stimulation** **Vibration** **Disruption** **Damage**
Reconstructed Image	
Medical devices on/in patient:	**Artifacts**

1 W/kg → ~1°C/hr
15 min @ 20 W/kg → ~5°C

Ancillary and partially implanted devices of primary concern in iMRI & ioMRI



Several key MR safety standards & guidance

SYSTEM

- **IEC 60601-2-33:** Particular Requirements for the Basic Safety and Essential Performance of Magnetic Resonance Equipment for Medical Diagnosis

PASSIVE IMPLANTS

- **ASTM F2052:** Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- **ASTM F2213:** Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- **ASTM F2182:** Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging
- **ASTM F2119:** Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants
- **ASTM F2503:** Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- **FDA:** Establishing Safety & Compatibility of Passive Implants in the MR Environment - Guidance for Industry and Food and Drug Administration Staff
- **FDA:** Assessment of Radiofrequency-Induced Heating in the MR Environment for Multi-Configuration Passive Medical Devices - Guidance for Industry and Food and Drug Administration Staff

AIMD

- **ISO TS 10974:** Assessment of the Safety of Magnetic Resonance for Patients with an Active Implantable Medical Device
- **ACR:** Guidance Document on MR Safe Practices

Note: None *directly* address issues with 'partially implanted' device heating & powered ancillary devices in the MRI.

Defino & Woods, Curr Radiol Rep (2016) 4:28

Pennes Bioheat Equation: simple model with local perfusion

$$\rho c \frac{\partial T(q_i,t)}{\partial t} = \nabla \cdot [(k \nabla T(q_i,t))] + \rho_b C_b V (\kappa - 1)(T - T_a) + P(q_i,t)$$

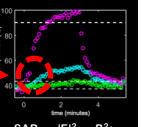
heat diffusion | heat convection | heat source

HEAT SOURCES (laser, ultrasound, RF, microwave, etc) :
P = absorbed power density (W m^{-3}) = SAR*ρ

SAR = Specific Absorption Rate (W/kg)

HEAT CONDUCTION (diffusion):
T = temperature (Kelvin)
c = specific heat of material (J kg^{-1} °C^{-1})
ρ = density (kg/m^3)
k = thermal conductivity of tissue (W m^{-1} °C^{-1})

HEAT CONVECTION (effects of perfusion):
ρ_b = blood density (kg m^{-3})
V = volume flow rate per unit volume (s^{-1})
C_b = specific heat of blood (J kg^{-1} °C^{-1})
κ = dimensionless convection scale factor



SAR ~ $\sigma|E|^2$ ~ $\sigma B^2{}_{1rms}$

Panych LP, Madore B. J Magn Reson Imaging. 2018 Jan;47(1):28-43
H. H. Pennes, "Analysis of tissue and arterial blood temperatures in the resting human forearm," J Appl Physiol 1948;1:93–122

Localized heating: thermal dose & risk assessment

- **Isotherm model ($T \geq T_{ref}$):** Only useful at higher temperatures (irreversible damage function of temperature exposure over time)
- **Arrhenius model (Ω):** First order kinetic rate model for irreversible isoeffects as a function of heat exposure

$$\Omega = A \int_0^t e^{\frac{-E_a}{RT(\tau)}} d\tau$$

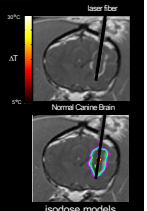
E_a = Activation Energy (6.3 x 10^5 J)
A = Frequency Factor (3.1 x 10^{98} s^{-1})
R = Universal Gas Constant

(different tissue or isoeffects have different A & E_a)

- **Cumulative Equivalent Minutes @ 43°C (CEM_{43}):** Empirical extrapolation of Arrhenius from low temperature hyperthermia results

$$CEM_{43} = \sum_{t=0}^{n} \Delta t \; R^{(43-T_n)} \cdot \Delta t, \; with \; R = \begin{cases} 0.25 & T_n < 43°C \\ 0.50 & T_n < 43°C \end{cases}$$

(different tissue or isoeffects have different CEM_{43})

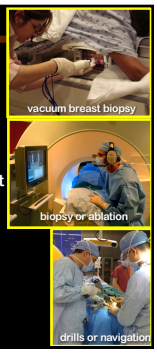


isodose models
$T \geq 57°C$
$\Omega \geq 1$
$CEM_{43} \geq 240$ min

Foster KR, Morrissey JJ, Int. J. Hyperthermia, 27(4): 307–319 (2011); Henriques FC, Arch Pathol, 1947; 43:489. (1947)
Sapareto SA, Dewey WC, Int. J Rad. Onc. Bio. Phys. 10: 787-800 (1984)

Partially implanted and procedure devices in MRI

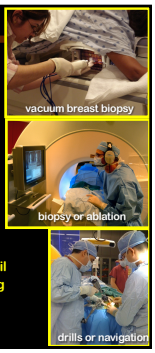
- Devices in fringe field or in-bore
- In-bore → partially implanted device concerns
  - heating, stimulation, artifacts
- Artifacts can obscure anatomy needed for guidance
- Heating of partially implanted items difficult to predict
  - length, orientation & location in magnet, depth in tissue, etc
  - many percutaneous procedures off-isocenter
  - critical length ~ $n_{odd}*\lambda_M/2$ → 25cm @ 1.5T & 12 cm @ 3T
- Often modified in material or function
  - compromise between function and safety
  - changes in procedures for for higher fields



IEEE TRANSACTIONS ON DEVICE AND MATERIALS RELIABILITY, VOL. 5, NO. 3, SEPTEMBER 2005

Partially implanted and procedure devices in MRI

- Example devices
  - neuromonitoring leads
  - biopsy needles and guns
  - treatment applicators
  - guidewires and catheters
- General recommendations
  - READ THE VENDOR IFU
  - minimize duration of exposure
  - active scan: avoid direct contact with conductors
  - critical lengths: >150 cm @ 1.5T => increased heating risk
  - heating risk higher parallel to field & close to the gradient coil
  - Use at 3T may require altered procedures to mitigate heating and artifact (i.e., plastic canula)



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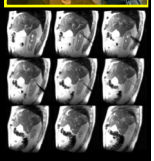
Partially implanted and procedure devices in MRI

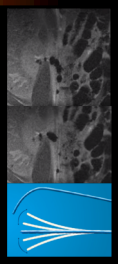
- Example devices
  - neuromonitoring leads
  - biopsy needles and guns
  - treatment applicators
    - cryotherapy needles have similar heating risk biopsy needles
    - multiple probes often placed at once
    - Close proximity of probes can promote unintended stimulation
  - guidewires and catheters



IEEE TRANSACTIONS ON DEVICE AND MATERIALS RELIABILITY, VOL. 5, NO. 3, SEPTEMBER 2005

Partially implanted and procedure devices in MRI

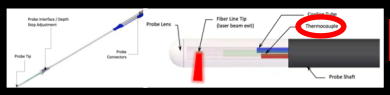
- Example devices
  - neuromonitoring leads
  - biopsy needles and guns
  - treatment applicators
  - guidewires and catheters
    - primary safety concern regarding the long metallic guidewires, such as those made of Nitinol, used in image-guided vascular procedures is heating
      - new PTFE coated glass bead systems resistant to heat



MRWire EmeryGlide (Nano4imaging)

Partially implanted and procedure devices in MRI

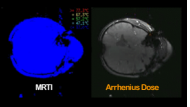
Monteris Medical NeuroBlate System Recalled Due to Unexpected Heating of Laser Delivery Probes FDA October 5, 2017



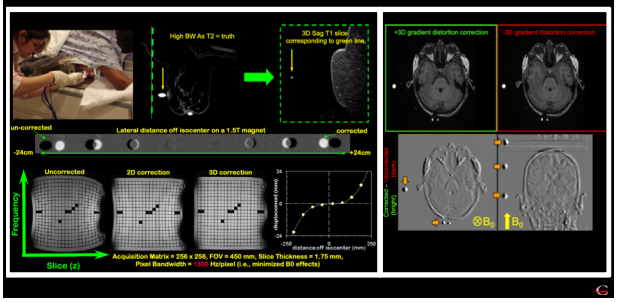
Magnetic Resonance-guided Laser Interstitial Thermal Therapy (MRgLITT) Devices: Letter to Health Care Providers - Risk of Tissue Overheating Due to Inaccurate Magnetic Resonance Thermometry FDA [Posted 04/25/2018]

MR physicist can provide expertise in both MR protocol and MR device safety to minimize risks of these procedures.

Note: this design has been changed to address heating issue.



Geometric & signal distortions also safety issues in ioMRI and iMRI



Geometric & signal distortions also safety issues in ioMRI and iMRI

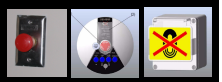
For high precision applicator placement, an image-driven hardware & software solution is available.

Deep brain stimulation lead placement

In collaboration with Ashwin Viswanathan, MD

Personnel training and screening in ioMRI and iMRI suites

- MR Screening for employees
  - RN circulators, scrub personnel, housekeeping, surgeons, anesthesia
- MR Safety training (annually)
  - Level 1 versus Level 2 training
- Suite Orientations
  - Emergent procedure and patient transfer
  - Equipment operation and safety interlocks
- Procedure Orientations
  - standard operating procedures/checklists
  - special equipment, monitoring, etc
  - dry runs for new procedures
  - observations/supervision of new staff
- Access control and core MR procedure group supervision



Summary

- Intraoperative and interventional MRI use expanding
- Systems often placed remote from MR department and resources with many traditionally non-MRI personnel involved
- Procedures can be complex and involve a variety of non-standard devices and instrumentation in the suite and patient
- Risk to staff and patient from missile effects and acoustic noise as well as heightened concern over patient heating and artifact management
- A small, highly trained team with clearly written and periodically reviewed policies and procedures is essential to both safety and long term success

THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Thank you for your time!

Email: jstafford@mdanderson.org