1
2
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Draft ACR Manual on MR Safety

ACR COMMITTEE ON MR SAFETY

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Return to Table of Contents

Table of Contents

PREFACE

This 2023 edition of the *ACR Manual on MR Safety* replaces all earlier versions. This document is published in a web-based format so that it can be revised and updated as needed.

In 2001, the American College of Radiology (ACR) formed a Blue-Ribbon Panel on Magnetic Resonance (MR) Safety in response to various reports in the medical literature and print media detailing MR imaging (MRI) adverse events and incidents involving patients, equipment, and personnel. Initially published in 2002, the ACR MR Safe Practices Guidelines established de facto industry standards for safe and responsible practices in clinical and research MR environments. Subsequently, these guidelines have been reviewed and updated throughout the years to address feedback from the field and installed base as well as changes in the MRI industry since the original publication. The *ACR Manual on MR Safety* represents the consensus of those representing the Committee on MR Safety of the ACR. The ACR Committee on MR Safety comprises professionals representing diverse fields and backgrounds that include research/academic radiologists, private-practice radiologists, MR/medical physicists, MR safety experts, patient safety experts/researchers, MR technologists, and others. It should be noted that these recommendations are not only appropriate from a scientific point of view but also reasonably applicable in the real world, with consideration given to patient care, throughput, financial pressures, and other considerations. The views expressed in this document are solely those of the authors and in no way imply a policy or position of any of the organizations represented by the authors.

The ACR sincerely thanks all who have contributed their knowledge and valuable time to this and all previous versions of this publication including the ACR MR Safe Practice Guidelines, ACR Guidance Documents on MR Safe Practices and the ACR Manual on MR Safety.

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REVISION HISTORY

The ACR Manual on MR Safety was published in 2020 as a web-based product. Content changes may take place as a result of changes in technology, clinical treatment, or other evidence-based decisions from the MR Safety Committee.

Date	Section	Change
4-15-2020	All	Creation of the *ACR Manual on MR Safety* based on the reorganization and updates to previously published "ACR Guidance Document on MR Safe Practices: 2013."
	Magnetic Resonance (MR) Personnel	Includes Expanded staffing guidance to align with the Veterans Health Administration Directive on MR safety, 2018.
		Includes addition a of expectation of formal safety roles
	Screening	Includes deference to the Heart Rhythm Society on guidance regarding the performance of MR examinations in patients with non–MR Conditional cardiac devices.
	Full Stop/Final Check	Newly added section.
	Final Patient/Research Participant Preparation	New section
	Special Patient Population Considerations	Includes updates to the pregnancy, prisoner/detainee, and parolee sections.
	MR Imaging (MRI) Contrast Agents	Includes updated language.
	MR Environment	Includes newly added atypical environments to include complex intraoperative and 7-T environments.
	Screening Form	Formerly Appendix 2: This section has been removed and will be available as a separate document available for download on the acr.org MR Safety webpage.
5/15/2020	All	Includes grammatical corrections and general editorial changes.
	Screening	Includes clarification for emergent patients.
2/1/2023	All	Reformat of the manual into chapters
	Introduction	Includes basic introduction of MR risks and safety concerns related to the MR fields.
	Management of MR Safety and Polies and Standard Operating Procedures	Formerly, establishing, implementing and maintaining MR safety policies and procedures. Provides new points to consider when developing MR policies and procedures.
	MR Environment	IEC update of fringe field to 9 gauss.
	MR Personnel	Includes updated language for MR Safety Training levels and responsibilities.
		Includes training checklist.
		Includes updated staffing guidance.

		Includes remote scanning guidance.
	MR Screening	Includes reorganization of information involving staff/personnel screening, patient screening, screening for ferromagnetic material, risk identification, MR Safe attire and ferromagnetic detection
	Final Stop/Final Check	Includes routine and augmented guidance and new language about removal of hearing aids before Zone IV entry.
	Zone IV Exam Preparation and Completion	New section
	MRI Fields and Safety Concerns	Includes reorganization of Time-Varying Radiofrequency (RF) Magnetic Field to include whole body heating, focal heating and resonant heating.
		Includes reorganization of Time-Varying Magnetic Field Gradient (dB/dt) to include auditory considerations, induced voltages and peripheral nerve stimulation.
	Classification of Objects and Medical Devices in the MR Environment	Formerly implants, devices and objects section. Includes MR safety labeling classifications.
	Introducing Portable Metallic Objects and Equipment in the MR Environment	New section (formerly included in implants, devices and objects) contains labeling and testing, MR Unsafe transport equipment temporary provisions and portable objects in Zone IV
	Managing Patients/Subjects with Medical Devices in the MR Environment	New section (formerly included in implants, devices and objects) containing active implanted/on-planted devices, passive implanted devices, and implants, devices, or objects discovered during MR examination.
	Emergency Situations	New Section (formerly included in MR Environment) includes emergency stop and emergency power off, quench, fire, code, and entrapment.
	Special Patient and Personnel Considerations	Formerly, special patient population considerations. Includes reorganization of information including pregnancy, pediatric MR safety concerns, claustrophobia, anxiety, and sedation, high BMI/large body habitus (new), prisoners/detainees and parolees.
	Alternative MR Environments	New Section (formerly found in MR environment) includes PET/MR, intraoperative/interventional MR, MR Simulator & MR-LINAC (new), point of care MR system (new) and mobile MR scanner (new) information.
	Appendix 1	New appendix containing MR Safety Policies and Standard Operating Procedures guidance.
	Appendix 5	New appendix containing implanted device MR risk/safety assessment.

126

127

128

129

CHAPTER 1: INTRODUCTION

It remains the intent of the ACR that this *ACR Manual on MR Safety* will prove helpful as the field of MR imaging (MRI) continues to evolve and mature, providing MR services that are not only safe but also valuable from a clinical or research point of view.

Introduction and Overview of Unique Risks in MRI

While generally considered a low-risk imaging modality, particularly due to the lack of ionizing radiation, the unique fields encountered in the MR environment do pose safety risks not only for patients, experimental participants, and health care staff, but also others who may encounter the MR environment, including patient family members, security officers, firefighters, police, housekeeping personnel, etc. MR safety accidents have led to serious injuries and deaths. There have been at least 3 deaths, in 2001, 2018, and 2021, from oxygen canisters that have become lethal projectiles, and deaths and serious injuries have resulted from improper scanning of patients with implanted devices.[1-2] A death occurred in 2023 when a firearm was brought into the MR environment and the magnetic field caused weapon discharge.[3] "On-planted" external devices, those worn or located largely external to the body, such as insulin pumps, can be the source of MR safety events if exposed to the MR environment in an unsafe manner. Many other non-lethal projectile-related injuries have also occurred. MRI-associated burns constitute the most frequently reported injury in MRI.[4-6]

Root cause analyses of MR safety accidents reveal that often the accident did not result from a malfunction of the MR equipment. Instead, accidents are more typically the result of how the equipment was being used, frequently involving a breakdown in adherence to policies and procedures or being impacted by previously unrecognized significant gaps in those policies and procedures. As there will always be potential for human error, it is essential that MR facilities design thoughtful policies and procedures that reliably address predictable, as well as unusual situations. Concurrent with this notion is the recognition that contemporary MRI practices encounter ongoing challenges associated with ever-evolving technology, patient throughput and staffing challenges, and increasingly complex patients with increasing numbers of implanted devices.

The following *ACR Manual on MR Safety* is intended to be used as a template for MR facilities to follow in the development of a safety program. These guidelines were developed to help guide MR practitioners and institutions regarding these issues and to provide a basis for them to develop and implement their own MR policies and practices. These guidelines, along with the policies and procedures that are developed, are intended to be reviewed and updated annually. This version of the manual includes a new appendix (Appendix 1) that should serve as a guide for the development of MR safety policies and standard operating procedures (SOPs).

The principles found in this safety manual are intended to apply to clinical diagnostic imaging, research, and atypical MR settings (e.g., linear accelerator MR, interventional MR, etc.) and encompass information for patients, research participants, and health care personnel. It is worth

noting that the use of remote MR system operation does not, in any way, diminish the obligations of the site to provide safe MR patient care.

Introduction to MR Fields and Potential Safety Concerns

The unique safety concerns in MR imaging are caused by the generation and/or presence of 3 independent magnetic fields used for imaging by the MR scanner, and all contribute to specific MR safety challenges:

- static magnetic field (B_0),
- time-varying radiofrequency magnetic field (B_1), and
- time-varying gradient magnetic field (dB/dt)

These topics are elaborated upon in the MRI Fields and Safety Concerns section.

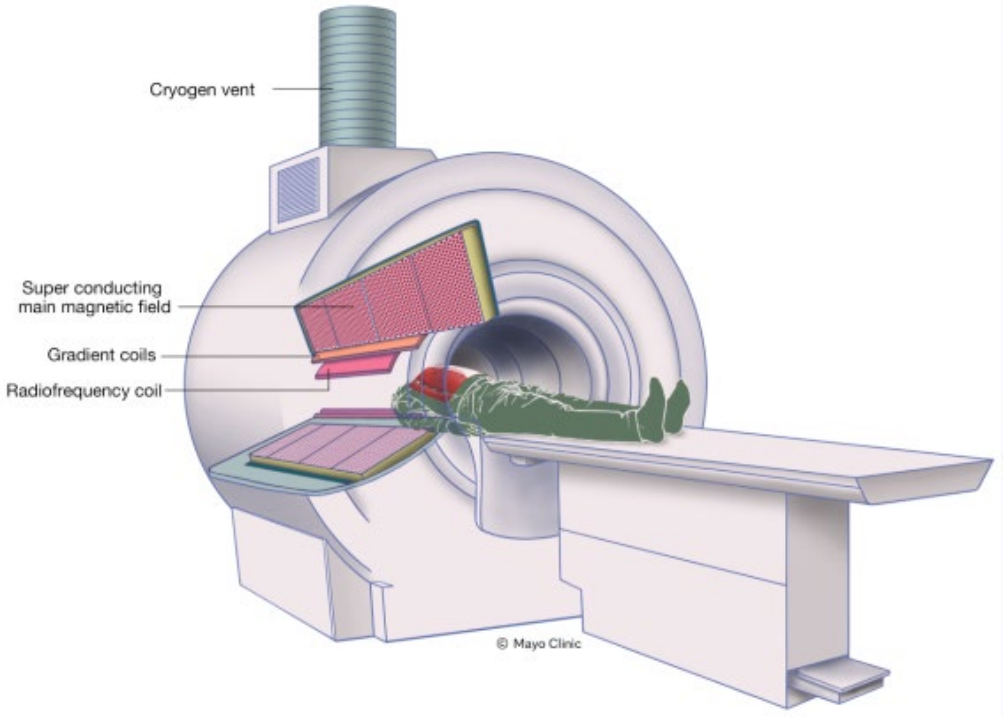

Figure 1. Schematic diagram of typical superconducting MRI. Closest to the bore wall adjacent to the patient are the radiofrequency (RF) coils; unsafe physical proximity to these can cause patient heating and burns. Peripheral to the RF coils are gradient coils; rapid current changes in these produce the characteristic loud noises in MRI. These fields can also cause peripheral nerve stimulation. The outermost ring is associated with the main magnetic field B_0 that creates the strong magnetic translational and torque forces in MRI. All 3 fields can interact with implanted or on-planted medical devices or any metallic object in the MR environment.

Static Magnetic Field (B_0). A very strong magnetic field to polarize the spin of protons in human tissue allows for MR imaging. This is typically measured in units of Tesla (T). This field, and its sharp increase approaching the MR system (spatial field gradients, T/m), are the source for potentially large magnetic forces on ferromagnetic objects entering the MR environment. Depending on scanner room configuration, shielding, and magnitude of the magnetic forces, these forces may extend outside the scanner room confines and potentially affect devices and personnel. For virtually all MRI scanners in use today, this field is usually generated by large currents circulating in cryogen-cooled superconducting coils and so **should be assumed to be always on,** making the safety concerns caused by this field omnipresent and requiring substantial access, supervisory control and vigilance over personnel and items entering the MR

environment.[7,8] Current FDA approved MR scanners for human use rely on magnetic fields between 0.064 and 7 T.[9] The main risks of the B_0 field include translational and torque forces (projectile effect). It is always on in typical superconducting magnets, even when imaging is not being performed.

Time-varying radiofrequency (RF) magnetic field (B1). A much smaller magnetic field (μT) oscillating at or near the MR frequency (MHZ) of protons is generated orthogonal to the static field by another set of current-carrying coils (i.e., built-in body coil in the bore of the scanner or dedicated anatomical transmit-receive coils placed directly around the anatomy of interest) close to the patient during imaging to excite and/or manipulate the polarized spins for signal and contrast. This field, characterized by its amplitude, frequency, and duty cycle, is responsible for risks caused by heating in the bore of the scanner. This field is only present during imaging.[7,8] The main risks of the B_1 field include patient heating and burns including interaction with implants.

Time-varying magnetic field gradient (dB/dt). Three orthogonal linear gradient magnetic fields are generated by another set of coils in the bore and are pulsed during image acquisition for image encoding. These switched gradients have magnitudes (mT/m) in space across the bore, with rise times (μs) that indicate their ramp-up rate defined as the magnetic field slew rate (T/m/s). Gradient fields' continual ramp-up and ramp-down leads to their standard definition as time-varying magnetic fields, dB/dt (T/s). The rapid switching of large currents through the gradient coils is the source of both the loud acoustic noise generated during MR imaging, and potential nerve stimulation. The main risks of the gradient (dB/dt) field include acoustic injury, induced voltages/currents, arrhythmogenesis, nerve stimulation and interaction with implants.

MRI Output Operating Modes: To aid in managing the bioeffects of exposure to these electromagnetic fields in patients, the International Electrotechnical Commission (IEC)/Food and Drug Administration (FDA) have recommended output limits for each field referred to as 'Operating Modes'.

- Normal Operating Mode. The lowest level of output in MRI is defined by the Normal Operating Mode, which presents negligible risk to the patient.
- First Level Controlled Operating Mode. This carries higher risk to the patient. Risk is mitigated by employing appropriate medical supervision of the patient for the specific scanning scenario.
- Second Level Controlled Operating Mode. Higher mode of operation typically not used in routine clinical practice and is generally reserved for human participant research with appropriate medical supervision.

It is important to note that the operating mode thresholds for each of the fields is independent of the others, and in no way takes into account issues with medical devices or other equipment in the bore that may cause a patient injury. MR operators should be aware and knowledgeable of these operating mode limits and when to employ them.

Other unique MR environments and MR-related risks addressed in this ACR Manual on MR Safety include:

- Implanted / onplanted medical devices and associated MR safety risks[10-12]

- Cryogens used for maintaining magnet coil superconduction and risks associated with cryogen exposure loss and magnet quenching
- MRI safety considerations in unique patient populations, including pregnancy, pediatric, those with claustrophobia and high BMI/large body habitus, and those with law enforcement considerations (prisoners, monitored parole, etc.)
- Alternative MR environments (PET/MR, Radiation Oncology, interventional/intraoperative, high/low field and mobile)
- Gadolinium based contrast media in MR (with reference to the ACR Manual on Contrast Media)

KEY POINTS

- Deaths and serious injuries have occurred in MRI. MR safety events are typically related to unsafe practices, failure to follow MR safety policies and procedures, or gaps in those policies and procedures. Equipment failure or shortcomings rarely underlie MR safety events.
- The 3 types of magnetic fields in MRI are associated with unique risks
  1. Main magnetic field B_0
     - Ferromagnetic object translation / torque and projectile incidents
  2. RF field B_1
     - Heating and burns
  3. Gradient field
     - Acoustic injury, peripheral nerve stimulation
- The risks associated with the RF field B_1, and gradient fields are managed in part using scanner Operating Modes (Normal and First Level Controlled)
- All 3 types of magnetic fields can interact with implanted and on-planted medical devices in potentially deleterious ways.
- Other MRI risks are addressed in other sections of this *Manual*.

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CHAPTER 2: MANAGEMENT OF MR SAFETY AND POLICIES AND STANDARD OPERATING PROCEDURES

All clinical and research MR facilities, irrespective of magnet format or field strength, including installations for diagnostic, research, interventional, and/or intra- or perioperative applications, should maintain MR safety policies.

Policies and Standard Operating Procedures (SOPs). These policies and procedures should be reviewed yearly. Also, concurrently with the introduction of any substantial changes in safety parameters of the MR system or site (e.g., related to hardware and/or software upgrades resulting in faster or stronger gradient capabilities or higher RF duty cycles) these policies and procedures should be updated as needed. A related consideration is the addition of non-typical MR units (e.g., PET/MR, hybrid procedural interventional suite, etc.) to a facility's MR fleet; due to the unique risks in these specialized environments, appropriate site-specific policies and procedures must be developed to ensure safety. During the review process, national and international standards and recommendations should be taken into consideration prior to establishing local guidelines, policies, and procedures. Points to consider when developing MR safety policies and standard operating procedures can be found in Appendix 1.

MR Safety roles. The American College of Radiology (ACR) Committee on MR Safety supports the recommendations of the consensus document calling for formal MR safety roles and responsibilities for facility management of MR safety. These roles include MR Medical Director (MRMD), MR Safety Officer (MRSO), and MR Safety Expert (MRSE).[1]

The following personnel organizational structure recommendations are aimed to ensure the implementation and management of MR safety in and around MRI facilities.

Consistent with the consensus document, the development, implementation, and ongoing management of MR facility responsibility will be shared between a designated Physician MRMD, an MR Safety Officer (MRSO), and, in an advisory role, an MR Safety Expert (MRSE). The specific job roles and responsibilities are described below.

MR Medical Director (MRMD)

This responsibility will be assumed by a licensed physician/radiologist with appropriate training in MR safety. The MRMD is responsible for overseeing overall MR facility operational safety. The MRMD shall ensure, at all times, either in person or via delegation to another qualified individual, the satisfactory performance of the following responsibilities:

1. The safe execution of all MR examinations
2. The appointment of an MRSO and advisory MRSE
3. The development, implementation, and maintenance of specific policies and procedures pertaining to the safe operation of MR services
4. The implementation and maintenance of appropriate MR safety and quality assurance programs
5. The development of an appropriate ongoing assessment of risk for the facility

6. The development of an appropriate system for record keeping and analysis of adverse events (with the MRSO and MRSE as needed)
7. The development of an appropriate investigation and recording of all reported MR safety adverse events

MR Safety Officer (MRSO)

This responsibility will be assumed by a suitably trained individual, often an MR Technologist. Multiple MRSOs can be appointed by a facility, but a single MRSO should be identified as being responsible and should oversee safety practices within a defined component of the MRI practice at all times. It might be appropriate to name an MRSO for each facility location (i.e., three magnets in the same location) for each shift. The MRSO responsibilities include:

1. Ensuring accessibility at all times to the operators of active MR facilities
2. Ensuring that proper policies and procedures of the MRMD are implemented and enforced at all times
3. Development, documentation, and execution, in conjunction with and under the authority of the MRMD, of safe working procedures for the MR environment
4. Ensuring that adequate written safety procedures, emergency procedures, and operating instructions are issued, in consultation with the MRMD and MRSE as needed
5. Ensuring the implementation and monitoring of appropriate measures for minimizing risks to staff and patients, in cooperation with the MRMD
6. Managing hazards posed by the MR equipment and monitoring the measures taken to protect against such hazards
7. Ensuring, in cooperation with the MRMD, that medical, technical, nursing, emergency, and all other relevant staff groups (including ancillary workers) who may be exposed to the MR environment are educated appropriately and updated as necessary as to MR safety requirements
8. Providing and/or ensuring the provision of MR safety education and training in cooperation with and as per the policies of the MRMD and maintaining records of personnel education
9. Consulting the MRMD and/or MRSE when further advice is required regarding MR safety
10. Reporting back to the MRMD in a timely fashion any and all MR safety-related issues
11. Ensuring that there is a clear policy for purchasing, testing, and clearly marking of all equipment that will be taken into Zones III and IV
12. Providing safety advice on the modification of MR protocols (in cooperation with the MRMD and/or MRSE) if/as needed
13. Maintaining regular contact with other relevant groups or committees responsible for the safety and welfare of personnel on site
14. Providing expertise in root cause analyses, solutions meetings, etc., related to MRI adverse events

MR Safety Expert (MRSE)

This individual is expected to serve as a resource for the MRMD and MRSO for nonmedically-related MR safety issues (i.e., issues other than contrast agents, anxiolytics, and other pharmaceuticals). It is assumed the MRMD and MRSO are part of the organization performing the scan. However, the MRSE may be external to the organization. It is expected that each organization will have an MRSE prospectively identified. The MRSE is often an MR physicist, but others with suitable expertise could also fill this role. It is expected that the MRSE will serve in an advisory role for one or several MR facilities and thereby does not need to be physically present at the MR facility, although a prospectively and clearly defined means to contact this individual is expected. The MRSE responsibilities include:

1. Providing advice on the engineering, scientific, and administrative aspects of the safe use of MR equipment, which includes quantification assistance for energy, force, and risk exposures
2. Providing advice on the development and continuing evaluation of a safety framework for the MR environment
3. Providing advice for the development of local rules and procedures to ensure the safe use of MR equipment
4. Providing safety advice regarding nonroutine MR procedures, which includes advice regarding safety related to implanted devices and other similar issues
5. Providing advice on the choice of MR Safety programs and MR Quality Assurance programs, evaluations, and audits
6. Providing safety advice regarding equipment acceptance testing
7. Establishing and maintaining links with appropriate regional and professional bodies and reporting back to the MRMD and MRSO on safety-related issues
8. Providing expertise in root cause analyses, solutions meetings, etc., related to MRI adverse events

Each MR facility will name a physician MRMD whose responsibilities will include ensuring that MR safe-practice guidelines are established and maintained as current and appropriate for the facility. The MR facility's administrative staff must ensure that the policies and procedures that result from these MR safe-practice guidelines are implemented and adhered to at all times by all of the site's personnel.

Further considerations and valuable information about safety structure related to the scanning of human participants in a research setting, including the role of an MRRD (MR research director), have been previously published.[2]

MR Safety Committee. An MR safety committee structure centered on MRMD, MRSO, and MRSE organizational structure, with inclusion of pertinent stakeholders (to possibly include other radiologists, physicists, technologists, advanced practice providers (APPs), nurses, anesthesia personnel, clinical assistants, MR technical maintenance personnel, desk operations, administrative personnel, facility management personnel, among others) is encouraged, allowing timely discussion of MR safety issues and an infrastructure focused on continual improvement.

Reporting of MR-related adverse events and incidents. Procedures should be in place to ensure that all MR-related adverse events, safety incidents, or "near misses" that occur are reported to the MRMD in a timely manner (e.g., within 24 hours or 1 business day of their occurrence) and used in continuous quality improvement efforts. The US Food and Drug Administration (FDA) requests that MR facilities also report adverse events and incidents to them via their MedWatch program.[3] The ACR Committee on MR Safety supports this recommendation and feels that it is in the best interest of MR practitioners to create and maintain this consolidated database of such events to help all of us learn about them and how to better avoid them in the future.[4]

KEY POINTS

- Management of MR safety should include
  - MRMD- licensed physician/radiologist with appropriate training in MR safety who is responsible for overseeing overall MR facility operational safety
  - MRSO- responsible for working with the MRMD and MRSE in implementation of day-to-day practice of a comprehensive MR safety program
  - MRSE- a resource for the MRMD and MRSO for nonmedically related MR safety issues (i.e., issues other than contrast agents, anxiolytics, and other pharmaceuticals)
- ACR MR Safety Committee supports FDA's request for facilities to report adverse events to MedWatch
- Adverse events and 'near misses' should be reported to the site's MRMD in a timely manner
- Facilities will create and maintain MR safety policies that are reviewed at least annually

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CHAPTER 3: MR ENVIRONMENT

Site planning. Many issues can impact MR safety that should be considered during site planning. This document includes information in separate sections and appendices that address such issues, including cryogen vent locations and pathways, magnetic fringe field (See 5 and 9 gauss discussion in Zone III paragraphs below), tether anchor point placement, patient access pathways and other design considerations. Plans should be carefully reviewed with those experienced with MR site planning and familiar with the patient safety and patient flow considerations prior to committing construction to a specific site design. Enlisting assistance from an architectural firm experienced with MR site design early in the planning process is anticipated to be beneficial. See Appendix 2 for further information on MR Facility Safety Design Guidelines.

MR Safety Zones

The MR facility may be conceptually divided into four zones for MR safety purposes (See Figure 2).

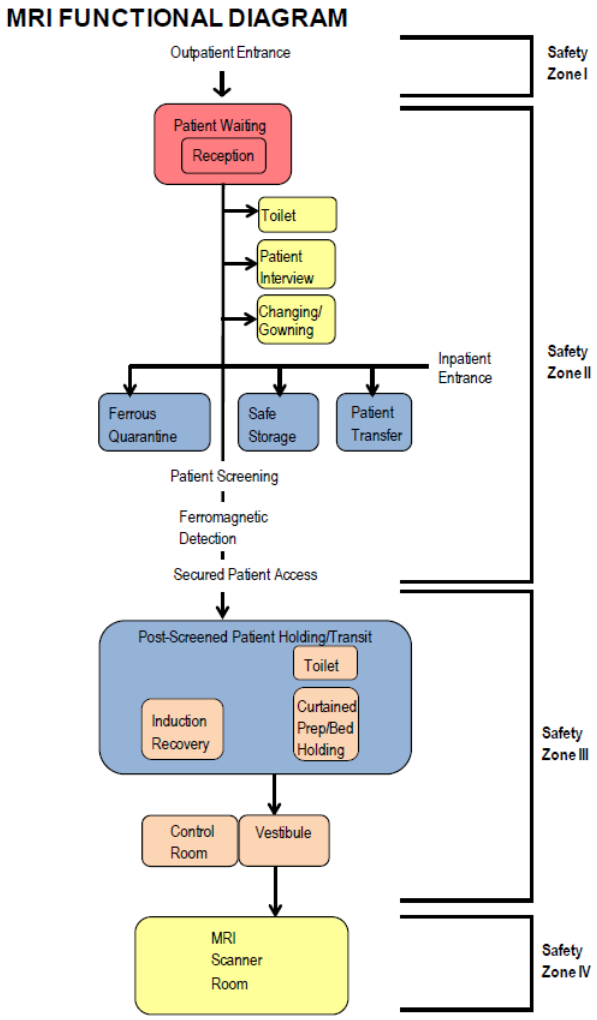

Figure 2. Schematic representation of the four Zone model.

Zone IV. Zone IV is synonymous with the MR scanner room and is comprised of the physical walled confines where the scanner is located. It includes the MR **projectile zone** where there is definite, potentially lethal, projectile risk. Zone IV, by definition, will generally be located within a surrounding controlled access Zone III. Note that in some special environments, such as perioperative MR (See Alternative MR environments), the precise boundaries of Zone IV and Zone III can be in flux depending on the clinical situation and configuration.[1]

Zone IV should be clearly labeled as being potentially hazardous because of the presence of the very strong magnetic fields. The entrance to Zone IV should also be clearly marked with a prominently displayed red warning sign stating, "The Magnet is Always On". The warning sign should remain prominently displayed, such as by an illuminated or reflective sign design. Illuminated signs should have a battery backup energy source in case of power failure. In the case of resistive MR systems, the sign may be active only when the magnet is energized.

The entry door to Zone IV (i.e., the MR scanner room) should be closed except when it must remain open for patient care or room/MR system maintenance. During the times that the door to

the MR system room must remain open, a "caution" barrier is recommended at the entry to Zone IV to inhibit unintended passage of personnel and/or materials from Zone III to IV. Examples of caution barriers include easily adjusted straps, plastic chains or other deployable barrier devices secured across the doorway to Zone IV. The entrance to Zone IV is a critical safety consideration for prevention of ferromagnetic objects entering the room. As such, when the entry door to Zone IV is not being actively monitored by MR Personnel it is advised that it remain closed and, preferably, locked.

Figure 3. Examples of Zone IV barriers.

Zone III. Zone III comprises the "**MR controlled access area**", and entrance should be restricted by reliable key locks, locking systems controlled by access control cards/badges with radiofrequency ID (RFID) or similar technology, or any method to ensure appropriate access by designated personnel. The use of combination locks is specifically not recommended because combination codes often become more widely distributed than intended, with possibility of unauthorized access. Doors should be self-locking. Zone III is also where there is access to Zone IV and potential exposure to magnetic fringe fields that can present a hazard to personnel with active implanted medical devices such as pacemakers or defibrillators. Entrances to Zone III should be identified with signage denoting the Zone III space. Statements on these signs could include "Caution", "Restricted Access", "Screened MRI patients and personnel only" and similar.

Three-dimensional static magnetic fringe fields in Zone III considerations: 5 and 9 gauss (G). Being three-dimensional, static magnetic fields may project beyond the confines of the Zone IV room on the same floor, as well as into adjacent upper and lower floors. The MR environment necessitating controlled access is defined by ASTM as "the three-dimensional volume of space surrounding the MR magnet that contains both the Faraday-shielded volume and the static field contour". It is advantageous during the facility planning process, especially with higher field magnets (i.e., 3 T and 7 T), that efforts are made to limit excessive static field extension outside the physical confines of Zone IV.

The 5 gauss (G) line (0.50 mT field contour) has been the standard threshold for risk. Historically, a magnetic fringe field of 5 gauss (0.5 mT) has been synonymous with the "pacemaker line" for MR safety. Cardiac implantable electronic device (CIED) manufacturers are required to demonstrate that these devices are immune to static magnetic fields up to 10 gauss (1.0 mT) (ISO 14117:2012 and 2019)[2,3] which has particular importance for devices that continue to use a reed switch or Hall effect switch for patient therapy control. Thus, prior IEC standards for basic safety of MR equipment specified 5 gauss to provide a substantial safety margin (IEC 60601-2-33:2002)[4]. A recent update to the IEC standard has revised the fringe field limit to 9 gauss (0.9 mT) (IEC 60601-2-33:2022)[5]. It is anticipated that MR scanner vendors will include instructions to control access to 9 gauss in the future, which allows for 1 gauss tolerance variability in the cardiac pacemaker test method. *The Manual will be updated with the new standards if and when they are adopted into the FDA guidance documents.*

In a Zone III region exceeding 5 gauss, an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.[6] For example, there is possibility of interaction with implanted electronic medical devices such as cardiac pacemakers if they come within the 5 gauss line that extends beyond Zone IV confines into areas on adjacent floors. For this reason, magnetic-field-strength spatial plots for all MRI systems should be analyzed in both horizontal and vertical orientations, identifying areas around, above, and/or below the scanner, which may pose potential hazards. These Zone III potentially harmful access areas should be clearly identified, and their potential hazard should be clearly marked, even in typically unoccupied areas such as rooftops, or storage and equipment rooms. Given its proximity to Zone IV, ferrous objects, including those brought by patients, visitors, contractors, etc., should be restricted from entering Zone III whenever practical. (Note: See the Introducing metallic objects, equipment and other portable items in the MR environment section for additional guidance in Zone III).

Zone II. This area is **the interface between the publicly accessible, uncontrolled Zone I and the strictly controlled areas of Zones III and IV**. This area typically contains a patient waiting area, patient prep areas, locker rooms etc. Screening and ferromagnetic detection is often performed in Zone II.

Zone I. This region includes all areas that are **freely accessible to the general public**. This area is typically outside the MR environment itself and is the area through which patients, health care personnel, and other employees of the MR facility access the MR environment

MR-related potentially hazardous environmental areas: Cryogen Venting. During a magnet quench in which there is loss of magnetic superconductivity, external cryogen vents are associated with potential hazards (frostbite, asphyxiation) given the typical explosive-like rapid venting of cryogen gases. The cryogen vents (i.e., typically located on the roof or on an outside wall of the facility) should have access restricted around them to personnel who have been educated about the risks associated with cryogen gas.

Figure 4: Example of cryogen vent labeling.

KEY POINTS

- MR facility is conceptually divided into four zones
- Zone IV
  - Includes the magnet and the associated **projectile zone**
  - "Magnet is Always On" signage must be visible under all conditions
  - Zone IV magnet room door will be closed at all times except for patient transport, etc.
    - During these times, a caution barrier is recommended to prevent unauthorized access to Zone IV
- Zone III
  - Strictly **controlled access zone**
  - **Appropriate magnetic hazard signage posted at all entrances**
  - Typically includes technologist control area
  - 5 gauss line can extend outside the confines of Zone IV into Zone III
- Zone II
  - **Interface between the publicly accessible, uncontrolled Zone I and the strictly controlled areas of Zones III and IV**
  - Typically includes patient waiting, changing and nursing preparation area
- Zone I: **Freely accessible** to the general public
- MR-related potentially hazardous environmental areas requiring access control and signage: Cryogen Venting

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CHAPTER 4: MR PERSONNEL

MR Personnel and Non-MR Personnel

MR Personnel. MR Personnel are directly responsible for safety in Zones III or IV and are to be documented as having been successfully educated in MR safety topics (as defined by the facility's MRMD) at least to a level sufficient to ensure that they do not represent a danger to themselves or others in the MR environment. Although basic MRI safety training is often offered at many institutions for personnel who may visit the MRI facility (e.g., physicians, nurses, etc., accompanying a patient), the level of training for MR Personnel is more in depth and formal than that which might be provided to Non-MR Personnel.

MR personnel can either be Level 1 or Level 2, as defined below. Throughout this document, all references to MR Personnel that do not specify Level 1 or Level 2 will apply to both Level 1 and Level 2 MR Personnel.

Non-MR Personnel. Non-MR Personnel are those that within the previous 12 months have not successfully completed the designated formal MR safety education defined by the MRMD of that facility to qualify as MR Personnel. Patients, visitors, facility staff, and healthcare providers including radiologists and technologists who do not meet the criteria for MR Personnel are Non-MR Personnel.

For maintenance, vendor and engineer personnel considerations, refer to Appendix 3: MR Facility Maintenance and Emergency Preparedness Guidelines for further guidance.

MR Personnel and Training: Level 1 and Level 2

It is the responsibility of the MRMD to identify those individuals who qualify as Level 1 and Level 2 MR Personnel and their roles in the MR environment, and the necessary and appropriate training for that role. **We recommend that all Level 1 and Level 2 MR Personnel, including the MRMD, undergo annual MR safety training in accordance with accreditation requirements from TJC.**[1]

Level 1 MR Personnel. Level 1 MR Personnel are those who have been educated and successfully mastered MR safety topics as defined by the facility's MRMD **to ensure that they would not constitute a danger to themselves or others in the MR environment**.

Level 1 MR Personnel must regularly and routinely work in the MR environment to maintain Level 1 status. Substantial ongoing engagement and experience in the MR environment in this role is the expectation; undergoing a single annual lecture and rarely performing a role in the MR environment may be insufficient to maintain Level 1 MR Personnel status as defined by the facility's MRMD. It is important to note that in some situations Level 1 MR Personnel must be prepared to respond to emergencies in the MR environment.

Roles in the MR environment often designated as Level 1 MR Personnel include patient aides/technologist assistants, some nursing roles, etc.

Level 2 MR Personnel. Level 2 MR Personnel are **those who have been more extensively trained and educated in MR safety topics**, beyond Level 1 MR training.

Included in the table below are training topics anticipated to be valuable for Level 1 and Level 2 MR Personnel. This is not considered to be exhaustive and the facility's MRMD and MR safety team can identify additional topics that may best serve the facility's needs, particularly as they relate to its staffing model.

- **Key Elements of MRI Safety Training**

Topic	Level 1 MRI Personnel	Level 2 MRI Personnel
Ferromagnetic Projectile risks	✓	✓
General Magnetic Field Safety- "Magnet is Always 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.

MR technologists and radiologists typically are required to be Level 2 MR Personnel with requirements as designated by the MRMD in order to perform their roles.

Note: MR safety may also be enhanced by appropriate annual job specific training for non-MR Personnel. Examples could include MR scheduling staff, patient transport personnel, non-radiology house staff and others.

Management of MR safety roles: MRMD, MRSO, MRSE. It is understood that those serving in the MRMD, MRSO, or MRSE role will have the necessary education and experience in MR safety to qualify as Level 2 MR Personnel and should also undergo MR safety–specific education on an annual basis.[2]

MR Technologists. MR Technologists should comply with the technologist qualifications listed in the ACR MRI Accreditation Program requirements.[3] With their advanced level of MR safety training, Level 2 MR Technologists play the central role in management of the local environment and are the main patient advocate for MR Safety.

Appropriately tailoring MR safety education. MR environments are becoming increasingly complicated (e.g., PET/MR facilities, Interventional MRI/Hybrid procedural suites, Intraoperative MRI facilities, etc.), and the personnel working in these environments are becoming increasingly diverse in their backgrounds (e.g., Nuclear Medicine, Ultrasound, Anesthesia). As a result, it is important that the MRMD and the MR safety education team appropriately tailor necessary and relevant education for these personnel relative to their roles being performed in the MR environment and that there are no unrecognized gaps. Firm expectations for subject matter proficiency must be maintained. **As such, there may be instances when stratification and specialization of Level 1 and Level 2 education and personnel designation may be beneficial to safety and operational efficiency, particularly as it could relate to specific responsibilities in the MR environment.** For example, there could be stratification such as Level 2a and Level 2b that could be appropriate for specific job roles.

Supervision and Independent Access

Level 1 and Level 2 MR Personnel are permitted unaccompanied access throughout Zones III and IV. The presence of untrained Non-MR Personnel in the MR environment poses definite safety risks. For this reason, MR facilities must have well designed policies and procedures to ensure safety when Non-MR Personnel are in Zone III and Zone IV.

Specific points related to presence of non-MR Personnel in the MR environment include:

- Level 1 MR Personnel are not permitted to directly admit or be responsible for Non-MR Personnel in Zones III or IV.
- Access by Non-MR Personnel to Zone III and Zone IV is controlled by and entirely under the supervision of Level 2 MR Personnel.
- Non-MR personnel must be accompanied, monitored, and under the direct supervision of a Level 2 Personnel while in Zone III and Zone IV. Visual contact is to be maintained. An exception to this is when the non-MR personnel individual is in a changing room and/or bathroom, when verbal communication is sufficient. For non-MR Personnel

visitors in the MR environment (non-patient), who are to be under the direct supervision of a Level 2 Personnel, a visually distinct identifier, such as a site-specific uniquely colored lanyard, surgical cap/bouffant, etc., can serve as a valuable adjunct for MR personnel monitoring these individuals.

Figure 5. Example of lanyard that could be used to identify non-MR Personnel.

- In the event of need for handoff of Level 2 responsibility, there must be formal transfer of responsibility for safety related to the presence of the non-MR personnel to another Level 2 personnel who fully accepts that responsibility.
- This function of the Level 2 MR Personnel is directly under the authority and responsibility of the MRMD or the Level 2 MR Physician of the day for the MR facility. MRSO(s) can lend valuable support to the proper implementation of policies and procedures related to this.

Note: Special considerations for Non-contiguous (i.e., without direct access to Zone IV) areas exceeding 5 gauss, which by definition are Zone III. An exception to the rule related to accompanying MR Personnel requirements occurs for non-contiguous Zone III areas that are defined by extension of the 0.5 mT field outside of Zone IV. These areas include crawl spaces underneath Zone IV, equipment rooms, rooftops, etc.) Access to these areas is permitted by non-MR Personnel that have been safety screened and cleared medically (i.e., See Chapter 5: MR screening).

Staffing

Overriding guiding principles:

1. **Emergency assistance.** MRI of patients or research participants necessitates that Level 2 MRI Personnel who are conducting scans have immediate access to other dedicated MR Personnel (Level 1 or Level 2) at all times to assist in case of an emergency. Level 2 MR Technologists performing human scanning should not be considered as the primary emergency responder for other Level 2 MR Technologists conducting MRI scans simultaneously.
2. **Minimum staffing plan.** A minimum staffing plan for each MR area in a facility must be established with the aim of ensuring an appropriate number of appropriately trained personnel are staffed to ensure safety.

3. **Additional MR Personnel.** During routine hours, there must be a minimum of one Level 2 MR Technologist per scanner. There must be a minimum of one additional Level 1 or Level 2 MR Personnel in Zone III. *Temporary exception is made when MR Personnel are interviewing the patient/research participant or retrieving the patient/research participant from the waiting/changing areas.* The two MR Personnel must be able to directly and immediately communicate and respond at all times. This is in accordance with the Veterans Health Administration Responsibilities Directive 1105.05 for the Medical Facility Director of 2018, which the ACR MR Safety Committee continues to endorse.[4]
4. **MR Technologist.** In typical clinical situations, it is presumed that the Level 2 MR Personnel operating the MR scanner for human scanning is a trained and certified Level 2 MR Technologist.
5. **Research settings**. In non-clinical, typically research settings, other Level 2 MR Personnel who are not technologists may be permitted to operate the MR scanner under the direction of the MRRD. There must be a minimum of one additional Level 1 or Level 2 MR Personnel in Zone III at these times. Ensuring MR safety in these research settings is the responsibility of the MRRD.

Example staffing scenarios:

Routine hours	
One MR magnet per Zone III	For facilities with one MR magnet per Zone III performing human scanning, it is recommended that there be a minimum of two MR Personnel. In addition to the Level 2 MR Technologist there is to be at least one additional MR Personnel (Level 1 or Level 2) within the immediate Zone III MR environment, whenever patients are in the MR environment. *Temporary exception is made when MR Personnel are interviewing the patient/research participants or retrieving the patient/research participant from the waiting/changing areas.* During this time, the two MR Personnel must be able to directly and immediately communicate with each other and respond at all times.
Two MR magnets sharing Zone III	For two MR magnets sharing Zone III with both machines in use at the same time, it is recommended that there be one Level 2 MR Technologist per machine and at least one additional MR Personnel (Level 1 or Level 2) in the immediate Zone III MR environment (noting the temporary exception when one may need to attend to a patient in Zone II as above), whenever patients are present. During this time, the two Level 2 MR Personnel/MR

	Technologists and the additional MR personnel must be able to directly and immediately communicate with each other and respond at all times.
Three or more MR magnets sharing a common Zone III	In facilities with multiple scanners in a common Zone III (i.e., three or more scanners), in addition to the single Level 2 MR Technologist per scanner additional MR Personnel should be thoughtfully staffed. This helps ensure appropriate emergency preparedness and safety for patients, research participants, and staff. These minimum staffing decisions should be based on the physical layout of the facility, complexity of the environment, etc. The MRMD and MR Safety team should participate fully with the facility's management to establish the appropriate staffing model and plan. Extrapolating the ratio of an additional MR Personnel per magnet pair may be appropriate for a site with multiple magnets sharing a large common Zone III, but final determination of the precise number of necessary personnel at a given facility in such a circumstance may remain locally determined, as above.
Emergent clinical situations	
In emergent, non-routine clinical situations a staffing model is recommended to be identical to that employed in routine hours in which an additional MR personnel is physically located within Zone III to help ensure patient and personnel safety, particularly as these cases can be complex.	

Research environments.

The ACR recognizes that in research facilities where operation of MRI systems involves the use of phantoms, animals, and human participants, such facilities should develop policies and procedures that ensure safe operation. Site specific emergency procedures appropriate for these unique environments should be developed.

Remote Scanning.

Remote scanning permits the MR Technologist to be off-site.[5] Such situations may be beneficial for patients by providing access to an MR Technologist with expertise not available at the facility. *For such an approach to be considered, there must be sufficient on-site trained MR personnel to ensure patient/research participant safety*. Particular attention must be directed to patient complexity (e.g., routine outpatient vs. inpatient requiring life support), anticipating potential safety concerns.

The overriding principle in situations where the MR Technologist is remotely scanning a patient or human research participant is that the safety of those being scanned must be maintained at all times to exactly the same level as for standard scanning with the technologist on site. The site's MRMD is to be responsible for the implementation and oversight of policy, staffing and training required for the safety of those being scanned at their facility.

SOPs must be developed and enforced to guarantee the safety of patients and research participants at all times by adequately trained personnel. Essential elements of this include:

1. A Level 2 MR Technologist must be in full control of the machine in either the facility's MR Zone III or at the remote location.
2. The patient / subject must be carefully monitored when being scanned remotely.
3. The following staffing is required (with situation-specific personnel variance possible depending on which Level 2 personnel is fulfilling the **Monitoring** and **Additional MR safety personnel** roles):

Role #1. **An Onsite Level 2 MR Technologist**

Role #2. **Onsite Monitoring Level 2 MR Personnel (technologist or non-technologist)**

- Onsite Level 2 MR Technologist or
- Specially trained onsite monitoring non-technologist Level 2 MR Personnel.

Role #3. **Additional onsite MR safety personnel.**

Role #4. Remote MR Technologist

Personnel Specific Responsibilities / Tasks in the Remote Scanning Scenario

Role #1. Onsite Level 2 MR Technologist.

1. Complete the patient/research participant MR safety screening process
2. Position the patient/research participant on the MRI scanner, including appropriate elements (as in Chapter 7) to include, but not limited to:
    a. Placement of MR coils
    b. Set-up of monitoring and other equipment with proper safe placement of wires/cables
    c. Placement of insulating padding, etc.
3. Be present in Zone III – IV whenever a patient/research participant is in Zone IV, or
    a. If applicable, supervise **Specially trained onsite monitoring non-technologist Level 2 MR Personnel** and be readily available in Zone II – IV in this scenario.

Role #2. Onsite Monitoring Level 2 MR Personnel. (Technologist or non-technologist)

1. At least one Level 2 MR Personnel per patient must be in Zone III during the time the patient is in Zone III and IV and be able to communicate with the patient / research participant and the **Remote MR Technologist** at all times.
2. Continuously monitor each specifically assigned patient/research participant while they are in Zone IV to include, but not limited to:
    a. Respond immediately to patient/research participant emergency notification (e.g., squeeze ball) and other verbal communication in which onsite response is appropriate
    b. Respond to contrast reactions, extravasation, concern for possible burns, etc.
    c. Obtain appropriate assistance from other personnel as necessary
    d. Respond appropriately to data / values from physiologic monitoring equipment in which onsite response is appropriate
    e. Serve as the point of contact for the **Remote MR Technologist**:
        i. Assist with conveying any necessary patient/research participant instructions (e.g., issues related to patient motion, etc.)
3. **Specially trained onsite monitoring non-technologist Level 2 MR Personnel** An MR Personnel fulfilling this monitoring role who is not a licensed/registered MR Technologist must have Level 2 MR Safety training as defined by the MRMD that is sufficient to ensure MR safety for patients/research participants in this scenario and to ensure that they do not pose a risk to themselves or others.
    a. These non-technologist individuals must be supported by the **Onsite Level 2 MR Technologist(s)** for the functions described above.
    b. If requested by the **Remote MR Technologist**, immediately contact the **On-site Level 2 MR Technologist**.
    c. In facilities with more than one MR scanner per Zone III, one or more **Onsite Level 2 MR Technologists** may be supplemented by these **Specially trained onsite monitoring non-technologist Level 2 MR Personnel**, under the direction of the **Onsite Level 2 MR Technologist(s).**

Role #3. Additional MR safety personnel.

To ensure safety at the site, at least one additional Level 1 or Level 2 MR Personnel is to be present within the immediate Zone III MR environment (noting temporary exception when personnel may need to briefly attend to a patient/research participant in Zone II), whenever patients/ research participants *are in the MR environment.*

Role #4. Remote MR Technologist.

Other staffing recommendations in the Remote Scanning scenario

1. During the time the patient/ research participant is in Zone IV, the two MR Personnel physically present must be able to directly and immediately communicate with each other and respond at all times.

2. A Level 2 MR Personnel or Level 1 MR Personnel under direct Level 2 MR Personnel supervision must remove the patient/ research participant from Zone IV.
3. Within remote scanning SOPs, provisions must be in place to ensure patient / research participants safety if the remote connection is interrupted or lost during the scan. Dedicated facilities equipped with high standard internet connection are strongly recommended for personnel scanning remotely (i.e., household internet connections are discouraged).

In some research environments, remote scanning may be performed by a remote operator who is not a certified MR technologist. These situations fall under the purview of the site's MRRD for developing SOPs to ensure research participant and personnel safety.

Simultaneous remote scanning of multiple patients. Reportedly, some remote operators and platforms now have the capacity to scan more than one patient simultaneously. Several challenges in such scenarios that could compromise patient safety must be considered. For example, recognition of unanticipated metallic objects requires careful evaluation of the MR images for susceptibility artifact. This task is potentially compromised if a single operator is concurrently scanning more than one patient. **The site's MRMD's role is to ensure that there is proper established policy and to provide oversight for the safe scanning of all being scanned at their facility. Therefore, they must be aware of this possibility and anticipate other potential emerging safety issues and prospectively develop SOPs such that safety is not compromised.** Given widespread lack of experience with simultaneous remote multiple patient scanning, sites are recommended to adopt this approach only if they are confident that they have developed sufficient staffing and SOPs that will in no way compromise patient safety and diagnostic efficacy of the MRI examination. Alternatively, sites may wish to avoid such an approach until more widespread information and peer-reviewed literature becomes available that better define best practices, ensure patient safety, and unanticipated harms (e.g., potential worse clinical outcomes due to suboptimal image quality). The ACR MR Safety Committee will actively consider new safety information related to this as it emerges.

823

KEY POINTS

- MR Personnel
  - Level 1 MR Personnel: Individuals who have passed the facility's MR safety educational requirements (as defined by the facility's MRMD) with the aim that they would not constitute a danger to themselves or others in the MR environment.
  - Level 2 MR Personnel: Those who have been more extensively trained and educated in the broader aspects of MR safety issues, including but not limited to issues related to the potential for RF-related thermal loading or burns and direct neuromuscular excitation from rapidly changing gradients.
- Non-MR Personnel
  - Patients, visitors, or facility staff who do not meet the criteria of Level 1 or Level 2 Magnetic Resonance (MR) Personnel
- Staffing
  - Appropriate staffing in routine operating hours is essential to maintain patient safety in the MR environment
  - Staffing in emergent situations must ensure the safety of MR personnel, staff, and patients. If staffing models other than those employed during routine operating hours are considered, essential safety measures must be implemented.
- Remote Scanning
  - Safety should be in no way diminished with the use of a remote MR operator and adequate staffing is essential.

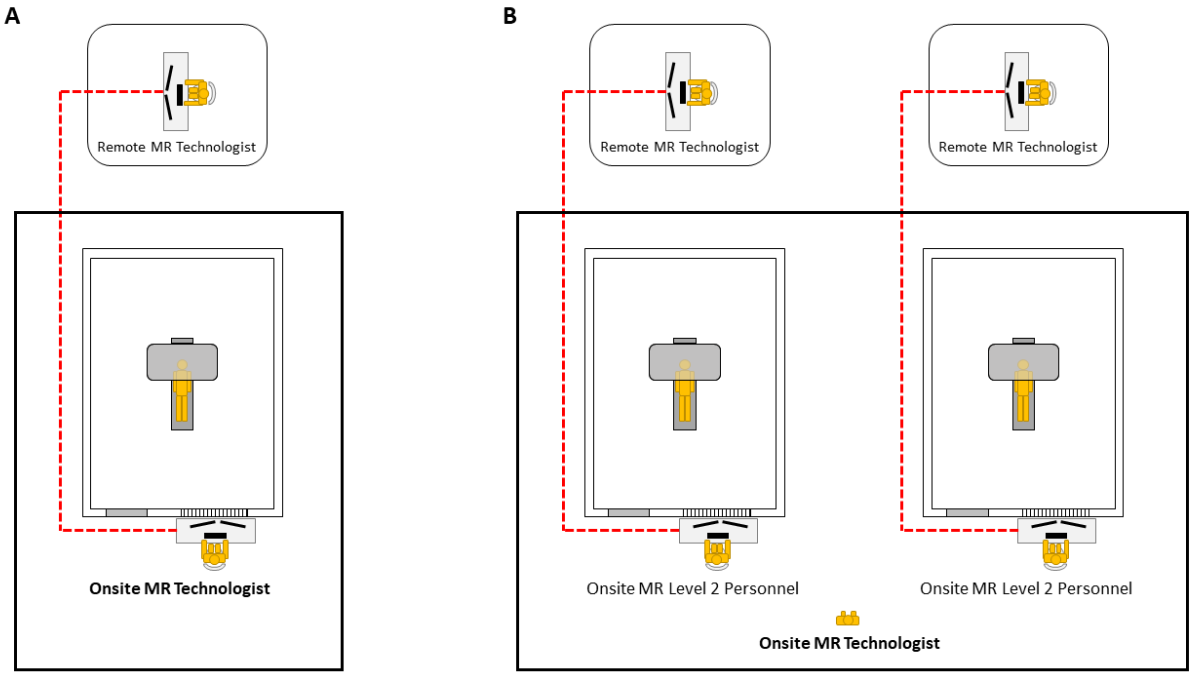

Figure 6. Possible staffing scenarios in remote scanning technologist situation. A) Single scanner per Zone III. On site Level 2 MR Technologist monitors patient while interacting with the remote scanning Level 2 MR Technologist. B) Two scanners sharing Zone III. Specially MR safety-trained onsite Level 2 personnel monitor an individual patient for whom they are responsible while interacting with the remote scanning Level 2 MR Technologist. An MR facility Level 2 MR Technologist is always onsite and immediately available to the monitoring personnel in this situation.

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849

CHAPTER 5: MR SCREENING

Due to the inherent dangers in the MR environment, well designed procedures and policies centered on thorough and effective screening of all entering Zones III and IV are essential.[1]

MR Safety Screening Forms

Well-designed written or electronic MR safety screening forms are essential in efforts to prevent unsafe exposures to the Zone IV MR environment for patients and research participants, as well as for MR personnel, non-MR personnel, and any others. A sample pre–MR screening form is provided on the ACR.org MR Safety webpage, found at https://www.acr.org/Clinical-Resources/Radiology-Safety/MR-Safety. This is the minimum information to be obtained. Additional information may be added at the discretion of the facility. No empty responses are accepted, and each question must be answered with a *yes* or *no*, or specific further information must be provided as requested. The patient, guardian, or research participant and the screening MR staff member must each physically or electronically sign the completed form. This form should then become part of the individual's medical record. Additional written or verbal information for inclusion on a screening form must be provided by a physician or an advanced practice provider (such as a licensed nurse practitioner, licensed physician assistant) or other reliable source (e.g., those knowledgeable about specifics related to an implanted device) and documented in writing.

Patient/Research Participants and Accompanying Companions

The MR safety screening form represents one facet of a comprehensive safety screening program. MR safety screening can be enhanced by a multi-tiered approach that also includes safety questions that are included with the referring physician order sets. Patient screening efforts can be augmented by Radiology pre-screening scheduling questions and implant device modules/alerts in electronic medical records (EMRs). In this way, scheduling considerations may be enhanced; for example, a patient may be scheduled at the correct magnet in coordination with the cardiology team if there is pre-visit knowledge of the presence of an MR conditional CIED.

Screening of conscious, nonemergent patient, research and volunteer participants. Conscious, nonemergent patients and research and volunteer participants are to complete a MR safety screening questionnaire (written or electronic) prior to their introduction to Zone III. A healthcare proxy may be indicated for a patient in a nonemergent setting if there is concern for lack of response accuracy due to the patient's condition (for example, in the setting of mild or more advanced cognitive impairment).

Conscious, nonemergent patients, research and volunteer participants must be MR safety screened at least twice prior to being granted access to the MR environment. At least one of these screens must be performed by Level 2 MR Personnel verbally and/or interactively. For example, following completion of the screening form, a Level 2 MR Personnel (typically the technologist) orally reviews the form's responses and contents in its entirety together with the patient. If safety concerns are identified, entrance into Zone III is not permitted until the concern is rectified. If no disqualifying safety concerns are identified, escorted passage into Zone III can proceed.

Return to Table of Contents

Pediatric/minor patients. Children may not be reliable historians and, especially for older children and teenagers, should be screened twice by Level 2 MR Personnel: once in the presence of parents or guardians and once separately to maximize the possibility that all potential dangers are disclosed. As with all patients, pediatric patients are recommended to change into MR Safe pocketless garments to help ensure that no metallic objects, toys, or other unsafe items enter Zone IV. Pillows, stuffed animals, and other comfort items brought from home represent potential risks and should be discouraged from entering Zone IV; these should be permitted only on a case-by-case basis if thorough screening has ensured their safety in the MR environment.

Unconscious, unresponsive, altered-level-of-consciousness, mentally impaired patients. As these patients cannot provide their own reliable histories regarding possible prior surgery, trauma, or injury by a metallic foreign body, a multifaceted approach to obtaining reliable information is recommended prior to proceeding with the MR examination.

1. Consultation of the EMR (including surgical records and any available implanted devices module), as well as evaluation of prior imaging can provide additional important safety screening information.
2. Available family members or guardians with appropriate knowledge of such patients should complete a written MR safety screening questionnaire prior to the patient's introduction to Zone III.
3. If no reliable patient history can be obtained, and if the requested MR examination cannot reasonably wait until a reliable history might be obtained it is recommended that:
    a. Visual inspection for scars, sites of trauma and/or obvious implants by MR Personnel designated by the MRMD be performed.
    b. If recently obtained radiographs, computed tomography [CT] studies, or MR studies of core anatomic regions (with the exception of distal extremities) are not available, patients undergo plain radiography to exclude potentially harmful embedded or implanted metallic foreign bodies, implants or devices. Plain-film radiography should include the head/neck, chest, abdomen/pelvis, and upper arms and thighs. If there are obvious post-traumatic changes to the distal extremities, those regions should also undergo imaging evaluation prior to MR exposure. (See specific note about orbit screening).

Emergent patients. Emergent patients and their accompanying Non-MR Personnel may be screened only once, provided that the individual is Level 2 MR Personnel. Any exceptions to this in extremely extenuating circumstances in which delayed diagnosis could have devastating consequences (such as but not limited to cases where a screening induced delay may result in imminent patient paralysis, blindness, and/or death) must be with the mutual agreement of the ordering physician and covering Level 2 MR Physician or MRMD, who specifically acknowledge the potential risks of a decision NOT to screen prior to granting that patient MR access.

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. It is

recommended that the accompanying individual change into facility-provided MR safe scrubs/gown if possible.

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

If screening reveals a potential conductive or metallic foreign body or other safety issue and they wish to proceed to Zone IV, a Level 2 MR Personnel or Level 2 MR Physician must discuss with them the requirement for further evaluation and to determine if it is safe for them to enter Zone IV.

Hearing protection and MR Safe/MR Conditional seating are recommended for accompanying companions within Zone IV.

Screening with Ferromagnetic Detector Systems (FMDS)

Screening for ferromagnetic materials by direct inspection and use of a FMDS is recommended prior to entering Zone III and Zone IV.[2,3] Implanted and on-planted medical devices, both MR Conditional and MR Unsafe, may include ferromagnetic material (including batteries) that can lead to FMDS activation.

The use of conventional metal detectors that do not differentiate between ferrous and nonferromagnetic materials is not recommended. The use of FMDSs is recommended as an adjunct and not replacement of thorough and conscientious screening of persons and devices prior to being permitted into Zone III and/or IV. [4] FMDS screening may help detect ferromagnetic objects missed during the standard screening. [5,6]

Staff/Personnel Screening

1. **MR Personnel.** All MR Personnel are to undergo an initial onboarding MR screening process to identify any potential devices or medical conditions that could impact their or others' safety in the MR environment as part of their employment agreement. This screening record should be reviewed annually. Interval pertinent medical/surgical changes in status (e.g., new implanted/on-planted device, pregnancy), and new injuries/trauma involving ferromagnetic objects could pose safety issues in MRI. These changes must be immediately reported to the MRMD or designated personnel, with appropriate updating of the MR safety screening record, to determine ongoing safety in Zones III and/or IV, with appropriate changes in roles, access, etc., implemented as necessary.
2. **Non-MR Personnel**. Entry into the Zone III/IV MR environment by non-MR personnel is granted only following appropriate safety screening by Level 2 MR Personnel. In the special circumstance of a Non-MR Personnel with legitimate need to be in the MR environment, with an implanted AIMD (e.g., cardiac pacemaker, implantable cardioverter defibrillator (ICD), medication pump, cochlear implant) as well as certain passive implants (including aneurysm clips) should be precluded from entering Zone IV and prevented from passing the 5 gauss line unless specifically cleared in writing by a Level 2 MR Physician or the MRMD of the MR facility.

969

KEY POINTS

- All Non-MR Personnel needing to enter Zone III must first pass an MR safety screening process
- Level 2 MR Personnel have the final authorization to admit non-MR Personnel into Zone III
- A sample pre–MR screening form is provided on the ACR.org MR Safety webpage
- Staff/Personnel screening
  - All MR Personnel must undergo initial onboarding MR screening and yearly review this screening
  - Significant changes in screening status must be reported to the MRMD or designee immediately before returning to the MR environment
- Conscious, nonemergent patients
  - Conscious, nonemergent patients and research and volunteer participants are to complete written or electronic MR safety screening questionnaires prior to their introduction to Zone III and must be screened twice including at least once by a Level 2 MR Personnel
- Pediatric/minor patients
  - Should be screened twice by Level 2 Personnel, once separately from their parents
  - Recommended that they be changed into MR Safety pocketless garments before entering Zone IV, like all patients and research participants
- Unconscious, unresponsive, altered-level-of-consciousness patients
  - Family members or guardians of such patients should complete a written MR safety screening questionnaire prior to the patient's introduction to Zone III
  - If no reliable patient history can be obtained, and if the requested MR examination cannot reasonably wait until a reliable history might be obtained, it is recommended that such patients be physically examined and undergo plain-film radiography as necessary to exclude potentially harmful embedded or implanted metallic foreign bodies, implants, or devices
- Emergent patients and their accompanying Non-MR Personnel may be screened only once, provided that the individual is Level 2 MR Personnel
  - In cases of extenuating circumstances there must be agreement between the ordering physician and covering Level 2 MR Physician or MRMD acknowledging the risks of a decision NOT to screen prior to proceeding
- 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

970

Risk Identification, Assessment, and Mitigation

Level 2 MR Physician/MRMD final determination. Final determination of whether or not to scan a patient is to be made by the Level 2 MR Physician responsible for the patient, or the MRMD. The Level 2 MR Physician/MRMD should consider both the benefit of the imaging (including diagnosis, care plan etc.) against the risks of proceeding as well as the risks that may occur if the study is not performed. Potential risks of proceeding with the requested MR imaging examination may include mechanical, thermal, and functional risks associated with MRI of implants as well as contrast reactions. See Appendix 5: Implanted Device MR Risk/Safety Assessment.

Implanted devices. If an implanted device is indicated on a screening form, medical record, referring physician order etc., it is imperative to accurately identify and/or verify the type of implant, location of implantation and exact make/model and materials of the implant.

Verification and positive identification should be in writing or electronically documented. Sources of information may come from operative notes, device identification cards, and electronic medical record implanted device modules. Other sources may include archived MR safety screening forms.

Once positive identification is complete, the implant must be accessed as being MR Safe, MR Conditional or MR Unsafe. For MR Conditional devices, the most recently available conditions for safe scanning as included with product information must be accessed. Other sources could include written records of the results of formal testing of the implant prior to implantation, and peer-reviewed publications regarding the conditions of MR safety of the specific make, model, and type of implant as long as the device/system is identical to the device that was tested. A key role of MRSOs and MRSEs includes helping ensure safe scanning of patients with implanted devices. For untested implanted devices for which MR safety or MR conditions are unknown, independent risk assessment may be necessary if scanning is being considered. Appendix 5 Implanted Device MR Risk/Safety Assessment may provide some guidance.

Foreign body. All patients and Non-MR Personnel with a history of injury or implantation associated with an unspecified metallic foreign body including bullets and shrapnel must undergo further investigation prior to being permitted entry to Zone III.[7] Examples of acceptable methods of screening/risk assessment include patient history, plain radiographs, prior CT (with adequate thin sections) or recent MR studies of the anatomic area in question, ferromagnetic detection, anatomic location, procurement of the same metallic object, or access to written documentation as to the type of implant or foreign object that is present. If the metallic object is less than 2 cm in size heating should not be an issue.[8] If the object is ferromagnetic or potentially ferromagnetic, the object's anatomic location relative to tissues and organs should be considered. Also, anticipated fibrous scarring about the object relative to the time since the injury should be considered. Scarring could effectively limit any translation, even if ferromagnetic, limiting possibility of potential injury. Proximity to sensitive tissues, such as spinal cord, clearly could be a contraindication versus location within a large muscle where a significant injury would not be anticipated.

Potential eye foreign body/orbital trauma. All patients with a history of orbital trauma by a potential ferromagnetic foreign body for which they sought medical attention or for which there is otherwise high clinical suspicion for globe penetration by a ferromagnetic body, are to have their orbits evaluated either by a single orbit radiograph[9,10] with additional views as necessary or by a radiologist's review and assessment of prior thin section CT (obtained since the suspected traumatic event), if available. Evaluation of a prior MR examination's susceptibility artifact of the region of the orbits may provide an experienced reader with important information on the ferromagnetic nature of the foreign body, but MR images alone are insufficient to clear orbits.

Patient Preparation/Gowning

Any individual undergoing an MR procedure must remove all readily removable metallic personal belongings and devices. This includes important on-planted devices such as insulin pumps and glucose monitors. Also, they should remove watches, jewelry, pagers, cell phones, body piercings, contraceptive diaphragms, cosmetics containing metallic particles (such as eye makeup, magnetic eyelashes, hair product), and clothing items that may contain metallic fasteners, hooks, zippers, or loose metallic components/threads or may have been treated with antimicrobial electrically conductive materials. Metallic drug-delivery patches should also be removed when appropriate (See section on **Drug-delivery patches and pads**). Patients or research participants should remove all clothing and wear site-supplied MR Safe pocketless garments in place of their own clothing and undergarments in the region undergoing direct RF irradiation (See Chapter 8 for thermal considerations). Face masks should not include metal in the form of nose pieces or fibers incorporated into the mask materials.[11]

KEY POINTS

- Risk Identification:
  - Final determination to scan a patient is to be made by the Level 2 MR Physician responsible for the patient, or the MRMD
  - Accurate identification of the type, location, make/model of an implanted device is essential
  - The most up-to-date conditions for safe scanning of a device should be identified
- Gowning:
  - Patients or research participants should remove all clothing, accessories and jewelry and wear site-supplied MR Safe pocketless garments in place of their own clothing and undergarments in the region undergoing direct RF irradiation
- Ferromagnetic detector screening:
  - FMD screening is recommended as an adjunct to other safety screening methods

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CHAPTER 6: FULL STOP/FINAL CHECK

"Full stop and final check" processes should be implemented. A tiered approach is suggested that appropriately address the different levels of anticipated MR safety risks in:

- **Routine**. Typically, ambulatory settings where there is no obvious increased risk due to additional equipment and personnel.
- **Augmented.** Complex MR settings (e.g., hospitalized, emergent, anesthesia, interventional, etc.) that require an **Augmented** process, including, in particular, when the patient is transported with support equipment and/or personnel.

Routine. A "full stop and final check" performed by the MR Technologist is recommended to review and confirm the satisfactory completion of MR safety screening for all patients before entering Zone IV. Elements of this include verification of:

- patient identification
- the examination to be performed
- appropriately performed screening
- proper preparation, programming, or removal of implanted/on-planted devices
- a lack of change in patient status while in Zone III

If hearing aids have been left in place to ensure communication with the patient in Zone III, strict attention must be paid to ensure these are removed and properly stored before entering Zone IV. Providing a graphic such as the one pictured in Figure 7 may be helpful to prompt a patient's memory of other items that have not been identified previously in the screening process.

Figure 7. Examples of visual cards used during full stop/final check

Augmented. The augmented "full stop and final check" process includes a verbal review by the supervising Level 2 MR Personnel and an acknowledgement by a second MR Personnel team

member, modeled on elements of Universal Protocol Final OR/pre-procedure check. Elements of this verification include:

- Items included in the routine process above
- Thorough screening for any support staff that will also enter Zone IV
- Completion, as appropriate, of augmented screening of unconscious, unresponsive, altered level of consciousness patients (as described in MR Screening, Unconscious, unresponsive, altered-level-of consciousness, mentally impaired patients)
- Completion of careful visual inspection of the patient as well as the transport/support equipment that will enter Zone IV for presence of concealed or previously unrecognized potentially dangerous items that could pose projectile, burn, or other risks
- Ensuring that the equipment that needs to be tethered in Zone IV is properly secured prior to patient entering the room
- Ensuring that there has been no change in patient, and/or equipment status while in Zone III

KEY POINTS

- Routine
  - Typically, ambulatory setting
  - 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.
  - Hearing aids must be removed and properly stored prior to Zone IV entry
  - Verbal review by Level 2 MR Personnel
- Augmented
  - Typically, complex setting
  - An augmented full stop and final check process helps ensure appropriate screening of patients in more complex environments (e.g., hospitalized, emergent, interventional, etc.)
  - Verbal review by Level 2 MR Personnel and second MR Personnel team member

CHAPTER 7: ZONE IV EXAM PREPARATION AND COMPLETION

Final steps that must be accomplished by MR Personnel prior to scanning include but are not limited to these elements:

1. Discuss the scan expectations (e.g., breath holding requirements, need to limit motion, etc.) to aid in obtaining a quality diagnostic exam. Discuss the need for the patient to disclose uncomfortable heating, pain, noise etc. Also concerns regarding claustrophobia (See claustrophobia, anxiety and sedation section) with the patient/subject and companion can be discussed.
2. Provide hearing protection and ensure proper fit and function.
3. Position the patient, choose and place coil appropriately, plug coils into MR system securely.
4. RF burn prevention
    a. Properly pad/insulate the patient from the scanner bore and RF transmission coil.
    b. Ensure no unsafe skin-skin contact points that would risk creating internal induced current loops (See induced tissue current burns).
    c. Ensure safety related to electronic cables (e.g., proper insulation, distance from edge of the magnet bore, central and straight coil positioning[1]).
    d. Ensure equipment such as ECG pads are properly attached to the patient consistent with their use and product labeling.
5. Ensure there is an effective means by which the patient/subject can communicate with the technologist during the scan.
    a. Provide the patient/subject a technologist notification device such as a squeeze ball and have patient test it. Provide a brief discussion on when it is appropriate to squeeze the ball (e.g., unanticipated heating, excessive noise, etc.).
        1. Other site-specific comfort methods (such as audio/video)
    b. Establish a two-way intercom.
6. Set conditions of scan duration.

MR Personnel under direct Level 2 MR Personnel supervision must remove the patient/ research participant from Zone IV.

Reference:

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CHAPTER 8: MRI FIELDS AND SAFETY CONCERNS

The magnetic fields associated with MRI are generally the primary sources of safety considerations associated with routine use of the equipment. These fields should thus be considered in terms of potential interactions and risks with respect to humans and objects exposed to the fields. The strong static magnetic field can induce torque and translational forces on ferromagnetic objects and devices that can lead to projectile events. Time-varying radiofrequency (RF) magnetic fields are predominantly responsible for whole body and localized heating of tissue and devices. Additionally, the pulsed gradient magnetic fields can cause peripheral nerve stimulation and damage to implanted and onplanted devices as well as generate loud acoustic noise. Each of these phenomena will be discussed in turn.

Static Magnetic Field (B_0)

The static magnetic field, often denoted as B_0, is the strong, unchanging field in MRI that, for most systems, remains on at all times. Generally, the B_0 field is designed to be constant within the magnet bore central to the imaging system and taper off quickly outside this region. The MR environment is typically defined as the region with magnetic field higher than 5 gauss, within which some medical devices, such as pacemakers, have been observed to malfunction and therefore present a threat for patients and personnel. This rapid spatial change in the magnetic field from the center of the magnet to the fringes of the MR environment is referred to as the 'spatial field gradient' (SFG). In terms of risk, rotational torque forces on objects are determined primarily by B_0 field strength and are greatest at the center of the magnet, while translational displacement forces tend to be greatest near the edge of the magnet, where the SFG is largest. As ferromagnetic objects approach the face of a cylindrical bore magnet, the translational forces can easily turn them into dangerous projectiles. This is a central risk in MRI and a fundamental reason why access of personnel and objects into Zone IV is highly restricted.

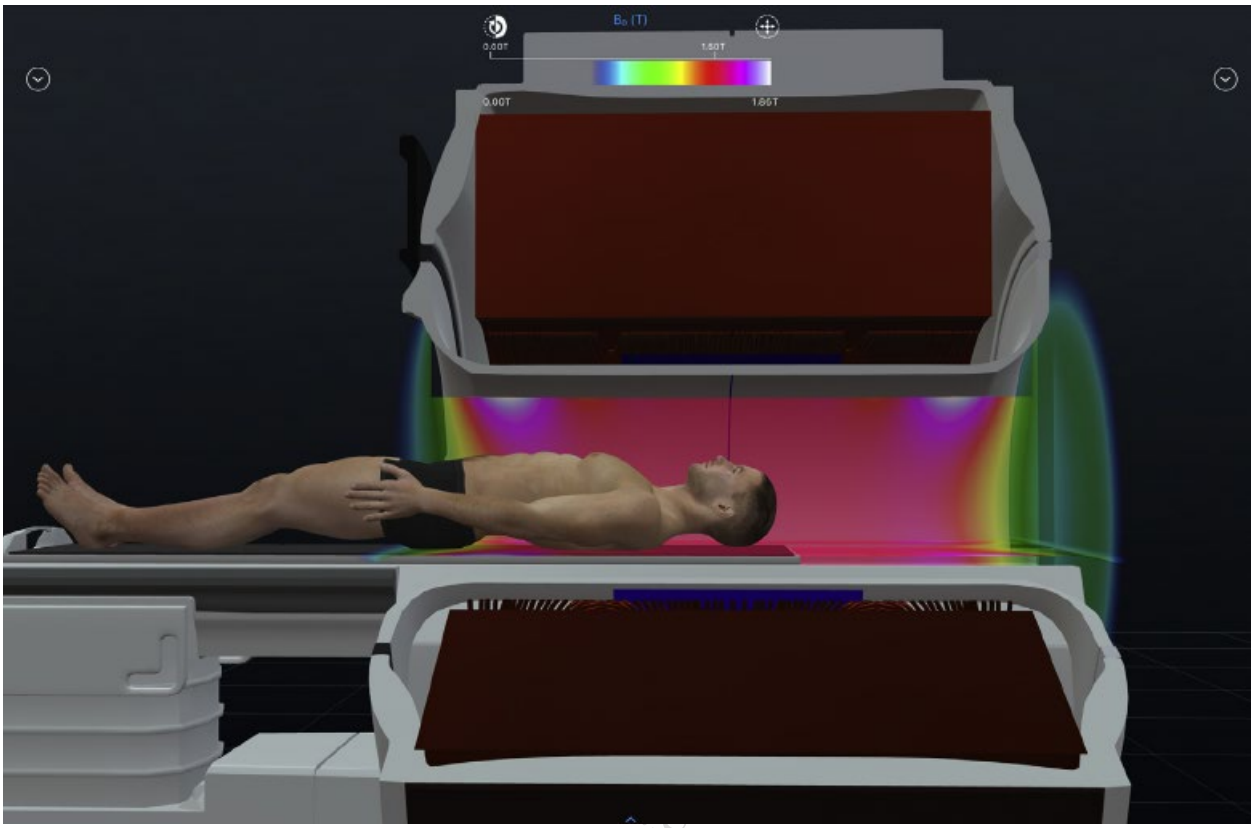


Figure 8. 3-dimensional depiction of the static magnetic field in a 1.5 T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed three dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the static magnetic field B_0 are depicted. (Courtesy of Dr. Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC.)

Spatial Field Gradient (SFG)

Strong magnetic fields can magnetize metallic objects placed within them, making the object itself interact with the magnetic field. The effect is strongest for objects with ferromagnetic content. The translational force on a metallic object in a magnetic field is proportional to the product of the induced magnetic field in the object and the spatial field gradient experienced by the object. The spatial field gradient (SFG; sometimes called the *static field gradient*) describes the rate of change in B_0 as a function of position around the MR system and is (typically cited in Tesla per meter [T/m] or Gauss per centimeter [G/cm]). The translational forces experienced by ferromagnetic objects near the MR scanner are directly influenced by the SFG. MR magnets are designed to confine the magnetic field to the area of imaging as much as possible. For typical cylindrical, horizontal-field magnets, the maximal translational forces exerted by the system on objects occurs at the magnet 'face' or opening of the bore.

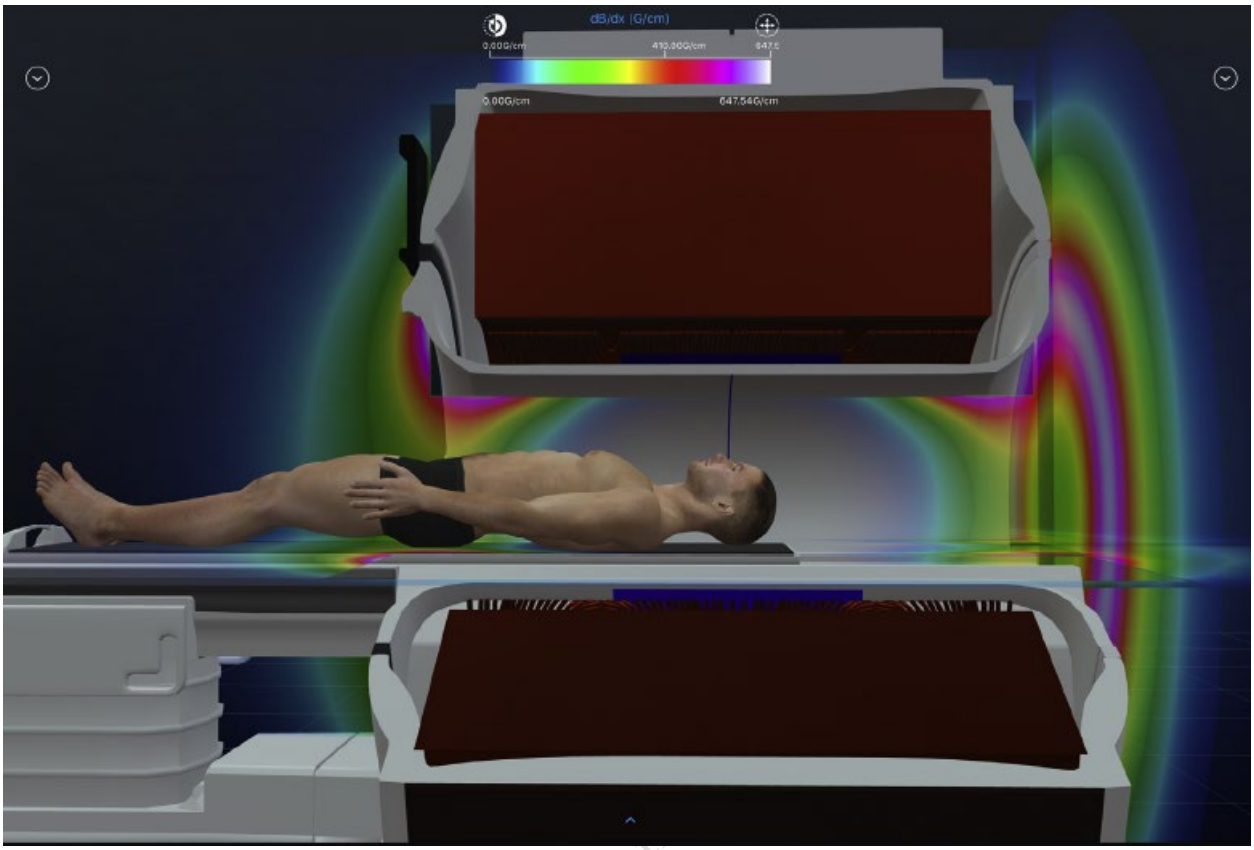
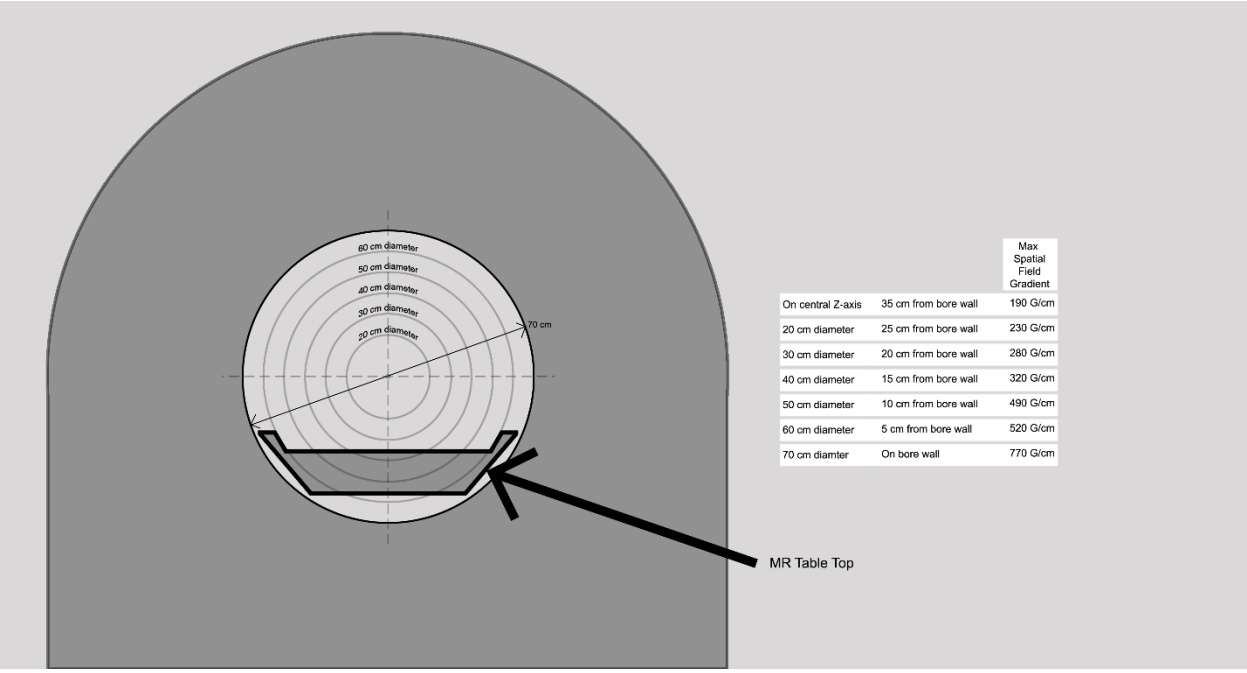


Figure 9. Three-dimensional depiction of the static/fixed spatial magnetic field gradient in a 1.5 T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed three dimensionally throughout the MR scanner bore and room. The strength and spatial distribution of the static/fixed spatial magnetic field gradient dB/dx is depicted. Notice that in the homogeneous static magnetic field at the center of the MR scanner, the strength of the dB/dx and therefore potential translational forces on ferromagnetic materials and objects are minimal. The greatest translational forces scale with the dB/dx of this magnet, which maximizes near the radial extremes/borders at the entrance (and exits) to the MR scanner bore. (Courtesy of Dr. Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC.)

To aid in evaluating forces on specific objects in the MR environment, in particular medical implants, MR system manufacturers are required to provide a map of both B_0 and the SFG for their system(s) to demonstrate to the MR system operator the strength of these fields at specific locations. Some vendors also provide the product of the SFG and B_0 at these locations.

These charts are designed to be used by the MR system operator to evaluate whether an object or implant will be exposed to fields exceeding the MR Conditions described on the device labeling.[1,2] Typically, device vendors will cite the MR system $B_0$and magnet configuration (i.e., cylindrical bore) along with the SFG known to facilitate safe scanning of an implant as determined by non-clinical testing. The operator must then determine the maximal SFG a device will be exposed to when entering/exiting the magnet to ensure that it is within the device conditions. In a cylindrical bore magnet, the maximum SFG a device may be exposed to while traveling into or out of the magnet increases with proximity to the magnet bore as shown in Figure 10.

Further information on how to evaluate SFG information provided by vendors for this purpose is provided in Appendix 4.



		Max Spatial Field Gradient
On central Z-axis	35 cm from bore wall	190 G/cm
20 cm diameter	25 cm from bore wall	230 G/cm
30 cm diameter	20 cm from bore wall	280 G/cm
40 cm diameter	15 cm from bore wall	320 G/cm
50 cm diameter	10 cm from bore wall	490 G/cm
60 cm diameter	5 cm from bore wall	520 G/cm
70 cm diamter	On bore wall	770 G/cm

Figure 10. Front view of an SFG map of an MR system indicating maximum SFG values that may be encountered within each of the cylindrical volumes within the diameter of the bore as a patient or device enters/exits the magnet.

Lenz effects. A conducting object experiencing a change in magnetic field will have current induced within the object that generates a magnetic field resisting that change. This resistive effect can result in mechanical forces on the object. This has important consequences for MRI: if an electrical conductor (i.e., an aluminum tray) is moved through the SFG of the static magnetic field, voltages and current will be generated within the conductor with a magnitude directly proportional to the rate of motion as well as the regional SFG value. The current will induce a secondary magnetic field oriented in opposition to the motion of the conductor, which will exert an opposing force on its motion. Note that this will occur even if the conductor is metallic but nonferromagnetic.

There are many scenarios in which these forces may pose concerns. For example, if a nonferrous metallic device such as an MR Conditional oxygen tank is moved toward the bore of an MR scanner, as the scanner bore is approached, the force that arises from these Lenz effects can be sufficiently strong to virtually stop forward progress of the device. Further, the faster one moves the device into the bore, the greater the opposing force that is created to stop this motion. There are also potential consequences for large implanted metallic devices. Even if these devices do not pose projectile hazards, rapid motion of the patient/implant in a direction perpendicular to the static magnetic field orientation can result in forces on the implant opposing this motion that may be detected by the patient. If the patient were to complain of experiencing forces tugging or pulling on the implant, this might lead to the patient or health care personnel erroneously concluding that the device has ferrous components, and possibly cancelling the examination. Slowly moving large metallic devices into and out of the bore is a key factor in decreasing any

Lenz effects that might be induced, decreasing the likelihood of a misunderstanding or unnecessary study cancellation.

As Lenz effects are proportional to the rate of motion through an SFG, and as these can be substantially higher at 7 T than 1.5 T or 3 T, these might bear special reconsideration for metal objects or devices used in or around 7 T MR scanners, such as metallic aortic or mitral valve replacements.[3] ECGs are significantly distorted within the bore of an MRI as a result of the magnetohydrodynamic effect, rendering those ECGs non-diagnostic. Magnetic field-induced voltage in flowing blood in the descending aorta underlies the MHD effect. Maximum blood flow in the descending aorta coincides temporally with the T wave on the ECG. Due to this, ST segment elevation or depression in an ECG acquired while in the magnet bore could mimic or obscure cardiac ischemia. The HMD can be associated with trace resistance to cardiac output, not considered to be clinically significant.[4]

KEY POINTS

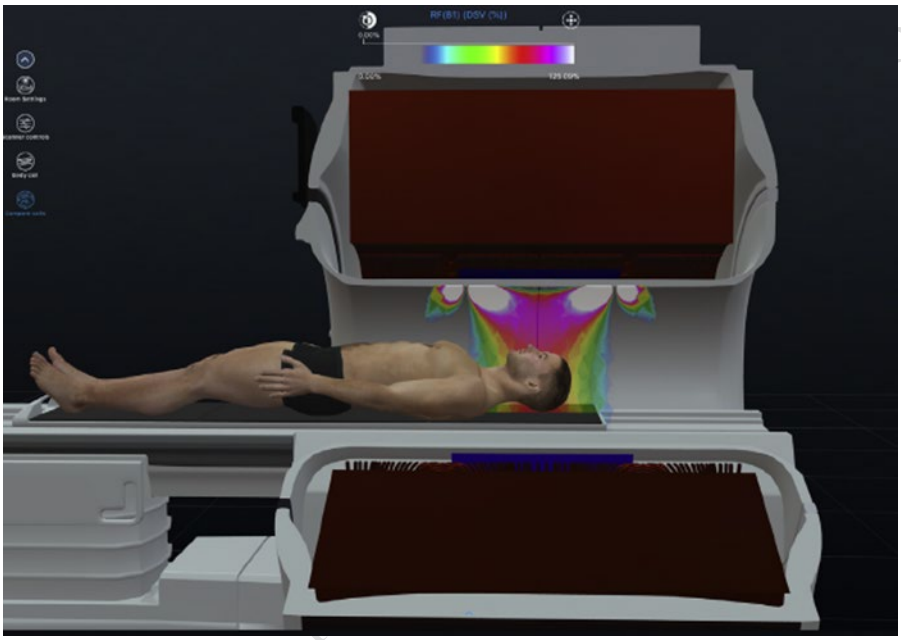
- Static Magnetic Field
  - The strong static magnetic field associated with MRI can interact with metallic objects, potentially turning them into dangerous projectiles. Access to these fields (Zone IV) must be strictly controlled. Personnel and devices entering this environment must be thoroughly screened.
  - The fringes of the static magnetic field above 5 gauss can interfere with implanted medical devices, such as pacemakers or ICDs, resulting in potential injury or death. Access to these fields (Zone III and IV) must be strictly controlled. Personnel entering this environment must be screened.
  - Metal devices and medical implants have defined limits for exposure to maximal field strength and/or the spatial field gradient to prevent damage to the person and/or device. MR operators should have access to, and understanding of, vendor documents that describe these fields to safely manage both patients and devices in the MR environment.
  - The spatial field gradient changes markedly about the magnet bore edges (also See Appendix 4 for further discussion).
    - Translational forces are greatest near the edge of the magnet where the spatial field gradient is largest.
    - Rotational B_0 torque forces are greatest at the center of the magnet.

Time-Varying Radiofrequency (RF) Magnetic Field (B_1)

Magnetic fields induced by the RF transmission in MR are the main sources of tissue heating and burns.

Focal heating during the MR exam can result in tissue burns. Most thermal injuries occur on the skin of the upper extremities or torso although they can occur virtually anywhere in the body. Direct communication between the patient and the MR Technologist during the exam is crucial as the patient may only experience minimal discomfort during the MR exam. Direct inspection of the area of discomfort may reveal only minimal skin redness but thermal injury with blisters or even ulcers may yet develop within 24 hours after completion of the MR exam. Unconscious patients and those with limited capacity to communicate are at higher risk and require careful preparation prior to the MR exam.

A



B

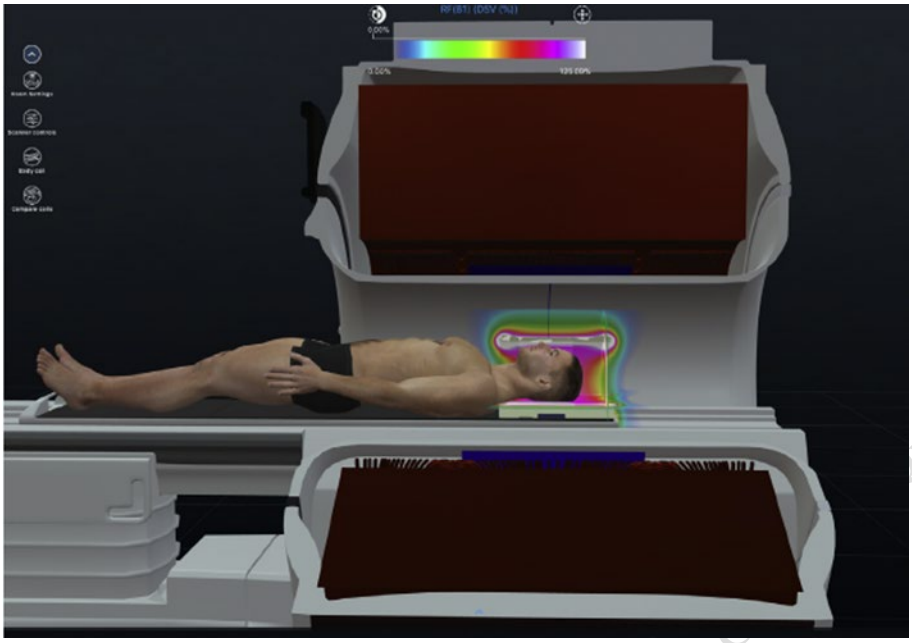


Figure 11. Three-dimensional depiction of the transmitted RF (B_1) oscillating magnetic fields in a 1.5 T MR scanner. The right side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed three dimensionally throughout the MR scanner bore and room. (A) The spatial distribution of the transmitted RF (B_1) oscillating magnetic fields with the body coil of this scanner being used as the RF transmitter hardware is depicted. (B) The spatial distribution of the transmitted RF (B1) oscillating magnetic fields with a transmit-receive head coil being used as the RF transmitter hardware is depicted. Note how the transmitted RF fields cover a smaller volume when a transmit-receive head coil is used for RF transmission in this same scanner. (Courtesy of Dr. Kanal, created using MagnetVision a, Advanced Magnetic Analytics, LLC.)

Whole body heating-Quantitative considerations

SAR and SED. The dosimetric term used to estimate the rate of absorption of RF energy by human tissue in MR is the Specific Absorption Ratio (SAR), which is the mass-normalized rate at which RF power is coupled to biological tissue. It is expressed in units of watts per kilogram on the MR system.[5] The most commonly used SAR metric presented on the scanner is the whole body–averaged value.[6-8] SAR is an estimation of the rate of energy absorption by the patient, not a total dose of energy. Total energy absorbed by the patient is referred to as the specific energy dose (SED) and can also be referred to as the specific absorbed energy. The SED is commonly reported in units of joules per kilogram or kilojoules per kilogram.

The thermal load associated with an MR examination is a separate phenomenon from focal RF-related thermal injury.[5] Although discomfort related to high thermal load during MR may be experienced by the patient, an actual burn does not occur if that load is sufficiently dissipated over time and/or space. Various health conditions may impair an individual's ability to manage a thermal challenge during MRI, including fever and obesity. Medications, including diuretics, beta-blockers, calcium blockers, amphetamines, and sedatives, can alter the patient's

thermoregulatory responses to a heat load.[7, 9] Importantly, certain medications may have a synergistic effect with RF radiation with respect to tissue heating.[7,9]

SAR limits are designed to avoid direct RF-related tissue heating and burns, while SED limits are means to protect a patient from experiencing core temperature elevations or physiologic stress or discomfort related to inordinately high thermal loads from long-duration and/or high-SAR pulse sequences (e.g., total spine or body exams).[10]

With sufficient rest and cooling-off periods between sequences, it should be possible to safely scan the patient even with high total SED values. It should be noted that although certain manufacturers have implemented SED limits on their MR scanners, limiting the SED of an MRI examination does not necessarily reduce the risks of a thermal injury (burns have occurred in patients even when MR systems were operating within guidelines for RF power deposition).[11-14]

The IEC permits each MR system manufacturer to conduct its own risk assessment and structure criteria for MR system operator alerts, warnings, and/or "lockouts" as it deems appropriate.[8, 15] Therefore, depending on the software operating on the MR system, the scanner may not present SED information (e.g., for older software versions); it may provide SED warnings at predetermined intervals with or without a lockout, or it may provide warnings and prevent additional scanning on a given patient for up to 24 hours if the MR system manufacturer–defined maximum SED threshold is reached. MR health care professionals should be aware of the SED procedure that a given MR system uses and understand the context of alerts and possible scanning restrictions. If restrictions exist, it may be necessary to modify the scanning protocol to successfully and safely complete the examination.

Specific heating safety risks

Electrically conductive material related burns. Electrical voltages and currents can be induced within electrically conductive materials that are within the bore of the MR scanner during the MRI process. This might result in heating of this material by resistive losses. This heat might be of a magnitude sufficient to cause injury to human tissue. As noted below, among the variables that determine the amount of induced voltage or current is the consideration that the larger the diameter of conductive loops, typically the greater the potentially induced voltages and currents, and thus the greater the potential for resultant thermal injury to adjacent or contiguous patient tissue.

Transmitting coil proximity burns. To help safeguard against thermal injuries or burns, pads meeting the MR system manufacturer's specifications should be placed between the patient's skin and any transmit RF coil.[16] These pads protect the patient from proximity to the transmit RF coil, to ensure spacing between the transmit coil and the patient. Careful attention to the physical condition of insulating padding is recommended, as with time pads can degrade, and become overly compressible such that their insulating capacity is compromised and sufficient clearance from the bore wall is not maintained. It is important to emphasize that insulating pads are necessary; a single-layer bedsheet is insufficient insulation or spacing to prevent burns.

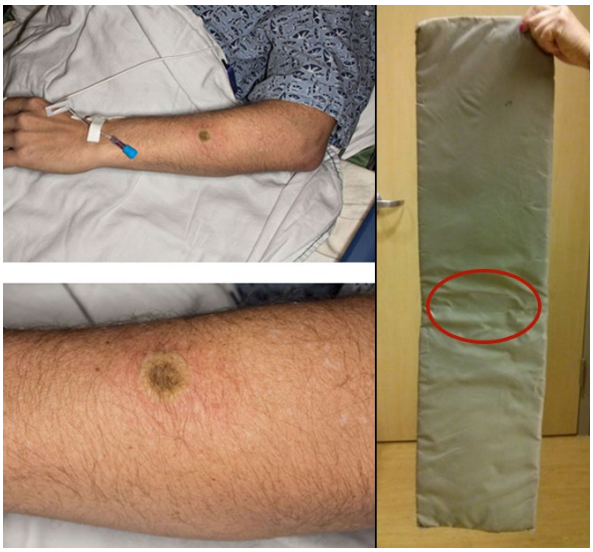


Figure 12. Example of a full thickness 3rd degree burn that resulted from the MR bore proximity associated with use of a worn-out insulating pad that was overly compressed (central circled area).

Induced tissue current burns. RF deposition can be exacerbated by electrically conducting loops within the patient's body. The greater the caliber of an induced current loop, the greater the amount of current, and therefore potential for heating, which may be induced within that loop. Burns can result in when there are small area/high resistance contact points where the energy is dissipated as heat. Therefore, it is important to prevent electrically conductive current loops that involve small area/high resistance contact points such as between a finger and a thigh, between small thigh to thigh contact areas, etc. Usage of supplied insulation pads to help prevent large caliber–induced current loops is recommended.[17]

Electrically conductive wires/leads. The concern for induced current loops is even greater when electrically conductive wires or leads are involved. When electrically conductive material (wires, leads, implants, etc.) are required to be entirely or partially within the volume undergoing direct RF irradiation during MRI, care should be taken to ensure that no large caliber electrically conducting loops (including patient tissue) are formed within the MR scanner during imaging. The FDA has noted several reports of serious injury, including coma and permanent neurological impairment, in patients with implanted neurological stimulators who underwent MRI examinations. The injuries in these instances resulted from heating of the electrode tips.[18, 19]

To avoid potential thermal issues and injuries associated with RF fields, all unnecessary or unused electrically conductive materials external to the patient should be removed from the MR system before the onset of imaging. It is insufficient to merely disconnect and leave unused, unnecessary electrically conductive devices, such as surface coils or EKG leads, in the MR scanner with the patient during imaging. All electrical connections, such as those used for surface coils or patient interfaces used for monitoring systems, must be visually checked by the scanning MR Technologist prior to each use to ensure the integrity of the thermal and/or electrical insulation.

Resonant heating

The length, orientation, shape, position, and inductance of any electrical conductor in MRI may be heated by transmitted RF radiation. Even if only part of a conductor is within range of the transmitted RF radiation, substantial unsafe heating can result. While heating concerns generally increase with stronger magnetic fields and longer conductors, specific conductor lengths and orientations, static magnetic field strength, and other settings can lead to resonant spikes in induced current.

Virtually any conductor lengths of more than a few centimeters can produce substantial heating under certain conditions.[20]

Internal. Very rapid and clinically significant internal lead heating can occur due to RF deposition. Especially at the uninsulated lead tips, this can occur in a matter of seconds with a magnitude sufficient to result in tissue thermal injury or burns. Residual or abandoned implanted leads or wires that are not connected to any other device are also prone to substantial heating under certain conditions.[21] For example, while it has been demonstrated in vitro that heating of certain implants or wires may be clinically insignificant at 1.5 T but quite significant at 3 T, the converse can also be true in some circumstances in which specific implants might demonstrate no significant heating at 3 T but may heat to clinically significant levels in seconds at 1.5 T.[21] Thus, it is important to follow established product MR Conditional labeling and safety guidelines carefully and precisely, applying them to the static magnetic field strengths at which they had been tested. MR scanning at either stronger and/or weaker magnetic field strengths than those tested may result in significant heating where none or insignificant heating had been observed at the tested field strength(s). For example, if MR Conditional labeling specifies 3 T, it cannot be assumed that similar scanning parameters at 1.5 T are safe.

It is possible to significantly limit RF deposition on implanted leads with use of transmit-receive coils located at distant anatomic sites relative to implanted devices. For example, a patient with an abandoned spinal cord stimulator lead located a sufficient distance from the head is likely able to safely undergo a head MRI using a transmit-receive head coil. Other transmit-receive coils, including wrist, knee, ankle, etc., may be used in similar situations to limit RF deposition on implanted devices and leads.[23]

External. When any portion of electrically conductive materials external to the patient are required to be within the volume of the transmitting RF coil during imaging, thermal insulation (including air, pads, etc.) should be placed between the patient and the electrically conductive material minimizing any contact with the patient. It is also appropriate to position the leads or wires as far as possible from the inner bore walls along the midline central long axis of the MR scanner if the body coil is being used for RF transmission.[24] When it is necessary that electrically conductive leads directly contact the patient during imaging, consideration should be given to prophylactic application of cold compresses or sealed ice packs to such contact areas. If using local transmit-receive coils (e.g., head, wrist, knee, etc.), the risk of heating of external leads can be significantly diminished.[23,25]

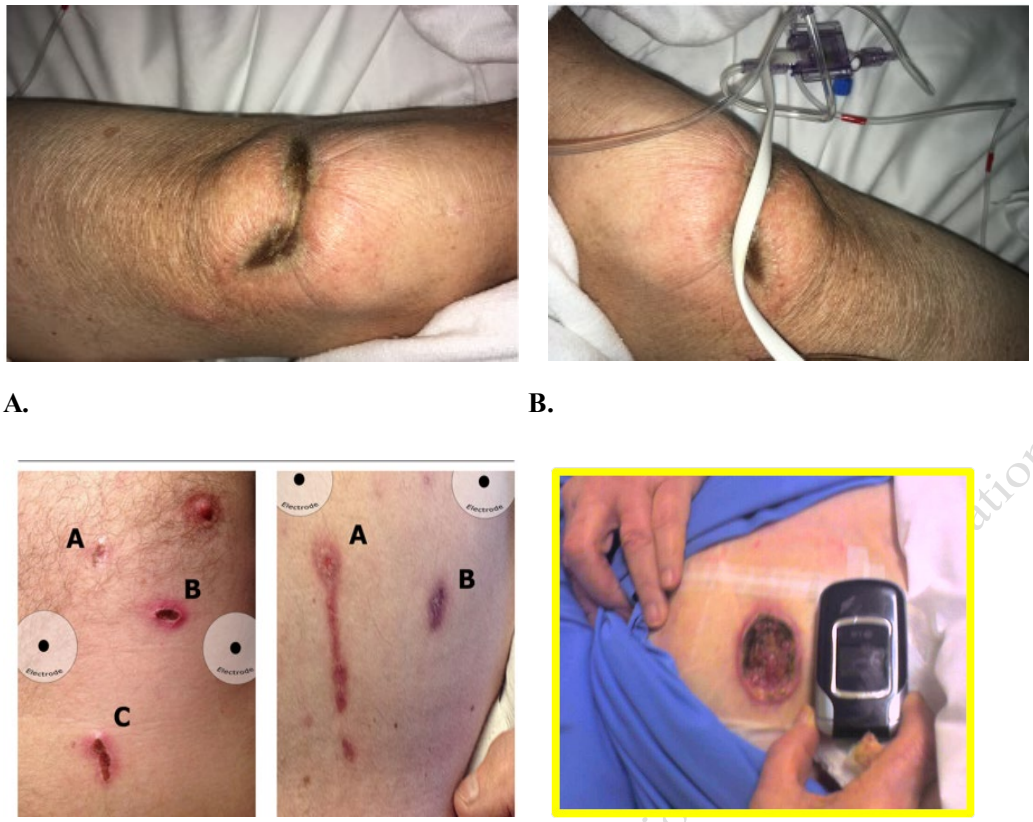


Figure 13. Examples of serious tissue burns resulting from RF-related heating in MR. A) Healing third degree burn at patient's knee. B) Reenactment of path of a transducer extension cable within the RF field that crossed an anesthestized patient's knee during an interventional MR procedure. Subsequent testing with the cable in that configuration demonstrated that T2-FSE sequences with SAR approximately 2W/kg produced local heating approaching 30 degrees Celsius. C) Skin burns caused by ECG lead heating in MR. The reader is referred to reference 23 for details. Figure used with permission. D) 3rd degree burn resulting from RF related conductive metal heating courtesy of Dr. Frank Shellock.

Special considerations for RF thermal issues

Electrically conductive clothing. Some materials used in clothing have been increasingly associated with thermal injury and/or burns in patients undergoing MRI. Recent trends in the manufacturing of clothing and other related products have incorporated metallic and conductive materials (e.g., antimicrobial silver and copper) that are not reliably disclosed in labeling.[26] Such clothing products include, but are not limited to, sportswear (including underwear), brassieres, orthotic-related items (e.g., stump covers or stump shrinkers), and blankets.[27] Reliance on clothing labeling is not sufficient, as the Federal Trade Commission guidelines allow clothing to contain impurities at levels as high as 5%, which could be significant for a patient undergoing an MRI examination.[28] For anatomic regions within or near the volume undergoing direct RF (B_1) field irradiation, to avoid such thermal concerns, we recommend gowning patients to skin, wearing only MR Safe pocketless garments supplied by the imaging facility.

Skin staples, multiple dermal implants or piercings in proximity to each other. Although, in general, thermal risks associated with individual small dermal implants (i.e., skin staples,

superficial metallic sutures, piercings that cannot be removed) are quite small, dermal implants that are in close proximity or directly contact one another may increase the risk of thermal injury. If the items are inside the MR bore and the built-in-body coil is being used for transmission, several precautions are recommended.

a. The patient should be instructed to report immediately if they experience warmth or burning sensations during the study by verbally alerting the technologist or using the technologist notification device (i.e., squeeze ball) and not wait until the end of the MR sequence.
b. Cold compresses or sealed ice packs may be helpful.

Alternatively, a transmit-receive coil may be used to avoid RF irradiation of the dermal implants in a different part of the body inside the bore (e.g., transmit-receive head coil for a brain MR in a patient with unremovable piercing in the abdomen).

Patients with tattoos within the RF transmit volume. Extensive, dark, or loop-shaped tattoos or tattooed eyeliner may increase the potential for RF heating. Patients should be instructed to immediately report any discomfort during scanning. If appropriate, placement of cold compresses or sealed ice packs could be considered. Parenthetically, although not an RF thermal concern, patients with tattoos that had been placed within 48 hours prior to the pending MR examination should be advised of the potential for smearing or smudging of the edges of the freshly placed tattoo.[29-33]

Drug-delivery patches and pads. Some drug-delivery patches contain metallic components. Scanning a patient with such medication patches may result in thermal injury or alteration in drug-delivery rate by heating, if the patch is within the MR bore during RF irradiation with the built-in body coil.[34] Options are to remove the patch, use a transmit-receive coil to scan a different anatomic region, or scan with means to minimize risk. Clinical implications of patch removal need to be assessed and reviewed by a Level 2 MR Physician.

In the case of clinically important drug delivery patches, removal or repositioning may be considered following consultation with the patient's prescribing physician. If the patch for a prescription medication is removed, an appropriate process must be in place to replace the medication (particularly for drugs that may cause undesired clinical symptoms or complications if not replaced in a timely manner).

An option to consider could include placing a cold compress or sealed ice pack directly on the patch recognizing this could substantially alter the rate of delivery or absorption of the medication and possibly be less comfortable for the patient.

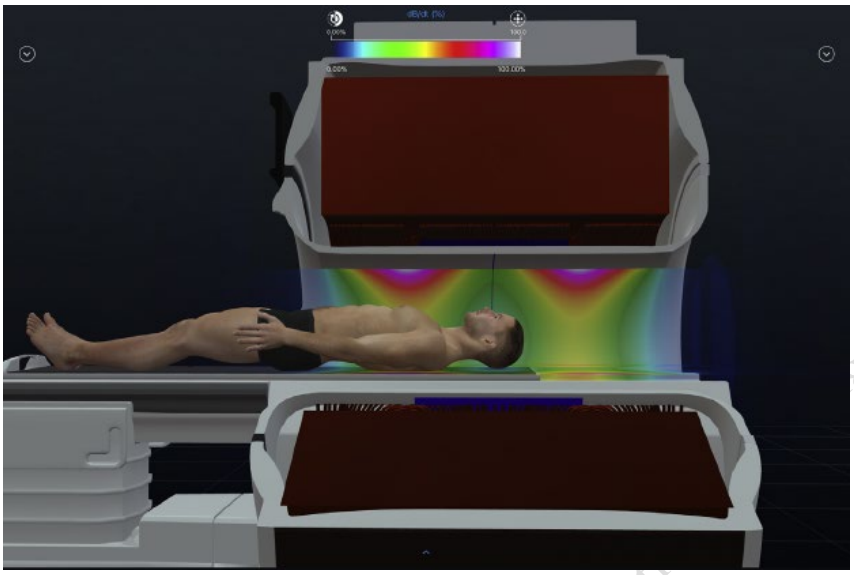
KEY POINTS

- Time-Varying Radiofrequency (RF) Magnetic Field
  - Remove all removable electrically conductive materials from the patient prior to imaging
  - Specific Absorption Ratio (SAR) estimates the rate of absorption of RF energy
    - SAR limits are designed to avoid direct RF-related tissue hearing and burns
    - RF burns are the most common adverse events in MR
    - Any conductor of more than a few centimeters can produce dangerous heating at specific lengths, orientation, and positions due to resonant heating
      - Follow established product MR Conditional labeling and safety guidelines carefully and precisely
      - Position any leads or wires as far as possible from the inner bore walls along the midline central long axis of the MR scanner if the body coil is being used for RF transmission
    - Currents can be induced within conductive materials
      - Avoid large caliber electrically conducting loops, including patient tissue
      - Avoid skin to skin contact especially small contact areas completing large caliber body loops
      - Insulation should be placed between the patient and any external conductive material including the bore wall
      - Local transmit-receive coils can reduce risk of heating
      - Metallic clothing can cause injury
        - Reliance on clothing labeling is not sufficient
        - MR Safe pocketless garments supplied by the facility are recommended
      - Dermal implants that are in close proximity or directly contact one another may increase the risk of thermal injury
        - Tattoos can heat
        - Consider cold compresses
      - Drug-delivery patches can contain metallic components which may result in thermal injury and/or alterations in drug-delivery rate
  - Specific energy dose (SED) refers to total energy absorbed
    - SED limits are means to protect a patient from adverse events related to core temperature elevation
    - Normal Operating Mode can reduce risk of whole-body heating but not necessarily burns
    - First level Controlled Operating Mode may increase risk and requires medical supervision (See discussion of Operating Modes in PNS)
    - Shorter sequence length and cooling-off periods between sequences can reduce risk

Time-Varying Magnetic Field Gradient (dB/dt)

Spatial localization of MR signal employs magnetic field gradients that are rapidly alternated and varied over time and are often described by their temporal rate of change, dB/dt.

A



B

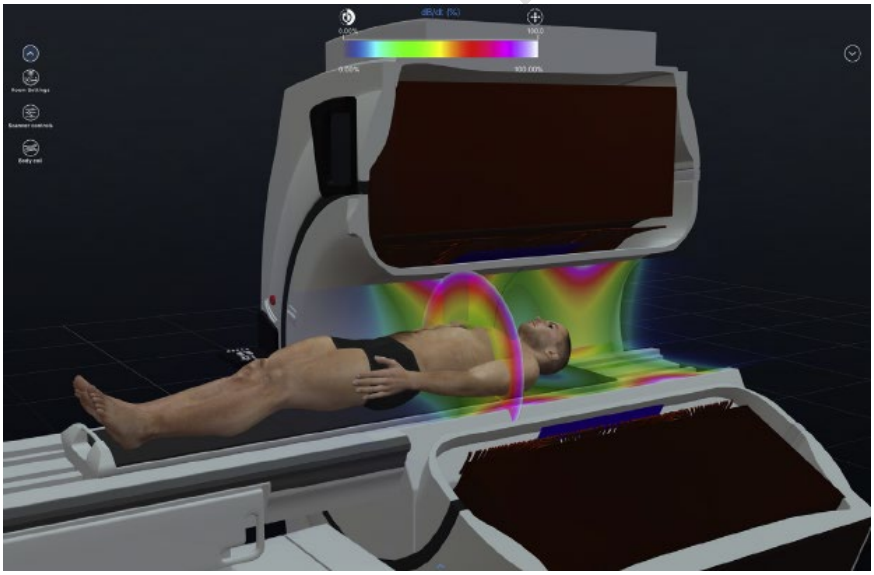


Figure 14. Three-dimensional depiction of the time-varying imaging gradient magnetic fields dB/dt in a 1.5 T MR scanner. The ride side of the scanner has been rendered transparent so that the energies/fields can be depicted as they are distributed three dimensionally throughout the MR scanner bore and room. (A) The strength and spatial distribution of the time-

varying imaging gradient magnetic fields dB/dt is depicted. Note that when centered on the brain the greatest dB/dt forces are over the chest of this patient, right where a cardiac pacemaker might be positioned. (B) The three-dimensional nature of the 3 orthogonally oriented gradient magnetic fields is depicted, which increase in strength as the radial and superoinferior distance from center increases and approaching the physical margins of the 3 gradient coils. (Courtesy of Dr. Kanal, created using MagnetVision, Advanced Magnetic Analytics, LLC.)

Auditory Considerations

Acoustic noise is generated by the switching of the gradient fields. It is recommended that all patients and volunteers use hearing protection prior to undergoing any imaging in any MR scanners. MRI sequences that are not FDA-approved should not be performed on patients or volunteers without hearing protection in place. The FDA considers MRI systems capable of producing sound pressures that exceed 99 A-weighted decibels (dB(A)) with hearing protection in place as a significant risk.[7] The International Electrotechnical Commission (IEC) standard on this issue (IEC 60601-2-33:2010)[14] also states that, for all equipment capable of producing more than an A-weighted root mean square (r.m.s.) sound pressure level of 99 dB(A), hearing protection should reduce the sound pressure level below that threshold for the safety of the patient.

It is important that staff are thoroughly trained on the proper placement of ear plugs and use of other types of hearing protection. Staff should work with all persons receiving the hearing protection to ensure proper placement and to verify fit and function of the hearing protection prior to the MR examination. Hearing must be adequately protected concurrent with being able to adequately hear patient instructions etc. In the event a patient refuses hearing protection, sites should have a process and procedure in place to discuss the risks of proceeding without the protection and may consider cancelling the exam.

All patients or volunteers in whom research sequences are to be performed (i.e., MR scan sequences that have not yet been approved by the FDA) should also have hearing protective devices in place prior to initiating any MR sequences. Without hearing protection in place, MRI sequences that are not FDA-approved should not be performed on patients or volunteers.

Peripheral Neural Stimulation (PNS)

Nerve and muscle cells can be stimulated by currents induced by the gradient magnetic field variation. The magnitude of the stimulation is a function of the pulse characteristics and repetition rate. Concerns related to this are addressed in the IEC standard 60601-2-33[14] which defines different scanning modes. Clinical scanners are usually restricted to the Normal and First-Level modes.

The IEC standard 60601-2-33[14] defines three modes for scanning:

1. Normal mode: Mode of operation of the MR equipment in which none of the outputs* has a value that may cause physiologic stress to patients.
2. First Level Controlled operating mode: Mode of operations of the MR equipment in which one or more outputs reach a value that may cause physiologic stress to patients which needs to be controlled by medical supervision.
    a. Software allowing access to this mode must require specific acknowledgement by the operator that the first-level control mode has been entered.

3. Second-Level Controlled operating Mode: Mode of operation of the MR equipment in which one or more outputs reach a value that may produce significant risk for patients in which explicit ethical approval is required (i.e., a Human Studies protocol approved to local requirements).

*Outputs refers to the magnitude of the magnetic fields

In Normal operating mode, the gradient system shall operate at a level that does not exceed 80% of the directly determined mean threshold for PNS, where the threshold for PNS is defined as the onset of sensation.

In First level controlled operating mode, the gradient system shall operate at a level that does not exceed 100% of the directly determined mean threshold for PNS.

Induced Voltages

Patients with implanted or retained wires and leads in anatomically or functionally sensitive areas (e.g., myocardium, implanted electrodes in the brain, adjacent to the spinal cord) should be considered at higher risk, especially from faster MRI sequences, such as echo planar imaging (i.e., often used with diffusion-weighted imaging, functional imaging, perfusion-weighted imaging, MR angiographic imaging, etc.) that require rapid variation of the gradient magnetic fields. These risks include whether the lead/wire is directly exposed to the time-varying gradient magnetic fields or may be part of an anticipated induced current pathway. The decision to alter the rate of magnetic field change (dB/dt) and maximum strength of the magnetic field of the gradient subsystems during imaging of such patients should be reviewed by the Level 2 MR Physician supervising the patient with attention to MR conditions of scanning.

Additionally gradient field effects can potentially be exerted on implanted devices causing vibration and possible damage to internal circuitry.

KEY POINTS

- Time-Varying Magnetic Field Gradient (dB/dt)
  - The rapidly switched magnetic field gradients used during imaging may result in uncomfortable or painful peripheral nerve stimulation (PNS). MR operators can reduce the probability of PNS by employing Normal Operating Mode for dB/dt versus First Level Controlled.
  - The rapid switching of this field can also result in peak acoustic noise in the MR suite requiring appropriately rated and positioned hearing protection to minimize discomfort and potential for auditory damage.
  - Additionally, devices and implants in this field may experience induced voltages, vibration, potentially permanent damage and, in some cases, additional heating. MR operators should be able to understand and apply recommended dB/dt limits for devices using information provided by the MR vendor.

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Return to Table of Contents

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CHAPTER 9: MR CONTRAST AGENTS

No patient is to be administered prescription MR contrast agents, typically gadolinium-based contrast media (GBCM), without orders from a licensed physician or advanced practice providers (APP) practicing under a supervising physician.[1] Research study participants may receive MR contrast agents as directed by the study protocol after they agree to enroll in the study that has undergone ethics committee (i.e., institutional review board) approval and sign the appropriate informed consent (and assent, as appropriate). Qualified MR Personnel may establish and attend to peripheral IV access lines if they have undergone the requisite site-specified training in peripheral IV access and have demonstrated and documented appropriate proficiency in this area. IV injection–qualified MR Personnel may administer FDA-approved MR GBCMs via peripheral IV routes as a bolus or slow or continuous injection as directed by the orders of a licensed site physician or APP.

Practices relating to administration of these agents and recommendations regarding GBCM usage, adverse reactions, nephrogenic systemic fibrosis, and retained or residual gadolinium in the body should follow the ACR Committee on Drugs and Contrast Media. The most recent version of the *ACR Manual on Contrast Media* may be downloaded from the ACR website at https://www.acr.org/Clinical-Resources/Contrast-Manual.

KEY POINTS

- No patient is to be administered prescription MR contrast agents without orders from a licensed physician or advanced practice provider
- Practices relating to administration of these agents and recommendations regarding GBCM usage, adverse reactions, nephrogenic systemic fibrosis, and retained or residual gadolinium in the body should follow the ACR Committee on Drugs and Contrast Media

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CHAPTER 10: CLASSIFICATION OF OBJECTS AND MEDICAL DEVICES IN THE MR ENVIRONMENT

This chapter will focus on the classification of materials/objects in the MR environment and ensuring safety. These fall into 2 major categories:

1. Objects, equipment, and other portable items that are peripheral to the patient, such as IV poles, anesthesia machines, injection pumps, etc. Introduction of these portable items into Zone IV is discussed in Chapter 11.
2. Medical devices directly related to the patient, including implanted devices, (e.g., cardiac pacemakers, aneurysm clips, etc.), as well as on-planted devices (insulin pumps, continuous glucose monitors, etc.). Several implanted devices are discussed in detail in Chapter 12.

Materials that are not required for the care of a patient should not enter Zone IV until the patient has been removed fully from the scanner room.

As part of the Zone III site restriction and equipment testing and clearing responsibilities, all sites should have ready access to a strong handheld magnet (>1000 G) and/or a FMDS. This will enable the site to test external, and even some superficial internal, devices or implants for the presence of grossly detectable ferromagnetic attractive forces. The use of conventional metal detectors that do not differentiate between ferrous and nonferromagnetic materials is not recommended.

MR Safety Labeling Classifications

Throughout this manual, the standard MR labeling terms (*MR Safe*, *MR Conditional*, and *MR Unsafe*) designated by the American Society for Testing Materials (ASTM) International, *ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the MR Environment*,[1] are used. These designations can apply to objects peripheral to the patient as well as implanted/on-planted devices.

Particularly with regard to nonclinical and incidental equipment, current products marketed with ill-defined terminology such as *nonmagnetic* or outdated classifications such as *MR compatible* should not be presumed to conform to a particular current ASTM International classification. Similarly, any product with metallic construction or components cannot by definition be MR Safe and must be considered as MR Unsafe or possibly MR Conditional. Objects intended for use in Zone IV, including nonclinical incidental products such as step stools or ladders, which are not accompanied by manufacturer or third-party MR safety test results under the ASTM International Standard F2503 criteria, should be site-tested as described below.

Figure 15. FDA labeling criteria developed by ASTM International[1] for objects and devices taken into Zone IV. The square green MR Safe label is for nonmetallic, nonconducting objects; the triangular yellow label is for objects with MR Conditional labeling; and the round red label is for MR Unsafe objects.

MR Safe. *A designation indicating that the object or device is safe in all MR environments, without conditions*. It is reserved for nonmetallic and nonconducting objects that pose no known hazards in any MR environment.

MR Conditional. *A designation indicating that the object or device may be safely used in the MR environment, provided the conditions for safe use are met.* Decisions based on published MR Conditional, or safety claims should recognize that all such claims apply to specifically tested static field and spatial gradient field strengths and only apply to the precise model, make, and identification of the tested object. For example, MR Conditional having been tested to be safe at 3 T at spatial gradient strengths of 400 G/cm or less and Normal Operating Mode.

Implant or device MR safety information must be documented in writing or in the medical record. Decisions based on published MR safety information should recognize that all safety claims regarding MR Conditional devices apply only to specifically tested conditions, such as the static magnetic field strength (B_0), the strength of the static magnetic field gradient (dB/dx), the strength and duration of the transmitted radiofrequency (RF) field (B_1), and the rate of change of the time-varying imaging gradients (dB/dt).

1714

1715 Examples of common MR safety conditions specified in the device vendor instructions for use
1716 (IFU):

Example Specified Conditions	Example Values for Generic Active Implanted Medical Device (AIMD) (Whole body transmit)
Device	
Allowed devices	Implantable pulse generator (IPG) & lead model(s)
Allowed configurations	Allowed IPG and lead model combination(s) for all conditions that follow
Implant configuration	IPG in upper buttock, low back, flank, abdomen, or midline
	Lead tip in the epidural space between the T7 and T12 vertebrae
Device status	Make sure IPG and patient controller fully charged
	No broken leads and lead impedance within specified parameters
Device mode	Set device to MRI Mode
MR System	
Configuration	Cylindrical-bore with horizontal-field
Field Strength(s)	1.5T or 3.0T
Maximum Spatial Field Gradient	25 mT/m (2,500 gauss/cm)
Maximum Gradient Slew Rate	200 T/m/s (per axis)
RF Transmit Equipment	
Frequency	Hydrogen (^{1}H) nuclei only
RF coil(s)	Integrated whole body transmit
RF transmit mode	Circularly polarized (CP) or Multichannel-2 (MC-2)
Scan Regions	Any landmark acceptable
RF Exposure	(For specific IPG and lead model combinations)
Anatomic scan region A	Isocenter superior to C7
RF output limits	For 1.5T MR Scanner: Normal Operating Mode (Whole-Body SAR $\leq$ 2 W/kg)
	For 3.0T MR Scanner: Normal Operating Mode (Whole-Body SAR $\leq$ 2 W/kg)
Anatomic scan region B	Isocenter inferior to C7
RF output limits	

Scan Duration	For 1.5T MR Scanner: Normal Operating Mode (Whole-Body SAR ≤ 2 W/kg) For 3.0T MR Scanner: $B_1^+{}_{rms} \leq 1.7$ mT or Whole-Body SAR ≤ 1.2 W/kg Active scan time ≤ 30 minutes per session with 30 minutes between sessions.
RF Receive Coil	Any
Image Artifacts	Signal loss expected up to 5 cm from IPG using a spin-echo acquisition. Some manipulation of scan parameters may be needed to compensate.
Patient	
Positioning/orientation	Supine or prone
Thermoregulatory Status	Patient should not have a fever. Do not cover patient with a blanket.
Cognitive status	Patient can notify MR personnel immediately if any discomfort, pain, heating, stimulation, or vibration is experienced
Monitoring	Visually and audibly monitor the patient, including verbal communication

Table 2. A summary table of common MR safety conditions specified in the device vendor instructions for use (IFU). Table is populated with example values for safely scanning a patient with a generic active implanted medical device that has leads (e.g., stimulator, pacemaker, defibrillator, etc.) which has conditions for full body imaging. This example is meant to highlight key conditions and not represent any specific device.[2]

MR Unsafe  . *A designation indicating that the object or device is known to present safety risks in the MR environment.* In the case of non-implanted devices, these are primarily ferromagnetic objects (e.g., stepstool with ferromagnetic components).

Object/device alteration. Alterations performed by the facility on MR Safe, MR Unsafe, and MR Conditional equipment or devices may change the MR safety properties of the device. For example, tying a ferromagnetic metallic twisting wire/binder onto a sign labeling the device as MR Conditional or MR Safe might result in image artifacts and/or safety issues if introduced into the MR scanner.

References

1. ASTM International. *ASTM F2503-20 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*. ASTM International; 2020. Accessed February 24, 2020. Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (astm.org)
2. FDA, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment Guidance for Industry and Food and Drug Administration Staff, May 2021.

CHAPTER 11: INTRODUCING PORTABLE METALLIC OBJECTS AND EQUIPMENT INTO THE MR ENVIRONMENT

Labeling and Testing

All sites should have ready access to a strong handheld magnet (>1000 G) and/or a ferromagnetic detection device for testing purposes.

All ***portable*** metallic or partially metallic objects intended to be stored/located in Zone III/IV are to be properly labeled as MR Unsafe  or MR Conditional  prior to permitting them into Zone III.

Never assume an MR Conditional or MR Safe status of an object unless it has been tested. The results of such testing, as well as the date, time, name of the tester, and methodology used for that particular object, should be documented in writing. If an object has not been tested or if its MR safety status is unknown, it should *not* be permitted unrestricted access into Zone III.

Zone III areas typically house electrically active stationary computers, printers etc. that are not intended to enter Zone IV. MR safety testing and labeling is not required for such stationary items.

Testing of objects that are not electrically activated (e.g., fire extinguishers, IV poles, oxygen tanks, step stools), is to be accomplished by MR Personnel exposing the object to a handheld magnet (>1000 G) or ferromagnetic detector. If grossly detectable ferromagnetic properties are observed, it is to be labeled with a circular red MR Unsafe label  . If none are observed, a triangular yellow MR Conditional label  is to be attached to the object. It is only when the composition of an object and its components are known to be nonmetallic and not electrically conductive that the green MR Safe label  is to be affixed to a device or object.

MR Unsafe Transport Equipment-Temporary Provisions

MR Unsafe transport equipment (e.g., wheelchairs, gurneys) may be brought into Zone III under specific **temporary** circumstances, if they are deemed by MR Personnel to be necessary and appropriate for patient care (e.g., minimize patient transfers in medically compromised patients, etc.) and conscientiously secured. This equipment should only be brought into Zone III if they are under the direct supervision of specifically designated MR Personnel who are thoroughly familiar with the equipment, its function, and the reason supporting its introduction to Zone III. These devices must be appropriately physically secured, tethered, and restricted at all times within Zone III to ensure that they never pose a risk of crossing the Zone IV threshold.

Figure 16. Tethering of an MR Unsafe gurney to a fixed anchor point in Zone III.

Figure 17. An example of a stop sign reminder that the tethered equipment cannot be taken into the magnet room.

Cellphones. Cellphones in Zone III represent a particular challenge because they can become projectiles if brought into Zone IV and are ubiquitous and commonly used for routine work in Zone III. Facilities should develop policies and procedures to ensure cellphones do not enter Zone IV (including potential use of pocketless scrubs, dedicated secured locations for their storage in Zone III, etc.).

Pocketless Attire. Items commonly found in personnel pockets (cellphones, scissors, etc.) present additional projectile risks. MR safe pocketless garments for all individuals entering Zone

IV can mitigate these risks and should be strongly considered. Pocketless attire is recommended for those MR Personnel that regularly work in Zone IV on a daily basis. Existing attire can be made functionally pocketless by oversewing the pockets. Due to potential issues at institutional laundries in accurately separating pocketless from pocketed attire, having them uniquely colored or conspicuously labeled / emblazoned would be anticipated to enhance efficiency at these facilities. Unique MRI Personnel attire would also be anticipated to aid rapid identification of MR Personnel from non MR Personnel.

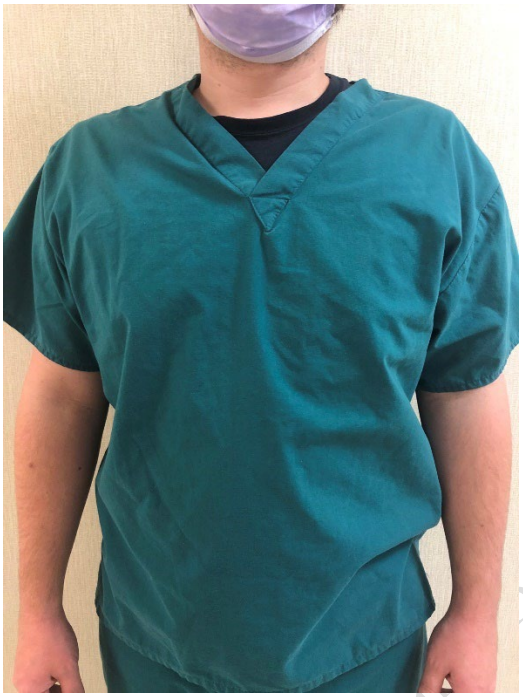


Figure 18. Example of pocketless scrub attire.

Portable Objects in Zone IV

In general, objects that are not required for the immediate care of a patient should not enter Zone IV if a patient is occupying the room. For example, introducing a MR Conditional ventilator in Zone IV should be done prior to a patient occupying the room. To the extent possible, it may be valuable for the patient to be last in and first out of Zone IV with respect to external objects.

All portable metallic objects that are to be brought into Zone IV must be properly labeled as MR Conditional or MR Unsafe. Items that are clearly ferromagnetic should be identified as MR Unsafe and labeled appropriately with the corresponding round red label. Proper precautions including tethering must be taken to prevent an MR Unsafe object from becoming a dangerous projectile (See MR Conditional External Non-Implanted Devices (Zone IV) in Appendix 2). It is advisable to position these objects in Zone IV when patients and staff are not occupying the room. If the patient is already in the MR scanner, if feasible, remove the patient

from the bore of the magnet prior to object transport. Objects with an MR Conditional status should be affixed with a triangular yellow MR Conditional label prior to being brought into the scan room/Zone IV (Figure 15) and the conditions clearly documented and communicated.

Figure 19.Tethering and placement of anesthesia equipment in Zone IV. Red arrow points to the tether. Black arrow represents the 200-gauss line.

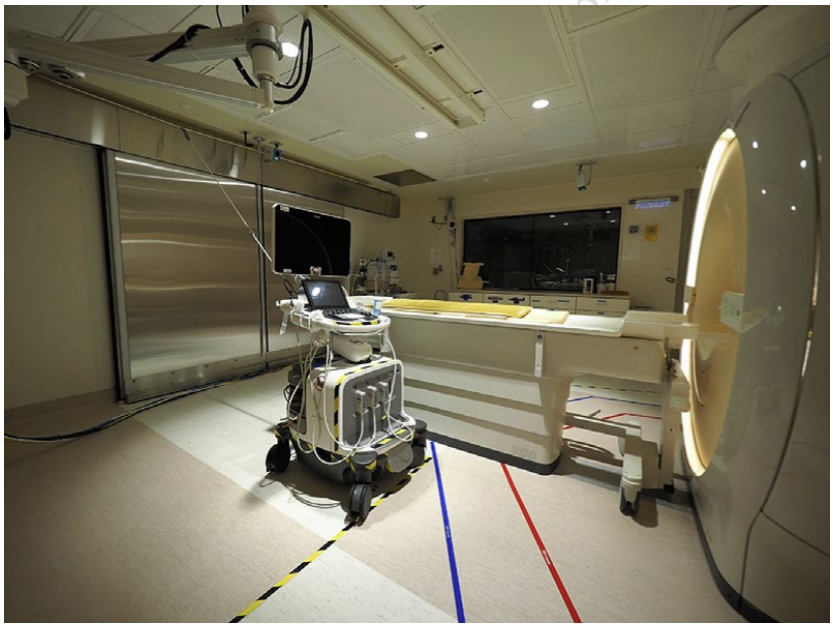


Figure 20. Tethering of MR unsafe ultrasound equipment in a hybrid procedural suite, preventing it from crossing the black and yellow striped line. This is beyond the blue line (100 Gauss) and red line (300 Gauss). The intention of the tether is not to directly prevent the unsafe equipment from becoming a projectile; it is to prevent it from attaining sufficient proximity such that becoming a projectile could be possible. Used with permission of Mayo Foundation for Medical Education and Research, all rights reserved.

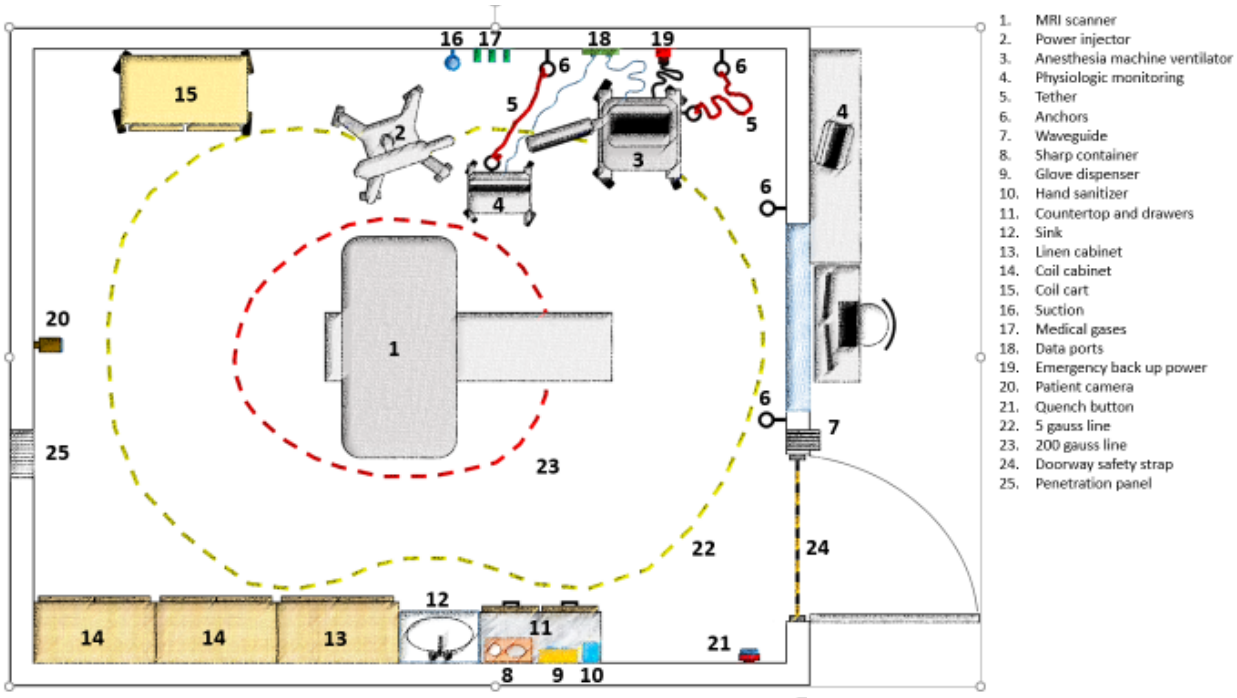


Figure 21. Typical configuration of an inpatient MR scanner. The design of Zone IV should consider the optimal workflow during more complex MR examinations, such as those requiring anesthesia. It is recommended that dedicated space is devoted to the anesthesia ventilator and physiologic patient monitoring equipment, typically away from the door. Similarly, anesthesiologists, respiratory technicians and other personnel supporting the patient must have dedicated space to perform their functions. A clear path between the scanner door and the patient ensures easy access to the patient by the MR Technologist and nursing, and a route for fast transportation of the patient out of Zone IV in the event of a medical emergency. In addition to the standard 5 gauss line marking on the floor, a 200-gauss line is recommended since this limit is often stipulated in labeling for MR Conditional equipment frequently used in Zone IV. Reliable tethering prevents this equipment from crossing the 200-gauss line.

MR scanning of hospitalized, higher-risk, or non-ambulatory patients presents additional challenges. In many instances, these patients are too sick to enter Zone IV by themselves and must be transported into the MR scanner using an MR Conditional wheelchair or stretcher. Similarly, metallic objects used for patient care (e.g., needles, small oxygen tanks, etc.) may be inadvertently transported after being used at other locations in the facility and hidden around the patient (e.g., within sheets or pillow covers). The full stop/final check is intended to mitigate these types of risk. (Refer to Chapter 6: Full stop/final check). When possible, transfer of these patients to the MR table should be done in Zone III (e.g., via a detachable MR table).

1836

KEY POINTS

- Processes/Procedures to decrease projectile risk from portable equipment/devices
  - Employ ferromagnetic detection equipment
  - Employ Zone IV doorway protection closed/strap/other barrier
  - Incorporate full stop/final check SOP
  - Tether MR Unsafe items in Zone III and Zone IV
  - Provide MR Safe pocketless attire to patients/research participants and MR Personnel
  - Employ proper ASTM MR safety labeling of equipment in Zone III and Zone IV
  - Employ proper and effective screening of all staff, subjects and patients including MR Personnel before crossing into Zone IV
  - Ensure all non-MR Personnel granted access to Zone III are closely monitored by and remain the consistent responsibility of Level 2 MR Personnel
  - Ensure Zone IV entry is appropriately secured when the area is unsupervised
  - Position external objects prior to patient entry to Zone IV; remove the patient from Zone IV prior to removing or manipulating objects when possible

1837

1838

CHAPTER 12: MANAGING PATIENTS/SUBJECTS WITH MEDICAL DEVICES IN THE MR ENVIRONMENT

Active Implanted/On-planted Devices

Active implanted medical devices (AIMDs) contain an energy source such as a battery or have the ability to be inductively coupled.[1,2] In contrast to implanted devices, on-planted devices are located external to a patient's body, at least in part.

An exhaustive discussion of the large number of AIMDs currently available is beyond the scope of this manual. This version of the manual will expand the scope of AIMDs discussed due to their frequency in the clinical environment and the important MR safety considerations related to them.

Infusion pumps. Implantable infusion pumps provide controlled delivery of medications primarily into the spinal subarachnoid space, with morphine and baclofen and their derivatives the most commonly infused agents, for control of pain and spasticity, respectively. If MR conditions for safe scanning are not followed carefully, there is potential for significant patient injury or death that can be related to drug overdosage or potentially from interrupted drug infusion. Safety issues related to implantable infusion pumps in MRI were the subject of a 2017 FDA alert.[3]

A number of deaths have occurred in MRI related to drug overdosing that are apparently attributable primarily to not adhering to MR conditions for safe scanning.[4] The drug reservoirs for some implantable infusion pumps must be entirely emptied of their contents prior to scanning as the drug can be subject to uncontrolled release while in MRI, with potentially catastrophic results. For other devices, the motors are expected to stall in MRI, temporarily interrupting drug infusion, but occasionally the pump motors may not restart as expected following removal of the patient from the MR environment. This can pose significant clinical problems associated with unanticipated opioid withdrawal or clinically more dangerous baclofen withdrawal syndrome, which is associated with approximately 20% mortality.[5] For this reason, these infusion pumps must be evaluated to ensure they are operating properly following scanning.

Insulin pumps. Due to increasingly widespread use, practices should be particularly vigilant for the presence of insulin pumps that can be implanted or worn externally (on-planted). At present, these devices are considered MR unsafe, with ferrous content in some on-planted systems creating the potential for attraction to the magnet. Importantly, if exposed to the MR environment, sensing and insulin delivery circuits may be damaged, such that there may be dangerous physiologically unsafe insulin delivery that could lead to significant hypo- or hyperglycemia.[6] For this reason, it is valuable to positively identify diabetic patients in the screening process in an effort to further ensure reliable detection of these devices and their removal before entering the MR environment.

Cardiac implantable electronic devices (CIEDs). CIEDs have expanded in number and complexity since their introduction in 1958 and now include cardiac pacemakers, implantable cardioverter defibrillator (ICDs), cardiac resynchronization therapy (CRT) devices, cardiac

contractility modulation (CCM) therapy device, implantable cardiovascular monitors (ICMs), and implantable loop recorders (ILRs). Cardiac pacemakers, which include implantable pulse generators (IPGs) and leads that are approved by the FDA and are labeled MR Conditional, became available in the United States in 2011. Since then, other commercially available CIEDs have been labeled MR Conditional, including ICDs, CRT devices, ILRs, and ICMs. Product instructions for use on wallet patient identification cards, manufacturer-maintained databases, lead and IPG identifiers visualized on plain radiographs, and operative notes may assist in the proper identification of MR Conditional CIEDs.

Guidance regarding performing MR examinations in patients with non–MR Conditional cardiac devices, including cardiac pacemakers, ICDs, CRT devices, ILRs, and ICMs, is deferred to current recommendations from the Heart Rhythm Society.[7] Key elements included in the document related to scanning of patients with non-conditional CIEDs include, but are not limited to:

- Institutional workflow/SOP with responsible MRMD and CIED MD and a Radiology/Cardiology team approach
- Medical necessity of the MR scan
- No fractured or abandoned leads
- ECG and pulse oximetry monitored during the exam
- Defibrillator/monitor with external pacing available (outside Zone IV)
- ACLS personnel in attendance during the exam until the CIED is reprogrammed following the exam
- CIED evaluation/programming immediately pre- and post-MRI

Epicardial pacing wires. Distinction of the type, MR safety labeling, and location / alteration associated with epicardial leads is important for MR safety decision-making considerations. In the majority of cases, epicardial leads are associated with 2 major scenarios:

1. **Temporary epicardial pacing leads / remnants.** After cardiac surgery, these typically small caliber leads are placed and are tunneled through the mediastinum to traverse the chest wall to permit attachment to an external pulse generator should it be necessary. While frequently these are completely extracted prior to patient discharge, not infrequently some remnant remains, often cut / snipped, and often extending to just below the skin surface. Previous publications have addressed scanning this patient group[8-9] noting another publication provided thoughtful consideration related to the conclusions.[10] In the typical clinical setting of a retained temporary epicardial lead fragment, the relatively short length together with lack of large conducting loops has not been shown to pose a barrier to scanning, with no adverse outcomes associated with this scenario reported to date. Post-surgical temporary epicardial leads that have been partially removed are not considered to be abandoned pacing leads in the Heart Rhythm Society document.[7]

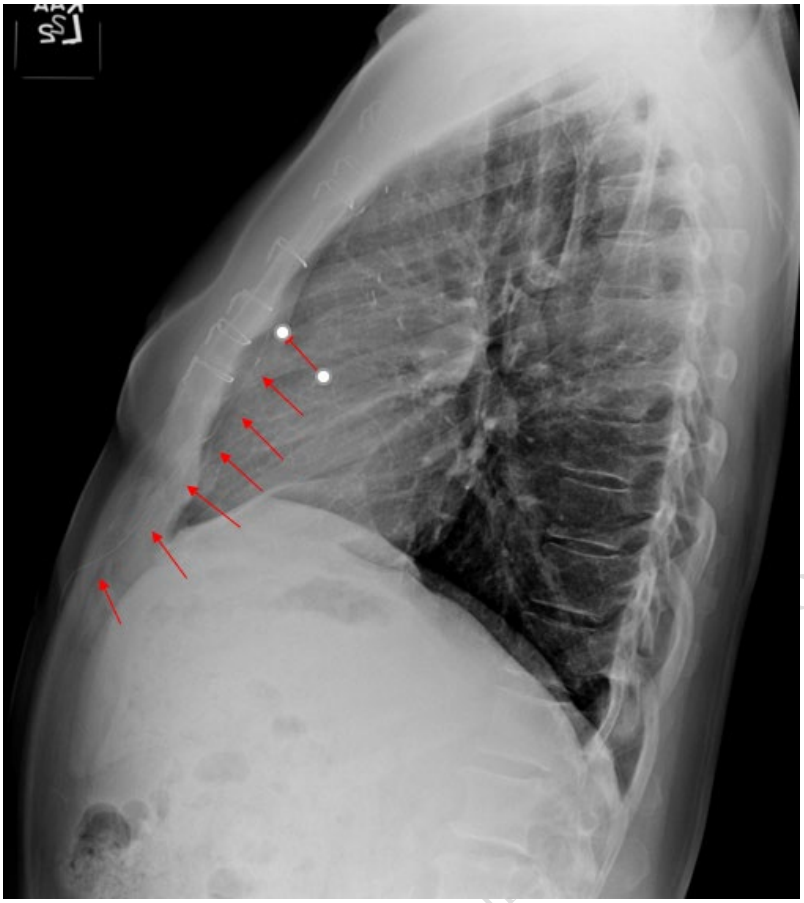


Figure 22. Lateral chest radiograph demonstrating a relatively short temporary epicardial pacing lead remnant. These have not been shown to be a barrier to scanning, without reported adverse events associated with these.

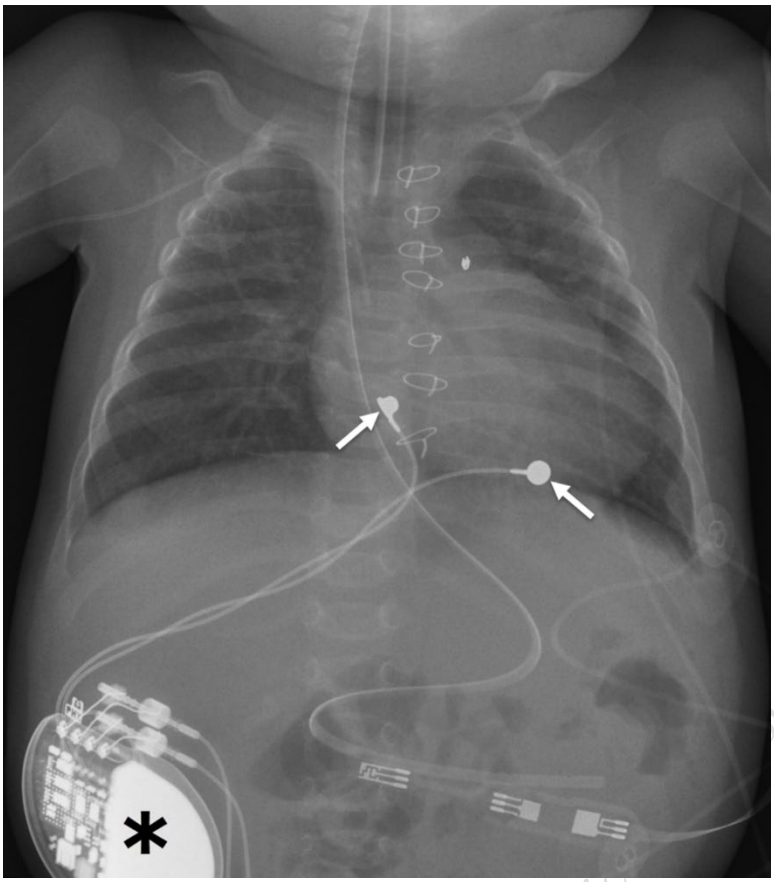


Figure 23. Typical appearance of permanent epicardial leads. Note that these are typically larger caliber than the finer temporary epicardial leads that are used commonly in cardiac bypass and related surgeries as shown in Figure 23.

2. **Permanently implanted epicardial leads / CIEDs**. These permanent epicardial leads/CIEDs are often implanted in the setting of patients, typically children or infants, with congenital heart defects in whom endovascular access would be difficult or impossible. Other applications are in those with infected endovascular CIEDs or endocarditis. They are typically of larger caliber than temporary epicardial pacing leads. As noted in the Heart Rhythm Society document, there are presently insufficient data to comment on the safety of MRI performance with permanent epicardial (as well as abandoned or fractured) leads.[7]

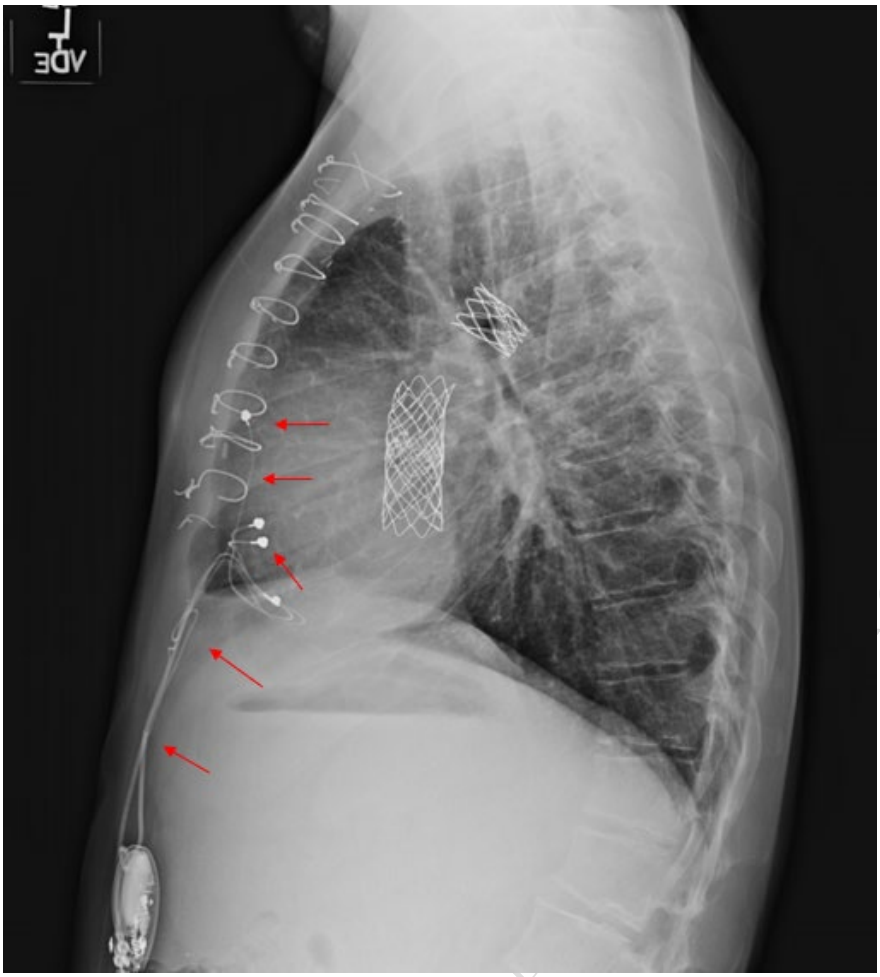


Figure 24. Lateral chest radiograph demonstrating relatively long permanently implanted epicardial leads (and attached to a pulse generator). There are presently insufficient data to comment on the safety of performing MRI with this class of leads.

Neurostimulators. An increasing number of neurostimulation AIMDs are now available, designed to stimulate central nervous system and peripheral nervous system targets for clinical benefit. These include deep brain stimulators, responsive neurostimulation systems, cochlear implants, spinal cord stimulators, vagus nerve stimulators, hypoglossal nerve stimulators, sacral nerve stimulators, and peripheral nerve stimulators.

As with all implanted devices, careful attention to accurate identification of the precise make and model is mandatory. Subtle differences in model numbers within a particular class of neurostimulation device can markedly change the MR safety scanning conditions, including from MR Conditional to MR Unsafe. Different model numbers within a particular type of neurostimulator class can be associated with ability to use body coil transmit, as opposed to being restricted to use of transmit/receive coils.

It is frequently necessary to have current imaging to accurately confirm location of pulse generators and lead systems, as well as to evaluate for possible broken or abandoned leads. Increasingly, patients can present with more than one neurostimulation system, requiring thoughtful considerations of the conditions for safe scanning, and frequently benefitting from a

coordinated evaluation by the MRSO, MRSE, and MRMD safety team. For MR conditional neurostimulation systems it is frequently valuable to contact the patient prior to their arrival to ensure that they bring the device programmer to allow the device to be programmed appropriately for scanning. Facilities should incorporate SOPs, often including eligibility forms / checklists, to ensure that all the necessary conditions for safe scanning are being met. Coordination with non-radiology subspecialty clinical teams can also be beneficial for post MRI reprogramming of certain devices (e.g., vagus nerve stimulators).

Passive Implanted Devices

Passive devices, unlike active devices, do not contain an intrinsic electrical power source. Metallic content in an implanted passive device, even if non-ferromagnetic, by definition makes these devices non-MR safe. Common passive implants and devices include aneurysm clips, intravascular stents, mechanical heart valves, orthopedic hardware, including screws and rods, intraocular lens implants and glaucoma shunts, programmable and non-programmable ventricular shunts, and auditory ossicular prostheses. The major risks in MRI of these devices relate to potential for electrical current induction, RF-associated heating, gradient-associated vibration or heating, magnetic field-associated translation and torque, and possible Lenz – related forces. Some devices, such as certain programmable ventricular shunts, may require confirmation of setting after exposure to the MR environment. A non-metallic non-conducting passive implant, such as hernia mesh, can be considered MR safe.

Intracranial aneurysm clips. If it is unclear whether a patient has an implanted intracranial aneurysm clip, if available, recent cranial radiographs or CT or MR examinations should be reviewed to assess for a possible intracranial aneurysm clip. If unavailable, radiographs or CT should be obtained.

In the event that a patient is identified to have an intracranial aneurysm clip, the MR examination should not be performed until the specific manufacturer, model, and type of aneurysm clip within that patient is identified. Next, MR Unsafe or MR Conditional status is determined. All documentation of types of implanted clips, dates, etc., must be in writing and signed by/attributable to a licensed physician. Electronic copies of operative reports, physician statements, etc., are acceptable as long as a legible physician signature or other electronic attestation accompanies the requisite documentation. A written history of the clip describing appropriate ferromagnetic testing methods (ASTM International F2503) used to characterize the clip prior to implantation by the operating surgeon is also considered acceptable.

All intracranial aneurysm clips manufactured in 1995 or later for which the manufacturer's product labeling continues to claim MR Conditional status may be accepted for MR scanning under the specified conditions without further testing. Implantation date, absent product manufacturing date information, is not sufficient to make a determination of acceptability for MR scanning without further testing.

Clips manufactured prior to 1995 require either pretesting (as per the ASTM International F2503 Standard Practice guidelines)[11] prior to implantation or individual review of previous MRI of the clip or brain in that particular case, if available. By assessing the size of the artifact associated with the clip relative to the static field strength on which it was studied, the MRI pulse sequence

type, and the MRI parameters selected, an opinion may be issued by one of the facility's Level 2 MR Physicians as to whether or not the clip demonstrates significant ferromagnetic properties. Access to the MR scanner would then be based on that opinion.

A patient with a previously unrecognized MR Unsafe aneurysm clip (or another implant) may have undergone a prior MR examination without a known adverse event. This fact is insufficient evidence of the safety of the implant and should not be relied on solely to determine the MR safety status of that aneurysm clip (or other implant) for future MR examinations.

For these previously scanned patients with unknown or unsafe aneurysm clips, it is important to note that variations in static magnetic field strength, static magnetic field gradient, orientation of the aneurysm clip (or other implant) relative to the static magnetic field or its static magnetic field gradient, and rate of motion through that static magnetic field gradient, as well as other factors, are presumably unknown variables that are impossible to control or reproduce. These variables may not have resulted in an adverse event in one circumstance but could potentially result in significant injury or death on a subsequent MR exposure.

Barring the availability of either pretesting or prior MRI-related data for the aneurysm clip in question, the supervising physician in each case must perform a risk-benefit assessment and review. Furthermore, for patients with intracranial aneurysm clips with no available ferromagnetic or imaging data, should the risk-benefit ratio favor the performance of the MR examination, the patient or guardian should provide written informed consent that includes death as a potential risk of the MR procedure prior to permitting that patient to undergo an MR examination. Because research scans in general do not offer benefit for the research participant, scanning patients without written information about the specific device is strongly discouraged.

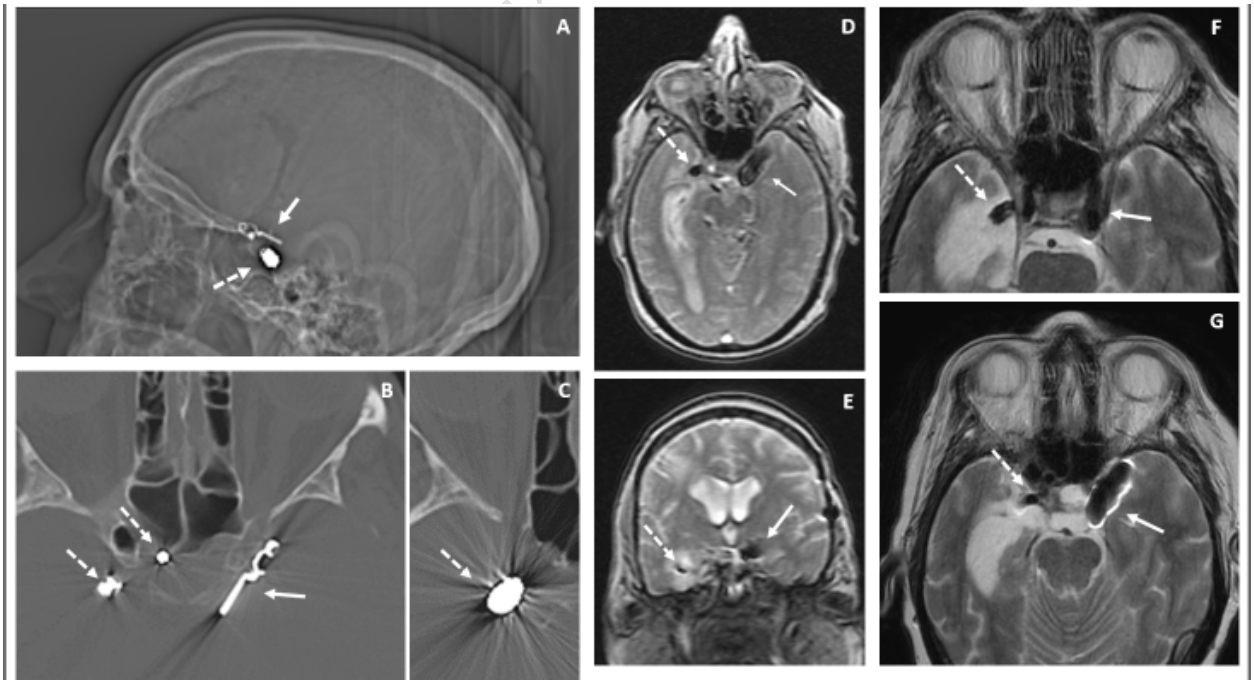
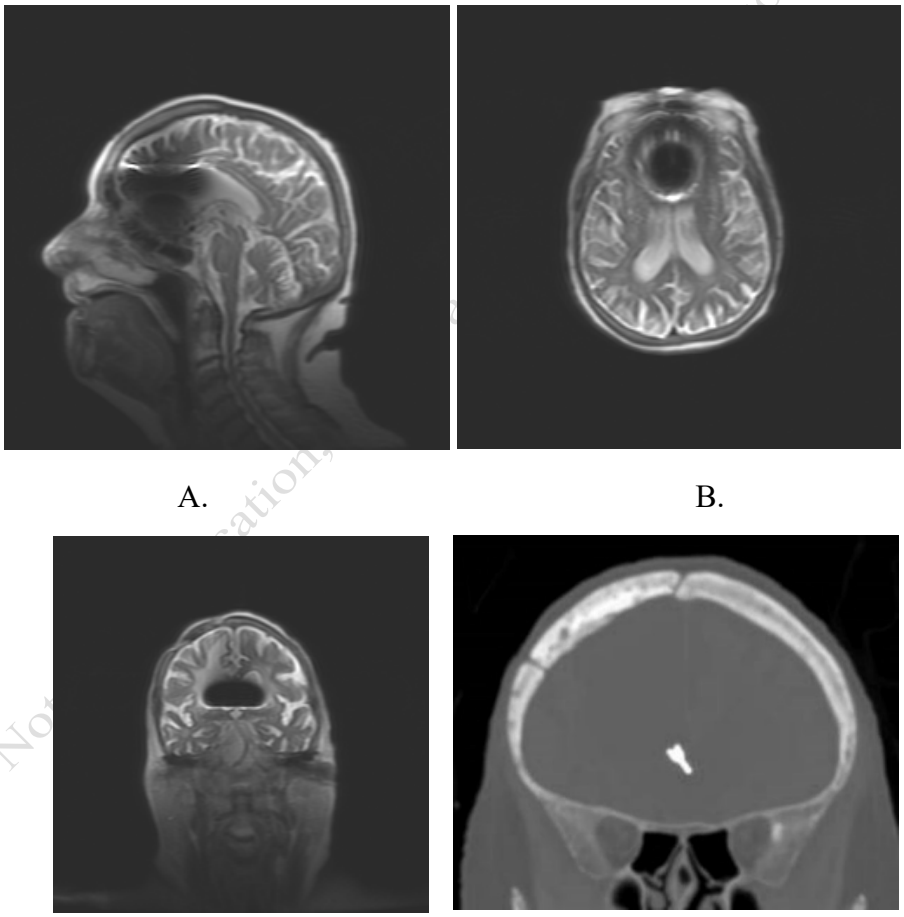


Figure 25. CT and 1.5T MRI appearance of MR conditional aneurysm clip and aneurysm coils. (A) CT topogram appearance of MR conditional aneurysm clip (arrow) and aneurysm embolization coil mass (dashed arrow). (B and C) CT

appearance of aneurysm clip and embolization coil mass. (D and E) 1.5T T2* GRE axial and coronal localizer images. Note the limited susceptibility artifact associated with the non-ferromagnetic aneurysm clip and embolization coil mass and compare this with the pronounced artifact associated with the MR unsafe ferromagnetic clip seen in Fig 26. (F and G) Relatively limited susceptibility artifact on T2 FSE images associated with the MR conditional non-ferromagnetic aneurysm clip and embolization coil mass.

Implant, Device, or Object Discovered During MR Examination

It is possible that during an MR examination, an unanticipated ferromagnetic implant or foreign body is discovered within a patient or research participant. This is typically suspected or detected on localizer images by sizable image distortion and/or signal-loss artifact that grows with increasing echo time and is more prominent on gradient-echo relative to spin-echo imaging sequences. In such cases, it is imperative that further image acquisition is put on hold and that the Level 2 MR Physician (and/or MRMD or MRSO when appropriate) responsible for the patient be immediately notified of the suspected ferromagnetic object. This individual should then assess the situation, review the imaging, and decide the best course of action.



A. B. C. D.

Figure 26. Examples of pronounced susceptibility artifact on 1.5T localizer images associated with ferromagnetic intracranial aneurysm clip (A, B, C). The ferromagnetic clip is seen on the CT images (D). In this case, the patient was removed safely from the scanner using slow table speed, the table detached and wheeled out of the room slowly without the patient sitting up.

It should be noted that there are numerous potentially acceptable courses that might be recommended that are dependent on many factors, including the status of the patient, the location of the suspected ferromagnetic implant/foreign body relative to local anatomic structures, the mass of the implant, MR B_0 field strength and other factors. Appropriate courses of action might include proceeding with the scan underway, immobilizing and slowly removing the patient from the scanner, or other intermediate steps. Regardless of the course of action selected, it is important to note that the forces on the implant will change, and may actually increase, during the attempt to remove the patient from the scanner bore. Further, the greater the rate of motion of the patient/device through the magnetic field near the scanner bore (spatial gradient magnetic field), the greater the forces acting on that device will likely be. In general, slow table speed and slow patient movement should be beneficial. Efforts to immobilize an unrecognized on-planted device can be helpful.

Figure 26 illustrates discovery and subsequent safe removal of a patient after identification of an aneurysm clip on the anatomical localizer. Reinforcing this critical need to carefully review patient localizer images to assess for the presence of ferromagnetic objects, a case reported in the literature documented a patient that went blind from interactions between an undetected metallic foreign body in his retina and the static magnetic field of the MR system after both entering the scanner and undergoing the entire MR examination without reported incident. This patient only went blind on exiting the MR system at the completion of the examination.[12]

The detection of unexpected focus of susceptibility artifact in MRI exams of the torso can be particularly challenging because of the multitude of devices that are implanted during surgical and interventional procedures (e.g., staples, hemoclips, coils, etc.). The Level 2 MRI personnel should be aware that some commonly used devices, such as certain clips used in endoscopic procedures, are indeed MR Unsafe.[13] Furthermore, ingested iron supplements within the bowel can cause substantial susceptibility artifact mimicking metallic clips on MRI.[14] Also, due to their ferrous content, some endoscopy clips impart susceptibility artifact that could adversely affect the diagnostic quality of the images.

When an unexpected artifact is encountered in the bore, the Level 2 supervising physician should be contacted before proceeding with the rest of the MRI examination. The magnetic fields associated with the MR scanner are three-dimensional. Thus, especially for superconducting systems, one should avoid the temptation to have the patient sit up as soon as they are physically out of the bore. Doing so may expose the ferrous object to significant torque- and translation-related forces despite its being physically outside the scanner bore.

> *It is therefore advisable to continue to extract the patient along a straight-line course parallel to the center of the magnet while the patient remains immobilized until they are as far as physically possible from the MR scanner in Zone IV and continuing directly into Zone III if possible before having the patient sit up.*

If the table is dockable, detach the table and move the patient into Zone III before allowing the patient to sit up. If the table is fixed, it is recommended to slowly horizontally transfer the patient to an MR Conditional stretcher in Zone IV and then moving the patient into Zone III.

Should an implanted device that may be altered by the magnetic field (e.g., programmable shunt, infusion pump, tissue expander, glucose monitor, etc.) inadvertently be discovered within Zone IV, the physician responsible for the maintenance of the device(s) should be contacted prior to

the patient's discharge from the MRI suite. Significant injuries have resulted from such partial exposures, and adequate functionality should be verified and never assumed for critical devices such as insulin pumps.

KEY POINTS

- Classifications
  - MR Safe- object or device is safe in all MR environments (must be nonmetallic and nonconducting)
  - MR Conditional- object or device may be safe in the MR environment if conditions for safe use are met
  - MR Unsafe- object or device presents safety risks in the MR environment
- External (non-implanted) devices, objects, and equipment
  - Portable metallic devices should be properly labeled prior to entry to Zone III
  - MR Unsafe equipment necessary for patient care in Zone III must be responsibly managed by physically securing/tethering or other means
  - Pocketless scrubs attire should be strongly considered for personnel entering Zone IV to decrease projectile risks
- Active implanted/on-planted devices
  - Active medical devices contain an energy source or can be inductively coupled
  - Careful attention to MR conditions for safe scanning of specific devices is essential
    - Legacy "non-conditional" CIED systems can be scanned provided a program is employed in accordance with the recommendations of the Heart Rhythm Society
  - Identify patients with CIED, neurostimulators, insulin pumps, and infusion devices early in the screening process to confirm whether and how the patient can be safely scanned
- Passive implanted devices
  - Passive implanted devices do not contain an intrinsic electrical power source
  - Metal containing passive devices cannot be MR Safe, only MR Conditional or MR Unsafe
  - Lack of a known adverse event in a patient scanned with an implanted device of unknown safety labelling does not ensure its safety in any way with future MR exams
- Implant, device, or object discovered during MR examination
  - Extensive susceptibility artifact can be an indicator of potentially unsafe ferrous content in an implant
  - Sites should have SOPs in place on processes/procedures to remove a patient from the magnet if potentially unsafe metal is identified
    - Slow table speed and keeping the patient recumbent until well away from the bore are important elements

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CHAPTER 13: PHYSIOLOGIC MONITORING DURING MR STUDIES

Visual and audio monitoring are basic required monitoring processes. Additional physiological monitoring for patients during MR examinations is often necessary. Monitoring techniques should be carefully selected primarily because of the risk of thermal injury associated with monitoring equipment in the MR environment. While not all RF-induced thermal injuries can be detected as they are developing, sedated, anesthetized, or unconscious patients are especially vulnerable to such injuries as they are unable to provide the operator with adequate warning of developing thermal injuries. This potential for injury is greater on higher-field-strength MR scanners (e.g., 1 T and above) but exists, at least theoretically, at all MRI field strengths. When needed, MR Conditional electrocardiogram (ECG) and electroencephalogram (EEG) electrodes should be used, and leads should be positioned per the manufacturers' direction during the scan.[1]

Distortion of the ECG within the magnetic field, particularly during sequence acquisition, can make interpretation of the ECG unreliable, even with filtering used by contemporary monitoring systems. For example, T-wave elevation is frequently noted.[2] ECG recordings in MRI are unreliable and may demonstrate ST segment elevation or depression due to the magnetohydrodynamic (MHD) effect. This may simulate or mask cardiac infarction (discussed in Lenz effects).

Routine monitoring of the patient's heart rate and rhythm may also be accomplished using pulse oximetry. Use of an MR Conditional pulse oximeter can address the risks of thermal injury if MR conditions are followed and/or the device and its leads are entirely positioned outside of the bore.

Additional physiological monitoring devices exist, including indwelling temperature probes and intracranial pressure monitors, and their conditions for safe scanning should be followed carefully in accordance with MRI labeling.

KEY POINTS

- Monitoring techniques should be selected and carefully implemented following manufacturer's MR Conditional instructions because of the risk of thermal injury.

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CHAPTER 14: EMERGENCY SITUATIONS

This section will discuss several MR safety switches that can be used in the case of an emergency as well as emergency response related issues such as fires, codes, and entrapment by ferromagnetic objects. For the safety of firefighters, code or rapid-response teams, and other emergent services responding to an emergent call at the MR facility, it is recommended that all fire alarms, cardiac arrests, or other emergent service response calls originating from or located in the MR facility should be forwarded simultaneously to a specifically designated individual from among the facility's MR Personnel. This individual should, if possible, be on site prior to the arrival of the firefighters or emergency responders to ensure that they do not have free access to Zones III or IV. The facility might consider assigning appropriately trained security personnel, who have been trained and designated as MR Personnel, to respond to such calls. For fire/police responses, clear lines of authority for screening, access restrictions, and quench are essential.

Given differences in design of MR facilities and between vendors, it is strongly advised that all MR facilities perform regular training and drills to reinforce knowledge of where key safety interlocks reside and their use as well as to rehearse and refine emergency response protocols to protect patients, MR staff, and responders.

Emergency Stop and Emergency Power Off

Two safety switches that do not ramp down the magnetic field are the Emergency Stop and the Emergency Power Off buttons. Vendors may give different names to these switches, but the operator/MR Personnel needs to be aware of where they are, when to use them, and how to recover the system after using.

The Emergency Stop button is generally designed to immediately stop MR scanning and table motion. Emergency Stop buttons (Figure 27) are usually found on or near the MRI console and on the MR bore or table itself. The Emergency Stop button should generally be used when something is caught on the table and further table motion may result in damage or injury.

The Emergency Power Off button is generally used to cut electrical power to the entire suite and computer room, including an uninterrupted power supply (UPS) if present. Use of the Emergency Power Off may require access to the main breaker to reset and require an electrician, and so should be used with caution in emergent situations only. These switches are generally present in the MR control room or on the wall inside Zone IV. In some cases, they may be covered with a plastic guard to avoid accidental activation, (i.e., if situated next to an RF door interlock). Emergency Power Off may be used in cases of fire, flooding or voltage accidents. Example scenarios for deploying an Emergency Power Off could include detecting smoke or having an uncontrolled water pipe burst in the MR environment.

In the case of Emergency Stop or Power Off, if a patient needs to be quickly removed from the scanner, the operator must be familiar with the manual process for moving the cradle and/or undocking the table. Fast and safe patient removal from the room is often a key component in any emergency response scenario.

(a)  (b) 

(c)  (d) 

Figure 27. (a) Universal symbol used for emergency table stop safety switch. (b) Example of an emergency power off safety switch. (c-d) Examples of Quench (emergency field run-down) units (Source: GE and Siemens Operator Manuals)

Quench

A primary safety interlock in the MRI suite is a button and/or process for quickly shutting down the magnetic field (i.e., 'quench'). These emergency field run-down units are usually activated by a button or lever in the MR operator room and/or Zone IV. The buttons are usually protected by a plastic cover to avoid inadvertently activating a quench. Because of the risks involved with quenching the magnet, the decision to quench a magnet should be deliberate.

If a situation arises in which emergency responders must enter a superconducting magnet Zone IV without screening or elimination of ferromagnetic items, quenching must seriously be considered. For superconducting systems, it is imperative that all personnel and patients be evacuated from Zone IV as quickly and safely as feasible and that the site access be immediately restricted for all individuals until the arrival of MR equipment service or other qualified personnel.

A Level 2 MR Personnel should monitor the quench to determine when it is safe for non-medical emergency responders to enter Zone IV. It may take more than a minute for the magnetic field to dissipate sufficiently for responders to safely enter Zone IV with ferromagnetic equipment.[1]

Quenching a magnet can introduce new hazards. This is especially true in the event of a venting failure in which cryogenic gases are vented partially or completely into the scan room, as evidenced in part by the sudden appearance of white "clouds" or "fog" around or above the MR scanner. Such circumstance could introduce the risk of cold related injuries (i.e., frostbite or hypothermia) and asphyxiation due to oxygen displacement from helium which is less dense than air.

In the case of a quench venting failure, it is important for Level 2 Personnel to remain calm and follow the established SOPs for their area including:

- If a patient is currently in the scanner and ambulatory, advise patient to leave Zone IV as soon as possible, walking as low as possible to maintain their head below the potential accumulation of cryogen gas to minimize the risk of asphyxia.
- Immediately turn on the exhaust fan in the MRI suites to help eliminate the cryogen gas from the room.
- Open the scan room door to ventilate Zone IV.
- Consider opening the door to other zones to help ventilate Zone III.
- Enter Zone IV to rescue the patient or personnel while staying as low to the ground as possible. If a gurney or wheelchair are needed, assume the magnet is still at field and use MR Conditional equipment if possible.
- When rescue is complete, close the door to Zone IV to stop helium flow into Zone III. Evacuate the area to allow helium gas to dissipate. MR vendor personnel will indicate when it is safe to re-enter the site.

There are newer systems in which an externally vented quench pipe is unnecessary due to low cryogen volume. While quenching does not lead to release of high volumes of cryogen in the room with such systems, the magnetic field in the room remains a risk until it can be verified it is completely dissipated.

For resistive systems (without cryogenic gases), the magnetic field of the MR scanner should be shut down as completely as possible and verified prior to permitting the emergency response personnel access to Zone IV. For permanent, resistive, or hybrid systems whose magnetic fields cannot be completely shut down, MR Personnel should ideally be available to warn the emergency response personnel that a very powerful magnetic field is still present in Zone IV and secure dangerous ferromagnetic objects as possible.

Fire

All MR facilities should arrange to prospectively educate their local fire marshals, firefighters' associations, and police and security personnel about the potential hazards of responding to emergencies in the MR suite.

It should be assumed that in the event of a fire (or other emergency) in Zone IV, the magnetic fields are present, fully operational, and potentially dangerous. Therefore, free access to Zone III or IV by firefighters or other Non-MR Personnel with air tanks, axes, crowbars, other firefighting equipment, etc., might prove catastrophic or even lethal to those responding or to others in the vicinity.

As part of the Zone III and IV restrictions, all MR facilities must have clearly marked, readily accessible MR Conditional or MR Safe fire extinguishing equipment physically stored within Zones III or IV. All conventional fire extinguishers and other firefighting equipment not tested and verified as safe in the MR environment should be restricted from Zone III and IV.

R.A.C.E. can be a useful mnemonic for MR staff response to fire:

- **R**escue persons in danger IF SAFE TO DO SO.
- **A**ctivate the nearest **A**larm, and call, when possible, to provide specific information.

- **C**ontain the fire by closing ALL doors of the room/area, including fire doors. An MR conditional fire extinguisher may be used to control the fire IF SAFE TO DO SO.
- **E**vacuate if instructed to do so by the fire department.

When a fire is in the magnet room (Zone IV) and cannot be contained by the in-room sprinkler system or by the safe use of an MR Conditional fire extinguisher, and the fire department will require access to the room, the magnet should be quenched to avoid potential serious injury to the fire department staff or damage to MRI equipment. Quench should be performed prior to power shut down (when necessary). (See Quench).

When a fire is in Zone II or III, restricting access to Zone IV by closing and locking the access doors is recommended to prevent entry of fire personnel or hazardous material.

Code

In case of cardiac or respiratory arrest or other medical emergencies within Zone IV for which emergent medical intervention or resuscitation are required, the patient or research participant must be removed immediately from Zone IV to a predetermined, magnetically safe location and appropriately trained and certified MR Personnel should immediately initiate basic life support or cardiopulmonary resuscitation as required by the situation. Facilities must have immediate access to an MR Conditional gurney to transfer the patient to in those situations where the MR table cannot be undocked. If transferring the unstable patient outside the Zone IV is delayed for more than a few seconds (i.e., for whatever reason), the emergency response team should prioritize patient safety and initiate cardiorespiratory resuscitation maneuvers, as needed, while still in Zone IV. However, MR Unsafe items such as AEDs should not be brought into Zone IV. Quenching is not routinely recommended. All priorities should be focused on initiating as necessary basic life support with cardiac compressions and manual ventilation and evacuating the patient as rapidly and safely as possible. Once the resuscitation is moved to Zone III, it is recommended that the Zone IV door be closed and secured to avoid inadvertent potentially dangerous entry by those responding to the code.

Entrapment

In the event of patient or personnel entrapment against the bore by a sizable ferromagnetic object causing injury or potential death, without possibility of timely extraction, quenching the magnet is recommended.

KEY POINTS

- Emergency Stop and Emergency Power Off
  - Emergency Stop button is generally designed to immediately stop MR scanning and table motion.
    - Generally used when something is caught on the table and further table motion may result in damage or injury
  - The Emergency Power Off button is generally used to cut electrical power to the entire suite and computer room, including an uninterrupted power supply (UPS) if present
    - Generally used in cases of fire, flooding or voltage accidents
- Quench
  - Quickly shutting down the magnetic field
    - Generally used if the magnetic field causes a ferromagnetic object to be an immediate risk (such as entrapment) to a person in Zone IV
  - May introduce new cryogen hazards
- Fire
  - Important to prospectively educate emergency responders
  - Assume magnets are present, fully operational, and dangerous
  - Follow RACE response practices
- Code
  - Begin BLS/CPR as required by the situation while the patient is moved from Zone IV to a predetermined magnetically safe location
- Entrapment
  - In the event of injury or potential death, recommend quench if timely extraction is not possible
- Additional information can be found in Appendix 2: MR Facility Maintenance and Emergency Preparedness Guidelines

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CHAPTER 15: SPECIAL PATIENT AND PERSONNEL CONSIDERATIONS

Pregnancy

Health care practitioner pregnancies. Pregnant health care practitioners are permitted to work in and around the MR environment, including Zone III and IV throughout all stages of their pregnancy.[1] There are no restriction of activities in Zone III. Physical presence in Zone IV is permissible for all activities when there is not active scanning occurring. Although there is no current evidence that exposure to the MR environment during scanning causes harm to the fetus, it seems prudent that pregnant staff, both MR Personnel and non-MR Personnel, should not be in Zone IV during scanning due to currently unknown side effects of interactions with the RF field and acoustic noise.[2] For example, the effects of noise to the fetus is unknown.[3] There is a paucity of data available to date regarding human pregnancy exposures to 7 T and higher magnetic fields.

Patient pregnancies. The vast majority of data today has failed to show that exposure to MR has deleterious effects on the developing fetus.[4-6] Nevertheless, there are indications that the embryo is potentially more sensitive to thermal events in the first trimester. To this end, if pregnancy is established, the decision to proceed with a non-contrast MR study in Normal Operating Mode for Whole-Body SAR (≤ 2 W/kg) should be based on the medical benefits weighed against unknown potential risk.

The preponderance of research studies has failed to demonstrate any reproducible harmful effects of exposure of the mother or developing fetus to the 3 T or weaker magnetic fields used in the routine clinical MR practice.[7] Theoretical concerns include time-varying gradient and RF magnetic fields, potential acoustically related safety issues, and heat deposition in tissue, respectively. There is not much peer-reviewed literature regarding the acoustic safety of fetal scanning, but the majority of published material on this topic has failed to find deleterious effects on newborn hearing if exposed to MRI in utero.[8-12] The thermally related theoretical concerns are mitigated by results from experiments in pregnant pigs exposed to standard MR sequences commonly used in clinical practice that are associated with relatively high specific absorption rate (SAR) levels (i.e., half-Fourier single-shot spin echo). Such studies failed to demonstrate substantial heating in fetal tissues or amniotic fluid when imaging at 3 T with normal-operating-mode SAR levels and a maximum scan time of 30 minutes.[13,14] Therefore, 3 T MR examinations performed within Normal Operating Mode should be considered safe in pregnant patients. At this point, the safety of imaging pregnant patients at field strengths greater than 3 T (i.e., 7 T) is unclear.

Use of gadolinium-based contrast material. The committee supports the recommendations of the ACR Manual on Contrast Media in relation to contrast administration to pregnant or potentially pregnant patients: MR contrast agents should not be routinely administered to pregnant patients.[15]

Also, there is widespread consensus that avoiding gadolinium-based contrast media (GBCMs) in pregnancy is prudent.[15] The decision to administer GBCM is typically made according to the

institutional contrast policy, on a case-by-case basis, by the responsible Level 2 MR physician who can assess the risk-benefit ratio for that particular patient. While additional research is needed, one paper suggests that exposure to GBCM at any time during pregnancy has been associated with an increased risk of a broad set of rheumatological, inflammatory, or infiltrative skin conditions and risk of stillbirth or neonatal death.[16] Thus, the decision should be accompanied by thoughtful risk-benefit analysis and well-documented with written informed consent. This analysis should be able to defend a decision to administer the contrast agent based on potential benefit to the patient or fetus outweighing the potential risks of exposure of the developing fetus to GBCMs.

A 2019 paper highlighted an increased exposure level of first-trimester pregnancies to GBCM, suggesting that increased screening and vigilance may be warranted when administering these contrast agents to potentially pregnant patient populations.[17]

Pediatric MR Safety Concerns

Pediatric patients may present with additional MR safety concerns including potentially increasing projectile risks in Zone IV, as well as body temperature considerations, and obtaining non-diagnostic MR exams due to inability to cooperate.

Projectile risks and the need for enhanced screening have been discussed in the Chapter 5: MR Screening.

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. MR Conditional 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.

Particular attention should be paid to the body temperature of neonates and infants while in the MRI environment. In a study by Don Paul et al.[18], only 43% of infants were normothermic upon return to the NICU following MRI, suggesting that MRI related unintentional hypothermia is common unless proactively managed. Predictors of a post-MRI decrease in body temperature in neonates and infants include younger age, lower weight, lower pre-MRI temperature, use of propofol as the primary anesthetic, use of an advanced airway device, and being outside the NICU [19]. In the event that the pediatric patient requires sedation / anesthesia, the ACR MR Safety committee defers to the American Society of Anesthesiologists on pediatric sedation guidelines.[20-23] Alternative methods to facilitate compliance without sedation / anesthesia may be considered (i.e., fast/accelerated MR sequences, engagement of child life specialists, MR conditional video entertainment headsets).

Claustrophobia, Anxiety, and Sedation

Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR practice parameters,[24] American Society of Anesthesiologists,[20-22] and TJC standards[25]. Implementation of SOPs and policies for management of claustrophobic/anxious patients is recommended. *Similarly, sites should develop policies for*

release of patients who receive sedation. For example, requirement of a responsible person, 18 years of age or older, to accompany and drive the patient after an MR procedure.

High BMI/Large Body Habitus

High BMI and very large patient / research participant body habitus are MR safety concerns primarily due to inherent risk of RF burns. As noted in earlier sections of this manual (See Chapter 8: RF section), contact or excessive proximity to the bore of the magnet can result in near field RF burns, and appropriate insulating pad thickness and positioning about the patient / subject is essential to prevent burns. Ensuring adequate appropriately placed padding can be difficult with very large patients / subjects, and particularly under general anesthesia or while sedated, padding must be scrupulously assessed to prevent burns. Another consideration in very large patients / subjects is the possibility of forming closed-loop tissued proximities and contacts, such that skin-to-skin contacts become more likely (e.g., between thighs, between abdominal panniculus and thigh, etc.). Insulating pads should be used accordingly. Strategies to reduce patient heating include using a local transmit-receive coil well as choosing lower SAR and reducing scan time to minimize overall energy deposition in the patient.

Prisoners/Detainees

MR scanning presents unique MR safety challenges for patients who are incarcerated. These patients may present wearing metallic or ferromagnetic handcuffs, ankle cuffs, or shackles. Accompanying correctional officers may be carrying ferromagnetic objects including guns and weapons. Prior to the patient arriving to the MR department, notification to the corrections department for an alternative nonferrous restraining option should be requested. MR screening of the patient and the accompanying correctional officer(s) should take place prior to entering Zone III. The accompanying officer(s) should be educated as to the static magnetic field safety issues and, if they agree following screening, should accompany the technologist into Zone IV for patient positioning and retrieval.

Ferromagnetic weapons should not be permitted into Zone III unless essential for maintenance of security. Firearms with ferromagnetic components pose a potential serious threat in Zone IV and can become dangerous projectiles, and may discharge, with resulting in a death as recently as 2023.[26,27]

Any accompanying officer carrying a firearm should not enter Zone IV, as firearms represent potential projectiles and are a potential hazard to all if brought into Zone IV.[26, 27]

Parolees

Patients on parole wearing metallic prisoner-monitoring devices such as RF identification or tracking bracelets could theoretically lead to adverse events, including:

1. Ferromagnetic attractive effects leading to patient injury
2. Ferromagnetic attractive effects leading to device/battery pack damage
3. RF interference with the MRI study and secondary image artifact
4. RF interference with the functionality of the device

5. RF power deposition leading to heating of the bracelet, tagging device, or its circuitry, and secondary patient injury (if the bracelet is in the volume of the RF transmitter coil being used for imaging)

Therefore, in cases in which a patient wearing RF or tracking bracelets needs an MR examination, a request should be made that the patient be accompanied by the appropriate authorities who can and will remove the monitoring device prior to the MR study and be charged with its replacement following the examination or other arrangements made with the proper authorities.

KEY POINTS

- Pregnancy
  - Pregnant health care practitioners are permitted to work in and around the MR environment, including Zone III and IV except in Zone IV during active scanning
  - Research studies have failed to demonstrate any reproducible harmful effects of exposure of the mother or developing fetus to the 3 T or weaker magnetic fields used in the routine clinical MRI practice. Nevertheless, the decision to proceed with an MR examination should be based on the medical benefits weighed against unknown potential risk.
  - If MR examination of a pregnant patient is indicated, the Level 2 MR Technologist should confirm Normal Operating Mode is selected
  - The committee supports the recommendations of the ACR Manual on Contrast Media in relation to gadolinium-based contrast media administration to pregnant or potentially pregnant patients
- Pediatric
  - Need enhanced screening for projectile risks
  - Need special attention to body temperature (particularly neonates and infants)
  - ACR MR Safety committee defers to the American Society of Anesthesiologists on pediatric sedation guidelines
- Claustrophobia, Anxiety, Sedation
  - Adult and pediatric patient anxiolysis, sedation, analgesia, and anesthesia for any reason should follow established ACR,[15] American Society of Anesthesiologists,[16-18] and TJC standards[19]
- High BMI/Large Body Habitus
  - Inherent increased risk of RF burns
  - Requires special attention to padding
- Prisoners/Detainees
  - Notification to the corrections department for an alternative nonferrous restraining option should be requested
  - MR screening of the patient and the accompanying correctional officer(s) should take place prior to entering Zone III
- Parolees
  - Arrangements should be made with proper authorities to remove and replace RF or tracking bracelets as needed

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Return to Table of Contents

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CHAPTER 16: ALTERNATIVE MR ENVIRONMENTS

MR systems are increasingly being operated in alternative environments outside of conventional diagnostic MR facilities. Examples of such facilities include hybrid positron emission tomography (PET)/MR, intraoperative/interventional MR, and MR-guided radiation therapy.[1-3] Each of these facilities presents unique challenges to implementing MR safety policies and SOPs, particularly with regard to unique devices, procedures, personnel, site-access restrictions, screening, site contamination and infection control, and adverse event management.

As the type and number of personnel who work in these complex MR settings are often more varied and numerous than in conventional diagnostic MR facilities, the MRMD should ensure specific SOPs are in place that define the roles and responsibilities of these MR Personnel.[4]

> *This should include identification of the responsible person to ensure the safety of the patient, MR Personnel, and other personnel who may care for the patient while in these alternative environments.*

Specialized personnel with MR safety training as well as specific training to the workflows and procedures in these more complex, alternative environments is recommended. Personnel working in the MR environment should have a minimum of Level 1 MR training or be supervised by Level 2 MR Personnel. It is crucial to develop a process to educate all other personnel who have need to access Zone IV in these complex environments (e.g., nurses, surgeons, anesthesiologists, respiratory technologist).

As in all MR settings, SOPs should include the process for evaluation and screening of patients and health care personnel, implants or devices, and equipment (e.g., patient support equipment and surgical, radiation, and anesthesia devices) that enter the MR environment.

PET/MR

Hybrid PET/MR systems are currently available for clinical and research imaging. These hybrid systems pose unique safety challenges since each modality requires a different group of personnel with varied training and access.[5-7] Governance can be complicated by the inherent multi-faceted challenges of each imaging technique, requiring careful communication and delineation of responsibilities. Often the best option is to form a co-directorship between the MRMD (i.e., responsible for MR safety) and another director such as a physician with specialized training in nuclear medicine and the handling/use of radioactive materials (i.e., authorized user). These co-directors must work together to develop policies and SOPs and ensure the facility follows current MR and PET safety procedures. All MR safety procedures must be overseen by Level 2 MR Personnel. Similarly, all radiation protection and handling of radioactive material must follow state and federal policies (refer to United States Nuclear Regulatory Commission 10 CFR part 20 and part 35)[8]. PET imaging personnel who work in Zone III and IV should additionally be trained as MR personnel following local standard policies and procedures.

Supplementary to standard MR safety considerations, PET imaging poses several additional challenges in the MR environment. Facilities must be appropriately shielded to avoid radioactive dose to personnel and the public, and facility cleaning must be executed to ensure infection control and to avoid potential radioactivity contamination. Additionally, handling, dissemination, and disposal of radioactive material requires specialized training and knowledge. Specialized equipment used in PET, such as shielded syringes or phantoms, need to be assessed for ferromagnetic properties before entering into Zone IV. Emergency procedures should be developed that incorporate quenches, radioactive spills, and other emergencies. In the event of spillage of radioactive material in Zone IV, a wipe test bringing the sample into Zone III may be required to assess radiation levels if the facility does not have access to an MR Conditional survey meter that allows interrogation of the contaminated site.

Intraoperative/Interventional MR

The physical environment for intraoperative/interventional MR presents substantial challenges. Each entrance to Zone IV (e.g., operative room patient entry, angiography suite, control room entry) require appropriate controlled access and effective screening practices to prevent the introduction of potentially dangerous objects or equipment. Transient changes in MR Zone labeling can occur in dynamic MR environments. A space that may be Zone IV in one instance may convert to Zone III at another time or configuration. Thus, multiple points of entry and variable room configurations can considerably increase the complexity required to achieve effective MR safety planning and design of these facilities.

Attempts to "retrofit" safe practices into intraoperative/interventional MR environments that have already been constructed can be challenging and lead to unintended consequences. Careful planning of the facility prior to construction is highly recommended.

These environments present unique circumstances that require site-specific coordination to manage time-sensitive emergent responses. Policies and procedures for emergency and adverse event management must be developed, reviewed by personnel expected to execute the defined procedures, and approved by the MRMD. In the development of such procedures, each person's role must be clearly identified and documented. Particularly, specific MR personnel responsible for overseeing MR safety should be clearly identified.

Although the challenges to each intraoperative MR environment vary from site to site, the guiding principles of MR safety remain. MR Personnel must be appropriately educated, be vigilant in their awareness of a dynamic environment, and apply that knowledge to successfully ensure patient and staff safety in the MR environment. Additionally, many devices that are not used in a routine diagnostic suite nor in and around a patient getting a diagnostic MR are frequently present in these environments. Rigorous adherence to testing, labeling, appropriate storage, securing, and usage guidelines are paramount to avoiding accidents. When it comes to devices used on or in the patient, it is also worth noting that there are no standards for testing partially implanted devices (i.e., biopsy needles, electrodes, antennae, etc.) in patients at this time, indicating further need for caution. Ultimately, the MRMD must facilitate a culture of safety where adverse events as well as 'near-misses' (e.g., accidental introduction of MR unsafe equipment or devices into Zone IV without unintended consequences) are reviewed regularly so

that policies and procedures can be updated and personnel education enhanced, as needed, to prevent similar events in the future.

MR Simulator & MR-LINAC

Owing to its unique and excellent soft-tissue contrast, MR has become a powerful tool for planning and delivering radiation therapy. Modern MR systems have better geometric accuracy than prior generations, and the use of MR simulators to image the patient in treatment position in a manner similar to CT is becoming more popular. Additionally, hybrid systems in which a linear accelerator is coupled with an MR are now available on the market. As with prior hybrid PET/MR scanners, unique challenges arise for guaranteeing patient and personnel safety in these environments.[9]

From an MR safety standpoint, the MR simulator is a standard MR scanner housed in a non-diagnostic imaging environment such as a Radiation Oncology department. Since MR safety is generally not a routine part of radiation oncology training and workflow, careful consideration needs to go into personnel access, training, and proficiency in MR safety tasks, such as patient and personnel screening, patient positioning and emergent procedures. Development of training programs and proficiency tests that include MR safety are likely beneficial in orienting staff to the new environment. It is worth noting that patients often receive multiple radiation doses (i.e., fractions) and may visit the MR simulator several times during the course of their therapy. Furthermore, such patients often undergo multidisciplinary care with other procedures being performed concurrently during the radiation therapy. Therefore, as in diagnostic imaging, it is important to screen the patient each time prior to the patient receiving the MR examination and make certain there has been no change in status. Many devices used during treatment simulation, such as immobilization devices, need to be evaluated for patient safety and artifacts. Conducting materials such as metal (both ferrous and non-ferrous) and some carbon fiber objects can potentially be a source of heating and can also generate severe artifacts. Alternative materials should be procured in these situations.

The hybrid MR-LINAC system requires additional consideration since the overall design of the facility must accommodate both radiation and the MR environment. Devices used during the delivery of radiation to immobilize the patient as well as those used to measure radiation should be MR conditional for the MR environment employed. Since motors and measurements used for calibration of these systems can be affected by the magnetic field, modified equipment may be needed. All considerations given for the MR simulator also apply to the MR-LINAC, where the unique environmental concerns of the hybrid system necessitate careful screening, access restriction, and training.

7 T MR environments

Ultra-high field strength MRI scanners (i.e., >3 Tesla) exist both for clinical and research imaging. Presently, the FDA limits on static magnetic field exposure vary depending on the age of the patient or research participant:

Main Static Magnetic Field[10]

Population	Main static magnetic field greater than (Tesla)
Adults, children, and infant aged > 1 month	8
Neonates (i.e., infants aged ≤ 1 month)	4

The FDA clearance for clinical use of 7 T MR necessitated the development of specific guidelines for these scanners .[11,12]

Transient bioeffects associated with the static magnetic field tend to increase with field strength and/or its associated spatial field gradient and are felt more strongly by some individuals and none by others.[13] At 7 T, the sensation of vertigo is the most often reported biologic effect. Other effects observed include dizziness, nausea, nystagmus (involuntary eye movements), magnetophosphenes (perceived visual flashes of light), and electrogustatory effects (metallic taste in the mouth). All effects are considered transient with no permanent cognitive or other health effects observed. These transient effects are not known to have a negative health effect for staff or patients; however, patient and staff discomfort should be managed. Because some of these effects are influenced by the Lenz effect, limiting patient motion during their positioning into the MR bore (i.e., during MR table motion) has been shown to decrease vertigo. Moving the patient with slow table velocity in and out of the MR scanner may also decrease this effect. Similarly, patient head motion during the MR examination should be minimized.[13] Given these potential side effects, MR Personnel should check with the patient or research participant prior to complete removal from the table. Sitting on the MR table for some time may be helpful. Similarly, access to an MR Conditional wheelchair may be helpful for some patients.

There are several particular considerations that should be taken into account for metallic implants, devices, and foreign bodies in the 7 T environment. Compared with lower-field-strength MR environments, 7 T strength is associated with greater transmitted RF energy. Devices that can be safely imaged at 3 T may represent a risk at 7 T because of length dependent RF heating. Thus, rapid resonance-related heating leading to dangerous temperature elevations of shorter electrically conductive objects is theoretically more likely at 7 T than at 1.5 T or even 3 T.

MR Conditional status at 7 T cannot be assumed from existing MR Conditional status at 3 T or other field strengths. A major concern for implants and devices in the 7 T environment or in patients undergoing MR is that relatively few objects have undergone standardized testing to determine their level of safety. Because 7 T MR exposes implants and devices to higher static magnetic field strength and RF energy, each item must be evaluated at 7 T, even if the object had been previously deemed safe for a patient undergoing an MR examination at 1.5 T or 3 T. For example, an aneurysm clip that can be imaged safely at 3 T (MR Conditional) may not be at 7 T.[14,15]

Translational forces on unsaturated ferromagnetic objects are broadly similar in the fringe-field region of actively shielded 7 T systems compared to modern lower-field systems, albeit subject to slightly more extended fringe fields while rotational forces may scale approximately with the field. Also note that significantly higher Lenz forces associated with conducting material

moving through the field may be associated with 7 T environments.[16] Additionally, certain implants, such as active implanted medical devices (e.g., neuromodulation devices, cochlear implants, etc.), that retain functionality at lower field strengths may potentially malfunction or suffer interference, altered settings, or permanent damage at 7 T.[17]

As with other complex MR environments, guiding MR safety principles must drive practice decisions in the 7 T setting. A risk-versus-benefit assessment with the most current information available to determine whether a certain patient diagnostic question, possibly with particular implant or device considerations, warrants undergoing MR at 7 T.

Point of Care MRI Systems

Point of care systems are gaining FDA clearance, including portable ultra-low field strength MRs (< 0.1 T) and higher field strength systems, to provide bedside head scanning in an effort to provide rapid results (e.g., recent infarcts, hemorrhages) and obviate the need to transport patients to fixed-location MR units. For the systems with ultra-low B_0 field strength, missile-effect projectile incidents are presently considered to be relatively low risk, particularly compared to conventional superconducting 1.5 T and 3 T magnets or recently introduced low field MR scanners (e.g., 0.55 T). No cryogens are used to maintain a superconducting environment, eliminating that safety concern. Although the relatively lower energies utilized in low field point-of-care MR make these systems lower risk than traditional MR systems, care should still be taken that staff, particularly non-MR Personnel, still follow appropriate safety procedures. In particular, noting the portable nature of these systems, a dedicated secure storage area should be designated for portable MR systems. This is an evolving field and continued evaluation and assessment of safety concerns related to this class of MRs will continue to be of interest to the ACR MR Safety Committee going forward as new information emerges. In situations where there is not a registered trained MR Technologist, there should be sufficient training for all individuals operating the unit to ensure safety. At present, there is insufficient data to assess safety related to scanning in the presence of active implanted medical devices (AIMDs), and other devices such as programmable ventricular shunts, although preliminary reports are emerging.[18]

Mobile MR Scanners

Mobile MR scanners are often constructed/sited near facilities with insufficient room but radiological need for additional MR capabilities. While these systems may offer imaging services at standard clinical field strengths, their environments generate unique MR safety considerations. Mobile units are often near parked and moving vehicles, which can potentially expose external persons to fringe MR fields. If the fringe fields extend outside of the mobile unit, there must be appropriate access restriction outside the 5 gauss line. Stray magnetic field interference and vibrations from outside the mobile unit can also directly affect image quality so appropriate siting restrictions (e.g., restricted parking around mobile MR unit) should also be in place. While some mobile facilities include a Zone II area outside the Zone III console room, many mobile structures only have an enclosed Zone III console room and Zone IV scan room. In these situations, Zone II could be a parking lot or other open area outside radiology that can be

difficult to manage. Not infrequently Zone III is relatively small necessitating strict Zone IV access restrictions.

Personnel need to develop SOPs to address emergencies in this unique environment, including patient contrast reaction/code situations, transport during emergent events and cryogen safety.

KEY POINTS

- Alternative MR Environments
  - Personnel working in the MR environment should have a minimum of Level 1 MR training or be screened and directly supervised by Level 2 MR Personnel
- PET/MR
  - MR Safety and radiation regulatory requirements often need shared responsibilities between two medical directors (MRMD and nuclear medicine authorized user)
- Intraoperative/Interventional MR
  - Policies and procedures must clearly indicate which specific Level 2 MR Personnel is responsible for overseeing MR safety
- 7 Tesla
  - The risk of accidents due to projectiles or complications related to implanted devices is substantially increased
  - MR Conditional status at 7 T cannot be assumed from existing MR Conditional status at 3 T or other field strengths.
- Point of Care MRI Systems
  - Low risk of missile-effect projectile incidents
  - Insufficient data to assess safety related to scanning in the presence of active implanted medical devices (AIMDs) and other devices
  - All involved staff, including non-MR Personnel, should follow appropriate safety procedures
- Mobile MR Scanners
  - Siting may be associated with additional challenges around MR Zone restrictions

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APPENDIX 1: MR SAFETY POLICIES AND STANDARD OPERATING PROCEDURES

Facilities should develop written MR safety policies and standard operating procedures (SOPs) to minimize risks to patients, patient families, research participants, visitors, and personnel. Whereas the general approach to MR Safety should be documented in institutional MR Safety policies, items that require frequent updates and/or include detailed instructions (e.g., MR imaging with implanted devices) may be better documented in SOPs. A checklist such as the one provided below can be of assistance in the development of such policies and SOPs. Note that policies related to use of contrast in MR should follow the recommendations from the ACR Committee on Drugs and Contrast Media and thus are not included in this checklist.

Designated MR Safety Committee with MR Medical Director (MRMD), MR Safety Officer (MRSO), Designated MR Safety Expert (MRSE) Designation of formal safety roles for the MRMD, MRSO, and MRSE should include specific duties, training and competencies for each role. The policy should also refer to a document with the current names and contact information for the designated individuals.	
Specific members of a MR Safety Committee	☐
Specific duties for MRMD	☐
Specific duties for MRSO	☐
Specific duties for MRSE	☐
Specific training and competencies	☐
Document with the current names and contact information	☐
Reporting of MR-related adverse events and near misses The reporting of MR-related adverse events and near misses should specify reporting procedures and corresponding time intervals.	
Reporting procedures	☐
Time interval	☐
Documented MR safety education / training for all MR Personnel The policy should define MR Personnel, required training for each level designation, specific training content and/or competency measures for each level, and the time interval of education training.	
Definition of MR Personnel training levels	☐
Specific training content and/or competency measures for each level	☐
Training time interval	☐
Site access privileges (MR zones) and methods of controlled access Areas to be controlled and the methods used to restrict unauthorized access to Zone III and IV should be defined. The policy should clearly associate the MR safety personnel levels and their site access privileges.	
Areas to be controlled	☐

Methods to grant access to Zone III and IV	□
MR safety personnel levels and site access privileges	□
MR safety warning signage Signage should include illuminated or reflective sign stating "Magnet is Always On" with a battery backup (if illuminated) at Zone IV entrance(s). Additional signage that describes hazards and access restrictions (at a minimum at entrances to Zone III and IV).	
MR Safety warning signage	□
MR safety screening Policies should include: Staff/Personnel Screening: Process for documented screening for all MR Personnel that includes initial onboarding MR screening, periodic annual screening, and provisions to update screening upon change in medical status. Patient Screening: Process for documented screening of all patients that includes screening practices for conscious, unconscious, unresponsive, altered-level of consciousness, communication-restricted, and emergent patients, in addition to companions/family members. The screening policy should also include the appropriate use of physical screening adjuncts (i.e., ferromagnetic detection). Pediatric Patients: Process for both screening with parents/guardian and private clinical screening.	
Staff/MR Personnel screening	□
Conscious, nonemergent patient screening	□
Unconscious, unresponsive, altered level of consciousness patient screening	□
Emergent patient screening	□
Companion/family member screening	□
Communication-restricted screening (i.e., medical translator, interpreter services)	□
Physical screening adjuncts (i.e., ferromagnetic detectors)	□
Pediatric patient screening	□
Risk identification, Assessment, and Mitigation Risk management should include processes for implanted devices, on-planted devices, foreign body and potential foreign body/orbital trauma noted during the screening process.	
Processes for identification of implanted devices, foreign body and orbital trauma during the screening process	□
Assessment of risk	□
Mitigation of risk	□
Patient preparation	

The policy should include MR safe attire (pocketless garments) and means to reliably remove metallic personal belongings and devices and gowning provisions for all patients/research participants. Provisions to ensure cell phones do not enter Zone IV (e.g., dedicated storage locations in Zone III, etc.).	
MR Safe attire	□
Removal of readily removable metallic personal belongings and devices	□
Prevention of cell phones entering Zone IV	□
Acoustic noise protection Hearing protection provisions for all patients/persons in Zone IV during scanning should include instructions on proper 'fit and function' of hearing protection and the process and procedure for patients who refuse hearing protection.	
Hearing protection	□
Fit and function of hearing protection	□
Process and procedures for patients who refuse hearing protection	□
MR scanning safety Guidance for patient positioning, coil choice and placement, and padding should be documented. A policy should also include patient communication management to include the use of a technologist notification device (i.e., squeeze ball) and continuous acoustic monitoring (i.e., open two-way intercom channel) during MRI examinations of conscious patients.	
Positioning	□
Coil choice and placement	□
Padding	□
Patient communication management	□
Implant/Device/Object management The process/methodology for exam approval/denial for patients with implants/devices/objects.	
Process/methodology for exam approval for implants/devices/objects that have manufacturer MR safety labeling	□
Process/methodology for exam approval for implants/devices/objects that have no or incomplete MR safety labeling	□
Emergency The processes for appropriate use of emergency stop and emergency power off switch should also include guidance on when to initiate an MR quench (vs. an emergency power-off) by designated authorized personnel. Processes of emergency response for various emergent situations including fire, medical e.g., code) and other emergencies (e.g., entrapment) should also be included.	
Emergency stop and emergency power off interlocks	□
Quench	□

Fire	□
Code	□
Entrapment/other emergencies	□
Education for first responders such as firefighters who may respond to emergencies in the MR environment	□
Cryogen safety (as applicable) The frequency and process for documentation of inspection of the MR quench pipe assembly and the education/training required for any person working or managing others working near the quench pipe discharge point (e.g., roofing or air-conditioning repair personnel) should be included in a cryogen policy.	
Frequency and documentation of inspection of MR quench pipe assembly	□
Education/training for any person working near the quench pipe discharge point	□
Pregnant patients and staff The policy should include the screening process for pregnancy and the management of pregnant patient care within the MR environment. The policy for pregnant health care practitioners should define permitted workplace activities and restrictions.	
Screening process for pregnancy	□
Management of pregnant patient care within the MR environment	□
Permitted workplace activities and restrictions for pregnant health care practitioners	□
Claustrophobia The policy should include the management of claustrophobic /anxious patients in the MR environment.	
Management of claustrophobic/anxious patients in the MR environment	□
Sedation / Anesthesia The policy should include the management of patients who have undergone sedation or anesthesia within the MR environment and actions related to the release of such patients.	
Management of patients who have undergone sedation/anesthesia within the MR environment	□
Actions for release of patients who have undergone sedation or anesthesia	□
Infection control and medical waste The policy should include requirements for MR area cleaning including access for environmental services, normal and terminal (following patient discharge) cleaning and the use of staff personal protective equipment (PPE) based on potential infection/contamination risk.	

Requirements of MR area cleaning	□
Access for environmental services, normal and terminal cleaning	□
Use of staff PPE based on potential infection/contamination risk	□
Policy access and review The policy should detail the process for annual review and update/re-endorsement of MR safety policies and SOPs by the MRMD and relevant institutional responsible person concurrently with the introduction of any substantial changes in safety parameters of the MR system or suite. Policies and SOPs should include citations/references to contemporary standards or best practice documentation and include appendices when applicable. Policies should be present and readily available to facility staff (either physically or electronically).	
Reviewed/updated/re-endorsed annually	□
Endorsed by current MRMD and relevant institutional responsible person	□
Policies include citations/references to contemporary standards or best practice documentation and appendices when applicable	□
Present and readily available to facility staff (either physically or electronically)	□

2763

APPENDIX 2: MR FACILITY SAFETY DESIGN GUIDELINES

According to safety and human factors engineering principles, employing multiple and varied safety strategies can enhance a program's effectiveness. This multi-faceted approach is sometimes termed *defense in depth*. The safety strategies outlined in the preceding main body of this MR Safety Manual can be enhanced by thoughtful safety-oriented architectural and interior design strategies. For example, a facility's physical design can strategically encourage safety and compliance with best practices by facilitating MR personnel safety related workflows while enhancing patient flow through the facility. Different design elements may be incorporated depending on the setting (e.g., inpatient vs outpatient, diagnostic vs. interventional) within the same institution that aim to optimize the main function of that particular site.

Some examples of designing prospectively in an effort to improve safety follow. For example, having a private area for patient screening interviews will make it more likely that patients will disclose sensitive types of implants. Similarly, dedicated permanent and temporary storage space in Zone III, including lockable space and equipment tether points for MR Unsafe equipment (e.g., ferromagnetic intravenous poles, oximetry monitors, wheelchairs, transport stretchers) is desirable.

For MR suites planning to use MR Conditional equipment in Zone IV (e.g., anesthesia machines), it is recommended that the installation of tethers in their appropriate locations is planned during the design phase. Similarly, marking relevant gauss lines (e.g., 200 gauss) on the floor of Zone IV is recommended to help define the necessary length of such tethers. There may special circumstances (e.g., hybrid procedural suites) where storage of MR Unsafe equipment in Zone IV can be accomplished with wall anchor and tether strap/cable systems that prevent such equipment from becoming a projectile. In certain circumstances, maintaining such equipment in Zone IV is crucial for standard operations (See Chapter 16: Alternative MR Environments). However, storage of unsafe equipment in Zone IV in routine MR settings is strongly discouraged.

Effective and safe MR suites must balance the technical demands of the MR equipment with local and state building codes, standards of accrediting bodies, clinical and patient population needs, payor requirements, and a collage of civil requirements from the Health Insurance Portability and Accountability Act (HIPAA) to the Americans with Disabilities Act.

Although it could be desirable to provide a universal MR safety design, the variables are too numerous to adequately address in a single template. The following MR Facility Safety Design Guidelines are provided to support the planning, design, and construction of MR facilities, including updates to existing MR facilities, which enhance the safety of patients, visitors, and staff. Sites may be faced with bringing existing facilities into compliance with modern MR safety standards. Until more complete renovation can occur, the primary goal should be safety in the MR suite including appropriately labeled and secured access to Zone III and IV as well as attention to what devices and types of procedures may be appropriate for the site.

This information is intended to supplement and expand on patient safety guidance provided throughout the *ACR Manual on MR Safety*.

General Principles

- **Facility location, access, etc.**
  - An important consideration is the physical weight of the MR unit and having adequate foundation to support it. Note that higher field magnets are heavier. The weight of the magnet may influence what floors it can be sited on. Magnets sited on the ground floor or lower may need to be protected from flooding.
  - Careful assessment of facility location to avoid potential areas of unintended interaction (magnetic field, vibrations) with MRI scanners (e.g., elevator shaft, train rail tracks, etc.).
  - Consider ease of access to Zone IV for deployment of the MR scanner and future upgrades/replacements. A location with a removable panel for Zone IV in the exterior wall of the building is desirable to allow direct access from the outside into Zone IV. Alternatively, a path for delivery of the MR scanner (or extraction and delivery of future replacements) should be available, including doors and hallways that are wide enough (i.e., 8 feet or larger).
- **MR Equipment Vendor Templates**
  - Design templates provided by MR equipment manufacturers are invaluable in developing suites that meet the minimum technical siting requirements for the specific equipment
  - Vendor design templates, however, typically depict only the control and equipment rooms, in addition to the magnet room, Zone IV.
  - Patient/family waiting, interview areas, physical screening/changing areas, access controls, storage, crash carts, induction, medical gas services, post-screened patient holding areas, infection control provisions, and interventional applications, among many other issues, are not addressed in typical vendor-provided drawings. These issues are left to facility owners, operators, and their design professionals to resolve.

Zone II

- **Patient Interview/Screening**
  - Reviewing the patient Safety Screening Form and MR Hazard Checklist requires discussing confidential personal information.
    - To facilitate full and complete patient disclosure of their medical history, this clinical screening should be conducted in an area that provides auditory and visual privacy for the patient.
    - Facilities should prospectively plan for electronic patient medical records, which are useful in clinical screening, and should provide for access to records in the MR suite in support of clinical patient screening.
    - Clinical screening of inpatients may be completed in the patient room for hospital-based MR facilities.
- **Changing Areas/Gowning**

    - A location should be provided for patients in which they may change out of their street clothes and into facility-provided MR Safe pocketless garments.
    - All facilities must provide means of identifying, removing, and temporarily storing items that the patient may have brought with them that might pose threats in the MR environment. It is recommended that keyless lockable storage or nonferromagnetic keys are available for valuable personal belongings.
- **Transfer Area/Ferrous Quarantine Storage**
    - An area should be provided to transfer the patient from MR Unsafe transport equipment (e.g., ferromagnetic wheelchair) to equipment appropriate for the MR environment.
    - Unsafe equipment accompanying the patient should be secured in a "ferrous quarantine" storage area outside of Zone III, distinct from storage areas for MR Safe and MR Conditional equipment.

Zone II or III

- **Emergency Resuscitation Space and Equipment**
    - It is recommended that emergency code and emergency resuscitation equipment be stored in a readily accessible area within either Zone II or Zone III, in close proximity to Zone IV. If the equipment is MR conditional and to be stored in Zone III, providing securing tethers is recommended.
    - A dedicated area to hold a patient in acute distress is recommended in Zone II or III, in close proximity to Zone IV, and sufficiently large to allow conducting a patient resuscitation (i.e., cardiopulmonary resuscitation maneuvers).
- **MR Conditional fire extinguisher storage**
- **MR Conditional housekeeping equipment storage**
- **MR Conditional patient transport equipment storage (e.g., wheelchairs, stretchers, walkers, lifts)**
- **Patient Recovery area**
    - Facilities performing MR examinations in patients undergoing moderate sedation or anesthesia, such as those imaging inpatient and performing MRI-guided procedures, should consider a patient recovery area in Zone II or III that is adequately equipped (e.g., medical gases, crash cart). It is recommended that the recovery area is in close proximity to Zone IV to minimize distance during the transport of intubated patients.
    - Involvement of personnel with expertise in anesthesia procedures is helpful during the design phase of the facility.
- **Ferromagnetic detection devices**
    - Permanently installed FMDS have been demonstrated to be highly effective as adjuncts to the MR safety screening process. It is recommended that new facility construction anticipate the use of ferromagnetic detection screening and provide for installation of the devices in a location that facilitates use and throughput.
    - Several types of FMDS and roles for them exist.
        - Wall mounted "pillar type" FMDS, at a distance from entrance to Zone IV (typically Zone II-III)

- Considered useful for screening of ambulatory patients/subjects who have changed into MR Safe pocketless garments in effort to identify any concealed / forgotten ferromagnetic object. Some evidence that some implanted and on-planted devices may be detected. Can be useful to verify ferrous free status of patients prior to passing into Zone III.
- Mounted / positioned "pillar type" FMDS in proximity to entrance to Zone IV
  - Intent is to provide a final ferromagnetic check immediately before entering Zone IV.
- Handheld FMDS
  - Can be useful to specifically assess specific body parts, particularly to more precisely determine location / identity of a potential ferromagnetic object indicated by "pillar type" FMDS.
  - Can be useful to screen non-ambulatory patients if on an MR conditional transport equipment.
- Permanent magnet (at least 1000 gauss)

- Depending on the workflow of the facility, FMDS should be optimally sited in Zone II and/or Zone III.
- Handheld FMDS and permanent magnets, while needing to be accessible, must have provisions / SOPs to prevent their introduction into Zone IV.

Zone III

- **Access Control**
  - Means of physically securing and restricting access to Zone III from all adjacent areas must be provided.
  - Access to Zone III should be limited by usage of a personalized electronic badge to those who have been granted access by the MRMD based on local policy.
  - Access to Zone III must be guaranteed in the event of a power outage either with emergency power or a mechanical release from inside Zone III.
- **Post Screened Patient Holding/Transit**
  - Depending on facility functionality, capacity and patient volume, it may be advisable to provide a post-screened patient holding area.
  - Zone III holding areas should be equipped and appointed to prevent patient exit and subsequent reentry to avoid introduction of unscreened objects and personnel.
  - Multimodal radiology facilities combine patient holding and/or induction areas for patients of different modalities.
    - This presents safety challenges because patients for a different modality would not typically be screened for MR contraindications or ferrous materials. This poses a risk for a patient with a contraindicated implant. Those in MR Zone IV would be subjected to a serious safety threat if an erroneously unscreened or suboptimally screened individual entered Zone IV with a ferrous object.

        - A patient holding area in Zone III should be used exclusively for post-screened MR patients.
    - A small Zone III may be sufficient in outpatient facilities performing diagnostic MR scans. In this scenario, the Zone III serves as a transit zone for the patient being transported from Zone II into Zone IV, with no patient holding occurring in Zone III.
- **Lines of Sight/Situational Awareness**
    - Level 2 MR Personnel should have a direct line of sight to the entrance to Zone IV.
    - The technologist seated at the MR operator console should be able to view the patient in the MR scanner.
    - Remote video and audio capabilities can be helpful to enhance the communication between personnel in Zone III and Zone II.
    - Video recording equipment monitoring the Zone IV door may be helpful in quality improvement efforts to evaluate best practices, near misses, and safety events. Prospective planning for such equipment could be helpful.
- **Potential Harmful Unique Aspects of the MR Environment**
    - For many MR system installations, the magnetic field may project beyond the confines of the magnet room (Zone IV) and can superimpose potential hazards on spaces that may be outside the MR suite, even on floors above or below the MR facility and perhaps even outside the building.
    - Facilities must identify all areas, including those outside the MR suite (including rooftops, storage areas, mechanical closets, crawling spaces, etc.) that are exposed to potentially hazardous forces related to the MR environment and that may be occupied.
    - Areas of potential hazard must be clearly identified, and access to these areas must be restricted and clearly indicated with appropriate signage, just as they would be within the MR suite.

Zone IV

- The design of Zone IV (and MR equipment room) is complex and typically requires following the MR vendor recommendations.
- Being the location of the MR magnet itself, many critical issues and items must be considered thoughtfully during the Zone IV design stage. Adjoining building space must be large enough, accessible enough, and with sufficient foundational support to accommodate delivery of the large and heavy MR unit.
- Adequate space must be devoted to adjacent equipment rooms, and access to these rooms must be planned for.
- Planning is essential for runs/chases for electrical lines, data management lines, heating, ventilation and air conditioning (HVAC: with considerations for unique temperature, humidity control and airflow requirements), and plumbing lines.
- Quench pipe routing pathways must be considered (See cryogen vent pathway below).

- Various shielding elements must be built into Zone IV walls to contain/limit the fringe field, RF field, and acoustic noise.
- If the RF door opens inward, discuss with the vendor the need for a pressure release mechanism during a quench. If the RF door opens outward, line of site and ferromagnetic detector placement should be considered.
- Planning for the contents of Zone IV is essential, and the overall room size must be sufficient to accommodate all the planned elements. These elements must be thoughtfully sited to maintain practice efficiency as well as safety. Please refer to Figure 21 for a depiction of a typical contemporary Zone IV room and its contents of a facility performing both inpatient and outpatient MR examinations, understanding that this is not intended to be absolutely all inclusive of room contents, and that individual practices need to tailor their facilities to best serve their unique needs. Common elements are included in the following table:

Visual in/on floor 5 and 200 gauss line markers	Physiologic monitoring equipment	In room storage, cabinets, shelves or other permitting access to coils/phantoms, RF insulating pad, contrast media, linen and entertainment/fMRI systems
Power injector	Patient monitoring camera and intercom system	Sink
Data Ports	Quench button	Sharps container
Anesthesia machine	Emergency Call/assistance button (either Zone IV or close proximity in Zone III)	Glove dispenser
Emergency backup power	Safety strap/access control barrier at Zone IV door	Hand antiseptic dispenser
Wall anchor and fixed length tethers	Waveguide and other cable management	Waste receptacle
Medical gasses	Temperature/Humidity control	
Suction	Ambient and procedural lighting and controls	

Table 3. Common elements for Zone IV.

- **Cryogen Safety**
  - For most MRI systems, if the magnet quenches (i.e., loss of superconductivity/magnetic field), the escaping cryogenic gases are ducted outside the building to an unoccupied discharge area. Accommodation for such area and plans for appropriate access restriction and signage must be included in the design phase (See below).
  - Superconductive MR scanners with very small volumes of cryogen do not require a quench pipe in the room.

- The following recommended MRI suite design and construction elements reduce patient and staff risks in the unlikely event of a quench in which the cryogen vent pathway (quench pipe) ruptures or leaks into Zone IV.
    - All magnet rooms/Zone IV regions for superconducting magnets should be provided with an emergency exhaust pathway (unless the vendor specifically indicates that the magnet does not require one). The emergency exhaust grille is to be located in the ceiling opposite the entrance to the magnet room (Zone IV) door. At this location, when activated in the unlikely event of a quench breach (inadvertent venting of cryogenic gases into Zone IV), the exhaust fan is positioned to draw the cryogenic cloud away from the magnet room exit.
    - Many MR manufacturers now require that magnet rooms for superconducting magnets also be provided with an additional form of passive pressure relief/pressure equalization to minimize the risks of positive-pressure entrapment. Designs for passive pressure-relief mechanisms should follow design criteria similar to that of cryogen vent pathway and active exhaust, including discharge to a protected area.
  - Even with an exhaust fan, designing the door to Zone IV to swing outward is not, by itself, an appropriate means of pressure relief.
  - 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.
- **Cryogen vent pathway**
  - Obstructions, inappropriate pipe materials, insufficient pipe caliber and/or length, or faulty connections in the length of the cryogen vent pathway can cause failure between the magnet and point of discharge.
  - Because minimum design requirements for some cryogen vent systems have been revised by magnet system vendors, facilities should obtain current standards from the original equipment manufacturers to use in evaluating their cryogen vent assembly and not rely on original siting requirements.
  - Because obstructions/occlusions of the cryogen vent can increase the likelihood of rupture in a quench event, facilities should ensure that:
    - The discharge point has an appropriate weather-head that prevents horizontal, wind-driven precipitation from entering, collecting, or freezing in the quench exhaust pipe
    - The discharge point is positioned so that snow or debris cannot enter or occlude the pipe
    - The discharge is covered by a material of sufficiently small openings to prevent birds, other animals, or other material from entering the quench pipe, while not occluding cryogenic gaseous egress in a quench situation.
  - To protect persons from cryogen exposure at the point of discharge during a quench, facilities should ensure the following:

        - At the point of cryogen discharge, a quench safety exclusion zone should be established and clearly marked with surface warnings and signage. Note that the quench pathway discharge point must be surrounded by physical restrictions for Non-MR Personnel.
        - The quench safety exclusion zone should be devoid of serviceable equipment, air intakes, operable windows or unsecured doors that either require servicing or offer a pathway for cryogenic gases to reenter the building.
- **MR Conditional External Non-Implanted Equipment and Devices**
    - It is recommended that the location of one or multiple critical iso line(s) be identified for MR Conditional equipment and devices used within the MR suite and delineated on the floor and walls of the magnet room to aid in the positioning and safe and effective operation of such equipment.
    - The use of tethering hooks in the wall of the MR suite (Zone IV) and tethers with specific length to prevent the conditional device from moving closer to the MR scanner beyond the conditions specified by the vendor are strongly recommended in those facilities using such devices routinely.
    - Tether anchor points should be prospectively planned in the design and construction of the Zone IV enclosure, as penetrations into existing RF-shielded walls or floors could damage the function of an RF-shielded enclosure.
- **Infection Control**
    - Magnet system room finishes, and construction details should be designed to facilitate cleaning by appropriately trained staff with nonmotorized equipment.
    - For interventional and MR-guided procedures, basic infection control protocols, such as seamless floorings, scrubbable surfaces, and hand-washing stations should be considered.

Disclaimers and Recommendations

The facility design issues identified in this appendix only address general safety design issues for MRI suites. There are a multitude of site-specific and magnet-specific operational and technical design considerations relevant to MR facility design and construction that are not addressed in this appendix. These issues include, but are not limited to, patient acuity, staff access, modality conflicts, vibration sensitivity, throughput/efficiency, HIPAA considerations, magnetic contamination, sound transmission, magnet shim tolerances, shielding design, moving metal interferences, MR equipment upgrades, and electromagnetic interference.

In addition to incorporating the guidance from this appendix, a facility would be well advised to seek expert assistance in the planning and design of MRI and multimodal radiology suites.

References

1. The Facility Guidelines Institute. *Guidelines for the Design and Construction of Hospitals*. 2018 ed.
2. Greenberg KL, Weinreb J, Shellock FG. "MR conditional" respiratory ventilator system incident in a 3-T MRI environment. *Magn Reson Imaging*. 2011; 29(8):1150–1154.

APPENDIX 3: MR FACILITY MAINTENANCE AND EMERGENCY PREPAREDNESS GUIDELINES

Health care facilities have a unique obligation to minimize the disruption from maintenance issues as well as disasters and hasten their ability to restore critical patient care services when interrupted.

Those charged with the operation of MR facilities have the added complexities of protecting not only the staff and structure but also the equipment, which may be extraordinarily sensitive to changes in its environment, including vibration, power supply, and water damage.

Depending on location, facilities may have to contend with earthquakes, tornadoes, fires, ice storms, snowstorms, or blackouts. Prospective disaster planning may prove beneficial to such sites.

1. Maintenance

Maintenance in Zone IV brings many challenges. Maintenance efforts should be well planned and monitored and an MRSO should be available to supervise contractors and maintenance personnel. Every effort should be made to have ferrous free tools and if ferrous material needs to be brought into Zone IV there must be a well-designed plan of action to ensure safety (i.e., tethering, potentially ramping the magnet down prior to the maintenance work).

2. Water Damage

Whether from roof failure, burst pipes, storm surges, or rising water levels, every facility has the potential for water damage to equipment and facilities. It takes only a small quantity of water in contact with an MRI scanner to incapacitate or destroy the equipment.

In the event of impending water damage, facilities may decide to prepare by covering gantries and equipment with sturdy plastic, taped in place. Where possible, electronic components should be raised from the ground. Radiofrequency (RF) shields, particularly the floor assembly, may be significantly damaged and may need to be replaced following a flood if not designed to be protected against water damage.

Temporary electrical power may be provided either through on-site or portable emergency generators. Facilities should evaluate risks from water damage and assess their preparations for failure of the building enclosure and be especially sensitive to emergency generators that may be located in basements or other low-lying areas.

3. Structural Damage

MRI presents a particular challenge with structural failure. Although unlikely with current magnet systems, vibrations from seismic events do have the potential to initiate a quench of the magnet system. Structural damage or motion may also damage the RF shield enclosure, potentially degrading image quality.

4. Power Outage

Without electrical power to the vacuum pump/cold head to reliquify the cryogen within a superconducting MR system, the cryogens will begin to boil off at an accelerated rate. Depending on cryogen vent design and boil-off rate, the additional cryogenic gas discharge may freeze any accumulated water or water vapor in the cryogen vent, occluding the pipe and increasing the possibility for a cryogen vent breach in the event of a quench.

At some point, if power to the vacuum pump is not restored, likely a couple days to perhaps a week after power is lost, the magnet will spontaneously quench, discharging most or all of its remaining cryogenic gases. This poses a safety risk to anyone near the discharge and runs a risk of potentially permanently damaging the magnet coils.

However, if power to the vacuum pump/cold head and cryogen levels is restored prior to a quench, there should be no long-term consequences to the magnet's operation from a power interruption.

5. Quench

Because of the risks to personnel, equipment, and physical facilities, manual magnet quenches are to be initiated only after careful consideration and preparation. In addition to following those specific recommendations provided by the MRI manufacturer, a facility should initiate a preemptive quench in nonemergent situations only after verifying the function of emergency exhaust systems and verifying or providing means of pressure relief. The facility should check for water leaking from fittings or condensation forming on vent pipe sections as possible signs for water or ice inside the pipe. If/when feasible, a discussion with the device manufacturer regarding an intentional controlled static magnetic field ramp-down may be advisable.

6. Prevention

Although it is the nature of emergencies to be surprises, we can anticipate the types of incidents that have higher likelihoods given our facilities, practices, and locations. Every facility can anticipate the potential for flooding, fire, and code situations.

State and federal offices of emergency preparedness are dedicated to anticipating and preparing for the specific threats a given region. These can serve as an excellent resource regarding risks and strategies for preparation.

Once a disaster has struck, it is important to assess what the immediate needs of the community are and to restore those critical patient care services first.

Damage to MRI equipment and facilities may not be repaired as quickly. For gravely incapacitated facilities, semi–trailer-based MRI units may be the only means of quickly restoring radiology capacity.

All health care facilities should have emergency preparedness plans. The health care plans for MRI facilities should specifically address the unique aspects of MRI equipment. These plans

should define who has the authority to authorize nonemergent quenches, procedures for emergency or backup power for the vacuum pump/cold head, and instructions on how to protect gantries and sensitive electronics. Facilities should have the necessary supplies prepositioned and checklists for preparatory and responsive actions. Emergency preparedness plans should also include information necessary for restoring clinical services, including contacts for the MRI system vendor, RF shield vendor, cryogen contractor, MR suite architect and construction contractor, local and state officials, and affiliated hospital and professional organizations.

Below are a few questions that may facilitate the development of an emergency preparedness plan specific to the needs of a facility.

- What are the likely/possible natural disasters to affect the area?
- What are the likely/possible man-made disasters to affect the area?
- Is electrical power likely to be interrupted?
- Would other utilities (natural gas, telecommunications, etc.) likely be interrupted?
- What equipment would be inoperative during the emergency?
- What equipment could be damaged by the emergency?
- What equipment should be provided with critical or backup power?
- If the utility service is not quickly restored, what other risks may arise?
- Would patients and staff be able to get to the facility?
- Would patients or staff be trapped at the facility?
- How critical is each patient care service provided at the facility?
- How does the facility protect the equipment needed to support each service?
- How does the facility protect the patient data (including such options as off-site storage) from each service?
- If the facility does not have the resources for the above on site, who can provide them?

APPENDIX 4: SPATIAL FIELD GRADIENT EVALUATION

The translational force on an object in the MR environment is proportional to the product of the induced field in the object by the magnetic field and the spatial field gradient (SFG). Therefore, the SFG plays an important role in the forces experienced by an object, in addition to the magnitude of the magnetic field itself. The spatial field gradient characterizes the static spatial gradient of the magnetic field surrounding an MR system. It is the spatial rate of change (Δ) in the magnetic field at any given position in space around the MR scanner. The SFG increases substantially as one approaches either end, or 'face', of a cylindrical MR scanner bore.

A map of the SFG is necessary to characterize or predict forces on ferromagnetic objects in the vicinity of the MR system, and so is required to be disclosed for each specific magnet configuration in the MR vendor operating manual.[1] Note this information is most often applied to assess the MR safety conditions on implanted medical devices.

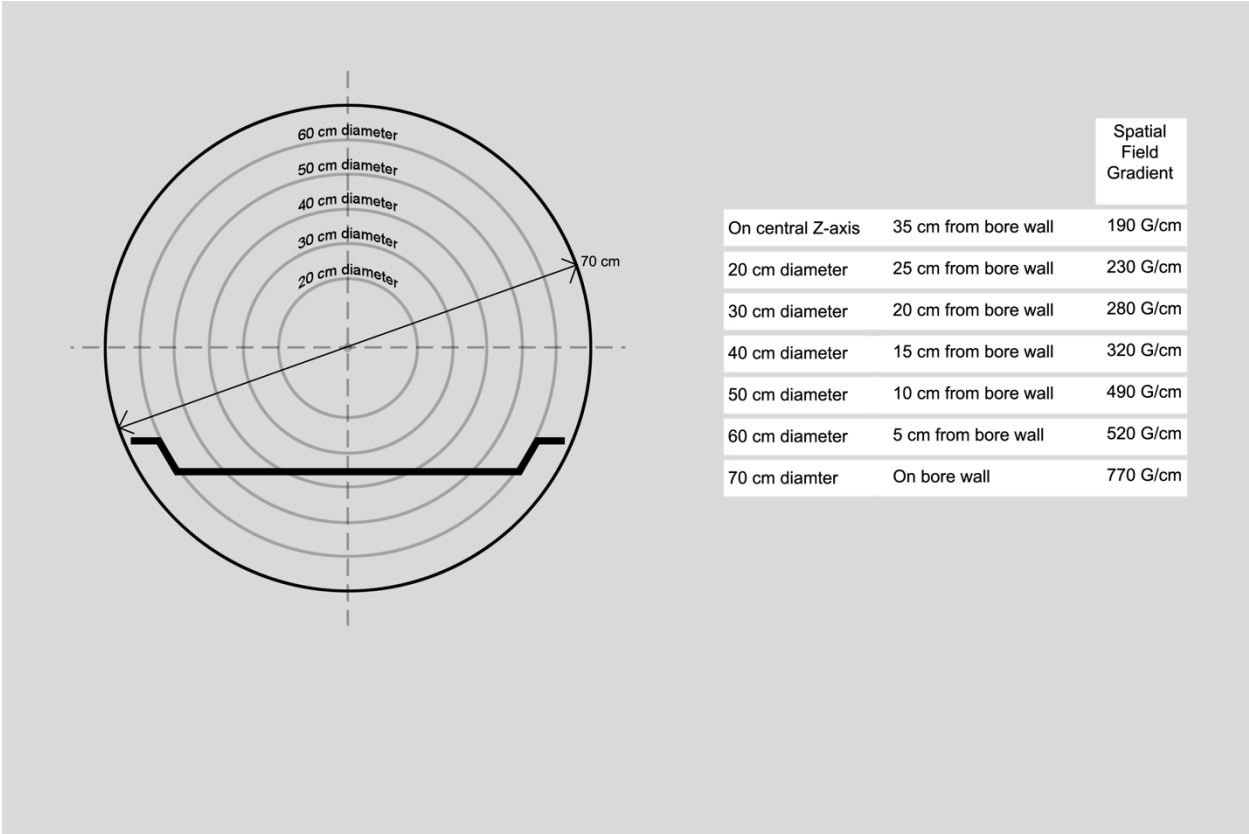
MR conditional labeling of implants and devices typically provide two numbers relevant to translational and rotational forces: the maximum static field (B_0) and the maximum spatial magnetic field gradient ($\Delta B/\Delta z$) to which the device/implant has been tested and shown to be safe when exposed.[2,3] The SFG varies as a function of the proximity to the bore wall, increasing with increased bore wall proximity. Based on the physical location of the implant in the patient's body, use of specific SFG plots provided by manufacturers for the specific MRI unit (See Figure 28) permits predicting the maximum SFG to which an implant would be subjected based on it physical location in the body, and its location relative to the bore wall. Implanted device vendors provide the maximum SFG value that should not be exceeded with the device's MR Conditional labeling in its instructions for use (IFU). Note the maximum allowable SFG may be quoted as a function of maximal static B_0 value or may be stated to be independent of this value .[1,3]

The relevant question to be answered is: What is the maximum SFG a device in the patient will be exposed to for a specific anatomic scan during movement into and out of the MR scanner bore?

In the past, MR vendors typically provided only the absolute maximum SFG values for their system. Unfortunately, applying those SFG values to day-to-day decisions could cause confusion because the maximum SFG value for a given MR system quoted by the manufacturer is often located under the shroud or cover of the MR system. Since this region is not directly accessible by the patient, no medical device will ever reside in this region and the maximum SFG value given is not necessarily relevant to clinical decision making for scanning MR Conditional device/implants.[1]

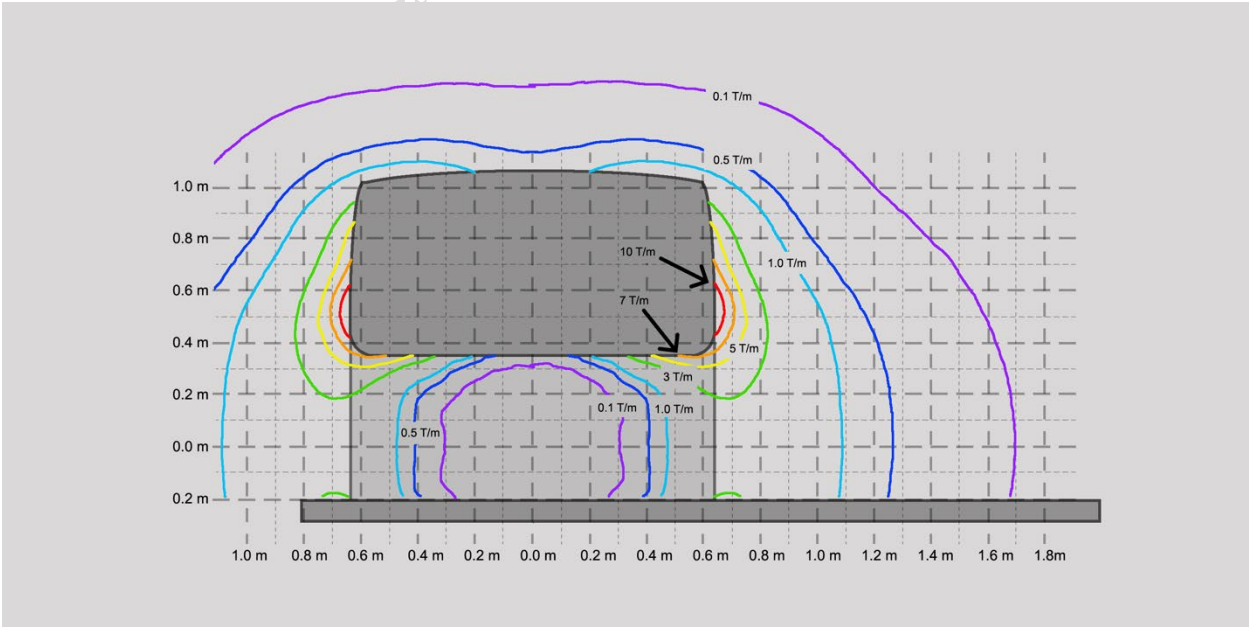
Currently, MR system vendors provide SFG maps specific to their magnets. The most useful visual manner of expressing this information is via manufacturer provided SFG maps that depict a transaxial view of the bore of the magnet and include the patient couch, with equidistant, concentric circles around the scanner isocenter (See Figure 28). Each concentric circle represents the cross-section of a cylindrical volume within the scanner bore, and the maximum estimated or measured SFG value within this volume, which is listed in a legend for reference. Limitations of such axial SFG maps include ambiguity of the exact location of the maximum SFG value along the cylindrical volume associated with each circle. Another common representation of SFG values are maps that depict either sagittal (See Figure 29) or coronal planes passing through the center of the magnet bore, with contours tracing out the regions of

constant SFG values (isogradient contours). If provided in only ¼ view, the operator should understand that these representations of SFG are typically both horizontally (about both the central Y- and central X-axes) and radially (about the central Z-axis) symmetric. Quarter SFG maps may be mirrored to yield a map that covers the entire MR bore.



		Spatial Field Gradient
On central Z-axis	35 cm from bore wall	190 G/cm
20 cm diameter	25 cm from bore wall	230 G/cm
30 cm diameter	20 cm from bore wall	280 G/cm
40 cm diameter	15 cm from bore wall	320 G/cm
50 cm diameter	10 cm from bore wall	490 G/cm
60 cm diameter	5 cm from bore wall	520 G/cm
70 cm diamter	On bore wall	770 G/cm

Figure 28. Transaxial view SFG map of an MR system indicating maximum SFG values that may be encountered within each of the cylindrical volumes within the diameter of the bore.



Return to Table of Contents

Figure 29. Sagittal-view spatial field gradient map of an MR system. The sold gray line just above the horizontal x-axis is the tabletop. Each dotted line represents spatial increments of 10 cm.

It is essential that the physician responsible for MR safety, or the physician's designee(s) (i.e., often the MRSE), be able to apply the manufacturer provided SFG values and maps to each scanning event as a means of safe scanning in the presence of a medical device, taking into consideration the anatomy scanned and the route the device will take during its course in Zone IV.[1]

References

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2. Shellock FG, Editor. Reference manual for magnetic resonance safety, implants, and devices. 2018 edition. Los Angeles, CA: Biomeical Research Publishing Group; 2018.
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APPENDIX 5: IMPLANTED DEVICE MR RISK/SAFETY ASSESSMENT

In clinical practice, medically necessary MRI examinations in the presence of implanted devices with potential safety concerns have become increasingly common with the unceasing development and approval of novel medical devices. MR conditional implanted devices may require specific MR conditions for safe scanning that may be difficult to meet or limit the ability to acquire MR images of sufficient quality to address the specific clinical question. Similarly, implanted devices may lack documentation in the medical record (e.g., implanted at a different medical center or several years prior) and thus challenge the ability to determine the risk level. Moreover, a patient with the need for MR imaging may have an implanted device labeled as MR Unsafe, precluding MR imaging.

Here, we provide a general approach to evaluating the potential risks of undergoing an MR examination when patients have implanted devices. It should be noted itemizing the complex, multifactorial decision tree in all clinical scenarios is not only beyond the scope of this manual, but also virtually impossible. Nevertheless, the guiding principle in this decision process should be to adequately address the risk/benefit ratio of undergoing an MR examination for the patient. This often requires a discussion between the treating physician(s) and MR Personnel with expertise in MR safety (i.e., Level 2 MR Physician, MRMD, MRSO and/or MRSE). Alternative imaging modalities (e.g., Computed Tomography, ultrasound) and the medical risk of not receiving an MR examination should be considered. Lastly, research participants generally do not benefit from a research MR examination and therefore the threshold for accepting an unknown or higher risk scenario should be much higher than that of a clinically indicated MR examination.

The following considerations, among potential others, should be addressed during the initial assessment, preparation, scanning and post-examination follow-up phases of the procedure:

Initial Assessment

1. Implanted device(s)
    a. Type of device(s)
    b. Manufacturer and model
    c. Anatomic location(s)
    d. Available information on MR conditions
        i. Device eligibility for MR
        ii. Vendor instructions for use (IFU)
        iii. Published recommendations from appropriate professional bodies
        iv. Published evidence of scanning device under similar conditions
    e. Current device status (operational, abandoned, damaged, implanted outside of vendor MR conditions, etc.)

    Note: addressing the above may require consulting the device manufacturer or local representative, a device specialist, relevant documentation, prior imaging, and/or operative reports, and could lead to the need to acquire x-rays or CT prior to making a decision.
2. MR Scanner
    a. Availability of a scanner to meet MR conditions

i. Field strength and orientation, spatial field gradient, gradient performance, RF coil (e.g., local transmit-receive)
ii. Sequences and options for obtaining needed information within SAR/$B_1{}^+_{rms}$ and/or dB/dt exposure limits with appropriate image quality
iii. MR Equipment Output Conditioning (MROC) options to manage RF and gradient outputs
iv. Availability of appropriate ancillary equipment, expert personnel and emergent response team for monitoring and managing patient and device in the MR environment

3. Patient
    a. Clinical question and/or requested exam
        i. Patient positioning permitting compliance with MR conditions location of implant(s) within the scanner to assess impact of static, RF and gradient field conditions
    b. Patient eligibility for MRI with device(s) via vendor IFU
    c. Patient status (routine, emergency, under anesthesia, compromised thermoregulatory system, etc.)
    d. Potential impact of device artifacts and/or MR protocol and parameters limitations on exam image quality/diagnostic capacity
    e. Further risk/benefit considerations
        i. Potential injury to the patient
        ii. Potential damage to the device and associated impact on the patient
        iii. Clinical impact of performing a procedure to remove a device prior to exam
        iv. Clinical impact of not performing, or delaying the MR exam
        v. Identification of alternative imaging approaches
    f. Document risk versus benefit decision and plan for managing risk during MR examination

Preparation and scanning

1. Implanted device(s) [as appropriate]
    a. Appropriate device expert, including MRSE and/or clinician present if needed
    b. Device battery level
    c. Patient/clinician implanted device programmer electrically charged and available
        i. Interrogate device to establish/verify eligibility (i.e., impedance check/lead damage)
        ii. Record/save settings (i.e., cardiac implantable devices [CIED], deep brain stimulator [DBS], vagal nerve stimulator [VNS], programmable shunt)
        iii. Program device for MR environment (e.g., MR Conditional mode)
    d. Secure and immobilize on patient (i.e., cochlear magnet, tissue expander with magnetic port)
    e. Plan for device damage or inability to recover normal function
2. MR Scanner and environment
    a. Patient scheduled to appropriate MR resource at an appropriate time
    b. MR safety screening and training of team members possibly to include non-MR Personnel that may need to be present during examination

c. Consultation or direct supervision (MRMD, MRSO or MRSE) as needed/required
d. Modified MR protocol available to meet planned conditions
e. Scanner in appropriate operating mode or MR Output Conditioning (MROC) setting for SAR/$B_1{}^+{}_{rms}$ and dB/dt
    i. Active monitoring of scanner output and timing during examination by appropriately trained personnel to meet MR conditions

3. Patient
    a. Verification of patient eligibility for MR
    b. Informed consent
    c. Educated on device preparation for exam
    d. Proper positioning of patient and device within bore or RF coil
        i. Management of external leads or cables
        ii. Distancing device from bore wall
        iii. Placement of sealed ice packs for cooling
    e. Communication plan (with the team and with the patient)
        i. Audible, visual and squeeze ball
        ii. Clear instructions to patient (and team) on what sensations to expect and when/how to stop exam or communicate with the team
    f. Patient monitoring and management plan
        i. Appropriate physiological monitoring
        ii. Sedation or anesthesia
        iii. Planned periods of non-scanning for cooling off if necessary

Post-examination follow-up

1. Patient: assess for pain or injury
2. Device: assess and/or reprogram device to normal function

Sites are encouraged to objectively assess their capability of safely performing an MR examination under challenging/unusual conditions. Thoughtful consideration of referring the patient to an alternate imaging facility with the necessary expertise is encouraged when appropriate.