MR Safety - Hybrid Environment:
Interventional and Intraoperative MR

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MRI Safety

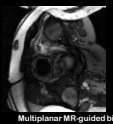
Source	Primary Safety Concern(s)
Static Magnetic Field (B_0 ~ Tesla) MAGNET is always on	Projectile "missile" hazards Medical device displacement, damage or disruption Transient bioeffects at high fields
Radiofrequency Field (B_1 ~ mT for ms at ≥32 MHz)	Tissue heating Medical device heating Medical device disruption Interference with auxiliary equipment (i.e., patient monitoring)
Pulsed Gradient Magnetic Field (G ~ 50 mT/m with 250 ms rise times)	Peripheral nerve stimulation Acoustic noise Interference with auxiliary equipment
Cryogens (Liquid Helium @ 4K)	Bodily harm Asphyxiation (oxygen displacement)
Gadolinium Based Contrast Agents	nephrogenic systemic fibrosis (NSF)

Evaluation of impact on patient, fetus, family, staff as well as interactions with auxiliary equipment and medical devices is of constant concern

What is different about the ioMRI & iMRI environments?

Why MRI for Image-Guided Intervention?

- US
- CT/Fluoroscopy
- **MRI**



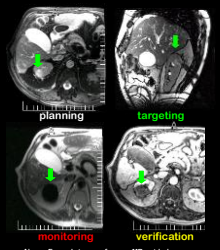
Multiplanar MR-guided biopsy in right acetabulum (metastatic carcinoma)

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

Example MRGI procedures:
Intraoperative & endoscopic
Implant/device placement
Biopsy & aspiration
Implant/device placement
Local drug & stem 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



Above: Example images from an MR-guided cryo-ablation procedure for renal cell carcinoma illustrating the ability to visualize and target the region for treatment as well as monitor progress of therapy and verify region of damage using changes in tissue perfusion.

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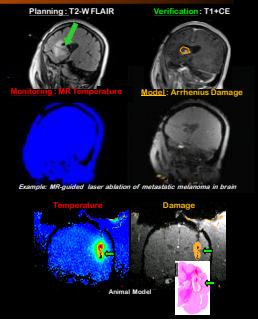
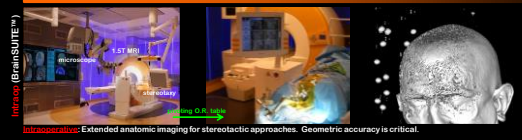


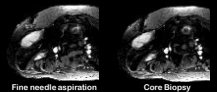
A Carpentier, RJ McNichols, RJ Stafford, et al, Neurosurgery 2008

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.

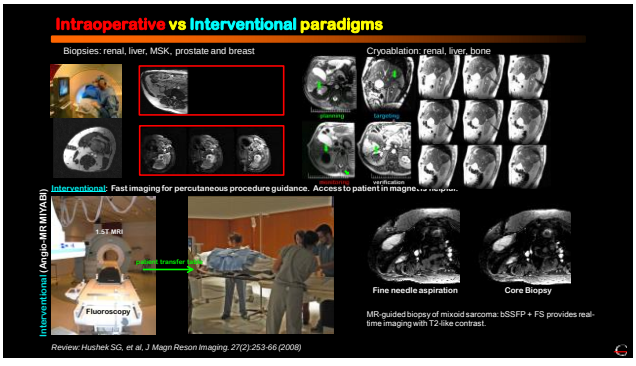


MR-guided biopsy of mixoid sarcoma: bSSFP + FS provides real-time imaging with T2-like contrast.

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

Intraoperative vs Interventional paradigms

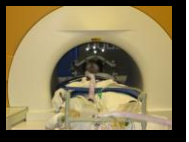
Intraoperative vs Interventional paradigms



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

MRI Safety considerations begin during siting of the suite

- Suite often embedded in department outside diagnostic radiology (OR, IR, Cath lab, etc)
- Zoning & access considerations for patients and employees critical
  - Multi-room design? Where will procedures be performed?
- In-room workflow + instrumentation + storage
- Anesthesia + patient management
- Ancillary equipment in Zone 4
  - Procedure mix? Multi-modal? Integrated therapy devices?
- Emergent procedures



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

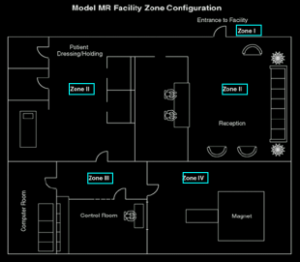
Special Communication

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.

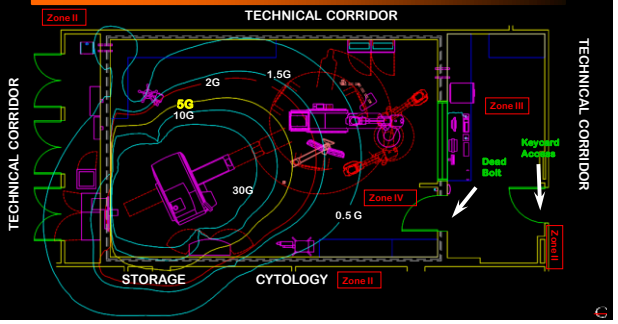
MR Site Safety Issues: Access Control & the 'Zone Defense'



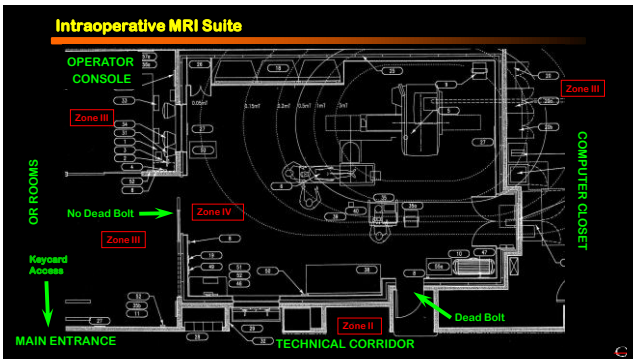
- Zone I
  - Open access
- Zone II
  - Preparation and holding
- Zone III
  - May be partially within 5 G exclusion zone*
  - Access to Zone IV achievable
  - Must be Level 1 or 2 to work in area unsupervised
- Zone IV*
  - MR scan room
  - No admittance w/o documented training and screening
  - Level 2 supervision of non-MRI personnel
- * Access to any space contained in the 5 G (0.5 mT) fringe field MUST have controlled access and appropriate signs posted
- There can be no exceptions

MRI Safety - ACR Guidance 2013 – Section B.1

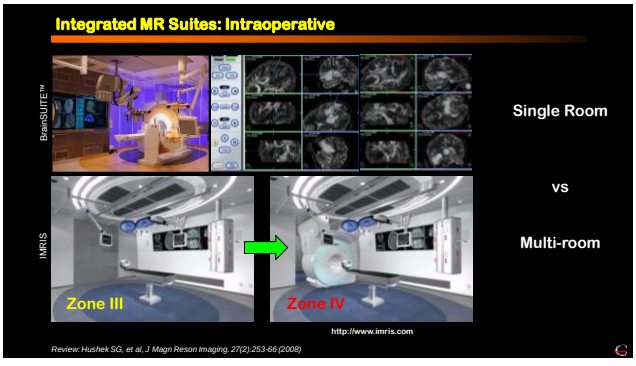
Interventional MRI Suite



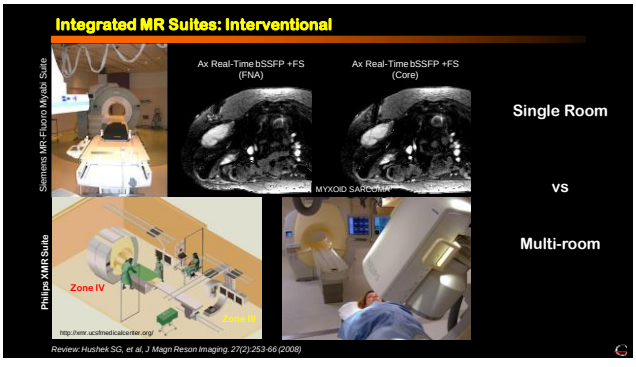
Intraoperative MRI Suite



Integrated MR Suites: Intraoperative



Integrated MR Suites: Interventional



Interventional MRI: Magnet Designs

Examples of several lower field "open" systems useful for interventions

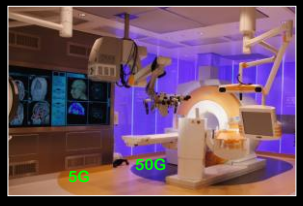
Compact length Wide Bore

0.12T Medtronic Polestar | 0.2T Siemens Magnetom Open Viva | 0.5T GE Signa SP | 1.0T Philips Panorama | 1.5T Siemens Espree | 3.0T IMRIS Visius

Increasing B_0

Trend toward high field systems for SNR advantage
- Primary benefit is image quality & functional imaging
- Increased safety and artifact issues
- Decreased access to patient in cylindrical bore
  - => Compact length
  - => Wide bore
  - => Stereotaxy and/or robotic assistance

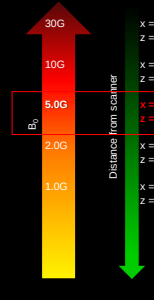
Ancillary equipment and room integration considerations



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

Ancillary equipment and room integration considerations



30G	x = 2.00 m z = 2.80 m	small motors, watches, cameras, magnetic disks/tapes, shielded monitors
10G	x = 2.20 m z = 3.40 m	hearing aids, processors, disk drives, oscilloscopes, CRT monitors, x-ray tube
5.0G	**x = 2.50 m z = 4.00 m**	**cardiac pacemakers, insulin pumps, neurostimulators, magnetic data carriers**
2.0G	x = 2.70 m z = 4.80 m	CT (Siemens), x-ray units cyclotrons, ultrasound
1.0G	x = 3.70 m z = 6.60 m	photomultipliers, image intensifiers gamma cameras, linear accelerators

Note: 5G or higher accessible in Zone III

- Access to any space contained in the 5 G (0.5 mT) fringe field MUST have controlled access and appropriate signs posted

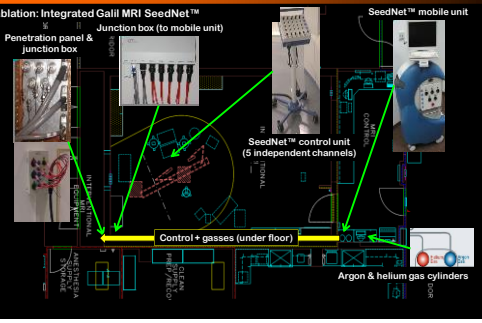
Ancillary equipment and room integration considerations

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

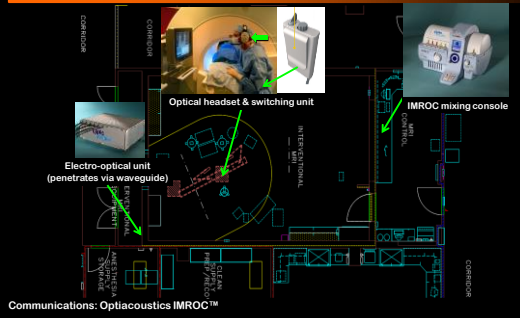
ASTM F2503-05 Standard Practice for *Marking Medical Devices and Other Items for Safety* in the Magnetic Resonance Environment

Ancillary equipment and room integration considerations

Cryoablation: Integrated Galil MRI SeedNet™



Ancillary equipment and room integration considerations



Communications: Optiacoustics IMROC™

Patient transfer from surgical arena into 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
  - ear protection if remaining in MRI room during procedure
  - pocket check (if pockets allowed)
- Ferromagnetic screening (if available)
- MR time out, visual checks and audibles + assess room readiness

(✔ checklists strongly encouraged)

RF heating considerations

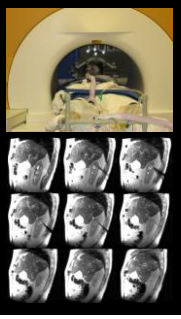
- From vendor safety manual:

WARNING

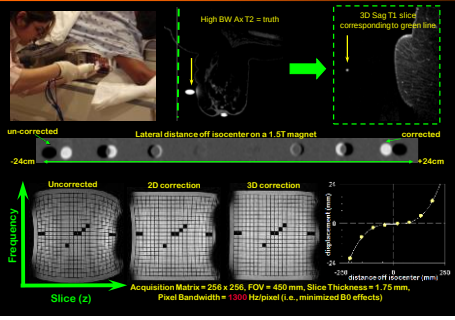
Exposure to RF electromagnetic fields in the *First Level Controlled Operating Mode*!

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.



Geometric distortion is a safety issue in ioMRI and iMRI



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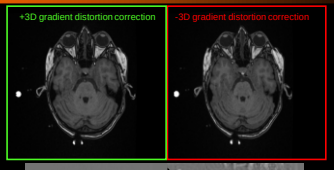
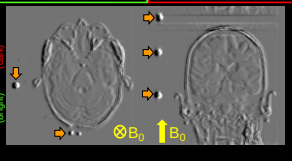


Distortions primarily from:

- Non-linear gradients
  - software correction
- Field inhomogeneity (B_0)
  - higher rBW
  - higher resolution
  - 3D vs 2D
  - shim …

(both worse away from isocenter)



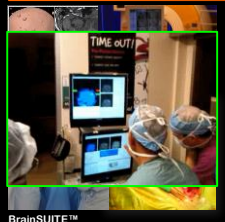
Geometric distortion is a safety issue in ioMRI and iMRI

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

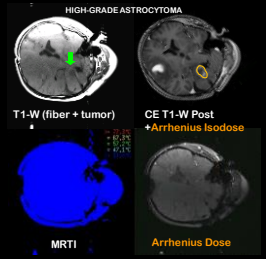
Deep brain stimulation lead placement

In collaboration with Ashwin Viswanathan, MD

MR-guided LITT: Intracerebral lesions



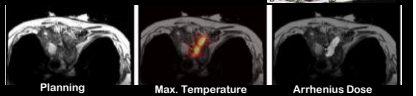
BrainSUITE™
- 1.5T Siemens Espree MRI
- Noras 8CH O.R. Head Coil
- BrainLAB VarioGuide Navigation
- Visualase® MRgLITT System



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

MRgLITT: spine

- MRI guided placement of laser in epidural space
- Ablation of epidural tumor volume in region of compression
- Significant and rapid reduction in pain symptoms
- Mobile C-Arm brought into room for invasive fiducial placement

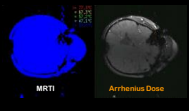


Planning | Max. Temperature | Arrhenius Dose

Tatsui C, Stafford, RJ et al, J Neurosurg Spine (2015)

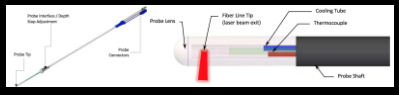
MRgLITT and the Medical Physicist

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]



MRTI | Arrhenius Dose

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



The ioMRI/iMRI physicist can provide expertise in both protocol and device safety to minimize risks of these procedures.

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

Additional policy and procedural considerations

- Policy considerations
  - dress codes (scrubs only, no pockets, etc)
  - no metal (pens, jewelry, watches, change, phones, etc)
  - personal item storage
- Inventory & Stocking
  - MR conditional equipment for in-bore procedures
  - Sterile processing
  - Storage locations
- Emergent procedure outlined, practiced & table weight limits establishe
- Pre-procedural room preparation procedure
- Periprocedural instrument management
- Post-procedural room cleaning procedure

Summary

- MRI use in intraoperative and interventional environments is expanding
- Systems often in a non-diagnostic area with many traditionally non-MRI personnel involved
- Procedures can be complex and involve both MR conditional and MR unsafe devices and instrumentation in the suite
- Risk to staff and patient from missile effects and acoustic noise as well as heightened concern over patient SAR 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 Joint Commission

Issue 38, February 14, 2008

Preventing accidents and injuries in the MRI suite

Sentinel Event Alert

Risk reduction strategies

Conventional metal detectors have been used to help identify metal objects in and on patients, but they are not 100 percent accurate and can give false-positives and false-negatives.(4) Furthermore, metal detectors cannot alert personnel to all objects that are subject to heating, malfunction or failure during an MRI scan. (5) However, the recent availability of ferromagnetic detectors may help in screening patients for objects left on their person, according to Dr. Emanuel Kanal, chair of the ACR's Magnetic Resonance Safety Committee. A recent study concludes that ferromagnetic detectors have 99 percent sensitivity. (6)

A report on projectile cylinder accidents in the American Journal of Radiology (7) recommends strategies to prevent missile-effect accidents, including implementing protocols that allow maintenance and housekeeping personnel to enter the MRI suite only after proper safety education and when no patient is in the suite. A number of preventive measures for hazards in the MRI-environment are recommended by Dr. Kanal (8) and are supported by the ECRI Institute (9), including:

- Appoint a safety officer who is responsible for implementing and enforcing safety procedures in the MRI suite.
- Implement systems to support safe MRI practice such as written protocols and checklists and periodically review, and assess compliance with your organization's MRI policies, procedures and protocols.
- In general, do not bring any device or equipment into the MRI environment unless it is proven to be MR Safe or MR Conditional. MR Safe items pose no known hazard in all MRI environments, and MR Conditional items have been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. (10) The Safety of "MR conditional" items must be verified with the specific scanner and MR environment in which they will be used.

References

1. White MJ, Thornton JS, Hawkes DJ, Hill DL, Kitchen N, Mancini L, McEvoy AW, Razavi R, Wilson S, Yousry T, Keevil SF. Design, operation, and safety of single-room interventional MRI suites: practical experience from two centers. J Magn Reson Imaging. 2015 Jan;41(1):34-43.
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Thank you for your time!

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